FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[HYDROXYCHLOROQUINE,HYDROXYCHLOROQUINE DIPHOSPHATE,HYDROXYCHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	05-May-2015	To:	05-May-2020
MedDRA® Version* :	23.0			
Total Cases**:	24841			
Number of Pages:	13734			

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

**. "Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

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Detailed Report

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting. Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.
Health Prof	Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Mfr Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
503B Facility	Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).

Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products.
Product	Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Comp.	Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.
OTC	Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Mfr	The manufacturer of the product, as indicated in the report.

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	10888264	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1006797			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Methotrexate			S		15 Mg, Qw		Not Reported
	Plaquenil /00072602/			S		200 Mg, Bid		Not Reported
	Plaquenil /00072602/			S				Not Reported
	Prednisone			S		Unk Unk, Qw		Not Reported
	Anti-Inflammatory			S				Not Reported
	Arava			S		Unk		Not Reported
	Actonel			C		Unk		Not Reported
	Folate			S		Unk		Not Reported
	Prevacid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11090835	EXPEDITED (15-DAY)		OT	US-BAYER-2015-189484		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Operation	Aleve Caplet			S	Oral	Unk		Bayer
	Diclofenac Epolaminum			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Hydroxychloroquine Phosphate			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Rofecoxib			S		Unk		Not Reported
	Methotrexate Sodium [Methotrexate Sodium]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11091514	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1015008			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate	S	Unk	Not Reported
	Celebrex	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Plaquenil /00072602/	S	Unk	Not Reported
	Simponi	S	Unk	Not Reported
	Humira	S	Unk	Not Reported
	Actemra	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Cimzia	S	Unk	Not Reported
	Cortisone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2015	11096545	EXPEDITED (15-DAY)		HO	2015COV00078		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Clostridium Difficile Infection; Drug Hypersensitivity; Large Intestine Perforation	Plaquenil Tablet (Hydroxychloroquine) Tablet			S				Not Reported
	Enbrel (Etanercept)			S		Unk, 1x/Week		Not Reported
	Clinoril			S		1 Tablets, Unk		Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Prednisone			C				Not Reported
	Gabapentin			C				Not Reported
	Lisinopril/ Hydrochlorothiazide			C				Not Reported
	Acetaminophen / Codeine (Lenoltec With Codeine No 1) (Unknown) (Codeine, Paracetamol)			C				Not Reported
	Xeljanz (Tofacitinib Citrate)			C				Not Reported
	Lidocaine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2015	11095416	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1015038			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Nausea; Rheumatoid Arthritis	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Enbrel	S		50 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Plaquenil /00072602/	S		200 (3, 0)	Not Reported
	Gold	S	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2015	11099130	EXPEDITED (15-DAY)	Y	OT	2015SA013353		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Plaquenil (Hydroxychloroquine Sulfate) / Oral / Tablet, Film Coated / 200 Milligram(S)			S				Not Reported
	Actemra (Tocilizumab) 200 Mg Vial Genentech			S	Intravenous (not otherwise specified)		3 MTH	Not Reported
	Rituxan (Rituximab)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2015	11100075	DIRECT	Y	HO			37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Antinuclear Antibody Positive; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug-Induced Liver Injury; Hepatitis B Surface Antibody Positive; Jaundice; Total Bile Acids Increased	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11103611	NON-EXPEDITED			US-PFIZER INC-2015149964		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Accupril			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11105914	DIRECT	Y				41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Symptom; Product Substitution Issue	Plaquenil			S	Oral	About 6 Months, 1 Pill, Bid, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2015	11106522	DIRECT		DS			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Trigger Finger	Hydroxychloroquine			S	Oral	1 Pill Twice Daily Taken By Mouth		Zydus Pharm
	Mercaptopurine (Purinethol)			C				Not Reported
	Hydroxychloroquine (Plaquenil)			C				Not Reported
	Sertraline (Zoloft) 100 Mg Lupin Pharmace			C				Not Reported
	Azelastine (Astelin)			C				Not Reported
	Cyclosporine (Restasis)			C				Not Reported
	Ophthalmic Emulsion			C				Not Reported
	Levothyroxine (Synthroid)			C				Not Reported
	Liothyronine (Cytomel)			C				Not Reported
	Cholecalciferol			C				Not Reported
	Vitamin D3			C				Not Reported
	Multivitamin			C				Not Reported
	Vitamin B-12			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	10514792	NON-EXPEDITED			US-PFIZER INC-2014275557		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Azulfidine			S		Unk, Weekly		Pfizer
	Folic Acid			S		Unk, Daily		Pfizer
	Plaquenil			S		Unk, Weekly		Not Reported
	Percocet			C		Unk		Not Reported
	Nortriptyline			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Aramis			C		Unk		Not Reported
	Armour Thyroid			C		Unk		Not Reported
	Angeliq			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11087135	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1014694			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11105319	EXPEDITED (15-DAY)		HO, OT	BE-ROCHE-1573845		12 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypertension; Oedema;	Cellcept			S	Unknown			Not Reported

Polyarthritis; Pulmonary Alveolar Haemorrhage	Cellcept	S	Unknown	Not Reported
	Lisinopril	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
	Furosemide	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2015	11111897	EXPEDITED (15-DAY)	Y	DE, HO	IPC201504-000279		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Gastrointestinal Disorder; Mucormycosis; Mucormycosis; Multiple Organ Dysfunction Syndrome; Septic Shock; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine Sulfate			S				Not Reported
	Phenytoin			C				Not Reported
	Levetiracetam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	8958806	EXPEDITED (15-DAY)		DE, HO	PHHY2012US114110		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiomegaly; Cardiomyopathy; Dyspnoea; General Physical Health Deterioration; Muscular Weakness; Myopathy;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Novartis
	Prednisone			C	Unknown	60 Mg, Qd		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported

Oedema Peripheral; Respiratory Failure; Sinus Node Dysfunction

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	9494443	EXPEDITED (15-DAY)		DE	PHHY2013US095307		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Ejection Fraction Decreased; Endocarditis; Renal Vessel Disorder; Right Ventricular Enlargement; Right Ventricular Hypertrophy; Splenic Infarction	Hydroxychloroquine			S		400 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	10830593	NON-EXPEDITED		OT	US-JNJFOC-20150211720		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bladder Disorder; Body Height Decreased; Fall; Finger Deformity; Foot Deformity; Ill-Defined Disorder; Impaired Healing; Infection; Memory Impairment; Rash Macular; Skin Cancer; Skin Laceration; Urinary Incontinence; Vitreous Floaters	Remicade			S	Intravenous (not otherwise specified)	Years And Years Ago		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11109774	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1015475			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Gastric Disorder; Nausea; Vomiting	Methotrexate			S		30mg, (15 Mg X2)		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine			S		1 G, Bid		Not Reported
	Leflunomide			S		20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Tylenol Arthritis			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Acebutolol			C		Unk		Not Reported
	Quinapril			C		Unk		Not Reported
	Nexium /01479302/			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Oxybutynin			C		Unk		Not Reported
	Cipralex /01588501/			C		Unk		Not Reported
	Aspirin /00002701/			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported
	Slow K			C		Unk		Not Reported
	Osto-D2			C		Unk		Not Reported
	Omega 3 /01333901/			C		Unk		Not Reported
	Multivitamin And Mineral			C		Unk		Not Reported
	Calcium Citrate W/Magnesium/Vitamin D Nos			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11111262	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1015769			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sinusitis	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Oral	15 Mg, Qw		Not Reported
	Plaquenil /00072602/	S		Unk		Not Reported
	Leflunomide	S		Unk		Not Reported
	Simponi	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11111458	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1508889US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Diabetes Mellitus; Drug Dependence; Hypertension; Ill-Defined Disorder; Off Label Use; Treatment Failure	Dapsone Unk			S		Unk		Allergan
	Prednisone			S				Not Reported
	Azathioprine			S		Unk		Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclosporin			S				Not Reported
	Methotrexate			S				Not Reported
	Montelukast			S				Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2015	11115317	EXPEDITED (15-DAY)	Y	OT	2015COV00097		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cystoid Macular Oedema; Maculopathy; Toxicity To Various Agents	Plaquenil Tablet (Hydroxychloroquine) Tablet			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	9543043	EXPEDITED (15-DAY)		OT	PHHY2013US102354			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Focal	Hydroxychloroquine			S	Unknown			Novartis

Dyscognitive Seizures; Mental Status Changes; Posterior Reversible Encephalopathy Syndrome; Status Epilepticus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	10698513	NON-EXPEDITED			US-PFIZER INC-2014290163		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Influenza Like Illness; Lip Blister; Oral Disorder; Oral Mucosal Blistering; Oral Pain	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Orencia			S	Intravenous (not otherwise specified)	(4 Infusions)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	(4 Infusions)		Not Reported
	Plaquinol			S		200 Mg, Unk		Not Reported
	Plaquinol			S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11101529	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1015081			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Disability; Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11111669	EXPEDITED (15-DAY)		DE, OT	PHHY2015US056768		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Myocardial Infarction; Aortic Dissection	Hydroxychloroquine		S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2015	11158184	NON-EXPEDITED	Y	DE	2015010068		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide	Zolpidem (Zolpidem)			S				Not Reported
	Hydroxychloroquine (Hydroxychloroquine)			S				Not Reported
	Bupropion (Bupropion)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2015	11114562	EXPEDITED (15-DAY)		OT	CA-ROCHE-1575709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2015	11045684	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1011958			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2015	11083711	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2015M1014166			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S		Unk		Not Reported
	Celebrex			S		Unk, Bid		Not Reported
	Arava			S		Unk		Not Reported
	Sulfasalazine			S	Rectal	Unk		Not Reported
	Leflunomide			S	Oral	20 G, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	8811813	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-A0993580A		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Arthropod Bite; Blood Bilirubin Increased; Cerebrovascular Accident; Headache; Ill-Defined Disorder; Induration; Joint Swelling; Limb Discomfort; Liver Function Test	Revolade			S	Unknown	50 Mg, Qd		Glaxosmithkline
	Revolade			S		50 Mg, Qd		Glaxosmithkline
	Revolade			S		25 Mg, Qd		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Oxazepam			C				Not Reported

Abnormal; Migraine; Nausea; Pain; Platelet Count Decreased; Sjogren'S Syndrome; Skin Warm; Swelling; Systemic Lupus Erythematosus; Tachycardia; Thrombophlebitis Superficial; Vomiting	Acyclovir	C	Unk		Not Reported
	Coumadin	C	12 Mg, Qd		Not Reported
	Hydrochlorothiazide	C	Unk		Not Reported
	Vagifem	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	10691237	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2014M1015972			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	10906438	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015021955		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Pressure Abnormal; Cardiac Flutter; Dental Cleaning; Diarrhoea; Endodontic Procedure; Fatigue; Gait Disturbance; Heart Rate	Enbrel			S	Unknown	25 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Bystolic			C		1 Pill A Day And 1 Extra As Needed		Not Reported

Abnormal; Nervousness; Pain; Pain In Extremity; Peripheral Swelling; Somnolence; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2015	11124658	EXPEDITED (15-DAY)		OT	2015COV00098		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Plaquenil Tablet (Hydroxychloroquine) Tablet			S				Not Reported
	Sulfasalazine			S				Not Reported
	Rituxan (Rituximab)			S	Intravenous (not otherwise specified)			Not Reported
	Irbesartan			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11122096	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1016253			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2x Week		Not Reported
	Leflunomide			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Imuran /00001501/			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11122625	EXPEDITED (15-DAY)		HO, LT	CH-SA-2015SA064208			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Hypokalaemia; Hypomagnesaemia; Long Qt Syndrome; Torsade De Pointes	Plaquenil			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Seroquel			S	Oral	Strength: 25 Mg		Not Reported
	Trittico			S	Oral			Not Reported
	Ciproxin			S	Oral			Not Reported
	Beloc-Zok			S	Oral			Not Reported
	Dospir			S	Respiratory (inhalation)			Not Reported
	Movicol			S	Oral	Form: Powders		Not Reported
	Rimactan			C	Oral			Not Reported
	Floxapen			C	Intravenous (not otherwise specified)			Not Reported
	Pantozol (Switzerland)			C	Oral			Not Reported
	Rasilez			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported
	Oxycontin			C	Oral			Not Reported
	Fragmin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2015	11123762	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1016437			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Subcutaneous	15 Mg - 25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S		500 Mg, Tid		Not Reported

	Plaquenil /00072602/			S		400 Mg, Qd				Not Reported
	Leflunomide			S	Oral	20 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	11113976	EXPEDITED (15-DAY)		HO, LT	CH-ASTRAZENECA-2015SE44523		81 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Hypokalaemia; Hypomagnesaemia; Long Qt Syndrome; Supraventricular Extrasystoles; Syncope; Torsade De Pointes	Beloc-Zok			S	Oral			Not Reported
	Seroquel			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Trittico			S	Oral			Not Reported
	Ciproxin			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Dospir			S	Respiratory (inhalation)			Not Reported
	Movicol			S	Oral			Not Reported
	Rimactan			C	Oral			Not Reported
	Floxapen			C	Intravenous (not otherwise specified)			Not Reported
	Pantozol (Switzerland)			C	Oral			Not Reported
	Rasilez			C	Oral			Not Reported
	Dafalgan			C	Oral			Not Reported
	Oxycontin			C	Oral			Not Reported
	Fragmin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	11124308	NON-EXPEDITED		HO, OT	US-AMGEN-USASL2015047816		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Lethargy; Nausea;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen

Pyrexia; Rash; Rheumatoid Arthritis	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2015	11126427	EXPEDITED (15-DAY)		HO, LT	CH-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-25		81 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Hypokalaemia; Hypomagnesaemia; Long Qt Syndrome; Torsade De Pointes	Dospir			S	Respiratory (inhalation)	4 Anz		Boehringer Ingelheim
	Seroquel			S	Oral	25 Mg		Not Reported
	Trittico			S	Oral	50 Mg		Not Reported
	Ciproxin			S	Oral	1500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Beloc-Zok			S	Oral	25 Mg		Not Reported
	Lasix			S	Oral	20 Mg		Not Reported
	Movicol			S	Oral	Dose Per Application And Daily Dose: 1 Dosage Form (Df)		Not Reported
	Rimactan			C	Oral	600 Mg		Not Reported
	Floxapen			C	Intravenous (not otherwise specified)			Not Reported
	Pantozol (Switzerland)			C	Oral	40 Mg		Not Reported
	Rasilez			C	Oral	150 Mg		Not Reported
	Dafalgan			C	Oral	2000 Mg		Not Reported
	Oxycontin			C	Oral	20 Mg		Not Reported
	Fragmin			C	Subcutaneous	5000 U		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	10992986	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1010583			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral; Stomatitis	Methotrexate			S		25 Mg, Qw		Not Reported
	Enbrel			S		25 Mg, Biweekly		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Humira			S		40 Mg, Biweekly		Not Reported
	Remicade			S		300 Mg, Monthly		Not Reported
	Cortisone			C		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Benadryl /00000402/			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Lasix /00032601/			C		Unk		Not Reported
	Enablex /01760401/			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Norflex /00018303/			C		Unk		Not Reported
	Omnaris			C		Unk		Not Reported
	Pantoloc /01263204/			C		Unk		Not Reported
	Vagifem			C		Unk		Not Reported
	Dilaudid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11095426	EXPEDITED (15-DAY)		DS, OT	US-MYLANLABS-2015M1014731			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation	Methotrexate			S		25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported

Rate Increased; Synovitis	Enbrel	S	Unk		Not Reported
	Hydroxychloroquine	S	400 Mg, Unk		Not Reported
	Humira	S	400 Mg, Unk		Not Reported
	Rituxan	S	1000 Mg, Unk		Not Reported
	Bupropion Hydrochloride	C			Not Reported
	Esomeprazole	C			Not Reported
	Folic Acid	C			Not Reported
	Levothyroxine Sodium	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11127949	EXPEDITED (15-DAY)		DE, OT	IN-ROXANE LABORATORIES, INC.-2015-RO-00812RO		21 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaplastic Large Cell Lymphoma T- And Null-Cell Types; Cardiomegaly; Pleural Effusion	Methotrexate			S	Unknown			Roxane
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2015	11130649	DIRECT					67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Rash; Rash	Hydroxychloroquine			S	Oral			Not Reported
	Lisinopril			C				Not Reported
	Fish Oil			C				Not Reported
	Boswellia Extract			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11103893	EXPEDITED (15-DAY)	Y	HO	2015COV00095			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Joint	Plaquenil Tablet (Hydroxychloroquine) Tablet			S	Oral			Not Reported

Swelling; Pneumonia; Therapeutic Response Decreased; Tuberculin Test Positive	Arava (Leflunomide)		S	Oral		Not Reported
	Sulfasalazine		C			Not Reported
	Inh (Isoniazid)		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11130691	EXPEDITED (15-DAY)		HO, LT, OT	US-JNJFOC-20150116650		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Decreased Immune Responsiveness; Pneumonia; Pyrexia; Renal Failure; Respiratory Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2015	11131493	NON-EXPEDITED			US-MALLINCKRODT-QSC-2014-0374		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bleeding Time Prolonged; Hair Growth Abnormal	H P Acthar			S	Subcutaneous	1 Ml, Q72hrs		Mallinckrodt
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Vitamin D Nos			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	10988653	NON-EXPEDITED		OT	US-JNJFOC-20130810551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For	Infliximab, Recombinant			S	Intravenous (not			Not Reported

Unapproved Indication; Infection; Pneumonia; Rash; Sarcoidosis				otherwise specified)	
	Corticosteroid		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11019602	NON-EXPEDITED			US-JNJFOC-20130508279		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ultram			S				Not Reported
	Aspirin			S				Not Reported
	Flexeril			S				Not Reported
	Ibuprofen		Y	S				Not Reported
	Ibuprofen			S				Not Reported
	Levaquin			S				Not Reported
	Motrin		Y	S				Not Reported
	Motrin			S				Not Reported
	Ultracet			S				Not Reported
	Orphenadrine Citrate			S				Not Reported
	Phenergan			S				Not Reported
	Plaquenil			S				Not Reported
	Relafen			S				Not Reported
	Keflex			S				Not Reported
	Paxil			S				Not Reported
	Cymbalta			S				Not Reported
	Naprosyn			S				Not Reported
	Acetyl Salicylic Acid			S				Not Reported
	Darvocet			S				Not Reported
	Aleve			S				Not Reported
	Prednisone			S				Not Reported
	Celebrex			S				Not Reported
	Neurontin			S				Not Reported
	Zoloft			S				Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Vitamins Nos			C		1xam		Not Reported
	Vitamin D3			C		2 Caps Am		Not Reported
	Tocopherol			C		2 Caps Pm		Not Reported

	Biotin	C	2 Caps Am, 2 Caps Pm	Not Reported
	Cellcept	C	3 Am 2 Pm	Not Reported
	Soma	C	1/2 To 1 Tablet 3 Times A Day	Not Reported
	Claritin	C	10 Am 1 Pm	Not Reported
	Klonopin	C		Not Reported
	Dilaudid	C	12 Daily In Divided Dose	Not Reported
	Percocet	C	10/325 Mg 12 Daily In Divided Doses	Not Reported
	Lyrica	C	2 Am 2 Noon 2 Pm	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2015	11019643	NON-EXPEDITED			US-JNJFOC-20140100152		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ibuprofen			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Cipro			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Sulindac			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	10886971	NON-EXPEDITED			US-PFIZER INC-2015075975		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain	Xeljanz			S		5 Mg, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	11137577	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1017367			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Rheumatoid Arthritis	Methotrexate			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Celebrex			S		Unk		Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11142202	EXPEDITED (15-DAY)		LT	FR-FRI-1000076952		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Escitalopram			S	Oral	5 Mg		Forest
	Plaquenil			S	Oral	400 Mg		Not Reported
	Procoralan			S	Oral	10 Mg		Not Reported
	Atacand			C	Oral	4 Mg		Not Reported
	Aldactone			C	Oral	12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11146099	DIRECT		DS, HO, LT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Guillain-Barre Syndrome; Neuralgic Amyotrophy	Plaquenil			S	Oral			Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Dilaudin			C				Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11148905	EXPEDITED (15-DAY)	Y	HO, LT, OT	2015COV00106		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Chest Pain; Diarrhoea; Drug Ineffective; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Hyperlactacidaemia; Hypokalaemia; Loss Of Consciousness; Malaise; Metabolic Acidosis; Mydriasis; Nausea; Torsade De Pointes; Vertigo	Plaquenil Tablet			S	Oral			Not Reported
	(Hydroxychloroquine) Tablet							
	Seroplex (Escitalopram Oxalate)			S	Oral			Not Reported
	Procoralan (Ivabradine Hydrochloride) Tablet			S	Oral			Not Reported
	Atacand (Candesartan Cilexetil)			C				Not Reported
	Aldactone (Spironolactone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11148955	EXPEDITED (15-DAY)	Y	HO, OT	2015COV00107		81 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Hypokalaemia; Hypomagnesaemia; Long	Plaquenil			S	Oral			Not Reported
	Lasix (Furosemide)			S	Oral			Not Reported

Qt Syndrome; Syncope; Torsade De Pointes	Seroquel (Quetiapine Fumarate)			S	Oral				Not Reported
	Trittico (Trazodone Hydrochloride)			S	Oral				Not Reported
	Ciproxin (Ciprofloxacin Hydrochloride) (Film-Coated Tablet) (Ciprofloxacin Hydrochloride)			S	Oral				Not Reported
	Beloc Zok (Metoprolol Succinate)			S	Oral				Not Reported
	Dospir			S					Not Reported
	Movicol(Macrogol/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride)			S	Oral				Not Reported
	Rimactan (Rifampicin)			C					Not Reported
	Floxapen (Flucloxacillin Sodium)			C					Not Reported
	Pantozol (Pantoprazole Sodium)			C					Not Reported
	Rasilez (Aliskiren Fumarate) (Aliskiren Fumarate)			C					Not Reported
	Dafalgan (Paracetamol)			C					Not Reported
	Fragmin (Dalteparin Sodium)			C					Not Reported
	Oxycontin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11146176	NON-EXPEDITED			US-PFIZER INC-2015176824		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11146598	EXPEDITED (15-DAY)		DE, OT	US-CELGENE-USA-2015055319			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Abraxane			S	Unknown			Not Reported
	Gemcitabine			S	Unknown			Not Reported

Increased; Blood Bilirubin Increased; Blood Glucose Increased; Decreased Appetite; Fatigue; Intestinal Obstruction; Nausea; Neuropathy Peripheral; Neutropenia; Pancreatic Carcinoma; Peripheral Ischaemia; Pneumothorax; Respiratory Failure; Sepsis	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2015	11147341	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC-2015-IPXL-00579		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Calcification	Omeprazole Delayed Release			S	Unknown	Unk		Impax
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	10596236	EXPEDITED (15-DAY)		DS, HO, OT	US-GLAXOSMITHKLINE-US2014GSK023954		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Colostomy; Cytomegalovirus Colitis	Benlysta			S	Intravenous (not otherwise specified)	10 Mg/Kg, Unk		Glaxosmithkline
	Cellcept			S	Oral	2500 Mg, 1d		Glaxosmithkline

	Prednisone	S	Oral	20 Mg, 1d		Not Reported
	Prednisone	S		5 Mg, Qd		Not Reported
	Plaquenil	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11081594	NON-EXPEDITED			US-PFIZER INC-2015145166		33 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Vancomycin			S		Unk		Unknown
	Aspirin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11148792	NON-EXPEDITED			US-PFIZER INC-2015176893			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11152542	EXPEDITED (15-DAY)		HO, OT	US-WATSON-2015-10642		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Mucosal Inflammation; Pancytopenia; Renal Impairment; Skin Ulcer; Toxicity To Various Agents	Methotrexate (Unknown)			S	Unknown	Unk Unk, 1/Week		Not Reported
	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	Unk		Watson
	Acetylsalicylic Acid (Unknown)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11152730	EXPEDITED (15-DAY)		OT	PHHY2015EG061925		28 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Hepatitis Toxic; Nausea; Vomiting	Hydroxychloroquine			S	Oral	400 Mg Per Day		Novartis
	Prednisolone			C	Oral	40 Mg/Day		Not Reported
	Prednisolone			C	Oral	25 Mg/Day		Not Reported
	Prednisolone			C	Unknown	10 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11153223	EXPEDITED (15-DAY)		HO, OT	FR-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-29		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hyperkalaemia	Tamsulosina			S	Oral			Boehringer Ingelheim
	Tegeline			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orocal D3			S	Oral			Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Gabapentin			S	Oral	1200 Mg		Not Reported
	Cortancyl			S	Unknown			Not Reported
	Diffu K			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	9696383	EXPEDITED (15-DAY)		OT	PHHY2013IN131324		30 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Corticosteroids			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	11008851	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1011350			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Methotrexate			S		Max 15/Week		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072602/			S		400 Unk, Qd		Not Reported
	Naproxen			S		Unk		Not Reported
	Leflunomide			S		10 Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	11101543	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1008466			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	11162600	EXPEDITED (15-DAY)	Y	DE, HO	2015COV00110		72 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ileus; Multimorbidity; Pneumonia Aspiration; Polyneuropathy; Sepsis	Plaquenil Tablet (Hydroxychloroquine) Tablet			S	Oral	200		Not Reported
	Methotrexate			S	Oral			Not Reported

	Omeprazole			C						Not Reported
	Calci-D3			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2015	11164202	EXPEDITED (15-DAY)	Y	HO	2015COV00111		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cough; Dyspnoea; Hyperkalaemia; Pulmonary Congestion; Tachypnoea	Plaquenil			S	Oral			Not Reported
	Fenofibrate			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Cortancyl			S				Not Reported
	Tegeline			S	Intravenous (not otherwise specified)			Not Reported
	Omexel			S	Oral			Not Reported
	Orocal (Calcium Carbonate)			S	Oral			Not Reported
	Diffu K (Potassium Chloride) (Potassium Chloride)			C				Not Reported
	Inexium (Esomeprazole)			C				Not Reported
	Lamaline (Caffeine/Papaver Somniferum Latex/Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11048831	NON-EXPEDITED			US-PFIZER INC-2015133825		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Diclofenac			S		Unk		Pfizer
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11158831	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015180358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Oedema; Visual Impairment	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Celebrex			S		Unk		Pfizer
	Indocin			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2015	11159189	EXPEDITED (15-DAY)		HO	FR-TEVA-565859ISR		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hyperkalaemia	Orocal Vitamine D3 [Calcium Carbonate\Cholecalciferol]			S	Oral	Long-Standing Treatment		Not Reported
	Fenofibrate			S	Oral	Long-Standing Treatment		Teva
	Gabapentine			S	Oral	1200 Milligram Daily; Long-Standing Treatment		Ivax
	Tegeline 10 G/200 Ml			S	Intravenous drip			Not Reported
	Tegeline 10 G/200 Ml			S	Intravenous drip			Not Reported
	Tegeline 10 G/200 Ml			S	Intravenous drip			Not Reported
	Plaquenil 200 Mg			S	Oral	Long-Standing Treatment		Not Reported
	Omexel Lp 0.4 Mg			S	Oral	Long-Standing Treatment, Prolonged Release		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			S	Oral	Long-Standing Treatment		Not Reported
	Cortancyl			S		Long-Standing Treatment		Not Reported
	Diffu-K			C	Oral			Not Reported
	Inexium			C		Long-Standing Treatment		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	8191654	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2011053546		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Autoimmune Hepatitis; Constipation; Disability; Dizziness; Dyspnoea; Fatigue; Gastrointestinal Infection; Gastrooesophageal Reflux Disease; Headache; Herpes Zoster; Hypotension; Impaired Driving Ability; Joint Stiffness; Musculoskeletal Stiffness; Neoplasm Malignant; Neuralgia; Pain; Pericarditis; Poor Peripheral Circulation; Syncope	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11163597	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2015GB063596		88 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Sepsis	Hydroxychloroquine			S	Oral			Novartis
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11165701	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018171			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported

	Plaquenil /00072602/			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2015	11168207	DIRECT	Y	OT				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Vomiting	Hydroxychloroquine 200mg Ranbaxy			S	Oral			Ranbaxy
	Hydroxychloroquine Mylan			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	10777076	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2015050014		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Musculoskeletal Stiffness; Pain	Aromasin			S	Oral	25 Mg, 1x/Day		Pfizer
	Aromasin			S		Unk		Pfizer
	Atorvastatin Calcium			S		20 Mg, 1x/Day		Pfizer
	Diltiazem Xr			S		120 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Diltiazem			C	Oral	120 Mg, Daily		Not Reported
	Vytorin			C	Oral	20 Mg, Daily		Not Reported
	Plaquenil			C	Oral	200 Mg, Daily		Not Reported
	Vitamin B Complex			C	Oral	1 Df, Daily		Not Reported
	Vitamin D3			C	Oral	1 Df, Daily		Not Reported
	Aleve			C		Unk, As Needed		Not Reported
	Ibuprofen			C	Oral	Unk, As Needed		Not Reported
	Advil			C		Unk, As Needed		Not Reported
	Bayer Aspirin			C		81 Mg, Daily		Not Reported
	Glucosamine & Chondroitin			C		Unk		Not Reported
	Magnesium			C		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11166211	EXPEDITED (15-DAY)		LT	CA-ROCHE-1588341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11167286	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018167			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11171774	DIRECT		DS, OT			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Erythema; Muscle Spasms; Muscle Spasms; Purulence; Rash	Plaquenil			S	Oral	1 Pill Once Daily Taken By Mouth		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2015	11173932	EXPEDITED (15-DAY)	Y	DE, HO	2015COVF00112		88 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased; Pneumonia; Pneumonia; Sepsis	Hydroxychloroquine (Hydroxychloroquine)			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11080156	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1013790			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Sleep Disorder	Methotrexate			S		20 Mg, Qw		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported
	Humira			S		40 Mg, Biweekly		Not Reported
	Actemra			S		720 Mg, Monthly		Not Reported
	Naprosyn /00256201/			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported
	Leflunomide			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11148438	EXPEDITED (15-DAY)		HO, OT	2015COV00102		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Dysstasia; Hallucination; Hallucination, Visual; Psychotic Disorder; Speech Disorder; Vision Blurred; Weight Decreased	Hydroxychloroquine (Hydroxychloroquine)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11170084	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-1504644		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Rectal Haemorrhage	Vemurafenib			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11172261	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018702			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2015	11175487	DIRECT					31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Hypersensitivity; Migraine; Pharyngeal Oedema	Hydroxychloroquine			S	Oral			Sandoz
	Acetaminophen\Hydrocodone Bitartrate			C				Not Reported
	Ventolin			C				Not Reported
	Atrovent			C				Not Reported
	Fluticasone			C				Not Reported
	Montelukast			C				Not Reported
	Zyrtec			C				Not Reported
	Benedryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	11175929	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018843			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S		1 G, Bid		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported
	Arava			S		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	11175934	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Red Blood Cell Sedimentation Rate Increased; Treatment Failure	Methotrexate			S		25 Mg, Qw		Not Reported
	Leflunomide			S		200 Mg, Qd		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2015	11176175	EXPEDITED (15-DAY)		HO	US-TEVA-565093USA		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Musculoskeletal Stiffness; Pain In Extremity	Hydroxychloroquine			S		400 Milligram Daily;		Teva
	Aromasin			S		25 Milligram Daily;		Not Reported
	Atorvastatin			C		20 Milligram Daily;		Not Reported
	Diltiazem Hcl Exte-Rel			C		120 Milligram Daily;		Not Reported
	Motrin			C		As Needed		Not Reported
	Bayer Aspirin			C		81 Milligram Daily;		Not Reported
	Glucosamine Sulfate W/Chondroitin			C				Not Reported
	Magnesium			C		400 Milligram Daily;		Not Reported
	Vytorin			C				Not Reported

	Vitamin B Complex	C				Not Reported
	Vitamin D3	C				Not Reported
	Aleve	C		As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11176491	EXPEDITED (15-DAY)		LT, OT	CA-ROCHE-1587460			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Naprosyn			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Indocin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Methotrexate			S	Oral	5 Pills Once Weekly		Not Reported
	Folic Acid			C	Unknown	1 Tablet Four Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11178948	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019203			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Oedema; Visual Impairment	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Indocin /00003801/			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2015	11179108	EXPEDITED (15-DAY)		OT	AU-ALLERGAN-1510724US			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Diabetes Mellitus; Drug Dependence; Drug Ineffective; Hypertension; Ill-Defined Disorder; Off Label Use	Dapsone Unk			S				Allergan
	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclosporin			S				Not Reported
	Methotrexate			S				Not Reported
	Montelukast			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2015	11179541	EXPEDITED (15-DAY)		DS, HO	US-ROCHE-1590081		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Rupture; Colostomy; Cytomegalovirus Colitis	Cellcept			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral	Regimen #2		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Benlysta			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2015	11181373	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2015193073		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma	Novatrex			S	Oral	2.5 Mg, Unk		Pfizer
	Salazopyrine			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Metoject			S		Unk		Not Reported

	Metoject	S		Unk		Not Reported
	Metoject	S		Unk		Not Reported
	Arava	S	Oral	Unk		Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Orencia	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2015	11182977	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019541			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2015	11182979	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019209			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		25 Mg, Qw		Not Reported
	Plaquenil /00072602/			S		200 Mg, Bid		Not Reported
	Arava			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2015	11189378	EXPEDITED (15-DAY)		OT	205MYN000009		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Infection; International Normalised Ratio Fluctuation	Erythromycin (Erythromycin) Unknown			S				Not Reported
	Arava (Leflunomide)			S				Not Reported
	Arthrotec			S				Not Reported
	Bisoprolol Fumarate (Bisoprolol Fumarate)			S				Not Reported

	Ceclor	S	Not Reported
	Demerol	S	Not Reported
	Flagyl /00012501/ (Metronidazole) (Metronidazole)	S	Not Reported
	Humira (Adalimumab)	S	Not Reported
	Levofloxacin (Levofloxacin) Unknown, 1000mg	S	Not Reported
	Norfloxacin	S	Not Reported
	Plaquenil /00072602/	S	Not Reported
	Prednisone (Prednisone) Unknown	S	Not Reported
	Sulfasalazine (Sulfasalazine)	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2015	10767140	EXPEDITED (15-DAY)		OT	TN-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-007093		32 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Glucophage			S	Oral	1 Df, Bid		Bristol Myers Squibb
	Lopril			S	Oral	1 Unk, Bid		Bristol Myers Squibb
	Prednisone			S	Oral	1 Df, Unk		Not Reported
	Ipproton /00661201/			S	Oral	1 Unk, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	2 Df, Unk		Not Reported
	Fixical			S	Oral	1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2015	11188848	EXPEDITED (15-DAY)		LT	FR-AMGEN-FRASP2015057617		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma	Enbrel			S	Unknown	Unk		Amgen
	Novatrex /00113801/			S	Oral	2.5 Mg, Unk		Not Reported
	Salazopyrine			S	Unknown	Unk		Not Reported
	Metoject			S	Unknown	Unk		Not Reported
	Metoject			S	Unknown	Unk		Not Reported

	Metoject			S	Unknown	Unk			Not Reported
	Arava			S	Oral	Unk			Not Reported
	Plaquenil /00072602/			S	Oral	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2015	11189495	EXPEDITED (15-DAY)		HO	US-DSJP-DSU-2014-116352		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Benicar			S		Unk		Daiichi
	Benicar			S		Unk		Daiichi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S				Not Reported
	Methotrexate Sodium			S		10 Mg, Unk		Not Reported
	Gabapentin			S		300 Mg, Unk		Not Reported
	Sulfasalazine			S		500 Mg, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Prednisone			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2015	11195086	EXPEDITED (15-DAY)	Y	OT	ADR-2015-01121			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia;	Baclofen			S				Not Reported
Atrophy; Back Pain;	Dilaudid (Hydromorphone)			S	Intrathecal			Not Reported
Burning Sensation; Bursitis; Complex	Bupivacaine Intrathecal			S	Intrathecal			Not Reported
Regional Pain Syndrome;	Lorazepam			S				Not Reported
Depression; Diarrhoea;	Baclofen			S				Not Reported
Fall; Fractured Sacrum;	Tramadol			S				Not Reported
Haemangioma;	Mobic			S				Not Reported
Hallucination;	Zantac			S				Not Reported
Hyperaesthesia;	Zanaflex			S				Not Reported

Hypoaesthesia; Insomnia; Joint Effusion; Mobility Decreased; Mood Swings; Muscle Spasms; Muscle Spasms; Muscular Weakness; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Neuralgia; Osteoarthritis; Osteoporosis; Pain In Extremity; Panic Reaction; Paraesthesia; Paralysis; Physical Deconditioning; Post Laminectomy Syndrome; Sacroiliitis; Scoliosis; Skin Discolouration; Social Avoidant Behaviour; Somatic Symptom Disorder; Stress Fracture; Substance-Induced Psychotic Disorder; Therapy Non-Responder; Urinary Incontinence; Urinary Retention	Valium	S		Not Reported
	Amitriptyline	S		Not Reported
	Naltrexone	S		Not Reported
	Hydroxyzine	S		Not Reported
	Lidocaine	S		Not Reported
	Lithium	S		Not Reported
	Mathocarbamol	S		Not Reported
	Melatonin	S		Not Reported
	Diclofenac	S		Not Reported
	Miralax	S		Not Reported
	Ranitidine	S		Not Reported
	Senna	S		Not Reported
	Docusate	S		Not Reported
	Vitamin B Complex With Vitamin C	S		Not Reported
	Multivitamin	S		Not Reported
	Vitamin D3	S		Not Reported
	Acetaminophen	S		Not Reported
	Topamax	S		Not Reported
	Heparin	S		Not Reported
	Topiramate	S		Not Reported
	Lorazepam	S		Not Reported
	Tramadol	S		Not Reported
	Meloxicam	S		Not Reported
	Diazepam	S		Not Reported
	Lidocaine	S	Topical	Not Reported
	Nortiptyline	S		Not Reported
	Olanzapine	S		Not Reported
	Hydroxyzine	S		Not Reported
	Fortco	S		Not Reported
	Savella	S		Not Reported
	Tizanidine	S		Not Reported
	Ketorolac	S		Not Reported
	Effexor	S		Not Reported
	Flexeril	S		Not Reported
	Lorazepam	S		Not Reported
	Vicodin	S		Not Reported
	Neuropathic Pain Compound 1	S		Not Reported
	Horizant	S		Not Reported
	Savella	S		Not Reported
	Medrol	S		Not Reported
	Celebrex	S		Not Reported

Celexa	S	Not Reported
Cymbalta	S	Not Reported
Lodine	S	Not Reported
Nexium	S	Not Reported
Nucynta	S	Not Reported
Pristiq	S	Not Reported
Seroquel	S	Not Reported
Skelaxin	S	Not Reported
Vallium	S	Not Reported
Piroxicam	S	Not Reported
Hyoscyamine	S	Not Reported
Librax	S	Not Reported
Bextra	S	Not Reported
Actonel	S	Not Reported
Xanax	S	Not Reported
Zoloft	S	Not Reported
Lamictal	S	Not Reported
Mobic	S	Not Reported
Percocet	S	Not Reported
Ultracet	S	Not Reported
Butrans	S	Not Reported
Toradol	S	Not Reported
Depakote	S	Not Reported
Ativan	S	Not Reported
Gabapentin	S	Not Reported
Abilify	S	Not Reported
Gabapentin	S	Not Reported
Osteoporosis Infusion	S	Not Reported
Hydromorphone	S	Not Reported
Toprol Xl	S	Not Reported
Plaquenil	S	Not Reported
Aspirin	S	Not Reported
Clonazepam	S	Not Reported
Venlaflaxine	S	Not Reported
Naproxen	S	Not Reported
Ondansetron	S	Not Reported
Tylenol	S	Not Reported
Roxicodone	S	Not Reported
Bisacodyl	S	Not Reported
Ketorolac	S	Not Reported
Carbamazepine	S	Not Reported
Cholecalciferol	S	Not Reported

Diclofenac Sodium	S		Not Reported
Enoxaparin	S		Not Reported
Nortriptyline	S		Not Reported
Olanzapine	S		Not Reported
Methocarbamol	S		Not Reported
Tranylcypromine	S		Not Reported
Divalproex	S		Not Reported
Ferrous Sulphate	S		Not Reported
Pantoprazole	S		Not Reported
Lactated Ringers	S		Not Reported
Magnesium Citrate	S		Not Reported
Pantoprazole	S		Not Reported
Milk Of Magnesia	S		Not Reported
Amitriptyline	S		Not Reported
Fluphenazine	S		Not Reported
Soma	S		Not Reported
Lithium	S		Not Reported
Phenergan	S		Not Reported
Benzoazepine	S		Not Reported
Amitriptyline	S		Not Reported
Prolixin	S		Not Reported
Bactrim	S		Not Reported
Macrobid	S		Not Reported
Melatonin	S		Not Reported
Ranitidine	S		Not Reported
Senna	S		Not Reported
Docusate	S		Not Reported
Prolixin	S		Not Reported
Pantoprazole	S		Not Reported
Naltrexone Hcl	S		Not Reported
Acetaminophen\Hydrocodone Bitartrate	S		Not Reported
Biaxin	S		Not Reported
Amoxicillin	S		Not Reported
Cyclobenzaprine	S		Not Reported
Alprazolam	S		Not Reported
Sertraline Hcl	S		Not Reported
Arthrotec	S		Not Reported
Methylprednisolone	S		Not Reported
Levaquin	S		Not Reported
Ibuprofen	S		Not Reported
Sulfamethoxazole	S		Not Reported

	Ambien			S					Not Reported
	Oxycodone			S					Not Reported
	Propoxy-N/Apap			S					Not Reported
	Lexapro			S					Not Reported
	Metaxalone			S					Not Reported
	Ciprofloxacin Hcl			S					Not Reported
	Cephalexin			S					Not Reported
	Limbrel			S					Not Reported
	Alendronate Sodium			S					Not Reported
	Valacyclovir			S					Not Reported
	Nitrostat			S					Not Reported
	Prednisone			S					Not Reported
	Doxycycline Hyclate			S					Not Reported
	Quetiapine Fumarate			S					Not Reported
	Promethazine			S					Not Reported
	Duloxetine Hcl			S					Not Reported
	Namenda			S					Not Reported
	Risperidone			S					Not Reported
	Orphenadrine			S					Not Reported
	Cimetidine			S					Not Reported
	Mexiletine			S					Not Reported
	Nuvigil			S					Not Reported
	Trazodone			S					Not Reported
	Zoloft			S					Not Reported
	Lidoderm Patch			S					Not Reported
	Fentora			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	10704526	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1000339			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Nasopharyngitis; Therapeutic Product Effect Incomplete	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		0.6 Mg, Qw		Not Reported
	Methotrexate			S		0.6 Ml,		Not Reported
	Methotrexate			S		0.4 Ml,		Not Reported
	Methotrexate			S		0.2 Ml,		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Plaquenil /00072602/				S		Unk			Not Reported
	Meloxicam				S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11137629	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1017090			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11191324	NON-EXPEDITED			US-AMGEN-USASL2015055911		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pharyngitis Streptococcal; Throat Irritation; Vomiting	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	200 Mg, Twice A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11193386	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019552			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072602/			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2015	11194107	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019182			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Malaise	Hydroxychloroquine Sulfate Tablets, Usp		S	Oral	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11045502	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015127253		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11158934	EXPEDITED (15-DAY)		HO	ES-SA-2015SA074339		79 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Invasive Ductal Breast Carcinoma	Arava			S	Oral	30 Tablets		Not Reported
	Arava			S	Oral	30 Tablets		Not Reported
	Metotrexate			S	Oral	3-0-3.		Not Reported
	Humira			S	Subcutaneous	1 Inyeccion Sc Cada 15 Dias, 2 Pre-Filled Syringes. Frequency: Twice A Month.		Not Reported
	Dolquine			S	Oral	1-0-0; Dolquine 200 Mg Film-Coated Tablets, 30 Tablets.		Not Reported
	Dacortin			C	Oral	1-0-0		Not Reported
	Ideos			C	Oral	1-0-1		Not Reported
	Mirtazapine			C	Oral	0-0-1		Not Reported
	Micardis			C	Oral	1-0-0, Strength 80mg		Not Reported
	Omeprazole			C	Oral	1 Cp.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11184380	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2015057139		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Pain In Extremity; Renal Impairment; Somnolence; Spinal Fusion Surgery; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Benadryl /00000402/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Methotrexate			C		Unk Unk, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11194753	EXPEDITED (15-DAY)		OT	US-ROCHE-1505478		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer	Vemurafenib			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Aspirin			C	Oral	8 Mg		Not Reported
	Lipitor			C	Unknown			Not Reported
	Metformin Hydrochloride			C	Oral			Not Reported
	Potassium Chloride			C	Oral			Not Reported
	Ramipril			C	Unknown			Not Reported
	Saxagliptin Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11196019	NON-EXPEDITED			US-AMGEN-USASP2015054677		20 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Range Of Motion	Enbrel			S	Unknown	Unk		Amgen

Decreased; Mobility Decreased	Humira	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Prednisone	C		10 Mg, Unk		Not Reported
	Ibuprofen	C		Two To Three 800s		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11196188	EXPEDITED (15-DAY)		LT	FR-SA-2015SA080928		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Novatrex			S	Oral			Not Reported
	Metoject			S	Unknown			Not Reported
	Metoject			S	Unknown			Not Reported
	Metoject			S	Unknown			Not Reported
	Metoject			S	Unknown			Not Reported
	Salazopyrine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11196862	EXPEDITED (15-DAY)		HO	PHHY2015ES068615		11 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperplasia; Oral Disorder; Oral Papilloma; Oral Papule; Papilloma Viral Infection	Mycophenolic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11201498	EXPEDITED (15-DAY)	Y	DS	CO-PL-DK-2015-064		56 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Deposit Eye; Retinal Depigmentation; Retinopathy; Visual Acuity Reduced	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11201502	EXPEDITED (15-DAY)	Y	OT	CO-PL-NZ-2015-063		68 YR	Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Failure	Hydroxychloroquine			S	Oral			Not Reported
	Fluoxetine			C				Not Reported
	Losartan (Losartan Potassium)			C				Not Reported
	Omeprazole			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2015	11201809	EXPEDITED (15-DAY)		OT	2015COV00121		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cataract; Macular Degeneration	Plaquenil Tablet (Hydroxychloroquine) Tablet			S	Oral			Not Reported
	Naproxen (Naproxen)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11148500	NON-EXPEDITED			US-PFIZER INC-2015168050		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasal Congestion	Pantoprazole			S	Oral	40 Mg, 2x/Day (40 Mg Tablet (Delayed Release),		Pfizer

				Sig- Route: 1 Tablet By Mouth)	
	Metoprolol Tartrate	S	Oral	50 Mg, 2x/Day (50 Mg Tablet, Sig: Take 1 Tablet By Mouth Twice A Day)	Not Reported
	Trazodone Hcl	S	Oral	150 Mg, 1df At Bedtime	Not Reported
	Furosemide	S	Oral	2 Df, Daily (40 Mg Tablet, Sig: Take 2 Tablets By Mouth Every Day)	Not Reported
	Potassium Chloride	S	Oral	Unk, 1x/Day (10 Meq Tablet, Extended Release, 1 Tab Q Day With Furosemide)	Not Reported
	Gentamicin Sulfate	S	Ophthalmic	4 Df, Daily, 0.3 % Solution, 4 Drops Rt Ear 4x A Day For 1 Week	Not Reported
	Plaquenil	S	Oral	400 Mg, 1x/Day (200 Mg Tablet, Sig: Route: 2 Tablets Qd)	Not Reported
	Trimethoprim	S	Oral	100 Mg, Daily (100 Mg Tablet, Sig: Take 1 Tablet)	Not Reported
	Wellbutrin Sr	S	Oral	150 Mg, 1x/Day (150 Mg Tablet Extended Release 12 Hour, 1 Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11148604	EXPEDITED (15-DAY)			US-MYLANLABS-2015M1017576			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Fatigue; Nausea; Vomiting	Methotrexate			S	Subcutaneous	0.6 Ml, Unk		Not Reported
	Humira			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2015	11199502	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019224			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Not Reported
	Humira			S				Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Prednisone			C		10 Mg, Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11153307	NON-EXPEDITED			PHHY2015CA062102			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vocal Cord Dysfunction	Methotrexate Sandoz			S	Unknown	20 Mg, Qw		Novartis
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11178776	EXPEDITED (15-DAY)		OT	CA-TEVA-568479USA		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Drug Ineffective; Intestinal Perforation	Leflunomide			S	Unknown			Barr
	Methotrexate (Pfizer)			S				Not Reported
	Sulfasalazine (Pfizer)			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Adalimumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11202722	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2014M1000118			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Injury	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11202724	NON-EXPEDITED			US-MYLANLABS-2014S1010870			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Rhinorrhoea; Sneezing; Vomiting	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	400 Mg,Qd		Mylan
	Fluconazole			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11202744	NON-EXPEDITED			US-MYLANLABS-2015M1013301		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Muscle Spasms; Paraesthesia; Vision Blurred	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Qd		Mylan
	Azathioprine Tablets Usp			S	Oral	50 Mg, Qd		Mylan
	Gabapentin			C		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2015	11202745	NON-EXPEDITED			US-MYLANLABS-2015M1011769		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Bid		Not Reported
	Sulphasalazine	S	Oral	300 Mg, Qd		Not Reported
	Prednisone	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11206620	EXPEDITED (15-DAY)	Y	OT	PHHY2014US174191		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Arthralgia; Asthenia; Atrophy; Back Pain; Bursitis; Contusion; Depression; Fall; Insomnia; Joint Effusion; Muscle Spasms; Myofascial Pain Syndrome; Osteoporosis; Panic Reaction; Social Avoidant Behaviour; Somatic Symptom Disorder; Substance-Induced Psychotic Disorder; Therapy Non-Responder	Baclofen Intrathecal			S	Intrathecal	10 Mg, Tid Prn		Not Reported
	Baclofen			S	Oral	10 Mg, Tid Prn		Not Reported
	Nortriptyline			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Clonazepam			S	Unknown	0.5 Mg, Bid		Not Reported
	Carbamazepine			S	Unknown	Unk		Novartis
	Ibuprofen			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Naltrexon Hcl			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Lidocaine			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported
	Topiramate			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Olanzapine			S	Unknown	Unk		Not Reported
	Tizanidine			S	Unknown	Unk		Not Reported

Ketorolac	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Enoxaparin Sodium	S	Unknown	Unk	Not Reported
Fluphenazine	S	Unknown	Unk	Not Reported
Ondansetron	S	Unknown	Unk	Not Reported
Trazodone	S	Unknown	Unk	Not Reported
Amoxicillin	S	Unknown	Unk	Not Reported
Alprazolam	S	Unknown	Unk	Not Reported
Cyclobenzaprine	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Sertraline Hydrochloride	S	Unknown	Unk	Not Reported
Ciprofloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Valaciclovir	S	Unknown	Unk	Not Reported
Metaxalone	S	Unknown	Unk	Not Reported
Quetiapine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Promethazine	S	Unknown	Unk	Not Reported
Risperidone	S	Unknown	Unk	Not Reported
Orphenadrine	S	Unknown	Unk	Not Reported
Cimetidine	S	Unknown	Unk	Not Reported
Gabapentin	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Effexor	S	Unknown	150 Mg, Qd	Not Reported
Zantac	S	Unknown	Unk	Not Reported
Flexeril	S	Endocervical	Unk	Not Reported
Vicodin	S	Unknown	Unk	Not Reported
Horizant	S	Unknown	Unk	Not Reported
Medrol	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported

Lithium	S	Unknown	Unk	Not Reported
Celexa	S	Unknown	Unk	Not Reported
Valium	S	Unknown	Unk	Not Reported
Cymbalta	S	Unknown	Unk	Not Reported
Lodine	S	Unknown	Unk	Not Reported
Nexium//Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Nucynta	S	Unknown	Unk	Not Reported
Seroquel	S	Unknown	Unk	Not Reported
Skelaxin	S	Unknown	Unk	Not Reported
Piroxicam	S	Unknown	Unk	Not Reported
Vitamin B Complex With Vitamin C /02146701/	S	Unknown	Unk	Not Reported
Hyoscyamine	S	Unknown	Unk	Not Reported
Melatonin	S	Unknown	Unk	Not Reported
Vitamin B3	S	Unknown	Unk	Not Reported
Savella	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Librax	S	Unknown	Unk	Not Reported
Senna	S	Unknown	Unk	Not Reported
Docusate	S	Unknown	Unk	Not Reported
Topamax	S	Unknown	Unk	Not Reported
Miralax	S	Unknown	Unk	Not Reported
Multi Vitamin	S	Unknown	Unk	Not Reported
Dilaudid	S	Intrathecal		Not Reported
Dilaudid	S	Intrathecal	5.996 Mg, 20.0 Mg/Ml (Dose Was Decreased 14 Percent) Per Day	Not Reported
Dilaudid	S		Unk, 10 Mg/Ml Minimum Rate	Not Reported
Zanaflex	S	Unknown	Unk	Not Reported

Mobic	S	Unknown	Unk	Not Reported
Methocarbamol	S	Unknown	Unk	Not Reported
Bextra	S	Unknown	Unk	Not Reported
Actonel	S	Endocervical	Unk	Not Reported
Xanax	S	Unknown	Unk	Not Reported
Zoloft	S	Unknown	Unk	Not Reported
Lamictal	S	Unknown	Unk	Not Reported
Percocet	S	Unknown	Unk	Not Reported
Ultracet	S	Unknown	Unk	Not Reported
Butrans	S	Unknown	Unk	Not Reported
Toradol	S	Unknown	Unk	Not Reported
Depakote	S	Unknown	Unk	Not Reported
Ativan	S	Unknown	Unk	Not Reported
Namenda	S	Unknown	Unk	Not Reported
Abilify	S	Unknown	Unk	Not Reported
Hydromorphone	S	Unknown	Unk	Not Reported
Toprol Xl	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Aspirin	S	Unknown	Unk	Not Reported
Venlafaxin	S	Unknown	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Roxicodone	S	Unknown	Unk	Not Reported
Bisacodyl	S	Unknown	Unk	Not Reported
Tranylcypromine	S	Unknown	Unk	Not Reported
Divalproex	S	Unknown	Unk	Not Reported
Ferrous Sulphate	S	Unknown	Unk	Not Reported
Lactated Ringers	S	Unknown	Unk	Not Reported
Magnesium Citrate Enteral	S	Unknown	Unk	Not Reported
Milk Of Magnesia	S	Unknown	Unk	Not Reported

Sona	S	Unknown	Unk	Not Reported
Phenergan /00488301/	S	Unknown	Unk	Not Reported
Benzodiazepines	S	Unknown	Unk	Not Reported
Prolixin	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Macrobid	S			Not Reported
Acetaminophen\Hydrocodone Bitartrate	S	Unknown	Unk	Not Reported
Biaxin	S	Unknown	Unk	Not Reported
Arthrotec	S	Endocervical	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Ambien	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Propoxyphene N/Apap	S	Unknown	Unk	Not Reported
Lexapro	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Limbrel	S	Unknown	Unk	Not Reported
Nitrostat	S	Unknown	Unk	Not Reported
Doxycycline Hyclate	S	Unknown	Unk	Not Reported
Duloxetine Hcl	S	Unknown	Unk	Not Reported
Mexiletine	S	Unknown	Unk	Not Reported
Nuvigil	S	Unknown	150 Mg, Qd	Not Reported
Lidoderm	S	Unknown	Unk	Not Reported
Bupivacaine	S	Intrathecal	Unk	Not Reported
Fentora	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11211846	DIRECT	Y	HO			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoglycaemia	Hydroxychloroquine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11212682	DIRECT		DS			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Deafness; Eye Disorder; Scan Abnormal; Tinnitus; Toxicity To Various Agents	Hydroxychloroquine 200mg Tabs			S	Oral	1 Pill		Cvs Caremark
	Aleve			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2015	11214652	EXPEDITED (15-DAY)		DS, OT	CO-PL-US-2015-060			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Retinal Toxicity	Plaquenil			S			5 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	10532268	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2014SP004352		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Methotrexate			S				Mylan
	Prednisolone			S				Not Reported
	Gabapentin			S				Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Xeljanz			S				Not Reported
	Benicar			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11069707	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2015M1013420			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11211439	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-039498			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Distress	Abatacept			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11211887	EXPEDITED (15-DAY)		DS, OT	US-MYLANLABS-2015M1020264			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Spinal Disorder; Therapeutic Product Effect Incomplete	Methotrexate			S		Unk, Qw		Not Reported
	Enbrel			S		Unk, Qw		Not Reported
	Prednisone			S		Unk		Not Reported
	Arava			S				Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11213737	NON-EXPEDITED			US-MYLANLABS-2014M1011060		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Migraine; Nausea; Photophobia	Methotrexate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11213740	NON-EXPEDITED			US-MYLANLABS-2014M1013595			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Discomfort; Hepatic Enzyme Increased; Migraine; Musculoskeletal Stiffness; Oedema Peripheral; Sinus Disorder; Therapeutic Product Effect Incomplete	Methotrexate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11217610	EXPEDITED (15-DAY)		OT	CO-PL-US-2015-074		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Depression; Drug Hypersensitivity; Suicidal Ideation	Plaquenil			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11218296	EXPEDITED (15-DAY)	Y	LT	CO-PL-FR-2015-073		74 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactate Dehydrogenase Increased; Lymphoma	Plaquenil (Tablet) (Hydroxychloroquine Sulfate)			S	Oral			Not Reported
	Arava (Tablet) (Leflunomide)			S	Oral			Not Reported
	Novatrex (Tablet) (Methotrexate)			S	Oral			Not Reported

		Metoject (Solution) (Methotrexate)			S					Not Reported
		Salazopyrine (Unknown) (Sulfasalazine)			S					Not Reported
		Enbrel (Unknown) (Etanercept)			S					Not Reported
		Orencia (Unknown) (Abatacept)			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11218303	EXPEDITED (15-DAY)	Y	DS	CO-PL-CA-2015-072		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Swelling	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S		Unknown, Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S		Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11218320	EXPEDITED (15-DAY)	Y	OT	CO-PL-CA-2015-069		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Ineffective; Lower Respiratory Tract Infection	Plaquenil			S				Not Reported
	Humira (Unknown) (Adalimumab)			S				Not Reported
	Enbrel (Unknown) (Etanercept)			S				Not Reported
	Orencia (Unknown) (Abatacept)			S	Intravenous (not otherwise specified)	Intra Venous (Not Otherwise Specified)		Not Reported
	Methotrexate			C				Not Reported
	Celebrex (Celecoxib)			C				Not Reported
	Arva (Leflunomide)			C				Not Reported
	Xeljanz (Tofacitinib Citrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11218332	EXPEDITED (15-DAY)	Y	OT	CO-PL-CA-2015-068		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Leflunomide (Unknown) (Leflunomide)			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate (Unknown)			S				Not Reported
	Rituxan			S				Not Reported
	Imuran			S				Not Reported
	Gold			S				Not Reported
	Anakinra			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11218351	EXPEDITED (15-DAY)	Y	OT	CO-PL-CA-2015-075		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection Susceptibility Increased; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Therapeutic Product Effect Decreased	Plaquenil			S				Not Reported
	Myocrisin (Sodium Aurothiomalate)			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Xeljanz			S				Not Reported
	Humira			S				Not Reported
	Remicade			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Methotrexate (Unknown)			S				Not Reported
	Abatacept			C				Not Reported
	Rituxan (Unknown) (Rituximab)			C				Not Reported
	Kineret (Unknown) (Anakinra)			C				Not Reported
	Benadryl (Unknown) (Diphenhydramine Hydrochloride)			C				Not Reported
	Synthroid (Unknown) (Levothyroxine Sodium)			C				Not Reported

	Lasix (Unknown) (Furosemide)	C		Not Reported
	Enablex (Unknown) (Darifenacin)	C		Not Reported
	Ativan (Unknown) (Lorazepam)	C		Not Reported
	Loperamide	C		Not Reported
	Norflex (Unknown) (Orphenadrine Citrate)	C		Not Reported
	Omnaris (Unknown) (Ciclesonide)	C		Not Reported
	Pantoloc (Unknown) (Pantoprazole Sodium Sesquihydrate)	C		Not Reported
	Vagifem (Unknown) (Estradiol)	C		Not Reported
	Dilaudid (Hydromorphone Hydrochloride)	C		Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2015	11218470	EXPEDITED (15-DAY)	Y	DS, HO, OT	CO-PL-FR-2015-009		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Influenza; Product Use In Unapproved Indication; Pyrexia; Splenomegaly; Transaminases Abnormal	Plaquenil (Tablet) (Hydroxychloroquine Sulfate)			S	Oral			Not Reported
	Doxycycline (Unknown) (Doxycycline Hyclate)			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11137620	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1017087			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Diverticulum; Drug	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

Ineffective; Rheumatoid Arthritis	Plaquenil /00072602/		S			Not Reported
	Arava		S			Not Reported
	Cimzia		S		Unk	Not Reported
	Celebrex		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11199538	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019770			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Nausea; Vomiting	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		1 G, Bid		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported
	Arava			S		Unk		Not Reported
	Naprosyn /00256201/			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11211894	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1020269			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Enbrel			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Remicade			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.750 Mg, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported

	Azathioprine	S	Unk		Not Reported
	Prednisone	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11214358	EXPEDITED (15-DAY)		OT	CA-ROCHE-1574856		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Tenormin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Premarin			C				Not Reported
	Cymbalta			C				Not Reported
	Euro-Cal			C				Not Reported
	Elavil (Canada)			C				Not Reported
	Lyrica			C				Not Reported
	Imitrex			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11214632	EXPEDITED (15-DAY)		DE, HO, OT	AU-ORION CORPORATION ORION PHARMA-TREX2013-0171		68 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatitis B Reactivation; Hepatorenal Syndrome	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11214771	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-TREX2015-0300		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obliterative Bronchiolitis	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11215152	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1020273			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2015	11220183	DIRECT					40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Muscle Spasms	Plaquenil			S	Oral			Zydus Pharm
	Fluticasone			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Plaquenil			C				Not Reported
	Albuterol			C				Not Reported
	Qvar			C				Not Reported
	Mobic			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Fexofenadine			C				Not Reported
	Benadryl			C				Not Reported
	Align Probiotic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218637	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015100375		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Haemoglobin Decreased; Hepatic Steatosis; Osteoporosis; Pyrexia; Rash; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported
	Cimzia			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Arthrotec			C		Unk		Not Reported
	Actonel			C		Unk		Not Reported
	Vitamin D Nos			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11218823	EXPEDITED (15-DAY)		OT	JP-SA-2015SA089352		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Arthralgia; Asthenia; Atrophy; Back Pain; Bursitis; Contusion; Depression; Fall; Insomnia; Joint Effusion; Muscle Spasms; Myofascial Pain Syndrome; Osteoporosis; Panic Reaction; Social Avoidant Behaviour; Somatic Symptom Disorder; Substance-Induced Psychotic Disorder; Therapy Non-Responder	Levaquin			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Baclofen			S	Intrathecal			Not Reported
	Baclofen			S	Oral			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Bupivacaine			S	Intrathecal			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Zanaflex			S	Unknown			Not Reported
	Zanaflex			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Hydroxyzine			S	Unknown			Not Reported
	Lidocaine			S	Topical	Form-Patch		Not Reported
	Lithium			S	Unknown			Not Reported
	Methocarbamol			S	Unknown			Not Reported
	Melatonin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Miralax			S	Unknown	Form-Powder		Not Reported
	Ranitidine			S	Unknown			Not Reported
	Senna			S	Unknown			Not Reported
	Docusate			S	Unknown			Not Reported
	Panthenol/Retinol/Thiamine Hydrochloride/Ascorbic Acid/Ergocalciferol/Folic Acid/Riboflavin/Nicotina			S	Unknown			Not Reported

Vitamin D3	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Topamax	S	Unknown	Not Reported
Heparin	S	Unknown	Not Reported
Topiramate	S	Unknown	Not Reported
Meloxicam	S	Unknown	Not Reported
Diazepam	S	Unknown	Not Reported
Nortriptyline	S	Unknown	Not Reported
Olanzapine	S	Unknown	Not Reported
Savella	S	Unknown	Not Reported
Tizanidine	S	Unknown	Not Reported
Ketorolac	S	Unknown	Not Reported
Effexor	S	Unknown	Not Reported
Flexeril	S	Unknown	Not Reported
Vicodin	S	Unknown	Not Reported
Medrol	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Celexa	S	Unknown	Not Reported
Cymbalta	S	Unknown	Not Reported
Lodine	S	Unknown	Not Reported
Nexium	S	Unknown	Not Reported
Nucynta	S	Unknown	Not Reported
Pristiq	S	Unknown	Not Reported
Seroquel	S	Unknown	Not Reported
Skelaxin	S	Unknown	Not Reported
Piroxicam	S	Unknown	Not Reported
Hyoscyamine	S	Unknown	Not Reported
Librax	S	Unknown	Not Reported
Bextra	S	Unknown	Not Reported

Actonel	S	Unknown	Not Reported
Xanax	S	Unknown	Not Reported
Zoloft	S	Unknown	Not Reported
Zoloft	S	Unknown	Not Reported
Lamictal	S	Unknown	Not Reported
Mobic	S	Unknown	Not Reported
Percocet	S	Unknown	Not Reported
Ultracet	S	Unknown	Not Reported
Toradol	S	Unknown	Not Reported
Depakote	S	Unknown	Not Reported
Ativan	S	Unknown	Not Reported
Abilify	S	Unknown	Not Reported
Gabapentin	S	Unknown	Not Reported
Hydromorphone	S	Unknown	Not Reported
Toprol Xl	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Aspirin	S	Unknown	Not Reported
Clonazepam	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Ondansetron	S	Unknown	Not Reported
Tylenol	S	Unknown	Not Reported
Roxicodone	S	Unknown	Not Reported
Bisacodyl	S	Oral	Not Reported
Enoxaparin	S	Unknown	Not Reported
Methocarbamol	S	Unknown	Not Reported
Tranylcypromine	S	Unknown	Not Reported
Divalproex Sodium	S	Unknown	Not Reported
Ferrous Sulphate	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported

Magnesium Citrate	S	Oral	Not Reported
Milk Of Magnesia	S	Unknown	Not Reported
Fluphenazine	S	Unknown	Not Reported
Phenergan	S	Unknown	Not Reported
Prolixin	S	Unknown	Not Reported
Bactrim	S	Unknown	Not Reported
Macrobid	S	Unknown	Not Reported
Acetaminophen\Hydrocodone Bitartrate	S	Unknown	Not Reported
Biaxin	S	Unknown	Not Reported
Amoxicillin	S	Unknown	Not Reported
Cyclobenzaprine	S	Unknown	Not Reported
Alprazolam	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Arthrotec	S	Unknown	Not Reported
Methylprednisolone	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Lexapro	S	Unknown	Not Reported
Metaxalone	S	Unknown	Not Reported
Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
Cephalexin	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Valaciclovir	S	Unknown	Not Reported
Nitrostat	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Doxycycline Hyclate	S	Unknown	Not Reported
Quetiapine Fumarate	S	Unknown	Not Reported
Promethazine	S	Unknown	Not Reported

	Duloxetine			S	Unknown				Not Reported
	Namenda			S	Unknown				Not Reported
	Risperidone			S	Unknown				Not Reported
	Orphenadrine			S	Unknown				Not Reported
	Cimetidine			S	Unknown				Not Reported
	Mexiletine			S	Unknown				Not Reported
	Nuvigil			S	Unknown				Not Reported
	Trazodone			S	Unknown				Not Reported
	Lidoderm			S	Unknown				Not Reported
	Carbamazepine			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2015	11219093	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1020858			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported
	Arava			S		20 Mg, Qd		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	10260795	EXPEDITED (15-DAY)		OT	BE-UCBSA-117068		63 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blister; Dyspnoea; Face Oedema; Pruritus; Rheumatoid Arthritis; Urticaria	Cimzia		S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)	Ucb
	Hydroxychloroquine		S	Oral	200 Mg, Once Daily (Qd)	Not Reported
	Prednisolone		C		10 Mg, Once Daily (Qd)	Not Reported
	Prednisolone		C		5 Mg, Once Daily (Qd)	Not Reported
	Prednisolone		C		7.5 Mg, Once Daily (Qd)	Not Reported
	Mtx		C	Oral	7.5 Mg, Weekly (Qw)	Not Reported
	Calcium		C			Not Reported
	Folium Acid		C		10 Mg, Weekly (Qw)	Not Reported
	Dedrogyl		C			Not Reported
	Aspirine		C		100 Mg, 2x/Week	Not Reported
	Fluoxetine		C			Not Reported
	Leflunomide		C		10 Mg, Once Daily (Qd)	Not Reported
	Vitamin D Nos		C	Oral	8 Df, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11220955	EXPEDITED (15-DAY)		OT	PT-ACCORD-031706		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma	Methotrexate			S				Accord
	Etanercept			S				Not Reported
	Salazopyrin			S				Not Reported
	Deflazacort			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11227494	DIRECT					63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Disorder; Product Quality Issue; Product Substitution Issue	Plaquenil Hydroxychloroquine 200mg Zydus			S	Oral			Zydus Pharm
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11227502	EXPEDITED (15-DAY)	Y	OT	CO-PL-US-2015-083		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinopathy; Toxicity To Various Agents; Visual Field Defect	Hydroxychloroquine Sulfate			S		Few Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2015	11228047	EXPEDITED (15-DAY)		OT	CO-PL-UK-2015-079			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blepharitis; Dry Eye	Plaquenil			S	Oral			Not Reported
	Systane (Unknown) (Propylene Glycol, Macrogol 400)			C				Not Reported
	Symbicort (Unknown) (Formoterol Fumarate, Budesonide)			C				Not Reported
	Amitriptyline (Unknown) (Amitriptyline)			C				Not Reported
	Adcal (Unknown) (Carbazochrome)			C				Not Reported
	Telebrix (Unknown) (Ioxitalamate Meglumine, Ioxitalamate Sodium)			C				Not Reported
	Gabapentin (Unknown) (Gabapentin)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11225080	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015211325		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Kidney Infection; Malaise;	Lyrica			S		Unk		Pfizer
	Lyrica			S	Oral	300 Mg, 2x/Day		Pfizer

Overdose	Hydroxychloroquine Sulfate	S	200 Mg, Unk	Not Reported
	Ciprofloxacin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11225623	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2015209176		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Campylobacter Infection	Sulfasalazine			S	Oral	500 Mg, 4x/Day 0. - 38.1. Gestational Week		Pfizer
	Quensyl			S	Oral	200 Mg, 2x/Day 0. - 38.1. Gestational Week		Not Reported
	Decortin			C	Oral	7.5 Mg, Daily 0. - 38.1. Gestational Week		Not Reported
	Decortin			C	Oral	0. - 38.1. Gestational Week10 Mg, Daily		Not Reported
	Decortin			C	Oral	15 Mg, Daily 0. - 38.1. Gestational Week		Not Reported
	Cimzia			C	Subcutaneous	200 Mg, Unk		Not Reported
	Folio Forte			C	Oral	0.8 Mg, Daily 0. - 38.1. Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11226184	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1001072			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Arava			S				Not Reported
	Gold			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11226236	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021237			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Imuran /00001501/			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2015	11228366	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine 200 Mg Bid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	10881406	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1006461			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Humira			S		Unk		Not Reported
	Golimumab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	10969882	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1010096			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Fatigue; Haemoglobin Decreased; Hepatic Steatosis; Hypersensitivity; Osteoporosis; Rheumatoid Arthritis	Methotrexate	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Prednisone	C		Unk	Not Reported
	Cimzia	S		Unk	Not Reported
	Arthrotec	C		Unk	Not Reported
	Actonel	C		Unk	Not Reported
	Vitamin D /00107901/	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11156573	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1017755			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S		12.5 Unk, Unk		Not Reported
	Methotrexate			S	Intramuscular	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		12.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Arava			S		200 Mg, 2x/Week		Not Reported
	Arava			S		10 Mg, Qd		Not Reported
	Arava			S		10 Mg, Alternate Day		Not Reported
	Arava			S		10 Mg, Alternate Day		Not Reported
	Arava			S		10 Mg, 3xw		Not Reported
	Arava			S		10 Mg, Biweekly		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Humira			S		40 Mg, Cyclic (Every Other Week)		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Cyclic (Jan/Feb2014, Oct2014)			Not Reported
	Rituxan			S		1000 Mg, Cycle			Not Reported
	Plaquenil /00072602/			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11213555	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1013108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Celebrex			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11227520	EXPEDITED (15-DAY)		CA	DE-PFIZER INC-2015208522		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Talipes	Sulfasalazine			S	Transplacental	500 Mg, 4x/Day, 0. - 38.1. Gestational Week		Pfizer
	Quensyl			S	Transplacental	200 Mg, 2x/Day, 0. - 38.1. Gestational Week		Not Reported
	Decortin			C	Transplacental	7.5 Mg, Daily, 0-12+6 Gestational Week		Not Reported
	Decortin			C	Transplacental	10 Mg, Daily, 13+0-14+6 Gestational Week		Not Reported
	Decortin			C	Transplacental	15 Mg, Daily, 15+0-38+1 Gestational Week		Not Reported
	Cimzia			C	Transplacental	200 Mg, Unk, 0. - 1.1. Gestational Week		Not Reported
	Folio Forte			C	Transplacental	0.8 Mg, Daily, 0. - 38.1.		Not Reported

Gestational Week

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11229479	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021619			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Guillain-Barre Syndrome	Methotrexate			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11349338	NON-EXPEDITED		HO, OT	2014COV00008		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Flushing; Oedema Peripheral; Right Ventricular Heave	Plaquenil Tablet (Hydroxychloroquine) Tablet			S	Oral			Not Reported
	Flolan Sterile Powder			S	Intravenous (not otherwise specified)	27 Unk, Unk, Intravenous		Not Reported
	Mycophenolate Mofetil Tablets			S	Oral			Not Reported
	Furosemide			C				Not Reported
	Loratadine			C				Not Reported
	Ocuvie Preservision			C				Not Reported
	Potassium Chloride			C				Not Reported
	Tadalafil			C				Not Reported
	Oxygen			C				Not Reported
	Bosentan			C				Not Reported
	Prednisone			C				Not Reported
	Epoprostenol Sodium			C				Not Reported
	Azathioprine			C				Not Reported
	Aspirin			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Timadol Hydrochloride			C				Not Reported
	Triamcinolone Acetonide			C				Not Reported
	Zolpidem Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11349340	NON-EXPEDITED	Y	OT	2014COV00011		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Scar; Retinopathy; Toxicity To Various Agents	Plaquenil Tablet (Hydroxychloroquine) Tablet			S				Not Reported
	Humira (Adalimumab)			S	Subcutaneous	2x/Month, Unknown 2x/Month		Not Reported
	Prevacid (Lansoprazole)			C				Not Reported
	Synthroid (Levothyroxine Sodium)			C				Not Reported
	Cytomel (Liothyronine Sodium)			C				Not Reported
	Cardizem Cd (Diltiazem Hydrochloride)			C				Not Reported
	Cardizem (Diltiazem Hydrochloride) (Tablets)			C				Not Reported
	Relafen (Nabumetone)			C				Not Reported
	Diflucan (Fluconazole)			C				Not Reported
	Chloral Hydrate (Chloral Hydrate)			C				Not Reported
	Estrace (Estradiol)			C				Not Reported
	Famotidine			C				Not Reported
	Lipitor (Atorvastatin Calcium)			C				Not Reported
	Lamotrigine			C				Not Reported
	Zofran (Ondansetron Hydrochloride)			C				Not Reported
	Codeine			C				Not Reported
	Propanolol (Propranolol Hydrochloride)			C				Not Reported
	Phenobarbitol			C				Not Reported
	Xyrem (Oxybate Sodium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11349342	NON-EXPEDITED		OT	2014COV00148		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration	Plaquenil Tablet			S				Not Reported

			(Hydroxychloroquine) Tablet							
			Methotrexate		C					Not Reported
			Prevacid		C					Not Reported
			Lovastatin		C					Not Reported
			Folic Acid		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11349345	NON-EXPEDITED		OT	2014COV00188		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration	Plaquenil Tablet			S				Not Reported
	(Hydroxychloroquine) Tablet							
	Tyvaso (Treprostinil Sodium) Inhalation Gas			S				Not Reported
	Adcirca (Tadalafil)			C				Not Reported
	Letairis (Ambrisentan)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11349356	NON-EXPEDITED		OT	2015COV00017		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Visual Acuity Reduced	Plaquenil Tablet			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2015	11349366	NON-EXPEDITED		DS	2015COV00075		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Nail Discolouration; Nail Disorder; Nail Pitting; Nystagmus; Psoriasis; Therapeutic Response Changed; Visual Acuity Reduced	Plaquenil Tablet			S				Not Reported
	(Hydroxychloroquine) Tablet							
	Humira (Adalimumab) Solution For Injection			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11231893	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1003969			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg "1/7"		Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Rituxan			S		1 G "1/2"		Not Reported
	Simponi			S		50 Mg, Monthly		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Monthly		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Naprosyn /00256201/			S		500 Mg, Bid		Not Reported
	Celebrex			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2015	11240384	DIRECT	Y	HO, RI			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Hydroxychloroquine			S	Oral			Not Reported
	Hydrochlorothiazide/Losartan			S	Oral	25/100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11226257	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021607			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Methotrexate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported

	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Cycle (Every 4 Weeks)			Not Reported
	Remicade			S		200 Mg, Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Unk, Unk			Not Reported
	Humira			S	Subcutaneous	40 Mg, Cycle (Every 2 Weeks)			Not Reported
	Arava			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11228556	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2015M1021624			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Type 2 Diabetes Mellitus	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Biweekly		Not Reported
	Remicade			S		5 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, Monthly		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
	Rituxan			S		1000 Mg, Every 15 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11240146	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021629			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Methotrexate			S		1.0 Ml, Qw		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Synthroid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11247359	EXPEDITED (15-DAY)	Y	OT	CO-PL-FR-2015-114		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Discolouration	Plaquenil			S	Oral			Not Reported
	Cortancyl (Prednisone)			C				Not Reported
	Hytacand (Hydrochlorothiazide, Candesartan Cilexetil)			C				Not Reported
	Inexium (Esomeprazole Magnesium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11247371	EXPEDITED (15-DAY)	Y	HO	CO-PL-FR-2015-113		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Test Positive; Drug Ineffective; Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema; Eyelid Oedema; Eyelid Oedema; Face Oedema; Pruritus; Pustule; Pyrexia; Rash Papular; Rash Pruritic; Toxic Skin Eruption	Plaquenil			S	Oral			Not Reported
	Altim (Unknown) (Cortivazol)			C				Not Reported
	Plavix (Unknown) (Clopidogrel Bisulate)			C				Not Reported
	Bi Tildiem (Unknown) (Diltiazem Hydrochloride)			C				Not Reported
	Crestor (Unknown) (Rosubastatin Calcium)			C				Not Reported
	Mianserine (Unknown) (Mianserin Hydrochloride)			C				Not Reported
	Inexium (Unknown)			C				Not Reported

		(Esomeprazole Magnesium)								
		Colchimax (Unknown) (Colchicine, Tiemonium Methylsulphate, Papaver Somniferum Powder)			C					Not Reported
		Allopurinol (Unknown) (Allopurinol)			C					Not Reported
		Cortancyl (Unknown) (Prednisone)			C					Not Reported
		Lamaline (Unknown) (Caffeine, Paracetamol, Papaver Somnieferum Latex)			C					Not Reported
		Klipal Codeine (Unknown) (Codeine Phosphate, Parachetamol)			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11247382	EXPEDITED (15-DAY)		OT	CO-PL-CA-2015-112			Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Rheumatoid Arthritis	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Not Reported
	Arthrotec			S				Not Reported
	Xeljanz (Tofacitinib Citrate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2015	11248012	EXPEDITED (15-DAY)	Y	OT	CO-PL-IE-2015-046		47 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Balance Disorder; Depressed Mood; Disorientation; Dizziness; Retching; Vertigo; Vestibular Disorder; Vomiting; Weight Decreased	Plaquenil			S	Oral			Not Reported
	Aldactone (Spironolactone)			C				Not Reported
	Neo Mercazole (Carbimazole)			C				Not Reported
	Mometasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11243371	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2015M1021937			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pericardial Effusion; Pulmonary Oedema; Renal Disorder; Rheumatoid Arthritis	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11245118	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2703657			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown	Not Reported		Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported		Not Reported
	Enbrel			S	Unknown	Not Reported		Not Reported
	Myfortic			S	Unknown	Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11245438	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2701916			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown	Not Reported		Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported		Not Reported
	Enbrel			S	Subcutaneous	Not Reported		Not Reported
	Myfortic			S	Unknown	Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11253320	EXPEDITED (15-DAY)		OT	CO-PL-CA-2015-118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Spinal Fusion Surgery	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2015	11253359	EXPEDITED (15-DAY)	Y	CA	CO-PL-DE-2015-116		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Drugs Affecting Foetus; Talipes	Quensyl			S	Transplacental			Not Reported
	Sulfasalazin			S	Transplacental	1 In 6 Hr,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11095396	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1014736			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Inflammation; Plantar Fasciitis; Rheumatoid Arthritis; Sciatica; Tendonitis	Methotrexate			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Celebrex			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Tylenol Extra Strength			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11228843	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021617			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate	S	Subcutaneous	Unk, Qw		Not Reported
	Plaquenil /00072602/	S		Unk		Not Reported
	Cimzia	S		Unk		Not Reported
	Sulfasalazine	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11247514	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1022046			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11247557	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2746065		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Eye Disorder; Herpes Zoster; Nasopharyngitis; Pain; Pulmonary Fibrosis	Methotrexate			S	Unknown	Not Reported		Not Reported
	Acetaminophen W/Codeine Phosphate			C		Not Reported		Not Reported
	Cranberry /01512301/			C		Not Reported		Not Reported
	Pantoprazole			C		Not Reported		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown	Not Reported		Not Reported
	Amlodipine			C		Not Reported		Not Reported
	Dexilant			C		Not Reported		Not Reported
	Duragesic			C		Not Reported		Not Reported
	Acetylsalicylic Acid			C		Not Reported		Not Reported
	Euro-Fer			C		Not Reported		Not Reported
	Irbesartan			C		Not Reported		Not Reported

	Lipitor	C		Not Reported	Not Reported
	Senokot /00142201/	C		Not Reported	Not Reported
	Tears Naturale Ii /00134201/	C	Ophthalmic	Not Reported	Not Reported
	Vitamin B Complex	C		Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11248155	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2747982			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown	Not Reported		Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported		Not Reported
	Enbrel			S	Unknown	Not Reported		Not Reported
	Mycophenolate Mofetil			S	Unknown	Not Reported		Not Reported
	Myfortic			S	Unknown	Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2015	11258473	EXPEDITED (15-DAY)	Y	HO	CO-PL-IT-2015-120		65 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Vertigo	Plaquenil			S	Oral	2 Dosage Forms, Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	10442389	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-A1088336A		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hip Fracture; Immune System Disorder; Ocular Toxicity; Staphylococcal Infection	Benlysta			S	Intravenous (not otherwise specified)	Unk Unk, U		Glaxosmithkline
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11168254	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018354			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11240132	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021955			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11256357	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2780910			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Enbrel			S	Subcutaneous	Not Reported		Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported		Not Reported

		Mycophenolate Mofetil			S	Unknown	Not Reported			Not Reported
		Methotrexate			S	Unknown	Not Reported			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11257294	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1022736			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Enbrel			S				Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2015	11257296	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1022731			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		1 Ml, Qw		Not Reported
	Enbrel			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Prednisone			S		7 Mg, Qd		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Kineret			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11260112	EXPEDITED (15-DAY)		OT	US-TEVA-576843USA		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinopathy; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Mg/Day For 5.8 Years		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11260501	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2773899			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Hydroxychloroquine			S	Unknown	Not Reported		Not Reported
	Mycophenolate Sodium			S	Unknown	Not Reported		Not Reported
	Methotrexate			S	Unknown	Not Reported		Not Reported
	Enbrel			S	Subcutaneous	Not Reported		Not Reported
	Mycophenolate Mofetil			S	Unknown	Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11262933	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2778755		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Eye Disorder; Herpes Zoster; Nasopharyngitis; Pain; Pulmonary Fibrosis	Amlodipine			C		Not Reported		Not Reported
	Euro-Fer			C		Not Reported		Not Reported
	Tylenol W/Codeine No. 3			C		Not Reported		Not Reported
	Vitamin B Complex			C		Not Reported		Not Reported
	Plaquenil /00072602/			S	Unknown	Not Reported		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cranberry /01512301/			C		Not Reported		Not Reported
	Dexilant			C		Not Reported		Not Reported
	Duragesic			C		Not Reported		Not Reported

	Irbesartan	C		Not Reported	Not Reported
	Senokot /00142201/	C		Not Reported	Not Reported
	Tears Naturale /00635701/	C		Not Reported	Not Reported
	Asa	C		Not Reported	Not Reported
	Lipitor	C		Not Reported	Not Reported
	Pantoprazole	C		Not Reported	Not Reported
	Methotrexate	S	Unknown	Not Reported	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	10962586	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1009868			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Methotrexate			S		20 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Hydroxychloroquine			S		300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11148608	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1017667			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Vomiting	Methotrexate			S		20, Unk, Weekly		Not Reported
	Sulfasalazine			S		1 G, Bid		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11175933	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018994			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Intolerance; Hypersensitivity; Infection; International Normalised Ratio Fluctuation	Methotrexate			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Erythromycin			S				Not Reported
	Bisoprolol Fumarate			S		Unk		Not Reported
	Flagyl /00012501/			S				Not Reported
	Levofloxacin			S		Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S				Not Reported
	Prednisone			S				Not Reported
	Demerol			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Norfloxacin			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11264651	NON-EXPEDITED			US-PFIZER INC-2015221135		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Piroxicam			S				Pfizer
	Diclofenac Sodium			S				Pfizer
	Bextra			S				Not Reported
	Cefalexin			S				Not Reported
	Plaquenil Sulfate			S				Not Reported
	Vioxx			S				Not Reported
	Keflex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11265431	EXPEDITED (15-DAY)		DS, OT	US-ACTAVIS-2015-13975		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	400 Mg, Daily		Watson
	Nabumetone (Watson Laboratories)			S	Unknown	High-Dose		Watson
	Ibuprofen (Amallc)			S	Unknown	Occasional		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11265811	EXPEDITED (15-DAY)		OT	MX-SA-2015SA099622		54 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Celebrex			C	Oral	Duration: 1 Year Approximately		Not Reported
	Paracetamol			C	Oral	Duration: 1 Year Approximately		Not Reported
	Folic Acid			C	Oral	Duration: 1 Year Approximately		Not Reported
	Azulfidina			C	Oral	Strength: 500 Mg Duration: 1 Year Approximately		Not Reported
	Prednisone			C	Oral	Duration: 1 Year Approximately		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11272037	EXPEDITED (15-DAY)	Y	HO	CO-PL-IT-2015-119		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pneumonia Influenzal	Plaquenil	S	Oral		Not Reported
	Deltacortene	S	Oral		Not Reported
	En (Delorazepam)	C			Not Reported
	Entact (Escitalopram Oxalate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11272040	EXPEDITED (15-DAY)	Y	OT	CO-PL-IT-2015-030		24 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S	Oral			Not Reported
	Urbason (Unknown) (Methylprenisolone)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11272056	EXPEDITED (15-DAY)	Y	OT	CO-PL-FR-2015-123		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Pneumococcal	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11190892	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015082873		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Wound	Benlysta Solution For Injection			S	Intravenous (not otherwise specified)	10 Mg/Kg, U		Glaxosmithkline
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	20 Mg, Qd		Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Adipex			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11268932	EXPEDITED (15-DAY)		HO, OT	FR-ORION CORPORATION ORION PHARMA-TREX2015-0208		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Sepsis; Bone Marrow Failure; Candida Infection; Diverticulum Intestinal; Dysphagia; Escherichia Infection; Haematemesis; Large Intestine Infection; Leukopenia; Melaena; Neutropenia; Pharyngitis; Thrombocytopenia	Imeth			S	Oral	Strength: 10 Mg		Not Reported
	Salazopyrine			S	Unknown	Strength: 500 Mg		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Inexium			S	Unknown	Strength: 20 Mg		Not Reported
	Fumafer			C	Unknown			Not Reported
	Prednisone			C	Unknown	Strength: 5 Mg		Not Reported
	Speciafoldine			C	Unknown	Strength: 5 Mg		Not Reported
	Voltarene (Diclofenac Sodium)			C	Unknown	Strength: 75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11271276	EXPEDITED (15-DAY)		HO	PHHY2015US081745		36 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Azotaemia; Lupus Nephritis; Renal Impairment; Renal Tubular Necrosis; Thrombocytopenia	Hydroxychloroquine			S	Unknown			Novartis
	Prednisone			C	Unknown	40 Mg, Unk		Not Reported
	Prednisone			C	Unknown	120 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11199452	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1019921			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea;	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported

Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Methotrexate		S	Subcutaneous	7.5 Unk, Unk	Not Reported
	Enbrel		S		50 Mg, Qw	Not Reported
	Celebrex		S		Unk	Not Reported
	Celebrex		S			Not Reported
	Arava		S		Unk	Not Reported
	Arava		S			Not Reported
	Prednisone		S		Unk	Not Reported
	Orencia		S		250 Unk, Unk	Not Reported
	Rituxan		S		Unk	Not Reported
	Sulfasalazine		S		2 G, Unk	Not Reported
	Plaquenil /00072602/		S		300 Mg, Unk	Not Reported
	Leflunomide		S	Oral	20 Mg, Unk	Not Reported
	Leflunomide		S		20 Mg, Unk	Not Reported
	Leflunomide		S		Unk	Not Reported
	Leflunomide		S		10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11204760	EXPEDITED (15-DAY)		OT	PT-AMGEN-PRTSP2015060816		64 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma Stage Iv	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Salasopyrine			S	Unknown	Unk		Not Reported
	Deflazacort			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11223040	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1020882			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspepsia; Hypertension; Rheumatoid Arthritis	Methotrexate	S	Unk		Not Reported
	Enbrel	S			Not Reported
	Sulfasalazine	S	Unk		Not Reported
	Azathioprine	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Humira	S	Unk		Not Reported
	Abatacept	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11272653	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1023767			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2015	11279050	EXPEDITED (15-DAY)	Y	HO	CO-PL-FR-2015-126		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Blood Pressure Increased; Limb Discomfort; Malaise; Oedema; Oropharyngeal Pain; Peripheral Swelling; Peripheral Swelling; Poor Quality Sleep; Taste Disorder; Taste Disorder	Plaquenil			S	Oral			Not Reported
	Preterax			S	Oral			Not Reported
	Maalox (Magnesium Hydroxide, Aluminium Hydroxide)			C				Not Reported
	Smecta (Diosmectite)			C				Not Reported
	Doliprane (Paracetamol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	10192587	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014138396		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia; Somnolence; Toxicity To Various Agents	Xanax			S	Oral	Unk		Pfizer
	Loxen Lp			S	Oral	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Dafalgan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11025902	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1011720			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Feeling Hot; Fine Motor Skill Dysfunction; Hypoaesthesia; Mobility Decreased; Paraesthesia	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11248914	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1022726			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Naprosyn /00256201/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Naprelan			C				Not Reported
	Folic Acid			C				Not Reported

	Crestor			C						Not Reported
	Metoprolol			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11275618	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1023490			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11275780	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1022745			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Omeprazole			C				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11276618	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015232178		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Complex Regional Pain Syndrome; Cough; Interstitial Lung	Xeljanz			S	Oral	10 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

Disease; Joint Swelling; Loss Of Personal Independence In Daily Activities; Middle Insomnia; Musculoskeletal Pain; Musculoskeletal Stiffness; Organising Pneumonia; Pain In Extremity; Pneumonitis	Leflunomide	S		Unk	Not Reported
	Premarin	C		1.25 Mg, 1x/Day	Not Reported
	Neurontin	C	Oral	800 Mg, (1 Po Tid To Qid)	Not Reported
	Klonopin	C		(1 Mg 1 Tabs In Am, 1 Tab Po Qhs)	Not Reported
	Lidoderm	C		(Patch 12 Hrs On /12 Hrs Off Prn)	Not Reported
	Vitamin D /00107901/	C		1000 Iu, 1x/Day	Not Reported
	Centrum Silver /02363801/	C		1 Df, 1x/Day	Not Reported
	Plaquenil /00072602/	C		200 Mg, 2x/Day	Not Reported
	Iron	C		1 Df, Unk (Not Taking Lately)	Not Reported
	Topiramate	C		100 Mg, (Qhs)	Not Reported
	Fish Oil	C		1 Df, 2x/Day	Not Reported
	Metamucil /00029101/	C		(1 Tpsn Bid), As Needed	Not Reported
	Voltaren	C		(1% 2-4 Grams Tid To Qid To Affect)	Not Reported
	Prilocaine	C		(2.5%/2.5 %), As Needed	Not Reported
	Budesonide	C		3 Mg, 1x/Day	Not Reported
	Calcium Citrate	C		Unk, 1x/Day	Not Reported
	Mirtazapine	C		15 Mg, (Qhs)	Not Reported
	Singulair	C		10 Mg, 1x/Day	Not Reported
	Promethazine	C		25 Mg, As Needed (Qd)	Not Reported
	Prednisolone	C		(1-2 As Prn Up To 4x/D), As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2015	11277227	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1023524			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported

	Plaquenil /00072602/			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	10205124	EXPEDITED (15-DAY)		HO	PHHY2014FR062547		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia; Somnolence	Loxen Lp			S	Oral	50 Mg, Unk		Not Reported
	Simvastatin			S	Oral	Unk		Novartis
	Prednisone			S	Oral	Unk		Not Reported
	Xanax			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Dafalgan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11168167	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1018339			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11247516	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1022989			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hyperhidrosis; Influenza; Rheumatoid Arthritis	Methotrexate			S		22.5 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil /00072602/			S		200 Mg, Unk		Not Reported
	Prednisone			S		5 Mg, Unk		Not Reported
	Folic Acid			C				Not Reported
	Vitamin D /00107901/			C				Not Reported

Celebrex	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11278885	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-100244		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Azotaemia; Focal Segmental Glomerulosclerosis; Lupus Nephritis; Mesangioproliferative Glomerulonephritis; Metabolic Acidosis; Thrombocytopenia	Prednisone			S	Unknown	Unk		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Methylprednisolone			C	Unknown	1 G, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2015	11279970	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1023539			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Methotrexate Sodium			S		12.5 Mg, Unk		Not Reported
	Salazopyrin			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2015	10901481	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015078388		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Sepsis; Bone Marrow Failure; Candida Infection; Diverticulum Intestinal; Dysphagia; Escherichia Infection; Haematemesis; Large	Salazopyrine			S	Oral	2 Tablets Of 500 Mg, 2x/Day		Pfizer
	Imeth			S	Oral	10 Mg, Weekly		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Inexium			S	Oral	20 Mg, 1x/Day		Not Reported

Intestine Infection; Leukopenia; Melaena; Neutropenia; Pharyngitis; Rectal Haemorrhage; Thrombocytopenia	Prednisone	C	Unknown	3 Df Of 5 Mg, 1x/Day		Not Reported
	Fumafer	C	Unknown	1 Df, Daily		Not Reported
	Speciafoldine	C	Unknown	5 Mg, 1x/Day		Not Reported
	Voltarene (Diclofenac Sodium)	C	Unknown	75 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2015	11285173	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1023769			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11285671	EXPEDITED (15-DAY)		HO	FR-ROCHE-1609946		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Bactrim Forte			S	Oral	3 Times/Week After Dialysis		Not Reported
	Cellcept			S	Oral	Daily		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Zelitrex			C	Unknown			Not Reported
	Zelitrex			C	Unknown			Not Reported
	Aprovel			C				Not Reported
	Cortancyl			C				Not Reported
	Lasilix			C				Not Reported
	Amlor			C				Not Reported
	Zovirax			C	Unknown			Not Reported
	Zovirax			C	Unknown			Not Reported
	Zovirax			C	Unknown			Not Reported

	Zovirax			C	Unknown					Not Reported
	Zovirax			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11285782	EXPEDITED (15-DAY)		HO, LT	GXKR2015DE003432			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Allopurinol 1a Pharma			S	Oral	2 Df, Qd		Novartis
	Metex (Methotrexate Sodium)			S	Subcutaneous	1 Df, Qw		Not Reported
	Quensyl			S	Oral	200 Mg, Qd		Not Reported
	Falithrom			C		According To Inr		Not Reported
	Ramipril			C		0.5 Df, Qd		Not Reported
	Omeprazol 1 A Pharma			C		1 Df, Qd		Not Reported
	Ramiplus Al			C		1 Df, Qd		Not Reported
	Dekristol			C				Not Reported
	Folsan			C		1 Df, Qw		Not Reported
	Simvastatin			C		1 Df, Qd		Not Reported
	Torasemid-1a Pharma			C		1 Df, Bid		Not Reported
	Novaminsulfon 1 A Pharma			C		Max. 4x1		Not Reported
	Tilidin Comp			C		1.5 Df, Bid		Not Reported
	Spirogamma			C		0.5 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11289324	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2015M1024027			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Decreased Appetite; Dizziness; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Headache; Musculoskeletal Disorder;	Methotrexate			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Aspirin /00002701/			S				Not Reported
	Arava			S				Not Reported
	Voltaren			S				Not Reported

Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Naprosyn /00256201/	S				Not Reported
	Humira	S				Not Reported
	Gold	S				Not Reported
	Plaquenil /00072602/	S				Not Reported
	Motrin	S				Not Reported
	Tramadol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11294556	EXPEDITED (15-DAY)		OT	CO-PL-MX-2015-129		54 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Paracetamol			C				Not Reported
	Folic Acid			C				Not Reported
	Azulfidine			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11294574	EXPEDITED (15-DAY)	Y	OT	CO-PL-CA-2015-131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Plaquenil			S				Not Reported
	Leflunomide (Unknown) (Leflunomide)			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2015	11294578	EXPEDITED (15-DAY)		OT	CO-PL-CA-2015-034			Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Peripheral Swelling; Plantar Fasciitis; Rheumatoid Arthritis;	Plaquenil			S				Not Reported
	Methotrexate (Unknown) (Methotrexate)			C				Not Reported

Sciatica; Tendonitis	Celebrex (Unknown) (Celecoxib)	C		Not Reported
	Xeljanz (Unknown) (Tofacitinib Citrate)	C		Not Reported
	Simponi (Unknown) (Golimumab)	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	10965583	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20150319864		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cutaneous Lupus Erythematosus; Drug Intolerance	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tridesonit			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11156577	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1017756			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug	Methotrexate			S		25 Mg, Qw		Not Reported

Ineffective; Eye Disorder	Enbrel			S		Unk			Not Reported
	Sulfasalazine			S		Unk			Not Reported
	Arava			S		Unk			Not Reported
	Plaquenil /00072602/			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11212585	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1020501			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Drug Ineffective; Dysgeusia; Dyspepsia; Epistaxis; Headache; Sinus Congestion; Sinusitis; Urinary Tract Infection	Methotrexate			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S	Subcutaneous	90 Mg, Biweekly		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11265714	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1022675			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	200 Mg, Bid		Not Reported
	Gold			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2015	11293230	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024199			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported

Maculopathy	Methotrexate	S	Oral	25 Mg, Qw		Not Reported
	Plaquenil /00072602/	S		Unk, Qd		Not Reported
	Naproxen	C		Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	10947608	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1008866			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Drug Ineffective; Fatigue; Limb Injury	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11243374	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1013591			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bronchitis; Drug Ineffective; Fibromyalgia; Influenza; Musculoskeletal Pain	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Xeljanz			S		Unk		Not Reported
	Sulfasalazine			S		1 G, Bid		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11279349	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015159681		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Sulfasalazine			S				Pfizer
	Methotrexate Sodium			S		17.5 Mg, Weekly		Pfizer
	Remicade			S		Unk		Not Reported

		Simponi			S					Not Reported
		Plaquenil /00072602/			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11300852	DIRECT						Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11307522	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Osteoarthritis; Osteoporosis; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2015	11311398	EXPEDITED (15-DAY)	Y	OT	CO-PL-FR-2015-047		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cataract; Maculopathy; Neck Pain; Osteoarthritis; Osteopenia; Prescribed Overdose; Visual Field Defect	Plaquenil			S				Not Reported
	Levothyrox (Levothyroxine Sodium)			C				Not Reported
	Doliprane (Pracetamol)			C				Not Reported
	Zamudol (Tramadol Hydrochloride)			C				Not Reported
	Seresta (Oxazepam)			C				Not Reported
	Morphine			C				Not Reported
	Lodine (Etodolac)			C				Not Reported
	Seroplex (Esitalopram Oxalate)			C				Not Reported
	Etodolac			C				Not Reported
	Raloxifene			C				Not Reported
	Calcium			C				Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11095424	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1014795			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chapped Lips; Fatigue; Gallbladder Disorder; Oropharyngeal Pain; Psoriasis; Rheumatoid Arthritis; Skin Fissures	Methotrexate			S	Subcutaneous	1 Ml, Qw		Not Reported
	Methotrexate			S	Subcutaneous	1 Ml, Biweekly		Not Reported
	Methotrexate			S	Subcutaneous	0.7 Ml, Biweekly		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin B Complex			C		Unk		Not Reported
	Losec /00661201/			C		Unk		Not Reported
	Tylenol Extra Strength			C		Unk Unk, Prn		Not Reported
	Ibuprofen			C		Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11168549	NON-EXPEDITED		HO	GR-JNJFOC-20150520161		68 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis; Transaminases Increased	Olysio			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Peg Interferon			C				Not Reported
	Ribavirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11221106	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1020879			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported

	Plaquenil /00072602/	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11283185	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024189			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S				Not Reported
	Rituxan			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11309916	NON-EXPEDITED			US-AMGEN-USASP2015072179		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11315972	EXPEDITED (15-DAY)	Y	HO	CO-PL-FR-2015-139		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Arava			S	Oral					Not Reported
	Hydrea(Hydroxycarbamide)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2015	11315982	EXPEDITED (15-DAY)	Y	OT	CO-PL-IT-2015-137		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Plaquenil			S	Oral			Not Reported
	Coumadin			S	Oral			Not Reported
	Deltacortene			S	Oral			Not Reported
	Dibase			S	Oral			Not Reported
	Alprazolam			C				Not Reported
	Omeprazole			C				Not Reported
	Tildiem			C				Not Reported
	Lanoxin ()Digoxin)			C				Not Reported
	Luvion (Canrenoic Acid)			C				Not Reported
	Aliflus			C				Not Reported
	Triatec (Ramipril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2015	11310632	EXPEDITED (15-DAY)		HO, LT	DE-MEDAC PHARMA, INC.-1040760		75 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Metex (Methotrexate Disodium)			S	Subcutaneous			Medac
	Quensyl			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported
	Falithrom			C				Not Reported
	Ramipril			C				Not Reported
	Omeprazole			C				Not Reported
	Ramiplus Al 5 Mg/25 Mg			C				Not Reported
	Dekristol 20000 I.E.			C				Not Reported
	Folic Acid			C				Not Reported
	Simvastatin			C				Not Reported
	Torasemide			C				Not Reported
	Novaminsulfon			C				Not Reported

	Tilidine 100/8 Retard			C						Not Reported
	Spirogamma 100			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2015	10812333	NON-EXPEDITED		OT	US-AMGEN-USASL2015014570		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis C; Mobility Decreased; Rash	Enbrel			S		50 Mg, Qwk		Amgen
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2015	11319240	DIRECT		DS			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Toxicity To Various Agents	Hydroxychloroquine 200 Mg			S	Oral	Taken By Mouth 1 Pill	15 YR	Not Reported
	Amlodipine			C				Not Reported
	Gabapentin			C				Not Reported
	Levothyroxine			C				Not Reported
	Nabumetone			C				Not Reported
	Preservision			C				Not Reported
	Calcium			C				Not Reported
	Refresh Plus			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multivitamin			C				Not Reported
	Omega 3			C				Not Reported
	Refresh Pm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2015	11319511	EXPEDITED (15-DAY)	Y	OT	CO-PL-AU-2015-143			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11240152	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021707			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Musculoskeletal Pain; Vulvovaginal Rash	Methotrexate			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11315764	EXPEDITED (15-DAY)		DS	CA-ROCHE-1613835			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Executive Dysfunction; Fatigue; Jc Polyomavirus Test Positive; Neurological Decompensation; Progressive Multifocal Leukoencephalopathy; White Matter Lesion	Mycophenolate Mofetil			S				Not Reported
	Belimumab			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11317590	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1021786			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Intolerance; Myalgia; Nausea	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Arava			S				Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11319532	DIRECT	Y	HO			33 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Sedation	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11322322	EXPEDITED (15-DAY)	Y	HO	CO-PL-FR-2015-138		58 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia; Somnolence; Toxicity To Various Agents	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S	Oral			Not Reported
	Paracetamol (Unknown) (Paracetamol) Unk, Unkunk			S				Not Reported
	Xanax			S	Oral			Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2015	11322326	EXPEDITED (15-DAY)	Y	OT	CO-PL-IT-2015-141		76 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Skin Lesion	Plaquenil			S	Oral			Not Reported
	Plaunac (Olmesartan Medoxomil)			C				Not Reported
	Plavix (Clopidogrel Bisulfate)			C				Not Reported
	Crestor (Rosuvastatin Calciu)			C				Not Reported
	Methylprednisolone			C				Not Reported
	Lansox (Lansoprazole)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11123761	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1016260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S		17.5 Mg, Qw		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11285174	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1023540			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Apo Hydroxyquine			C		Unk		Not Reported
	Leucovorin /00566701/			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11319472	NON-EXPEDITED			US-AMGEN-USASP2015075497		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchospasm; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Nausea; Rash;	Enbrel			S	Unknown	Unk		Amgen
	Cyclosporine			S	Unknown	Unk		Not Reported

Toothache; Urticaria; Vomiting	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Cipro /00697201/	C	Oral	250 Mg, Bid	Not Reported
	Triamcinolone Acetonide	C		Unk Unk, Qd	Not Reported
	Prilosec /00661201/	C	Oral	20 Mg, Bid	Not Reported
	Retin-A	C		Pea Size Amount To The Entire Face At Bedtime	Not Reported
	Junel Fe 1/20	C		1-20 Mg 1 Tablet By Mouth 1 Time Per Day	Not Reported
	Valtrex	C		1000 Mg, Bid	Not Reported
	Oscal 500 + D	C	Oral	500 Mg-200 Unit Tablet, Bid	Not Reported
	Advil /00109201/	C	Oral	200 Mg, Every 4 Hours As Needed	Not Reported
	Motrin Ib	C	Oral	200 Mg, Every 4 Hours As Needed	Not Reported
	Vitamin D3	C	Oral	1000 Unit, Qd	Not Reported
	Vitamin C /00008001/	C	Oral	500 Mg, Qd	Not Reported
	Vitamin B-12	C		1000 Mug, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11320238	EXPEDITED (15-DAY)		CA	FR-PFIZER INC-2015247724		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby; Trisomy 21	Solu-Medrol			S	Transplacental	1 Mg/Kg, 2 Bolus		Pfizer
	Cortancyl			S	Transplacental	60 Mg, 1x/Day		Not Reported
	Plaquenil			S	Transplacental	200 Mg, 2x/Day		Not Reported
	Imurel			S	Transplacental	25 Mg, 1x/Day		Not Reported

		Aspegic [Acetylsalicylate Lysine]			S	Transplacental	100 Mg, 1x/Day			Not Reported
		Lovenox			S	Transplacental	4000 Iu, 1x/Day			Not Reported
		Zelitrex			S	Transplacental	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11320425	NON-EXPEDITED			US-AMGEN-USASP2015075629		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11321288	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024951		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2015	11322083	EXPEDITED (15-DAY)		OT	PR-ABBVIE-15K-131-1385753-00		33 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Asthenia; Drug Interaction; Hypertension;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Hypertension; Pain; Vomiting; Vomiting	Plaquenil	S	Unknown		Not Reported
	Prozac	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11239076	EXPEDITED (15-DAY)	Y	HO, OT	CO-PL-CA-2015-015			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Influenza Like Illness; Joint Swelling; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Response Decreased; Tuberculin Test Positive	Plaquenil (Hydroxychloroquine Sulfate)			S	Oral			Not Reported
	Arava (Leflunomide)			S	Oral			Not Reported
	Sulfasalazine (Sulfasalazine)			C				Not Reported
	Inh (Isoniazid)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11309013	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024620			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S				Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11324987	NON-EXPEDITED			US-PFIZER INC-2015249895			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S				Pfizer
	Xanax			S				Pfizer
	Metronidazole			S				Pfizer
	Cleocin			S				Pfizer
	Ciprofloxacin			S				Not Reported
	Codeine			S				Not Reported
	Ketorolac			S				Not Reported
	Neosporin /00130801/			S		Unk		Not Reported
	Oxycontin			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Ultram			S				Not Reported
	Cefdinir			S				Not Reported
	Azasite			S	Ophthalmic	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11325128	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024618			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Gold			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11325146	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1025149			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate			S		0.6 Ml, Qw		Not Reported
	Methotrexate			S		0.3 Ml, Qw		Not Reported
	Arava			S				Not Reported
	Plaquenil /00072602/			S				Not Reported

	Orencia			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11325148	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1025248			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		200 Unk, Bid		Not Reported
	Arava			S		20 Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2015	11329539	EXPEDITED (15-DAY)	Y	OT	CO-PL-AU-2015-144			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic Purpura	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11327838	NON-EXPEDITED		HO	US-CELGENEUS-USA-2015074099		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous	Revlimid			S	Oral	10 Milligram		Celgene
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11334815	EXPEDITED (15-DAY)		DS, OT	CO-PL-US-2015-134		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Count Abnormal; Flatulence; Optic Atrophy;	Plaquenil			S	Oral	(Exact Date Not Known)	1 YR	Not Reported
	Fluticasone			C				Not Reported

Vision Blurred	Propionate\Salmeterol Xinafoate Mometasone Furoate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2015	11334821	EXPEDITED (15-DAY)	Y	HO, OT	CO-PL-US-2015-146		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Fracture; Immune System Disorder; Staphylococcal Infection	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Not Reported
	Belimumab Powder For Infusion			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11333431	EXPEDITED (15-DAY)		CA	FR-SA-2015SA111023			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Trisomy 21	Cortancyl			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Transplacental			Not Reported
	Lovenox			S	Transplacental			Not Reported
	Solumedrol			S	Transplacental			Not Reported
	Imurel			S	Transplacental			Not Reported
	Zelitrex			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11339684	EXPEDITED (15-DAY)	Y	HO, LT	CO-PL-DE-2015-150		75 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Hydroxychloroquine Sulfate (Unknown) (Hydroxychloroquine Sulfate)			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

					Allopurinol (Allopurinol)	S	Oral		Not Reported
					Falithrom (Phenprocoumon)	C			Not Reported
					Omeprazole	C			Not Reported
					Ramipril	C			Not Reported
					Dekristol (Colecalciferol)	C			Not Reported
					Folsan (Folic Acid)	C			Not Reported
					Simvastatin	C			Not Reported
					Torasemid (Torasemide)	C			Not Reported
					Novaminsulfon (Metamizole Sodium)	C			Not Reported
					Tilidin (Naloxone Hydrchloride, Tilidine Hydrochloride)	C			Not Reported
					Spironolactone (Sipronolactone)	C			Not Reported
					Hydrochlorothiazide/Ramipril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11339690	EXPEDITED (15-DAY)		HO	CO-PL-MX-2015-156			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Systemic Lupus Erythematosus	Plaquenil (200 Milligram, Tablet (Hydroxychloroquine Sulfate)			S	Oral			Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11339691	EXPEDITED (15-DAY)		OT	CO-PL-CA-2015-151			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Productive Cough	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Sanofi
	Tofacitinib Citrate			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11339694	EXPEDITED (15-DAY)		OT	CO-PL-CA-2015-152			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Musculoskeletal Stiffness; Nausea; Rheumatoid Arthritis	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)	S		Sanofi
	Leflunomide	S		Not Reported
	Methotrexate	C		Not Reported
	Sulfasalazine	C		Not Reported
	Abatacept	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11339943	EXPEDITED (15-DAY)	Y	OT	CO-PL-DE-2015-148			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinoatrial Block	Hydroxychloroquine Sulfate (200 Milligram, Film -Coated Tablet)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2015	11340466	EXPEDITED (15-DAY)	Y	HO	IPC201507-000481		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Azotaemia; Blood Creatinine Increased; Glomerulosclerosis; Haemodialysis; Metabolic Acidosis; Proteinuria; Renal Impairment; Renal Tubular Necrosis; Thrombocytopenia	Hydroxychloroquine Sulfate (Hydroxychloroquine Sulfate) (Hydroxychloroquine Sulfate)			S				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Prednisone			C				Not Reported
	Methylprednisolone			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11277773	EXPEDITED (15-DAY)		OT	US-JAZZ-2015-US-010436			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.25 G, Bid		Jazz
	Plaquenil			S		Unk		Not Reported

	Depakote			C					Not Reported
	Mvi			C					Not Reported
	Vitamin C			C					Not Reported
	Enbrel			C		Unk			Not Reported
	Imuran			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2015	11334416	EXPEDITED (15-DAY)		HO	IL-DEXPHARM-20151009		80 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pneumonitis	Omeprazole			S				Not Reported
	Methotrexate			S				Not Reported
	Simvastatin			S				Not Reported
	Amlodipine			S				Not Reported
	Propranolol			C				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2015	11342020	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150723933		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	9760241	NON-EXPEDITED			US-GILEAD-2010-0028339			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Unevaluable Event	Letairis			S				Gilead
	Adcirca			S				Not Reported
	Digoxin			S				Not Reported
	Plaquenil			S				Not Reported
	Warfarin			S				Not Reported
	Famtidine			S				Not Reported
	Lasix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11358725	EXPEDITED (15-DAY)		OT	CO-PL-CA-2015-157		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Colic; Chapped Lips; Fatigue; Oropharyngeal Pain; Psoriasis; Rheumatoid Arthritis; Skin Fissures	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Folic Acid			C				Not Reported
	Vitamin B Complex (Pyridoxine Hydrochloride, Thiamine Hydrochloride, Ribhoflavin, Nicotinamide, Calcium Pantothenate)			C				Not Reported
	Omeprazole			C				Not Reported
	Tylenol Extra-Strength (Paracetamol)			C				Not Reported
	Ibuprofen			C				Not Reported
	Methotrexate			C				Not Reported
	Embrel (Etanercept)			C				Not Reported
	Ximzia (Certolizumab Pegol)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2015	11358729	EXPEDITED (15-DAY)	Y	OT	CO-PL-CA-2015-165			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S	Oral			Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11353316	EXPEDITED (15-DAY)		DE	AU-GLAXOSMITHKLINE INC.-AU2015GSK113774		32 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bezoar	Quetiapine			S				Glaxosmithkline
	Venlafaxine			S				Glaxosmithkline
	Hydroxychloroquine			S				Not Reported
	Topiramate			S				Not Reported
	Oxycodone			S				Not Reported
	Loratidine			S				Not Reported
	Lorazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11353318	EXPEDITED (15-DAY)		CA	FR-GLAXOSMITHKLINE-FR2015GSK106830		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Trisomy 21	Zelitrex			S	Intra-uterine	Unk		Glaxosmithkline
	Cortancyl			S	Intra-uterine	60 Mg, 1d		Not Reported
	Plaquenil			S	Intra-uterine	Unk		Not Reported
	Imurel			S	Intra-uterine	25 Mg, 1d		Glaxosmithkline
	Aspegic [Acetylsalicylate Lysine]			S	Intra-uterine	100 Mg, 1d		Not Reported
	Solumedrol			S	Intra-uterine	Unk		Not Reported
	Lovenox			S	Intra-uterine	4000 Iu, 1d		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11358804	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Dyskinesia; Gait Disturbance; Laryngeal Inflammation; Mouth Ulceration; Muscle Spasms; Myalgia; Pain; Product Substitution Issue; Therapeutic Product Effect Decreased; Vision Blurred	Hydroxychloroquine 200 Mg			S	Oral	2 Pills		Ranbaxy
	Plaquenil			C				Not Reported
	Ventolin			C				Not Reported
	Cymbalta			C				Not Reported
	Vit. D			C				Not Reported
	Biotin			C				Not Reported
	B12 Complex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11363004	EXPEDITED (15-DAY)		CA	CO-PL-FR-2015-162			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplasia Cutis Congenita; Maternal Drugs Affecting Foetus; Premature Baby; Trisomy 21	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S	Transplacental			Not Reported
	Cortancyl (Unknown) (Prednisone)			S	Transplacental			Not Reported
	Solumedrol (Unknown) (Methylprednisolone Sodium Succinate)			S	Transplacental	1 Mg/Kg , Transplacental		Not Reported
	Imurel (Unknown) (Azathioprine)			S	Transplacental			Not Reported
	Zelitrex (Unknown) (Valaciclovir Hydrochloride)			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2015	11364112	DIRECT		LT, OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder; Urticaria	Plaquenil			S	Oral	1 Pill		Not Reported
	Prednisone			C				Not Reported

		Hydroxyzine			C					Not Reported
		Ranitidine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2015	11373430	EXPEDITED (15-DAY)	Y	OT	CO-PL-NZ-2015-161			Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2015	11339699	EXPEDITED (15-DAY)		HO, OT	CO-PL-CA-2015-153			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Localised Infection; Renal Failure; Sepsis	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Sanofi
	Arava (Unknown) (Leflunomide)			S				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Indomethacin			C				Not Reported
	Prednisone			C				Not Reported
	Fluconazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2015	11360151	EXPEDITED (15-DAY)		HO	PHHY2015FR095255		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Voltarene (Diclofenac Sodium)			S	Oral	Unk Unk, Prn		Not Reported
	Prednisone			S	Oral	Unk		Novartis
	Prednisone			S				Novartis
	Plaquenil			S	Oral	200 Mg, Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2015	11381062	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Nausea; Product Substitution Issue	Hydroxychloroquine Sul Tabs 200mg Mylan			S		1.5 Tab		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11382947	NON-EXPEDITED			US-PFIZER INC-2015260337			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Percocet /00867901/			S		Unk		Not Reported
	Vancocin			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11392368	EXPEDITED (15-DAY)	Y	HO	CO-PL-AU-2015-169		71 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug-Induced Liver Injury; Hepatic Encephalopathy	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Not Reported
	Aspirin (Acetylsalicylic Acid)			C				Not Reported
	Candesartan/Hydrochlorothiazide (Hydrochlorthiazide, Candesartan Cilexetil)			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dabigatran			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Pramipexole Hydrochloride			C				Not Reported
	Prednisone			C				Not Reported
	Salbutamol			C				Not Reported

	Seretide (Fluticasone Propionate, Salmeterol Xinafoate)			C						Not Reported
	Tiotropium			C						Not Reported
	Verapamil Hydrochloride			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11392384	EXPEDITED (15-DAY)	Y	OT	CO-PL-CA-2015-172		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Synovitis	Plaquenil (Unknown) (Hydroxychloroquine Sulfate)			S				Not Reported
	Actemra (Tocilizumab)			C				Not Reported
	Remicade (Infliximab)			C				Not Reported
	Celebrex (Celecoxib)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2015	11392399	EXPEDITED (15-DAY)	Y	HO, OT	CO-PL-CA-2015-171		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Sensory Loss; Thrombosis	Plaquenil (Unknown) (Hydroxychoroquine Sulfate)			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Remicade (Infliximab)			C				Not Reported
	Arava (Leflunomide)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2015	11388503	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-17		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Vimovo			S	Oral					Not Reported
	Twinrix			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	10897105	NON-EXPEDITED			US-PFIZER INC-2015074929		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11374839	EXPEDITED (15-DAY)		HO, LT	PHHY2015CA095889			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Near Death Experience; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Novartis
	Leflunomide			S				Novartis
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate			S					Not Reported
	Plaquenil			S	Unknown				Not Reported
	Plaquenil			S					Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S					Not Reported
	Gold			S	Unknown				Not Reported
	Gen-Hydroxychloroquine			S	Unknown				Not Reported
	Gen-Hydroxychloroquine			S					Not Reported
	Kineret			S	Unknown	Unk			Not Reported
	Kineret			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11392672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15P-028-1447156-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Synthroid			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Calcium Pantothenate W/Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11392749	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15P-028-1447155-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Synthroid			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Methotrexate Sodium			S	Unknown				Not Reported
		Pantoloc			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2015	11392898	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15P-028-1447171-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Synthroid			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Vitalux			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2015	11397788	EXPEDITED (15-DAY)		HO	CONCORDIA PHARMACEUTICALS INC.-CO-PL-KR-2015-181		74 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Electroencephalogram Abnormal; Hallucination, Auditory; Psychotic Disorder	Hydroxychloroquine			S	Oral			Not Reported
	Chloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2015	11398910	DIRECT		OT			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burn Oral Cavity; Cough; Dizziness; Pruritus; Pulmonary Congestion;	Hydroxychloroquine			S	Oral	1 Tablet Then 2 Per Day, 1@ Bedtime Then 2/Day		Not Reported

Rash Papular; Rash Papular; Rhinorrhoea; Skin Exfoliation; Skin Exfoliation; Skin Texture Abnormal; Therapy Non-Responder; Tongue Discomfort; Urticaria	Prednisone			C		Taken By Mouth			Not Reported
	Fish Oil			C					Not Reported
	D3			C					Not Reported
	B12			C					Not Reported
	Tums			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11398055	EXPEDITED (15-DAY)		OT	TW-ROCHE-1620326			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthenia; Diarrhoea; Fatigue; Leukopenia; Mucosal Inflammation; Nausea; Thrombocytopenia; Vomiting	Capecitabine			S	Unknown			Not Reported
	Rapamycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Irinotecan			S	Unknown			Not Reported
	Vinorelbine			S	Oral			Not Reported
	Gemcitabine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11401340	EXPEDITED (15-DAY)		DE	CA-BAUSCH-BL-2015-019828		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Metformin			S	Unknown			Santarus
	Nitrazadon			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Combivent Inhalation Aerosol			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Salmeterol Xinafoate			S	Unknown				Not Reported
		Tylenol			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2015	11409446	DIRECT		HO			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Bundle Branch Block Left; Drug Ineffective; Left Ventricular Failure; Myocardial Infarction	Hydroxychloroquine Sulfate 200 Mg			S	Oral	1 Pil		Zydus Pharm
	Neurontin			C				Not Reported
	Celexa			C				Not Reported
	Singular			C				Not Reported
	Cargel			C				Not Reported
	Lasix			C				Not Reported
	Plavix			C				Not Reported
	Lisinopril			C				Not Reported
	Folate			C				Not Reported
	Vistaril			C				Not Reported
	Ultramax Nutrient Mvi			C				Not Reported
	Probiotics			C				Not Reported
	Vit. D3			C				Not Reported
	Fish Oil			C				Not Reported
	Benadryl			C				Not Reported
	Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	10590471	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014315256		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Condition Aggravated; Depressed Mood; Dermatitis; Fall; Peripheral Swelling; Rheumatoid Arthritis; Rib Fracture; Vomiting	Celebrex			S		200 Mg, 2x/Day		Pfizer
	Celebrex			S		200 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk Unk, 2x/Day		Not Reported
	Prednisone			S		14 Mg, 1x/Day		Not Reported
	Actemra			S		1 Df, 1x/Month		Not Reported

	Dilaudid	C		4 Mg, 3x/Day As Needed	Not Reported
	Hydromorph Contin	C		18 Mg, 1 Capsule Every 8 Hours	Not Reported
	Lyrica	C	Oral	2 Capsules In Am, 1 In Pm, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11397742	EXPEDITED (15-DAY)		DE	TW-CONCORDIA PHARMACEUTICALS INC.-CO-PL-TW-2015-17			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis B Reactivation; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Rapamycin			S	Unknown			Not Reported
	Rapamycin			S				Not Reported
	Gemcitabine			S				Not Reported
	Etoposide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11404338	EXPEDITED (15-DAY)		DE, OT	PHHY2015ES099101		12 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthosis Nigricans; Cachexia; Depressed Level Of Consciousness; Disease Recurrence; Encephalitis Brain Stem; Headache; Hyperinsulinism; Hypoglycaemia; Hypotension; Meningism; Metabolic Syndrome; Nephritis; Pericarditis; Polycystic Ovaries;	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Novartis
	Prednisone			S	Oral	2 Mg/Kg/Day		Not Reported
	Prednisone			S	Oral	35 Mg Per Day		Not Reported
	Prednisone			S	Oral	45 Mg Per Day		Not Reported
	Mycophenolate Mofetil			S	Unknown	1.5 G, Per Day		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)	500 Mg/M2, 3 Monthly		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	375 Mg/M2/ Week (4 Doses)		Not Reported

Psychiatric Symptom; Pustule; Pyrexia; Streptococcal Infection; Systemic Lupus Erythematosus; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11405159	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-16			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diarrhoea; Drug Ineffective; Gait Inability; Memory Impairment; Musculoskeletal Disorder; Sleep Disorder	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2015	11407068	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-18		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	11218963	NON-EXPEDITED		OT	CA-JNJFOC-20150614239		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Incomplete; Abortion Spontaneous; Exposure During Pregnancy; Haemorrhage; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Prednisone				S	Unknown				Not Reported
	Folic Acid				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2015	11409837	NON-EXPEDITED			US-ASTRAZENECA-2015SE79667			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium			S	Oral	Unk		Astrazeneca
	Epinephrine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown	Unk		Not Reported
	Neosporin			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Dexilant			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Neurontin			S	Unknown	Unk		Not Reported
	Aldara			S	Unknown			Not Reported
	Savella			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Lyrica			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2015	10436303	EXPEDITED (15-DAY)		OT	AU-SA-2014SA118858			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Limb Reconstructive Surgery;	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Medical Device Implantation; Osteopenia; Paraesthesia; Pruritus; Red Blood Cell Sedimentation Rate Increased	Cholesterol- And Triglyceride Reducers			C					Not Reported
	Vitamin D Nos			C					Not Reported
	Calcium			C					Not Reported
	Vitamin B			C					Not Reported
	Iron			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	10635850	EXPEDITED (15-DAY)		HO, OT	CA-SA-2014SA158630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cystitis; Deformity; Depressed Mood; Dermatitis; Encephalitis Brain Stem; Fall; Immobile; Immunodeficiency; Insomnia; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Psychiatric Symptom; Rib Fracture; Scar; Seizure; Sepsis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Furosemide			C				Not Reported
	Dilaudid			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C		2 Capsules In Morning And 1 At Night By Mouth		Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11418827	EXPEDITED (15-DAY)		OT	GB-ACCORD-033189			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunodeficiency	Methotrexate			S	Unknown			Accord
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11419349	EXPEDITED (15-DAY)		HO, OT	GXBR2015US001920		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Retinal Injury; Visual Field Defect	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Bid		Novartis
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Enalapril			C	Oral	10 Mg, Qd		Not Reported
	Prednisone			C	Oral	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11420296	EXPEDITED (15-DAY)		HO	PHHY2015ES100351		36 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Hallucination, Auditory; Intentional Self-Injury; Suicidal Ideation	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11420454	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-18		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Eosinophilia	Plaquenil			S	Oral			Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11420563	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-19		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Vitamin D Nos	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Lozide	C	Unknown	Not Reported
	Lantus	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2015	11422787	DIRECT	Y	HO			55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Synaesthetic; Insomnia; Pressure Of Speech; Self-Medication; Sensory Disturbance; Tachyphrenia; Therapy Cessation	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2015	11362007	NON-EXPEDITED		OT	US-AMGEN-USASP2015078010		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dry Mouth; Immunosuppression; Impaired Healing; Nasal Congestion; Nasal Ulcer; Rhinitis; Rhinitis Allergic; Rhinorrhoea; Sneezing; Urinary Tract Infection	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11230399	EXPEDITED (15-DAY)	Y	OT	2015MYN000009		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Hypersensitivity; Impaired Work Ability; Infection; International Normalised Ratio Fluctuation; Joint Swelling; Mobility Decreased; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Vomiting	Erythromycin (Erythromycin) Unknown			S				Not Reported
	Arava (Leflunomide)			S				Not Reported
	Arthrotec (Diclofenac Sodium, Misoprostol)			S				Not Reported
	Bisoprolol Fumarate (Bisoprolol Fumarate)			S				Not Reported
	Ceclor (Cefaclor)			S				Not Reported
	Demerol (Pethidine Hydrochloride)			S				Not Reported
	Flagyl /00012501/ (Metronidazole) (Metronidazole)			S				Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Levofloxacin (Levofloxacin)			S				Not Reported
	Norfloxacin (Norfloxacin)			S				Not Reported
	Plaquenil /00072602/ (Hydroxychloroquine Phosphate)			S	Oral			Not Reported
	Prednisone (Prednisone)			S				Not Reported
	Sulfasalazine (Sulfasalazine)			S				Not Reported
	Celebrex (Celecoxib)			S	Oral			Not Reported

		Methotrexate Sodium (Methotrexate Sodium)			S	Oral					Not Reported
		Lyrica (Pregabalin)			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11407022	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-18		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11428617	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015008523		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Femur Fracture; Musculoskeletal Disorder; Oedema Peripheral; Psoriasis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11432244	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-19			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Respiratory Disorder	Plaquenil			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2015	11432877	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-18			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11439435	EXPEDITED (15-DAY)		HO	CA-ROCHE-1627154		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11442818	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-18			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Pruritus; Rash	Plaquenil			S	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11442821	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2015-16		71 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatic Encephalopathy; Hepatotoxicity	Plaquenil			S	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Candesartan/Hydrochlorothiazide			C	Unknown			Not Reported
	Cholecalciferol			C	Unknown			Not Reported
	Dabigatran			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Pramipexole Hydrochloride			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Seretide			C	Unknown			Not Reported
	Tiotropium			C	Unknown			Not Reported
	Verapamil Hydrochloride			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2015	11443577	EXPEDITED (15-DAY)		HO	CH-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CH-2015-19		46 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Blood Bicarbonate Decreased; Bronchial Wall Thickening; C-Reactive Protein Increased; Chest Pain; Chest X-Ray	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Abnormal; Cough; Dyspnoea; Eosinophilic Pneumonia Acute; Hypoxia; Leukocytosis; Lung Infiltration; Oxygen Consumption Increased; Oxygen Saturation Decreased; Pco2 Decreased; Pyrexia; Tachycardia; Tachypnoea

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11348211	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015261324		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Eye Infection	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11446974	EXPEDITED (15-DAY)		OT	CA-ACTAVIS-2015-18302		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Naproxen (Aellc)			S	Oral	500 Mg, Bid		Actavis Elizabeth
	Methotrexate			S	Oral	25 Mg (2.5 Mg X 10), Weekly		Not Reported
	Pms-Sulfasalazine 500mg/Tab Usp			S	Oral	1000 Mg, Bid		Not Reported
	Palafer Cf			S	Unknown	1 Df, Daily		Not Reported
	Co Atenolol			S	Unknown	25 Mg, Daily		Not Reported
	Folic Acid			S	Unknown	5 Mg, 2/Week		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, Bid		Not Reported
	Pantoloc /01263204/			S	Unknown	40 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11449268	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-20			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11449352	EXPEDITED (15-DAY)		HO, OT	MX-CONCORDIA PHARMACEUTICALS INC.-CO-PL-MX-2015-19			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Mitral Valve Incompetence; Mitral Valve Replacement	Plaquenil			S	Oral			Not Reported
	Acetaminophen\Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11452025	DIRECT					79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine 200mg			S	Oral	2 Pills		Not Reported
	Prednisone			C				Not Reported
	Benlysta			C				Not Reported
	B12			C				Not Reported
	D3			C				Not Reported
	Iron			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11444478	EXPEDITED (15-DAY)		OT	GB-HOSPIRA-2989549			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11451672	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015089613		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Macular Degeneration; Spinal Operation	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11455071	EXPEDITED (15-DAY)		DE	CA-GLAXOSMITHKLINE-CA2015GSK125532		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Flovent Diskus			S	Respiratory (inhalation)	Unk		Glaxosmithkline
	Alendronate Sodium			S		70 Mg, We		Glaxosmithkline
	Atorvastatin Calcium			S		10 Mg, Unk		Glaxosmithkline
	Lasix			S		40 Mg, Unk		Glaxosmithkline
	Metformin			S		500 Mg, Bid		Glaxosmithkline

	Nitrazadon	S		10 Mg, Unk	Glaxosmithkline
	Omeprazole	S	Oral	20 Mg, Unk	Glaxosmithkline
	Salmeterol Xinafoate	S		Unk	Glaxosmithkline
	Tylenol	S		500 Mg, Unk	Not Reported
	Combivent	S	Respiratory (inhalation)	Unk	Not Reported
	Plaquenil	S		300 Mg, Qd	Not Reported
	Prednisone	S		5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11455447	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-20		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11456380	EXPEDITED (15-DAY)		DS, HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-20			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cystitis; Deformity; Depressed Mood; Dermatitis; Encephalitis Brain Stem; Fall; Immobile; Immunodeficiency; Insomnia; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Psychiatric Symptom; Rib Fracture; Scar; Seizure; Sepsis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Furosemide			C				Not Reported
	Dilaudid			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C				Not Reported

	Actemra				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11456381	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2015-14			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conduction Disorder; Sinoatrial Block	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11456382	EXPEDITED (15-DAY)		HO	CONCORDIA PHARMACEUTICALS INC.-CO-PL-KR-2015-197		74 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Hallucination, Auditory; Psychotic Disorder	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11456383	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2015-19		52 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Haemorrhage	Plaquenil			S	Oral			Not Reported
	Ticagrelor			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Acetylsalicylzuur			C				Not Reported
	Foliumzuur			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazol			C				Not Reported
	Metoprolol			C				Not Reported
	Simvastatin			C				Not Reported
	Pneumovax 23			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11456384	EXPEDITED (15-DAY)		HO	RU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-RU-2015-20		20 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Cholestatic	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11458741	EXPEDITED (15-DAY)		OT	CA-TEVA-590818USA		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Chloroquine (Mah Unknown)			S		Variable Dosages		Teva
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			S		Variable Dosages		Not Reported
	Arava			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	11458761	EXPEDITED (15-DAY)		OT	US-TEVA-578065USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Complex Regional Pain Syndrome; Cough; Interstitial Lung Disease; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Organising Pneumonia; Pain In Extremity; Pneumonitis;	Hydroxychloroquine			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Xeljanz			S	Unknown			Not Reported

Poor Quality Sleep

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2015	11439888	EXPEDITED (15-DAY)		OT	GB-ACCORD-033309			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Methotrexate			S	Oral			Accord
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11404330	EXPEDITED (15-DAY)		OT	PHHY2015GB099012			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Methotrexate			S	Oral	20 Mg, Unk		Novartis
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Q4h		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported
	Lansoprazole			C	Oral	30 Mg, Unk		Not Reported
	Prednisolone			C	Oral	3 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11467276	EXPEDITED (15-DAY)		DE	TW-HOSPIRA-2995356			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine			S				Not Reported

	Cyclophosphamide			S	Oral	Every Other Day	Not Reported
	Rapamycin			S			Not Reported
	Gemcitabine Hydrochloride			S	Intravenous (not otherwise specified)		Not Reported
	Etoposide			S	Oral	Every Other Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11467762	EXPEDITED (15-DAY)		OT	GB-TEVA-590062ACC		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Prednisolone			S	Oral	30 Milligram Daily;		Teva
	Hydroxychloroquine			S	Oral	200 Milligram Daily;		Not Reported
	Elocon			C		Twice Daily As Necessary. Ongoing.		Not Reported
	Hydroxyzine			C	Oral	1 Dosage Forms Daily; At Night. Ongoing.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11469263	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK127133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Benlysta			S	Unknown	Unk, U		Glaxosmithkline
	Plaquenil			S	Unknown	Unk, U		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2015	11473274	EXPEDITED (15-DAY)		OT	PHHY2015TR107481		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Novartis
	Methotrexate			S	Unknown	7.5 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	12.5 Unk, Unk		Not Reported

	Tacrolimus			C		10 Mg, Qd			Not Reported
	Prednisone			C	Unknown	1 Mg/Kg, Unk			Not Reported
	Prednisone			C	Unknown	30 Mg, Qd			Not Reported
	Prednisone			C	Unknown	40 Mg, Qd			Not Reported
	Prednisone			C	Oral	1.5 Mg/Kg, Qd			Not Reported
	Methylprednisolone			C	Unknown	1000 Mg, Qd			Not Reported
	Methylprednisolone			C	Unknown	1000 Mg, Qw			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	9467168	EXPEDITED (15-DAY)		OT	CA-ROCHE-1151322		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diplopia; Dizziness; Enterobiasis; Influenza; Infusion Related Reaction; Nasopharyngitis; Nausea; Oxygen Saturation Decreased; Oxygen Saturation Decreased; Tooth Fracture; Vision Blurred; Visual Impairment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Alendronate			C				Not Reported
	Codeine			C				Not Reported
	Prednisone			C				Not Reported
	Calcite			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11480417	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-21		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haematocrit Decreased; Haemoglobin Decreased; Red Blood Cell Count Decreased; Rheumatoid	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Arthritis	Naprosyn			S	Oral		Not Reported
	Sulfasalazine			S	Oral		Not Reported
	Palafer Cf			S	Unknown		Not Reported
	Atenolol			S	Unknown		Not Reported
	Folic Acid			S	Unknown		Not Reported
	Pantoloc			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11481735	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2015-020916		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Prednisolone			S	Oral			Bausch And Lomb
	Hydroxychloroquine			S	Oral			Not Reported
	Elocon			C				Not Reported
	Hydroxyzine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11485646	NON-EXPEDITED			US-AMGEN-USASP2015091164		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Eye; Ill-Defined Disorder; Infection; Musculoskeletal Stiffness; Pain In Extremity; Rash; Swelling	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg X 2 Each Day		Not Reported
	Actemra			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2015	11487140	NON-EXPEDITED			US-JAZZ-2015-US-001217			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Diarrhoea; Dyspepsia; Unevaluable Event	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Pantoprazole			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Nuvigil			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Diovan			C		Unk		Not Reported
	Torsemide			C		Unk		Not Reported
	Potasium			C		Unk		Not Reported
	Vitamin C			C		Unk		Not Reported
	Vitamin D Nos			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Fluticasone			C		Unk		Not Reported
	Vitamin B 12			C		Unk		Not Reported
	Metolazone			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Aller Tec			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Prolia			C		Unk		Not Reported
	Omeprazole Dr			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Nexium Dr			C		Unk		Not Reported
	Magnesium Malate			C		Unk		Not Reported

	Tums E-X	C	Unk	Not Reported
	Calcium Citrate +D	C	Unk	Not Reported
	Provigil	C	Unk	Not Reported
	Metoprolol Tartrate	C	Unk	Not Reported
	Ropinirole Hydrochloride	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	11491583	EXPEDITED (15-DAY)		OT	PHHY2015IT107499		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Synovitis; Therapeutic Product Effect Incomplete	Methylprednisolone			S	Unknown	250 Mg, Unk		Novartis
	Methylprednisolone			S	Unknown	12 Mg, Qd		Novartis
	Methylprednisolone			S	Unknown	4 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2015	11491819	DIRECT	Y	HO, LT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer Perforation; Pneumonia	Sorafenib			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Dilaudid			C				Not Reported
	Zofran			C				Not Reported
	Morphine			C				Not Reported
	Versed			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11307523	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1024410			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Parkinson'S Disease; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Pregabalin			S	Oral	2 Df, Qd		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Risedronate			S	Oral	1 Df, Qd		Not Reported
	Leflunomide			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11493434	NON-EXPEDITED			US-AMGEN-USASL2015091965		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11497595	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-21		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Hearing Loss	Plaquenil			S	Oral			Not Reported
	Travatan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11497872	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-17		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Remicade			C				Not Reported
	Celebrex			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2015	11498306	EXPEDITED (15-DAY)		DS	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-22		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2015	11166915	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-035166			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Product Dose Omission	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Azathioprine			C	Unknown	100 Mg, Bid		Not Reported
	Aspirin /00002701/			C	Unknown	Unk Mg, Unk		Not Reported
	Pepcid /00305201/			C	Unknown			Not Reported
	Meloxicam			C	Unknown	15 Mg, Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

	Tramadol				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2015	11003557	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1373242-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Erythema; Fatigue; Malaise; Pharyngeal Swelling; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2015	11499733	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3006267		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cystitis; Drug Ineffective; Guillain-Barre Syndrome; Micturition Disorder; Walking Aid User	Hcq			S				Not Reported
	Humira			S				Not Reported
	Simponi			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2015	11502718	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-21		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alveolitis; Pneumonia; Pruritus	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Arthrotec			C				Not Reported
	Lyrica			C				Not Reported

	Ultram			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11316478	EXPEDITED (15-DAY)		OT	BE-BEH-2015051368		67 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Fatigue; Limb Discomfort; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Nightmare; Respiratory Tract Infection	Hizentra			S	Subcutaneous	8 G (40 Ml)		Not Reported
	Hizentra			S	Subcutaneous	8 G (40 Ml)		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2015	11409412	EXPEDITED (15-DAY)		OT	GB-ROCHE-1624796			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Q4h		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported
	Lansoprazole			C	Oral	30 Mg, Unk		Not Reported
	Prednisolone			C	Oral	3 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11317465	EXPEDITED (15-DAY)		OT	BR-JNJFOC-20150716699		65 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Drug Delivery System Malfunction; Drug Ineffective; Osteoporosis; Pain In Extremity; Rash;	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Daflon (Diosmin/Hesperidin)			S	Unknown			Not Reported

Therapeutic Response Unexpected; Underdose	Naprosyn		S	Unknown		Not Reported
	Arcoxia		S	Unknown		Not Reported
	Endofolin		C	Unknown		Not Reported
	Vitamin D Nos		C	Unknown		Not Reported
	Tecnomet		C	Unknown		Not Reported
	Inellare		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11513741	NON-EXPEDITED		OT	US-PFIZER INC-2015308483		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Celecoxib			S		200 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		2 G, Daily		Pfizer
	Folic Acid			S		1 Mg, Daily		Pfizer
	Methotrexate			S		20 Mg, Weekly		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		10 Mg, Daily		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Leflunomide			S		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11515811	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-22		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2015	11516704	DIRECT		HO			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine			S			3 MTH	Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin B 12			C				Not Reported
	Vit D2			C				Not Reported
	Hctz			C				Not Reported
	Insulin			C				Not Reported
	Lisinopril			C				Not Reported
	Metformin			C				Not Reported
	Prednisone			C				Not Reported
	Simvastain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11458105	EXPEDITED (15-DAY)		DS	CA-ABBVIE-15P-028-1455274-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11518951	EXPEDITED (15-DAY)		OT	AR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AR-2015-26			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11518957	EXPEDITED (15-DAY)		OT	IN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IN-2015-15		44 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Bullosa Haemorrhagica; Bleeding Time Prolonged; Haemoglobin Decreased; Ocular Toxicity; Oral Disorder; Oral Mucosal Blistering; Petechiae; Red Blood Cell Sedimentation Rate Increased; Thrombocytopenia	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aceclofenac			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2015	11519175	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3010099		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell	Prednisone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Sedimentation Rate Increased; Synovitis	Methotrexate	S	Unknown	Various Dosages From 10-20 Mg		Not Reported
	Rituxan	C				Not Reported
	Enbrel	S	Unknown	Weekly		Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11441823	EXPEDITED (15-DAY)		OT	GB-TEVA-588314ACC			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Methotrexate			S	Oral			Barr
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Q4h		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Lansoprazole			C	Oral	30 Mg, Unk		Not Reported
	Prednisolone			C	Oral	3 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2015	11525946	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-24		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Abnormal; Hypoaesthesia; Migraine; Nausea; Pharyngeal Swelling; Rheumatoid Factor Positive; Swelling Face; Synovitis; Uveitis	Prednisone			C						Not Reported
	Arthrotec			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11009321	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1373265-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11455446	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-20		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Fluid Retention; Gastrointestinal Disorder; Hepatic Enzyme Increased; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2015	11530093	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK134128			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Rash; Renal Disorder; Swelling	Belimumab			S		10 Mg/Kg		Glaxosmithkline
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11467753	NON-EXPEDITED			US-ROXANE LABORATORIES, INC.-2015-RO-01509RO			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diplopia	Methotrexate			S	Unknown			Roxane
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11491807	EXPEDITED (15-DAY)		OT	US-TEVA-591712USA		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Asthenia; Dizziness; Drug Ineffective; Faeces Discoloured; Gait Disturbance; Gait Inability; Malaise	Methotrexate			S	Unknown			Teva
	Methotrexate			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown	1 Milligram Daily;		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11525948	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-22		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Autoimmune	Plaquenil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Prednisone			C				Not Reported

Hepatitis; Fatigue;
Lymphocytic Infiltration;
Malaise; Necrosis;
Transaminases Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11538473	EXPEDITED (15-DAY)		OT	NZ-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NZ-2015-22			Unknown	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11538474	EXPEDITED (15-DAY)		OT	NZ-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NZ-2015-24			Unknown	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11538475	EXPEDITED (15-DAY)		OT	NZ-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NZ-2015-24			Unknown	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2015	11538476	EXPEDITED (15-DAY)		DS	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-25		75 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Erythematous	Hydroxychloroquine Sulfate			S				Not Reported
	Adcal (Calcium Carbonate)			C				Not Reported
	Atorvastatin			C				Not Reported
	Azathioprine			C				Not Reported
	Codeine Phosphate			C				Not Reported
	Doublebase			C				Not Reported

	Epaderm	C	Not Reported
	Clobex	C	Not Reported
	Flucloxacillin	C	Not Reported
	Folic Acid	C	Not Reported
	Hydrocortisone	C	Not Reported
	Hydroxocobalamin	C	Not Reported
	Hypromellose	C	Not Reported
	Ibuprofen	C	Not Reported
	Methotrexate	C	Not Reported
	Naftidrofuryl Oxalate	C	Not Reported
	Prednisolone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11424389	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-18		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Fatigue; Headache; Nausea; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539416	NON-EXPEDITED			US-TEVA-568854USA		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Decreased Appetite; Diarrhoea	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539417	NON-EXPEDITED			US-TEVA-520699USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Hydroxychloroquine			S		Dose And Frequency Not Provided		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539418	NON-EXPEDITED			US-TEVA-558258USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Influenza; Nasopharyngitis; Pain; Respiratory Tract Congestion; Stress	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539419	NON-EXPEDITED			US-TEVA-518117USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S	Unknown			Teva
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Vitamin B12			C				Not Reported
	Levoxyl			C				Not Reported
	Lipitor			C				Not Reported
	Naproxen			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539424	NON-EXPEDITED			US-TEVA-573399USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539425	NON-EXPEDITED			US-TEVA-522313USA		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash Pruritic; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	100 Milligram Daily;			Teva
	Biotin	C				Not Reported
	Vitamin D Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539426	NON-EXPEDITED			US-TEVA-576906USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness	Hydroxychloroquine			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Ranitidine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539427	NON-EXPEDITED			US-TEVA-569868USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539428	NON-EXPEDITED			US-TEVA-567613USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Gastrooesophageal Reflux Disease; Glossitis; Oral Disorder	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Minocycline\Minocycline Hydrochloride			S	Unknown	100 Milligram Daily;		Not Reported
	Metoclopramide			S	Unknown	20 Milligram Daily;		Not Reported
	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported
	Valaciclovir			S	Unknown	2 Bid		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11539860	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015315367			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diabetes Mellitus; Diarrhoea; Drug Ineffective; Swelling	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11540170	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3018374		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Response Decreased	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11540850	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3018697		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11541118	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3019122		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Fall; Feeling Hot; Joint Effusion; Liver Function Test Abnormal; Local Reaction; Weight Increased; Wrist Fracture	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown	On And Off Since Diagnosis		Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11541791	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-26		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Actemra			S				Not Reported
	Kineret			S				Not Reported
	Remicade			S				Not Reported
	Cimzia			S				Not Reported
	Simponi			S				Not Reported
	Orencia			S				Not Reported
	Cellcept			S				Not Reported
	Rituxan			S				Not Reported
	Enbrel			S				Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2015	11541921	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-SE-2015-25		64 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Hypoaesthesia; Maculopathy; Palpitations; Paraesthesia; Photophobia; Retinal Disorder; Skin Disorder; Skin Lesion; Visual Field Defect	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	10977216	EXPEDITED (15-DAY)		OT	CA-ROCHE-1289423		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastrointestinal Carcinoma; Nasopharyngitis; Pneumonia	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Unknown	Decreased Dosed Of Prednisone From 7.5mg Daily To 5mg Daily On Oct 2.		Not Reported
	Aclasta			C				Not Reported
	Amlodipine			C				Not Reported
	Ramipril			C				Not Reported
	Plavix			C				Not Reported
	Lactulose			C				Not Reported

	Rosuvastatin			C						Not Reported
	Lansoprazole			C						Not Reported
	Ferrous Sulfate			C						Not Reported
	Enbrel			C						Not Reported
	Tylenol Arthritis			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11544946	EXPEDITED (15-DAY)		HO	CA-HOSPIRA-3020096		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Inflammation; Joint Swelling; Joint Swelling; Migraine; Paraesthesia; Rheumatoid Arthritis; Treatment Failure	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11545212	EXPEDITED (15-DAY)		HO	TR-IPCA LABORATORIES LIMITED-IPC201509-000603		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Varicella Zoster Virus Infection	Hydroxychloroquine Sulfate			S				Ipca
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methylprednisolone			S				Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

	Tacrolimus			C					Not Reported
	Mycophenolate Mofetil			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11547211	EXPEDITED (15-DAY)		OT	HU-MYLANLABS-2015M1031642			Unknown	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Toxicity; Gastrointestinal Toxicity	Hydroxychloroquine Sulfate			S	Unknown			Mylan
	Methotrexate			S	Oral			Mylan
	Methotrexate			S	Subcutaneous			Mylan
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Etanercept			C	Unknown			Not Reported
	Golimumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11550255	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-25			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Pruritus; Pyrexia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2015	11552937	DIRECT	Y	RI			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Paralysis	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11492446	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-15			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11552327	NON-EXPEDITED		OT	US-AMGEN-USASP2015098696		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Cystitis; Glaucoma	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Mtx /00113801/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11555640	EXPEDITED (15-DAY)		OT	NZ-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NZ-2015-16			Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11555641	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-25			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C			Not Reported
	Lansoprazole	C			Not Reported
	Prednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11555646	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-25		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11555648	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-26		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S				Not Reported
	Hyzaar			C				Not Reported
	Effexor			C				Not Reported
	Folic Acid			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11555649	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-26		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Plaquenil			S					Not Reported
	Arava			S					Not Reported
	Rituxan			S					Not Reported
	Humira			S	Subcutaneous				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Sulfasalazine			S					Not Reported
	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Parenteral				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Imuran			S					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11555651	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-27		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Loose Tooth; Musculoskeletal Stiffness; Therapeutic Response Decreased; Tooth Abscess	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Humira			S				Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11556168	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-15K-163-1465810-00		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blindness; Decreased Appetite; Hallucination; Kidney Infection; Oral Mucosal Blistering; Product Administration Error;	Humira			S	Subcutaneous			Not Reported
	Ambien			S	Oral	At Bedtime		Not Reported
	Plaquenil			S	Oral			Not Reported
	Levothyroxine			C				Not Reported
	Cymbalta			C				Not Reported

Product Storage Error; Urinary Tract Infection; Vomiting; Weight Decreased	Cymbalta	C				Not Reported
	Lyrica	C				Not Reported
	Pilocarpine	C				Not Reported
	Methotrexate	C				Not Reported
	Mobic	C				Not Reported
	Prednisone	C				Not Reported
	Tramadol	C				Not Reported
	Calcium	C				Not Reported
	Vitamin D Nos	C				Not Reported
	Cyclobenzaprine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11556626	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-07		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Peripheral Swelling; Therapy Non-Responder	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11556628	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-26		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Pain;	Plaquenil			S				Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Rheumatoid Arthritis; Swelling	Rituxan		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Cimzia		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2015	11556629	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-26		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2015	11557814	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3021608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S				Not Reported
	Remicade			S				Not Reported
	Remicade			S				Not Reported
	Cimzia			S				Not Reported
	Cimzia			S				Not Reported
	Cimzia			S				Not Reported
	Simponi			S				Not Reported
	Simponi			S				Not Reported
	Simponi			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Folic Acid			S				Not Reported

	Fosamax	S	Not Reported
	Prednisone	S	Not Reported
	Reactine /00884302/	S	Not Reported
	Orencia	S	Not Reported
	Orencia	S	Not Reported
	Orencia	S	Not Reported
	Enbrel	S	Not Reported
	Enbrel	S	Not Reported
	Enbrel	S	Not Reported
	Rituxan	S	Not Reported
	Rituxan	S	Not Reported
	Rituxan	S	Not Reported
	Plaquenil /00072602/	S	Not Reported
	Plaquenil /00072602/	S	Not Reported
	Plaquenil /00072602/	S	Not Reported
	Sulfasalazine	S	Not Reported
	Sulfasalazine	S	Not Reported
	Sulfasalazine	S	Not Reported
	Methotrexate	S	Not Reported
	Arava	S	Not Reported
	Arava	S	Not Reported
	Arava	S	Not Reported
	Actemra	S	Not Reported
	Actemra	S	Not Reported
	Actemra	S	Not Reported
	Cortisone	S	Not Reported
	Cortisone	S	Not Reported
	Cortisone	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11292177	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-046604		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; International Normalised Ratio Increased	Coumadin			S	Oral	20 Mg, Qwk		Bristol Myers Squibb
	Deltacortene			S	Oral	10 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Dibase			S	Oral	1 Df, Qwk		Not Reported
	Alprazolam			C	Unknown			Not Reported

	Omeprazole	C	Unknown			Not Reported
	Tildiem	C	Unknown	Unk		Not Reported
	Lanoxin	C	Unknown	Unk		Not Reported
	Luvion /00252501/	C	Unknown	Unk		Not Reported
	Aliflus	C	Respiratory (inhalation)	1 Df, Unk		Not Reported
	Triatec /00116401/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11559002	EXPEDITED (15-DAY)		HO	PHHY2015US114648		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Pulmonary Alveolar Haemorrhage	Prednisone			S	Unknown			Novartis
	Prednisone			S	Unknown	60 Mg(Increased)		Novartis
	Prednisone			S	Unknown	50 Mg, Qd		Novartis
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Cellcept			S	Unknown	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11560528	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3021527		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypoaesthesia; Hypoaesthesia; Paraesthesia	Amitriptyline			C		Daily At Night (Hs)		Not Reported
	Amitriptyline			C		Daily At Night (Hs)		Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Cymbalta			C		Daily		Not Reported
	Cymbalta			C		Daily		Not Reported
	Vimovo			C				Not Reported
	Methotrexate			S	Subcutaneous	Weekly		Not Reported
	Modafinil			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2015	11563381	EXPEDITED (15-DAY)		OT	US-TEVA-597194USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Minocycline\Minocycline Hydrochloride			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ibuprofen			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11573791	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-27		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bicarbonate Decreased; Blood Pressure Decreased; Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose; Seizure; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tramadol			S				Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2015	11573792	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-27		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bicarbonate Decreased; Blood Lactic Acid Increased; Blood Pressure Decreased;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperkalaemia; Hypokalaemia; Overdose; Seizure; Sinus Tachycardia; Unresponsive To Stimuli	Potassium Chloride			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11579696	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2015M1032531			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown			Not Reported
	Cellcept /01275102/			S	Unknown			Not Reported
	Prednisone			C	Unknown	Dose Was Increased To 60 Mg On 1/15/15		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11580080	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-27		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypoaesthesia; Paraesthesia	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Modafinil			C				Not Reported
	Cymbalta			C				Not Reported
	Amitriptyline			C				Not Reported
	Vimovo			C				Not Reported
	Esomeprazole			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2015	11580082	EXPEDITED (15-DAY)		OT	PR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-27			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Drug Interaction; Hypertension; Pain; Vomiting	Plaquenil			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S				Not Reported
	Prozac			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11455997	EXPEDITED (15-DAY)		OT	US-TEVA-582372USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Hypersensitivity; Extrasystoles; Mental Status Changes; Nausea; Pyrexia; Ventricular Tachycardia; Vomiting	Azithromycin			S	Unknown			Not Reported
	Cimetidine			S	Unknown			Teva
	Ciprofloxacin			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Meperidine Hydrochloride			S	Unknown			Barr

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11520204	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1031574			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Headache; Nausea	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	300 Mg, Hs		Mylan
	Hydroxychloroquine Sulfate			S	Oral	300 Mg, Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11586620	NON-EXPEDITED			US-PFIZER INC-2015296649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Arthrotec			S		Unknown		Pfizer
	Azulfidine			S		Unknown		Pfizer
	Amoxicillin			S		Unknown		Pfizer
	Naproxen Sodium			S		Unknown		Pfizer
	Vectrin			S		Unknown		Not Reported
	Hydroxychloroquine Sulfate			S		Unknown		Not Reported
	Methotrexate			S		Unknown		Not Reported
	Imuran /00001501/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2015	11587950	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3018373		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Ineffective; Dysgeusia; Epistaxis; Headache; Hypertension; Sinus Congestion; Sinusitis; Synovitis; Urinary Tract Infection	Methotrexate			S	Subcutaneous	Weekly		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11589872	EXPEDITED (15-DAY)		HO	TW-FRESENIUS KABI-FK201504682		60 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infective Aneurysm	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2015	11590867	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-28			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Pain	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2015	11590973	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-009152		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Bone Marrow Disorder; Cutaneous Vasculitis; Drug-Induced Liver Injury; Dyspnoea; Haemoglobin Decreased; Pulmonary Alveolar Haemorrhage	Hydroxychloroquine			S		200mg B.I.D		Not Reported
	Prednisone			S				Not Reported
	Mycophenolic Acid			S		1000 Mg Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11004190	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1373379-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Injury; Neck Pain; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11591781	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1372862-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11592003	EXPEDITED (15-DAY)		HO	US-TEVA-598169USA		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	6g		Teva
	Tramadol			C	Oral	1.5g		Not Reported
	Meloxicam			C	Oral	450mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11592057	NON-EXPEDITED			US-PFIZER INC-2015324512		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S	Oral	200 Mg Twice Daily And As Needed		Pfizer
	Celebrex			S				Pfizer
	Sulfasalazine			S				Pfizer
	Folic Acid			S				Pfizer
	Plaquenil /00072602/			S				Not Reported

	Methotrexat /00113801/			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11593132	EXPEDITED (15-DAY)		DE	US-SA-2015SA151239			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Oxaliplatin			S	Intravenous (not otherwise specified)			Not Reported
	Fluorouracil			S	Intravenous bolus			Not Reported
	Fluorouracil			S	Intravenous (not otherwise specified)	Over 46h		Not Reported
	Leucovorin			S	Intravenous (not otherwise specified)			Not Reported
	Bevacizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594521	EXPEDITED (15-DAY)		HO	US-TEVA-598161USA		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown			Teva
	Cellcept			S	Unknown			Not Reported
	Rg 7212			S	Unknown	20 Mg/Kg		Not Reported
	Prednisone			C	Unknown	Dose Was Increased To 60 Mg On 1/15/15		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11594892	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2015-29			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Sudden Hearing Loss	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2015	11595047	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3023222		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Fracture; Lower Limb Fracture; Osteoarthritis; Osteoporosis; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Therapeutic Product Effect Incomplete	Xeljanz			S	Oral	Daily Dosage: 10 Mg		Not Reported
	Methotrexate			S	Subcutaneous	Weekly, Daily Dosage: 3.58 Mg		Not Reported
	Plaquenil /00072602/			S	Oral	Daily Dosage: 400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2015	11587853	EXPEDITED (15-DAY)		HO, OT	PHHY2015US116832		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	6 G, Unk		Novartis
	Tramadol			C	Unknown	1.5 G, Unk		Not Reported
	Meloxicam			C	Unknown	450 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2015	11596000	NON-EXPEDITED			US-PFIZER INC-2015328013		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2015	11596643	EXPEDITED (15-DAY)		OT	AR-FRESENIUS KABI-FK201504713			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anotia; Choroidal Coloboma; Cleft Lip And Palate; Ear Disorder; Exposure During Pregnancy; Hypertelorism Of Orbit; Iris Coloboma; Low Birth Weight Baby; Maternal Drugs Affecting Foetus; Microtia; Oesophageal Atresia; Off Label Use; Patent Ductus Arteriosus; Retinal Coloboma; Spinal Disorder	Calcium (Manufacturer Unknown)			S	Transplacental			Fresenius Medical Care
	Prednisolone (Manufacturer Unknown)			S	Transplacental			Not Reported
	Mycophenolate			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2015	11599140	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2015M1033272			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	6g		Not Reported
	Tramadol			C	Oral	1.5g		Not Reported
	Meloxicam			C	Oral	450mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11289905	EXPEDITED (15-DAY)		DS, OT	US-MYLANLABS-2015M1023317			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Macular Degeneration; Toxicity To	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Depakote			C		500 Mg, Bid		Not Reported

Various Agents	Levothyroxine	C	100 Mg, Qd	Not Reported
	Depakote	C	250 Mg, Qd	Not Reported
	Loratadine	C		Not Reported
	Allergy Relief /00072502/	C		Not Reported
	Calcium W/Vitamin D /00944201/	C	1 Df, Bid	Not Reported
	Lutein /01638501/	C	1 Df, Qd	Not Reported
	Nasacort	C		Not Reported
	Omeprazole	C	20 Mg, Qd	Not Reported
	Restasis	C		Not Reported
	Verapamil	C	120 Mg, Qd	Not Reported
	Leflunomide	C	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11603726	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-15-01		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hypokalaemia; Overdose; Seizure; Sinus Tachycardia; Toxicity To Various Agents; Unresponsive To Stimuli	Hydroxychloroquine			S	Oral			Hikma
	Tramadol			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11605099	NON-EXPEDITED			US-PFIZER INC-2015325662			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer

	Plaquenil			S		Unk				Not Reported
	Humira			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11609283	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-28			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Diarrhoea; Hypertension; Infection	Plaquenil			S	Unknown			Not Reported
	Vioxx			C				Not Reported
	Cortisone			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11609284	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-28			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Monitoring Procedure Not Performed; Retinal Toxicity; Visual Impairment	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2015	11609294	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-28			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Immobile; Insomnia; Movement Disorder; Pain; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	10700421	EXPEDITED (15-DAY)			TR-SA-2015SA001701		30 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Exposure Via Breast Milk	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Deltacortril			C	Subcutaneous	Dose And Frequency: 1 X 1/2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11529368	EXPEDITED (15-DAY)		HO	PHHY2015KR112984		41 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemophagocytic Lymphohistiocytosis; Pancytopenia; Product Use In Unapproved Indication; Pyrexia; Serum Ferritin Increased; Splenomegaly	Ciclosporin			S	Unknown	2 Mg/Kg, Qd		Novartis
	Ciclosporin			S	Unknown	3 Mg/Kg, Qd		Novartis
	Prednisolone			S	Oral	15 Mg, Bid		Not Reported
	Prednisolone			S	Oral	25 Mg, Bid		Not Reported
	Prednisolone			S	Oral	7.5 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	60 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown	500 Mg, (Three Times, 1 Week Apart)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11574108	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3022741		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Eczema; Erythema; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis;	Prednisone			C				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

Rhinorrhoea; Swelling Face; Therapeutic Response Decreased	Methotrexate			S	Subcutaneous	Weekly		Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11610865	EXPEDITED (15-DAY)		OT	CA-ROCHE-1643237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11610891	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-104205		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Increased; Hypokalaemia; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Unk		Ipca
	Tramadol			S	Oral	Unk		Sun
	Meloxicam			S	Oral	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2015	11611698	NON-EXPEDITED			US-PFIZER INC-2015332344		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

	Dyazide			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11525947	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-22		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Function Test Abnormal; Cardiotoxicity; Ejection Fraction Decreased; Product Use Issue; Sinus Tachycardia; Tachycardia; Ventricular Hypokinesia	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11614708	EXPEDITED (15-DAY)		DS, OT	CA-HOSPIRA-3035050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Gait Disturbance; Joint Swelling	Pantoloc /01263204/			C				Not Reported
	Amitriptyline			C				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Calcium /00405001/			C				Not Reported
	Citalopram			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin C /00008001/			C				Not Reported
	Vitamin D /00107901/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11615665	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2015US07806			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Overdose; Sedation; Seizure; Sinus Tachycardia; Unresponsive To Stimuli	Meloxicam			S	Unknown	450 Mg, Unk		Cipla
	Hydroxychloroquine			S	Unknown	6 G, Unk		Not Reported

	Tramadol			S	Unknown	1.5 G, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11616038	EXPEDITED (15-DAY)		HO, LT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-54		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Seizure; Sinus Tachycardia; Unresponsive To Stimuli	Mobic			S	Unknown	450 Mg		Boehringer Ingelheim
	Hydroxychloroquine			S	Unknown	6 G		Not Reported
	Tramadol			S	Unknown	1.5 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11617771	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-29			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Meloxicam			C				Not Reported
	Cozaar			C				Not Reported
	Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2015	11622433	DIRECT		OT			23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disorientation; Rheumatoid Arthritis; Vision Blurred	Plaquenil 200 Mg			S	Oral	1 Pill		Not Reported
	Once A Day Women'S Vitamin			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11618329	EXPEDITED (15-DAY)		OT	BR-ABBVIE-15K-020-1476792-00		26 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Finger Deformity; Insomnia; Pain; Peripheral Swelling	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11618619	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-067727			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Orencia			S	Unknown			Bristol Myers Squibb
	Remicade			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2015	11620703	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201508-000562			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Condition Aggravated; Drug Ineffective For Unapproved Indication; Haemorrhage; Mouth Ulceration; Pharyngeal Inflammation; Product Substitution Issue; Vision	Hydroxychloroquine Sulfate			S				Ipca

Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2015	11621772	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-009217		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Heart Rate Decreased; Hyperkalaemia; Hypokalaemia; Overdose; Seizure; Sinus Tachycardia; Toxicity To Various Agents	Hydroxychloroquine			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2015	11624380	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2015-03161		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Overdose	Hydroxychloroquine			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2015	11626734	NON-EXPEDITED			US-APOTEX-2015AP006500		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cat Scratch Disease; Drug Ineffective	Cyclosporine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Methotrexate			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported

	Prednisone			S	Unknown	Greater Than 20mg			Not Reported
	Tocilizumab			S	Other	8 Mg/Kg, Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11629818	NON-EXPEDITED			US-PFIZER INC-2015339027		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2015	11631047	EXPEDITED (15-DAY)		DE	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-30			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Oxaliplatin			S	Intravenous (not otherwise specified)			Not Reported
	Fluorouracil			S	Intravenous bolus			Not Reported
	Fluorouracil			S	Intravenous (not otherwise specified)			Not Reported
	Leucovorin			S	Intravenous (not otherwise specified)			Not Reported
	Bevacizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11592714	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2015102096		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Interaction; Feeling Hot; Inflammation; Pruritus; Rash	Prolia	S	Subcutaneous	60 Mg/Ml, Unk	Amgen
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Cortisone	C		Unk	Not Reported
	Synthroid	C			Not Reported
	Triazide (Trichlormethiazide)	C			Not Reported
	Vitamin C /00008001/	C			Not Reported
	Vitamin D /00107901/	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11631656	EXPEDITED (15-DAY)		HO, OT	CA-HOSPIRA-3022450		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Short Stature; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Immunoglobulin /00025201/			S	Intravenous (not			Not Reported

						otherwise specified)				
		Immunoglobulin /00025201/			S	Intravenous (not otherwise specified)				Not Reported
		Triamcinolone Hexacetonide			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11634930	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-16			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Musculoskeletal Stiffness; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Arthrotec			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11636091	DIRECT	Y	HO, OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Vorinostat			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Zofran			C				Not Reported
	Tylenol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Compazine			C				Not Reported
	Bystolic			C				Not Reported
	Hydralazine			C				Not Reported
	Fenofibrate			C				Not Reported
	Protonix			C				Not Reported
	Magnesium			C				Not Reported
	Vit B-12			C				Not Reported
	Vit D			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2015	11636590	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Middle Insomnia; Palpitations; Panic Attack; Product Substitution Issue	Hydroxychloroquine 200mg Avkare			S	Oral			Avkare
	Meloxicam (Mobic), Generic			C				Not Reported
	Cranberry Pill			C				Not Reported
	Baby Asprin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11518336	NON-EXPEDITED			US-ROXANE LABORATORIES, INC.-2015-RO-01543RO			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Increased Tendency To Bruise; Product Quality Issue; Skin Fragility	Methotrexate			S	Unknown			Roxane
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11583317	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3024002		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Plaquenil /00072602/			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous	3.58 Mg Daily		Not Reported
	Acetaminophen			S				Not Reported
	Dilaudid			S				Not Reported
	Prednisone			S		7.5 Mg For One Month Will Decline To 0.5 Mg		Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2015	11638521	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-30		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11287963	NON-EXPEDITED			US-PFIZER INC-2015238548		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Xeljanz			S	Oral	5mg (1 Tablet) Twice Daily		Pfizer
	Hydroxychloroquine			S	Oral	500 Mg, 2x/Day		Not Reported
	Tramadol			C	Oral	50 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11639323	EXPEDITED (15-DAY)		OT	CA-ROCHE-1646960		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2015	11640927	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2015346577		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pseudoporphyria	Amiodarone Hcl			S	Oral	200 Mg, Daily		Pfizer
	Plaquenil			S	Oral	200 Mg, 3x/Day		Not Reported
	Furosemide			C		Unk		Not Reported
	Levothyrox			C		Unk		Not Reported
	Ezetrol			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11544067	EXPEDITED (15-DAY)		DE, OT	CA-HOSPIRA-3013033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Death; Nausea; Vomiting	Sulfasalazine			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11590869	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-28		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue; Retinal Toxicity; Retinogram Abnormal	Hydroxychloroquine Sulfate			S				Not Reported
	Erlotinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11594893	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-28		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Optical Coherence Tomography Abnormal; Product Use In Unapproved Indication; Product Use In Unapproved Indication; Retinal Toxicity; Retinogram Abnormal	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11642886	EXPEDITED (15-DAY)		OT	CA-ROCHE-1646834		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastrointestinal Carcinoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11643698	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3041909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	Weekly		Not Reported
	Plaquenil /00072602/			S				Not Reported
	Cortisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11644300	EXPEDITED (15-DAY)		OT	US-SA-2015SA163047			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Remicade			C						Not Reported
	Aleve			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11254712	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015224060		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Joint Swelling; Macule; Pain; Skin Cancer	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11323182	NON-EXPEDITED		OT	US-AMGEN-USASP2015075941		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Injection Site Bruising; Injection Site Discolouration; Injection Site Erythema; Injection Site Extravasation; Injection Site Pain; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Insomnia; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Discomfort; Musculoskeletal Pain; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tooth Fracture	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11399549	EXPEDITED (15-DAY)		OT	CA-SA-2015SA114900		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Intolerance; Malaise; Renal Impairment	Arava			S	Unknown	Doses: 4 Doses.		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11634758	EXPEDITED (15-DAY)		HO, OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-56		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Subdural Haematoma	Pradaxa			S	Oral	300 Mg		Boehringer Ingelheim
	Ecotrin			S	Oral	81 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Actonel			C	Oral	5 Mg		Not Reported
	Lanoxin			C	Oral	125 Mcg		Not Reported
	Lantus			C	Subcutaneous	50 U		Not Reported
	Zyloprim			C	Oral	100 Mg		Not Reported
	Lopresor			C	Oral	300 Mg		Not Reported
	Feosol			C	Oral	130 Mg		Not Reported
	Erivedge			C	Oral	150 Mg		Not Reported
	Flexeril			C	Oral	15 Mg		Not Reported
	Tylenol Extra Str			C	Oral	2000 Mg		Not Reported
	Feiba			C	Intravenous (not otherwise specified)			Not Reported
	Feiba			C				Not Reported

Fentanyl	C	Intravenous (not otherwise specified)		Not Reported
Cerebyx	C	Intravenous (not otherwise specified)		Not Reported
Dulcolax	C	Rectal		Not Reported
Nacl	C	Intravenous (not otherwise specified)	Strength 0.9%	Not Reported
Diprivan	C	Intravenous (not otherwise specified)		Not Reported
Scopolamine	C	Transdermal		Not Reported
Elavil	C	Oral	20 Mg	Not Reported
Ultram	C	Oral	150 Mg	Not Reported
Humalog	C	Subcutaneous	26 U	Not Reported
K-Dur	C	Oral	40 Meq	Not Reported
Zetia	C	Oral	10 Mg	Not Reported
Lasix	C	Oral	80 Mg	Not Reported
Zaroxolyn	C	Oral	2.5 Mg	Not Reported
Norvasc	C	Oral	10 Mg	Not Reported
Nexium	C	Oral	40 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11652937	EXPEDITED (15-DAY)		DS	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-31		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Toxicity To Various Agents; Visual Acuity Reduced; Visual Impairment	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11652939	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-30		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Pain; Red Blood Cell Sedimentation Rate Increased; Suicidal Ideation	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Chloroquine Phosphate			S				Not Reported
	Arava			S				Not Reported
	Zorvolex			C				Not Reported
	Humira			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11653582	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-31			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immunodeficiency; Lyme Disease	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11653583	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-31		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Sensory Loss	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11449267	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-20		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Ineffective; Nasopharyngitis; Oropharyngeal Pain;	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Rheumatoid Arthritis;	Methotrexate	C		Not Reported
Rheumatoid Arthritis;	Folic Acid	C		Not Reported
Rhinorrhoea; Stress; Throat Irritation	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11609292	EXPEDITED (15-DAY)		DE	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-28		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate Sodium			C				Not Reported
	Leflunomide			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11654877	EXPEDITED (15-DAY)		OT	US-ABBVIE-15K-163-1485058-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Musculoskeletal Stiffness; Visual Field Defect	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11654986	EXPEDITED (15-DAY)		DE, DS, HO, OT	BR-WATSON-2015-22264		10 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Coma; Cutaneous Vasculitis; Hypertension; Meningitis Cryptococcal; Pneumonia Bacterial; Septic Shock	Prednisolone (Unknown)			S	Unknown	Diminished To 10 Mg, Daily		Watson
	Prednisolone (Unknown)			S	Unknown	2 Mg/Kg, Daily		Watson
	Hydroxychloroquine (Unknown)			S	Unknown	Unk		Watson
	Azathioprine (Unknown)			S	Unknown	3 Mg/Kg, Daily		Not Reported

	Cyclophosphamide (Unknown)			S	Intravenous (not otherwise specified)	1000 Mg/M2, Once A Month, Every 3 Months			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11655908	EXPEDITED (15-DAY)		HO	US-IPCA LABORATORIES LIMITED-IPC201510-000682		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Overdose; Seizure; Toxicity To Various Agents; Unresponsive To Stimuli	Hydroxychloroquine Sulfate			S				Ipca
	Tramadol			S				Ipca
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11656357	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-31		53 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11658817	EXPEDITED (15-DAY)		OT	US-HOSPIRA-3055612		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Bladder Disorder; Blood Urine Present; Bone Density Abnormal; Cough; Drug Ineffective; Fall; Gait Disturbance; Injection Site Erythema; Injection Site Mass; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction;	Prolia			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Magnesium			C				Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Medrol /00049601/			C				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Injection Site Warmth; Joint Fluid Drainage; Joint Range Of Motion Decreased; Joint Swelling; Joint Warmth; Knee Deformity; Micturition Urgency; Musculoskeletal Discomfort; Oesophageal Disorder; Pain; Sinus Disorder; Sinusitis; Sleep Apnoea Syndrome; Spider Vein; Tooth Repair; Vascular Rupture	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Calcium	C			Not Reported
	Cortisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11661735	EXPEDITED (15-DAY)		HO, OT	US-SA-2015SA164457		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blindness; Decreased Appetite; Hallucination; Kidney Infection; Oral Mucosal Blistering; Product Administration Error; Product Storage Error; Urinary Tract Infection; Vomiting; Weight Decreased	Ambien			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	Start Date: For Maore Than 7 Years		Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Pilocarpine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Mobic			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Cyclobenzaprine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2015	11432071	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-17		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Pain; Gait Disturbance; Knee Arthroplasty; Malaise; Sensory Loss; Thrombosis; Unevaluable Event	Plaquenil			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2015	11590868	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-TU-2015-28		35 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Pruritus; Pyrexia; Rash	Plaquenil			S	Oral			Not Reported
	Deltacortil			C				Not Reported
	Salazopyrin			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2015	11662277	EXPEDITED (15-DAY)		DS	CA-HOSPIRA-3044183		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dysstasia; Malaise; Migraine; Mobility Decreased; Nausea; Pain; Rheumatoid Arthritis	Leflunomide			S	Unknown			Not Reported
	Arava			C		Daily		Not Reported
	Celebrex			C		Daily		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11420453	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-19		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Intolerance; Malaise; Renal Impairment	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11639910	EXPEDITED (15-DAY)		DE, HO, OT	US-AMGEN-USASP2015107958			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adenocarcinoma Of Colon; Diverticulum Intestinal; Eye Disorder; Headache; Infection; Injection Site Rash; Intestinal Ischaemia; Intestinal Obstruction; Large Intestine Perforation; Lymphadenitis; Malignant Gastrointestinal Obstruction; Migraine; Osteomyelitis; Procedural Haemorrhage; Vascular Access Complication	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

	Excedrin Extra Strength			C		Unk			Not Reported
	Prednisone			C	Oral	5 Mg, Unk			Not Reported
	Tums E-X			C	Oral	750 Mg, Qd			Not Reported
	Acetaminophen W/Hydrocodone			C	Oral	Unk,5-325 Mg			Not Reported
	Cyclobenzaprine Hcl			C	Oral	10 Mg, Unk			Not Reported
	Imitrex /01044801/			C		100 Mg, Unk			Not Reported
	Colcrys			C		0.6 Mg, Unk			Not Reported
	Prilosec /00661201/			C	Oral	20 Mg, Unk			Not Reported
	Orencia			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11661840	EXPEDITED (15-DAY)		OT	RU-PFIZER INC-2015355573		43 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyelonephritis	Jaqinus			S	Oral	5 Mg, 2x/Day		Pfizer
	Metypred			S		12 Mg, Daily		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Nise			S		100 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11670462	NON-EXPEDITED			US-AMGEN-USASL2015111028		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Injection Site Bruising; Injection Site Reaction; Knee Operation	Enbrel			S	Unknown	50 Mg, Once Weekly		Amgen
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11675882	NON-EXPEDITED			GXBR2015US002051		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Headache; Nausea	Hydroxychloroquine Sulfate Tablets Usp		S	Oral	400 Mg, Qd	Novartis
	Hydroxychloroquine Sulfate Tablets Usp		S	Oral	400 Mg, Qd	Novartis
	Pilocarpine		C	Oral	Unk Df, Tid	Not Reported
	Trazodone		C	Oral	50 Mg, Qhs	Not Reported
	Metformin		C	Oral	1000 Mg, Qd	Not Reported
	Lexapro		C	Oral	10 Mg, Qd In The Morning	Not Reported
	Restasis		C	Ophthalmic	1 Gtt, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11677244	EXPEDITED (15-DAY)		DS	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2015-32			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11678403	EXPEDITED (15-DAY)		HO	US-ABBVIE-15P-163-1487260-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthenia; Asthenia; Blood Pressure Increased; Chest Pain; Crohn'S Disease; Dehydration; Drug Ineffective; Nausea; Nausea; Nausea; Obstruction; Pancreatic Enzymes Increased; Stress; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Colestipol			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Losartan			C				Not Reported
	Losartan			C				Not Reported
	Lansoprazole			C				Not Reported
	Levothyroxine			C				Not Reported
	Calcium With Vitamin D			C				Not Reported
	Centrum Silver			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11678882	EXPEDITED (15-DAY)		HO	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2015-33		15 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis; Product Use Issue	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2015	11678886	EXPEDITED (15-DAY)		HO	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2015-33		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11646524	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-30		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11683285	EXPEDITED (15-DAY)		OT	GB-FRESENIUS KABI-FK201505414		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Humira			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Metformin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2015	11683971	NON-EXPEDITED			GXBR2015US002059			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Flatulence; Urine Odour Abnormal	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk Df, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	10655760	NON-EXPEDITED			US-PFIZER INC-2014344395		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Doxepin Hcl			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Zanaflex			S		Unk		Not Reported
	Allegra			S		Unk		Not Reported
	Paxil			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Claritin-D			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported
	Delsym			S		Unk		Not Reported
	Lasix			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Cafergot			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11456294	EXPEDITED (15-DAY)		OT	US-TEVA-590441USA		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Depression; Diplopia	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S		3 Tabs		Teva
	Humira			S				Not Reported
	Atenolol			C		Half Tablet		Not Reported
	Omeprazole			C				Not Reported
	Levothyroxine			C				Not Reported
	Folic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Fish Oil			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11685097	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1451502-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Hcq			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2015	11687933	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC-2015354167		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adenocarcinoma Of Colon; Diverticulum	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Pfizer
	Enbrel			S		Unk		Pfizer

Intestinal; Drug Ineffective; Eye Disorder; Headache; Infection; Injection Site Rash; Intestinal Ischaemia; Intestinal Obstruction; Large Intestine Perforation; Lymphadenitis; Malignant Gastrointestinal Obstruction; Migraine; Osteomyelitis; Procedural Haemorrhage; Vascular Access Complication	Enbrel	S	Subcutaneous	25 Mg, 2x/Week	Pfizer
	Enbrel	S	Subcutaneous	25 Mg, 2x/Week	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Xeljanz	S	Unknown	Unk	Pfizer
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Excedrin Extra Strength	C		Unk	Not Reported
	Prednisone	C	Oral	5 Mg, Unk	Not Reported
	Tums E-X	C	Oral	750 Mg, Qd	Not Reported
	Acetaminophen W/Hydrocodone	C	Oral	Unk,5-325 Mg	Not Reported
	Cyclobenzaprine Hcl	C	Oral	10 Mg, Unk	Not Reported
	Imitrex /01044801/	C		100 Mg, Unk	Not Reported
	Colcrys	C		0.6 Mg, Unk	Not Reported
	Prilosec	C	Oral	20 Mg, Unk	Not Reported
	Orencia	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2015	11624279	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3036772		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Dry Mouth; Joint Range Of Motion Decreased; Lip Dry; Liver	Citalopram			C				Not Reported
	Gliclazide			C				Not Reported
	Synthroid			C				Not Reported
	Domperidone			C				Not Reported
	Pantoloc /01263204/			C				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tylenol /00020001/	C				Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Calcite D	C		500 Mg + 1000 Mg Die		Not Reported
	Gabapentin	C				Not Reported
	Enbrel	S				Not Reported
	Cimzia	S	Unknown			Not Reported
	Orencia	S				Not Reported
	Folic Acid	C		6/7		Not Reported
	Xeljanz	S	Oral			Not Reported
	Actonel	C		On Tuesday		Not Reported
	Lipitor	C				Not Reported
	Nifedipine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2015	11690280	EXPEDITED (15-DAY)		DE	BR-MYLANLABS-2015M1037146			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Cryptococcal; Septic Shock	Azathioprine			S	Unknown	10 Mg/Day		Mylan
	Azathioprine			S	Unknown	3 Mg/Kg/Day		Mylan
	Hydroxychloroquine			S	Unknown	10 Mg/Day		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	7 Monthly Sessions Of Cyclophosphamide 0.5-1 G/M2/Month		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Three Pulses, Given Every 3mo		Not Reported
	Prednisone			S	Unknown	10 Mg/Day		Not Reported
	Prednisone			S		2 Mg/Kg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11323684	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015082112		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Cellulitis; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Insomnia; Oral Allergy Syndrome; Tinnitus	Methotrexate Sodium	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Eltroxin	C	0.05 Mg, 1x/Day	Not Reported
	Folic Acid	C	5 Mg, 1x/Day	Not Reported
	Vitamin D Nos	C	2000 Iu, 1x/Day	Not Reported
	Advil	C	400 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11419270	EXPEDITED (15-DAY)		OT	CA-ROCHE-1626128		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 93 Days		Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11427669	EXPEDITED (15-DAY)		HO	CA-ROCHE-1626566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11634940	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-30		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eosinophilia; Erythema; Rash Maculo-Papular	Plaquenil			S	Oral					Not Reported
	Cortancyl			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695126	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-32			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695127	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-32			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Device Dislocation; Humerus Fracture; Joint Arthroplasty; Joint Dislocation	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695128	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Methotrexate			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695129	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695130	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-34			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Autoimmune Thyroiditis; Bone Erosion; Bone Marrow Oedema; Cartilage Injury; Eye Disorder; Groin Pain; Immunodeficiency; Inflammation; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased; Sjogren'S Syndrome; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S				Not Reported
	Methotrexate			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695182	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			C				Not Reported
	Aleve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695183	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Pain; Rheumatoid Arthritis; Sepsis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695184	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Invasive Breast Carcinoma	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695185	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2015	11695186	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-33			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11254527	NON-EXPEDITED			US-PFIZER INC-2015227649		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Daypro			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Propanolol Hcl			S		Unk		Unknown
	Nasacort			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported
	Ceftin /00454603/			S		Unk		Not Reported
	Norflex			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Savella			S		Unk		Not Reported
	Sulindac			S		Unk		Not Reported
	Trazodone Hydrochloride			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11498671	EXPEDITED (15-DAY)		HO, OT	AU-AMGEN-AUSSP2015092049		45 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aplasia Pure Red Cell; Fatigue; Myelodysplastic Syndrome; Night Sweats; Pleural Effusion; Renal	Aranesp			S	Subcutaneous	60 Unk, Q2wk		Amgen
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Myfortic			C	Oral	360 Mg, Bid		Not Reported
	Prednisolone			C	Oral	5 Mg, Qd		Not Reported

Cyst; Therapeutic Product Effect Decreased; Thyroid Mass; Weight Decreased	Tacrolimus	C	Oral	2 Mg, Bid		Not Reported
	Furosemide	C	Oral	20 Mg, Qd		Not Reported
	Cyclophosphamide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11695396	EXPEDITED (15-DAY)		OT	CA-ROCHE-1654559			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11695550	EXPEDITED (15-DAY)		OT	CA-ROCHE-1654574		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; No Adverse Event	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11697011	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201501-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Plasma Cell Myeloma; Visual Field Defect	Hydroxychloroquine Sulfate			S				Ipca
	Lantus			C				Not Reported
	Amlodipine			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2015	11699120	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-34			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Feeling Hot; Malaise; Nausea; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11674217	EXPEDITED (15-DAY)		HO, LT, OT	ES-WATSON-2015-12302		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Pancreatitis; Lupus Vasculitis; Pulmonary Alveolar Haemorrhage; Systemic Lupus Erythematosus; Withdrawal Syndrome	Hydroxychloroquine (Unknown)			S	Unknown	Unk		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11699601	EXPEDITED (15-DAY)		OT	CA-ROCHE-1655116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown	11.0 Year		Not Reported
	Arava			C				Not Reported
	Ativan			C				Not Reported
	Benadryl (Canada)			C				Not Reported
	Dilaudid			C				Not Reported
	Enablex			C				Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C				Not Reported
	Pantoloc			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11699603	EXPEDITED (15-DAY)		HO	CA-ROCHE-1654548		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11702303	EXPEDITED (15-DAY)		HO	TW-ROXANE LABORATORIES, INC.-2015-RO-01813RO		60 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infective Aneurysm	Methotrexate			S	Unknown			Roxane
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisolone			S	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2015	11703151	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-34		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2015	11555653	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2015-26		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Bisoprolol			C				Not Reported
	Flecainide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2015	11714231	DIRECT	Y	OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Decreased	Humira 40mg Abbvie	S	Subcutaneous		Abbvie
	Methotrexate	S			Not Reported
	Hydrochloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2015	11715734	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2015-026048			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Metronidazole			S	Unknown			Not Reported
	Captopril			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lantus			C				Not Reported
	Mircera			C				Not Reported
	Ms Contin			C				Not Reported
	Amoxicillin Trihydrate			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Buprenorphine Transdermal			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ciprofloxacin			C				Not Reported
	Enoxaparin			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Ethacrynic Acid			C				Not Reported
	Flucloxacillin Sodium			C				Not Reported
	Frusemide			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Lercanidipine Hydrochloride			C				Not Reported
	Oxycodone Hydrochloride			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisolone			C				Not Reported
	Pregabalin			C				Not Reported
	Spironolactone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Vancomycin Hydrochloride			C				Not Reported
	Warfarin Sodium			C				Not Reported
	Novorapid			C				Not Reported
	Paracetamol Sr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11717364	EXPEDITED (15-DAY)		OT	CA-ROCHE-1656003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Ativan			C				Not Reported
	Benadryl (Canada)			C				Not Reported
	Codeine			C				Not Reported
	Cortisone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dilaudid			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog (Canada)			C	Unknown			Not Reported
	Kineret			C	Unknown			Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C	Unknown			Not Reported
	Oxyneo			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported

	Restasis			C	Unknown				Not Reported
	Rituxan			C	Intravenous (not otherwise specified)				Not Reported
	Synthroid			C					Not Reported
	Trimethoprim			C					Not Reported
	Urispas			C	Unknown				Not Reported
	Vagifem			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11720846	NON-EXPEDITED			US-PFIZER INC-2015382961		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Singulair			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2015	11721146	EXPEDITED (15-DAY)		DE	KR-CONCORDIA PHARMACEUTICALS INC.-CO-OR-KR-2015-01		40 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Hepatic Enzyme Increased	Prednisolone			S				Concordia
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11617748	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-29			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Malaise;	Plaquenil			S				Not Reported

Nasopharyngitis; Rheumatoid Arthritis	Methotrexate	C	Not Reported
	Celebrex	C	Not Reported
	Sulfasalazine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11724156	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015349277		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Hordeolum; Hypokinesia; Joint Swelling; Nephrolithiasis; Oral Herpes; Peripheral Swelling; Rheumatoid Arthritis	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Leflunomide			S		10 Mg, Daily		Not Reported
	Hydroxychloroquine			S		450 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2015	11726857	EXPEDITED (15-DAY)		OT	CA-ROCHE-1659861		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2015	11726915	EXPEDITED (15-DAY)		HO, OT	ES-WATSON-2015-23620		17 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Hydroxychloroquine (Unknown)			S	Unknown	200 Mg, Single		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2015	11729152	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-36		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2015	11729421	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-35		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11173542	EXPEDITED (15-DAY)		OT	CA-ROCHE-1589855		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis;	Rituxan			S	Intravenous (not			Not Reported

Treatment Failure			otherwise specified)	
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11734804	NON-EXPEDITED			US-PFIZER INC-2015387613		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benzylpenicillin Potassium			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Indocin /00003801/			S	Unknown	Unk		Not Reported
	Flexeril /00428402/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2015	11703697	NON-EXPEDITED			US-AMGEN-USASP2015116939		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Injection Site Haemorrhage; Injection Site Mass; Injection Site Reaction; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S				Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2015	11745436	DIRECT					51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dysgeusia; Migraine; Wrong Technique In Product Usage Process	Hydroxychloroquine 200 Mg Tablets Zydus - Substituted For Plaquenil			S	Oral			Zydus Pharm
	Vitamin C			C				Not Reported
	Vitamin D3			C				Not Reported
	Calcium			C				Not Reported
	Fish Oil			C				Not Reported
	Glucosamine Chondroitin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11668161	EXPEDITED (15-DAY)		DE, OT	PHHY2015BR137691		10 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Coma; Meningitis Cryptococcal; Sepsis; Septic Shock	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	0.5 G/M2, Qmo		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11729145	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-35		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis;	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Tecta	S	Unknown		Not Reported
	Voltaren	S	Oral		Not Reported
	Synthroid	S	Unknown		Not Reported
	Lisinopril	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11747536	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2015391415		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster	Methotrexate Sodium			S	Oral	Unk, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Every Two Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11748455	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-36		67 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Neutropenia	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Eliquis			S	Unknown			Not Reported
	Bisoprolol			C				Not Reported
	Tinzaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2015	11748652	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2015M1039948			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Hydroxychloroquine			S	Unknown	200 Mg/12 Hours		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11753168	EXPEDITED (15-DAY)		OT	FR-AMGEN-FRASP2015121133		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lichenoid Keratosis	Nplate			S	Intravenous (not otherwise specified)	0.142 Unit, Qwk		Amgen
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11753729	NON-EXPEDITED			US-PFIZER INC-2015386853			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11753775	EXPEDITED (15-DAY)		HO, OT	TR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-TU-2015-36		26 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Eyelid Oedema; Immune System Disorder; Pain; Pruritus; Rash Erythematous; Skin Exfoliation	Plaquenil			S	Oral			Not Reported
	Euthyrox			S				Not Reported
	Ferro "Sanol"			C				Not Reported
	Benexol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11753884	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201504007916		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Inability; Hypokinesia; Nausea; Pain; Weight Increased	Cymbalta	S	Unknown	Unk, Unknown		Eli Lilly And Co
	Plaquenil /00072602/	S	Unknown	Unk, Unknown		Not Reported
	Rituxan	S	Unknown	Unk, Unknown		Not Reported
	Prednisone	S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2015	11755640	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-609712USA		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction; Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Naproxen			S	Unknown			Teva
	Prednisone			S				Not Reported
	Methotrexate			S		2.1429 Mg/M2 Daily;		Not Reported
	Etanercept			S	Subcutaneous	1.7857 Milligram Daily;		Not Reported
	Etanercept			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	.0714 Mg/Kg Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5mg/Dose		Not Reported
	Adalimumab			S				Not Reported
	Ivig			S				Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Abatacept			S	Intravenous drip	8.3333 Milligram Daily;		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg/Kg Daily;		Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone			S				Not Reported
	Triamcinolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11404861	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Pain; Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11717774	EXPEDITED (15-DAY)		OT	CA-ROCHE-1658544		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Naproxen			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 4 Months		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 18 Years		Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration 12 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11726478	NON-EXPEDITED			CHPA2014US007914		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Discolouration; Application Site Pain; Condition	Voltaren			S	Topical	Unk, 5 To 6 Qd		Novartis
	Voltaren			S	Topical	Unk, Every 3 To 4 Hours		Novartis

Aggravated; Dry Skin; Inappropriate Schedule Of Product Administration; Incorrect Dose Administered; Pain; Product Administered At Inappropriate Site; Product Use In Unapproved Indication; Skin Disorder; Skin Sensitisation; Swelling; Therapeutic Response Unexpected	Voltaren	S					Novartis
	Vitamin D Nos	S	Unknown	Unk			Not Reported
	Prednisone	S	Unknown	5 Mg, Qd			Not Reported
	Folic Acid	S	Unknown	Unk			Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid			Not Reported
	Colcrys	C	Unknown	0.6 Mg, M/W/F			Not Reported
	Advil//Ibuprofen	C	Unknown	Unk, Qid			Not Reported
	Biofreeze /01638601/	C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11761897	EXPEDITED (15-DAY)		OT	RU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-RU-2015-37		43 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyelonephritis	Plaquenil			S	Unknown			Not Reported
	Jaqinus			S	Oral			Not Reported
	Metypred			S	Unknown			Not Reported
	Nise			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11762393	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-37			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ophthalmic Vein Thrombosis	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2015	11765743	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201408004829		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Genital Rash; Rash; Wrong Technique In Product Usage Process	Forteo	S	Unknown	Unk, Qd		Eli Lilly And Co
	Plaquenil /00072602/	S	Unknown	Unk, Unknown		Not Reported
	Prednisone	C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2015	11771008	EXPEDITED (15-DAY)		OT	CA-ROCHE-1665041		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11773649	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-38			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Eye Disorder; Musculoskeletal Stiffness; Therapeutic Product Effect Decreased; Visual Field Defect	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11774217	EXPEDITED (15-DAY)		OT	PHHY2015ES148060		36 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung Disease; Irritability; Vision Blurred	Hydroxychloroquine			S	Unknown	200 Mg, Q12h		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11497576	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-22		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Joint Swelling; Knee Arthroplasty; Mycobacterium Tuberculosis Complex Test Positive; Nausea; Pain; Treatment Failure; Vomiting	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Naprosyn			C				Not Reported
	Metformin			C				Not Reported
	Ramipril			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11624273	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1642806		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Anaphylactic Shock; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Heart Rate Increased; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	1 G/M, 8 Doses		Not Reported
	Cyclophosphamide			S	Unknown	X 3 Courses		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methylprednisolone			C				Not Reported

	Solumedrol	C	Unknown	15 To 30 Mg.		Not Reported
	Solumedrol	C	Intravenous (not otherwise specified)	15 To 30 Mg.		Not Reported
	Diphenhydramine Hcl	C	Oral			Not Reported
	Acetaminophen	C	Oral			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11776195	EXPEDITED (15-DAY)		OT	CA-ROCHE-1665032		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 2 Week(S)		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 2 Week(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11778962	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-37		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Productive Cough; Temporomandibular Joint Syndrome	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Arava			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2015	11778966	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-37			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hodgkin'S Disease	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11719852	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-34		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780276	NON-EXPEDITED			US-JNJFOC-20150927058		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Plaquinol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2015	11783131	NON-EXPEDITED			US-BAYER-2015-458363			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Intentional Product Use Issue	Adempas			S		Unk		Bayer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2015	11783688	EXPEDITED (15-DAY)		HO	DK-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DK-2015-38			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Anembryonic Gestation; Benign Hydatidiform Mole; Exposure During Pregnancy; Vaginal Haemorrhage	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2015	11783689	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-CO-PL-ES-2015-38		36 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bicarbonate Increased; Bronchoalveolar Lavage Abnormal; Chest X-Ray Abnormal; Cough; Diarrhoea; Dyspnoea Exertional; Interstitial Lung Disease; Irritability; Malaise; Pco2 Decreased; Po2 Decreased; Rales; Vision Blurred	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11741142	EXPEDITED (15-DAY)		OT	AR-AMGEN-ARGSP2015120516		51 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Enbrel			S	Unknown	50 Mg, Weekly		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levotiroxina (Levothyroxine Sodium)			C		Unk		Not Reported
	Pregabalina			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11787865	NON-EXPEDITED		OT	GXBR2015US000777		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Dysphonia; Feeding Disorder; Lymphadenopathy; Oral Lichenoid Reaction; Oral Pain; Scab; Stomatitis; Weight Decreased; Wound	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Qd		Novartis
	Prednisone			C	Unknown	2 Mg, Qod		Not Reported
	Multi Vitamin			C	Unknown	Unk Df, Unk		Not Reported
	Calcium			C	Unknown	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11787867	NON-EXPEDITED			GXBR2014US002363			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Nausea	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Qd		Novartis
	Pantoprazole			C		Unk Df, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11787874	NON-EXPEDITED			GXBR2015US000727			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Mobility Decreased	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk Df, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2015	11790847	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Inflammation; Product Quality Issue; Swelling Face; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11788944	EXPEDITED (15-DAY)		OT	GB-WATSON-2015-18859		62 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Prednisolone (Unknown)			S	Oral	30 Mg, Daily		Watson
	Hydroxychloroquine (Unknown)			S	Oral	200 Mg, Daily		Watson
	Elocon			C	Unknown	Unk Unk, Prn; Twice Daily As Necessary.		Not Reported
	Hydroxyzine			C	Oral	1 Df, Qpm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11790488	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-39		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Flatulence; Varicose Vein	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11790496	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-38			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Vision Blurred	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11791195	EXPEDITED (15-DAY)		OT	ES-IPCA LABORATORIES LIMITED-IPC201511-000785		36 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung Disease; Irritability; Vision Blurred	Hydroxychloroquine Sulfate			S				Ipca
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2015	11791361	EXPEDITED (15-DAY)		HO	PHHY2015FR156334		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Tegretol			S	Oral	Unk		Novartis
	Levothyrox			S	Oral	75 Ug, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Tid		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11797453	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Electrocardiogram Qt Prolonged; Impaired Gastric Emptying	Plaquenil			S	Oral			Not Reported
	Thyroid Med			C				Not Reported
	Crestor			C				Not Reported
	B-12 Injection			C				Not Reported
	Prilosec			C				Not Reported

	Vit D			C						Not Reported
	Aleve			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2015	11681224	EXPEDITED (15-DAY)		OT	GB-HOSPIRA-3056480		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2015	11796384	NON-EXPEDITED			US-PFIZER INC-2015407924		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benzylpenicillin Potassium			S		Unk		Pfizer
	Sulfa /00076401/			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2015	11797081	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015410750		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis	Xanax			S	Oral			Pfizer
	Levothyrox			S	Oral	75 Ug, 1x/Day		Not Reported
	Plaquenil			S	Oral	200 Mg, 3x/Day		Not Reported

	Cortancyl			S	Oral	Unk			Not Reported
	Tegretol			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11405107	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-15		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Burning Sensation; Constipation; Cough; Cough; Dyspepsia; Fatigue; Fungal Infection; Gait Disturbance; Headache; Hypertension; Neuralgia; Oedema Peripheral; Oropharyngeal Pain; Pain; Pneumonia; Pollakiuria; Productive Cough; Renal Disorder; Rheumatoid Arthritis; Secretion Discharge; Tongue Geographic; Upper Respiratory Tract Congestion; Upper Respiratory Tract Infection	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11678876	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-33		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Nausea; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Methotrexate		S	Oral	Not Reported
	Celebrex		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11684310	EXPEDITED (15-DAY)		OT	GB-MEDAC PHARMA, INC.-1043556		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Methotrexate			S	Unknown			Medac
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11746268	EXPEDITED (15-DAY)		OT	AU-ABBVIE-15K-008-1500298-00			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Thyroiditis; Balance Disorder; Condition Aggravated; Fibromyalgia; Head Titubation; Impaired Work Ability; Pain; Pigmentation Disorder; Psoriatic Arthropathy; Unevaluable Event; Vitamin D Deficiency	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Levothyroxine			C				Not Reported
	Flexeril			C				Not Reported
	Cymbalta			C				Not Reported
	Folic Acid			C				Not Reported
	Zipsor			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11771924	EXPEDITED (15-DAY)		OT	RO-ACTAVIS-2015-25457			Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid	Cyclophosphamide (Unknown)			S	Unknown	Unk		Not Reported

Syndrome; Autoimmune Thyroiditis; Cardiac Failure; Gangrene; Lupus Endocarditis; Nephrotic Syndrome; Nervous System Disorder	Hydroxychloroquine (Unknown)	S	Unknown	Unk		Watson
	Belimumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11803690	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-39			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Inflammation; Lung Disorder; Nasopharyngitis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Actemra			C				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2015	11803692	EXPEDITED (15-DAY)		OT	AR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AR-2015-40		51 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Levotiroxina (Levothyroxine Sodium)			C				Not Reported
	Pregabalin			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2015	11805201	NON-EXPEDITED			US-AMGEN-USASL2015126173		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Vision Blurred	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11756770	NON-EXPEDITED			US-AMGEN-USASL2015120585		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibiotic Therapy; Asthenia; Malaise; Nausea; Sinusitis	Enbrel			S	Unknown	50 Mg, Once Weekly		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11805764	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2015128781			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mobility Decreased; Pain; Product Dose Omission; Vision Blurred; Vitreous Detachment	Enbrel			S	Unknown	Unk Unk, Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11808676	NON-EXPEDITED			US-ROCHE-1591627			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Hypersensitivity; Oral Herpes	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11808821	NON-EXPEDITED			US-ROCHE-1616198		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Flushing	Actemra			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednison			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2015	11809323	EXPEDITED (15-DAY)		OT	CA-ROCHE-1673309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)	Frequency: Cyclical; Therapy Duration: 10 Months		Not Reported
	Rituxan			S	Unknown	Frequency: Cyclical		Not Reported
	Arava			S	Unknown	Therapy Duration: 3 Months		Not Reported
	Arava			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Arava			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 3 Months		Not Reported
	Arava			S	Unknown	Therapy Duration: 5 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 8 Years		Not Reported
	Humira			S	Unknown	Frequency: Cyclical		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 3 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11695473	EXPEDITED (15-DAY)		OT	GB-GLENMARK PHARMACEUTICALS INC, USA.-2015GMK02029			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S		Unk Unk, Unk		Glenmark
	Humira			S		40 Mg, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Od		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11811522	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015427335		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxyzine Pamoate			S	Oral			Pfizer
	Hydroxychloroquine			S	Oral			Not Reported
	Acetaminophen/Butalbital/Caffeine			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported
	Cetirizine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11611475	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA046519		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Malaise; Osteomyelitis; Pleurisy; Pneumonia	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate			S	Unknown					Not Reported
	Actemra			S	Unknown					Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11673994	EXPEDITED (15-DAY)		OT	GB-WATSON-2015-22867		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin (Unknown)			S	Unknown	Unk		Watson
	Methotrexate (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine (Unknown)			S	Unknown	200 Mg, Daily		Watson
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11700971	EXPEDITED (15-DAY)		OT	GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-074228		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Humira			S	Unknown	40 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11803691	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-39			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Deposits	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Gold			C				Not Reported

	Rituxan			C						Not Reported
	Cimzia			C						Not Reported
	Humira			C						Not Reported
	Enbrel			C						Not Reported
	Motrin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11812886	EXPEDITED (15-DAY)		DS	CA-ROCHE-1674105		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 12 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration : 366		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 365		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration:8 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 8 Years		Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11812994	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015128327		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthroscopy; Asthenia; Back Pain; Balance Disorder; Chest Pain; Chronic Obstructive Pulmonary Disease;	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Promethazine /00033002/			S	Unknown			Not Reported

Clostridium Difficile Infection; Constipation; Dehydration; Drug Hypersensitivity; Fall; Gait Disturbance; Gastritis; Haemoglobin Decreased; Head Injury; Hip Arthroplasty; Hypercoagulation; Hyperlipidaemia; Hypertension; Hysterectomy; Joint Contracture; Knee Arthroplasty; Liver Function Test Increased; Musculoskeletal Pain; Neuropathy Peripheral; Osteoarthritis; Rheumatoid Arthritis; Spinal Operation; Thrombosis; Thyroid Disorder; Trigger Finger; Uterine Dilation And Curettage; Vena Cava Filter Insertion; Vitamin D Decreased	Levothyroxine	C	Oral	112 Mug, Qd	Not Reported
	Temazepam	C		30 Mg, Unk	Not Reported
	Centrum Silver /02363801/	C	Oral	Unk	Not Reported
	Fenofibrate	C	Oral	160 Mg, Qd	Not Reported
	Fentanyl	C		25 Mug, Unk	Not Reported
	Folic Acid	C	Oral	Unk Unk, Qd	Not Reported
	Protonix /00661201/	C	Oral	40 Mg, Unk	Not Reported
	Megestrol	C	Oral	40 Mg, Qd	Not Reported
	Aspirin /00002701/	C	Oral	81 Mg, Unk	Not Reported
	Dilaudid	C	Oral	4-6 Hours As Needed	Not Reported
	Metoprolol Succinate	C	Oral	50 Mg, Unk	Not Reported
	Meloxicam	C	Oral	7.5 Mg, Qd	Not Reported
	Zoloft	C	Oral	50 Mg, Qd	Not Reported
	Neurontin	C	Oral	600 Mg, Tid	Not Reported
	Ferrous Sulfate	C	Oral	65 Mg, Unk	Not Reported
	Vitamin D3	C	Oral	Unk Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11813181	NON-EXPEDITED			US-AMGEN-USASL2015129733		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11814088	EXPEDITED (15-DAY)		HO	PHHY2015PE156744		35 YR	Male	PER

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intermittent Claudication; Leukocytosis; Malaise; Neutrophilia; Osteomyelitis Salmonella; Pain In Extremity; Product Use In Unapproved Indication; Pyrexia; Transaminases Increased	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Qw	Not Reported
	Ciclosporin	S	Unknown	50 Mg, Qd	Not Reported
	Ciclosporin	S		150 Mg, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown	10 Mg, Unk	Not Reported
	Prednisone	S	Unknown	10 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Novartis
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Novartis
	Azathioprine	S	Unknown	150 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Warfarin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11816255	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-40		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Pain; Condition Aggravated; Condition Aggravated; Constipation; Decreased Appetite; Dyspepsia; Gait Inability; Haemoptysis; Hypertension; Insomnia; Nasopharyngitis; Neuralgia; Oedema Peripheral; Opportunistic Infection; Oral Fungal Infection; Pain In Extremity; Pneumonia; Pollakiuria; Rash; Renal Disorder; Rheumatoid Arthritis; Skin Mass;	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Cortisone			C				Not Reported

Tongue Geographic; Upper Respiratory Tract Infection; Vascular Pain; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2015	11824671	EXPEDITED (15-DAY)		HO, LT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-40		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Ecchymosis; Foetal Exposure During Pregnancy; Haematoma; Pulmonary Haemorrhage	Plaquenil			S	Transplacental			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Transplacental			Not Reported
	Calciparine			S	Transplacental			Not Reported
	Ciclosporin			S	Transplacental			Not Reported
	Imurel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11642246	NON-EXPEDITED			US-PFIZER INC-2015348906		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celecoxib			S		Unk		Pfizer
	Etodolac			S		Unk		Pfizer
	Amox			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Aripiprazole			S		Unk		Not Reported
	Indomethacin			S		Unk		Not Reported
	Bupropion			S		Unk		Not Reported
	Chlorpromazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11826510	EXPEDITED (15-DAY)		OT	CA-WARNER CHILCOTT, LLC-1045358		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Lower Respiratory Tract Infection; Parkinson'S Disease	Actonel			S				Warner Chilcott
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Selective Immunosuppressants			S	Oral			Not Reported
	Pregabalin			S				Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11826986	EXPEDITED (15-DAY)		HO	CA-ABBVIE-15K-028-1515009-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11827974	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-41		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Unevaluable Event	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxyzine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11828128	NON-EXPEDITED			US-PFIZER INC-2015419497			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830113	EXPEDITED (15-DAY)		OT	CA-ROCHE-1674812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Humira			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 7 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cymbalta			C				Not Reported
	Elavil (Canada)			C				Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C				Not Reported
	Premarin			C				Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tenormin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830788	NON-EXPEDITED			ZYD-14-AE-322			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Arrhythmia; Chills; Diarrhoea; Dizziness; Gastrooesophageal Reflux Disease; Headache; Oropharyngeal Pain	Fish Oil			C				Not Reported
	Hydroxychloroquine			S	Oral			Zydus Pharm
	Bismuth			C				Not Reported
	Ranitidine			C				Not Reported
	Lisinopril/Lisinopril Dihydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830806	NON-EXPEDITED			ZYD-15-AE-077		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Erythema Of Eyelid; Eye Swelling; Pruritus; Rash	Hydroxychloroquine			S	Oral	200 Mg, Daily, Oral		Zydus Pharm
	Lisinopril			C	Oral	5 Mg By Mouth Daily		Not Reported
	Fish Oil			C	Oral	One Capsule Of Fish Oil By Mouth Daily		Not Reported
	Diphenhydramine			C	Oral	One Tablet By Mouth		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830807	NON-EXPEDITED			ZYD-15-AE-151			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Feeling Abnormal; Memory Impairment; Oedema Peripheral; Pain In Extremity; Panic Attack; Rash	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830833	NON-EXPEDITED			ZYD-15-AE-213		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain; Photopsia; Retinal Phototoxicity; Retinal Toxicity	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830843	NON-EXPEDITED			US-ZYDUS-008630		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Vyvanse			C				Not Reported
	Taclonex			C				Not Reported
	Clobetasol			C				Not Reported
	Atorvastatin/Atorvastatin Calcium			C				Not Reported
	Hydroxychloroquine			S	Oral			Zydus Pharm
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830850	NON-EXPEDITED			ZYD-15-AE-234			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Product Substitution Issue	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830856	NON-EXPEDITED			US-ZYDUS-008688			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11830858	NON-EXPEDITED			US-ZYDUS-009024		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Cough; Headache; Nausea; Polyuria; Vision Blurred	Hydroxychloroquine			S	Oral	200 Mg Twice Daily		Zydus Pharm
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11831153	EXPEDITED (15-DAY)		HO	CA-SA-2015SA205944		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fatigue; Femur Fracture; Osteoporosis; Pain; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Every 2 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11831362	EXPEDITED (15-DAY)		DE	US-JNJFOC-20151204350		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Acetaminophen/Diphenhydramine		Y	S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2015	11835038	NON-EXPEDITED			ZYD-15-AE-050			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Diarrhoea; Flatulence	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2015	11836143	EXPEDITED (15-DAY)		OT	PHHY2015US159560		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type Iv Hypersensitivity Reaction	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2015	11837194	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CH-2015-42			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Pyelonephritis; Sepsis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Certolizumab Pegol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2015	11837466	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-12		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pneumonia Pneumococcal; Pyrexia	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

					otherwise specified)				
	Cortancyl			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2015	11217255	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1597841		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Tablet		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Neurontin (Canada)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2015	11839098	EXPEDITED (15-DAY)		CA	CA-BEH-2015056542			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias	Privigen			S	Transplacental			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11634941	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Malaise; Osteomyelitis; Pleurisy; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Gold			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843294	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3107435		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity; Infection; International Normalised Ratio Fluctuation	Levofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Flagyl /00012501/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

	Leflunomide		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843375	EXPEDITED (15-DAY)		OT	CA-ROCHE-1676985		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843716	NON-EXPEDITED			ZYD-15-AE-049			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Nausea	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843731	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3107481		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Flagyl /00012501/			S	Unknown			Not Reported
	Humira			S	Subcutaneous	3 Months		Not Reported

	Norfloxacin			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Lyrica			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil /00072602/			S	Oral				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Ceclor			S	Unknown				Not Reported
	Celebrex			S	Oral				Not Reported
	Erythromycin			S	Unknown				Not Reported
	Arthrotec			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11843970	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC-20151205893		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cetirizine Hydrochloride		Y	S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Oral			Not Reported
	Meloxicam			S	Oral			Not Reported
	Acetaminophen W/Butalbital			S	Oral			Not Reported
	Caffeine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxyzine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11845233	NON-EXPEDITED			US-PFIZER INC-2015422257			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11846978	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-40		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Plaquenil			S	Oral			Not Reported
	Esberiven			C				Not Reported
	Condrosulf			C				Not Reported
	Lamisil			C				Not Reported
	Coltramyl			C				Not Reported
	Lodine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11847777	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-42		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fatigue; Femur Fracture; Osteoporosis; Pain; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2015	11847778	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-41		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Hearing Loss	Plaquenil			S	Oral			Not Reported
	Cortancyl			C				Not Reported

	Nplate			C						Not Reported
	Cacit Vitamine D3			C						Not Reported
	Revolade			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11786433	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015125032		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Blood Cholesterol Increased; Brain Neoplasm; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Photosensitivity Reaction; Rash; Sinusitis	Enbrel			S	Unknown	Unk		Amgen
	Mobic			S	Unknown	Unk		Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Fosamax			C		70 Mg, Qwk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11804512	EXPEDITED (15-DAY)		OT	PHHY2015US158780			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteomyelitis; Skin Ulcer	Lioresal Intratecal			S	Intrathecal	217.29 Ug, Qd		Not Reported
	Lioresal Intratecal			S				Not Reported
	Lioresal Intratecal			S				Not Reported
	Baclofen			S	Oral			Not Reported
	Methadone Hydrochloride			S	Unknown			Novartis
	Synthroid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11849417	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2015M1045506			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Deafness Neurosensory; Osteoporosis	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2015	11852765	EXPEDITED (15-DAY)		HO, OT	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2015-41			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aplasia Pure Red Cell; Myelodysplastic Syndrome; Renal Transplant; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Not Reported
	Aranesp			S	Subcutaneous			Not Reported
	Cyclophosphamide			C				Not Reported
	Frusemide			C				Not Reported
	Myfortic			C				Not Reported
	Prednisolone			C				Not Reported
	Tacrolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2015	11315666	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1431208-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2015	11854148	EXPEDITED (15-DAY)		DE	US-PAR PHARMACEUTICAL COMPANIES-2015SCPR014821		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Death; Poisoning	Tramadol			S	Oral	Unk, Unknown		Par
	Hydroxychloroquine			S	Oral	Unk, Unknown		Not Reported
	Amitriptyline			S	Oral	Unk, Unknown		Not Reported
	Cyclobenzaprine			S	Oral	Unk, Unknown		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11311104	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-15K-028-1431152-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Impaired Quality Of Life; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Every Day Beside Sundays		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown	2 Df, Alternate Day (Every Second Day For The Next 2 Weeks)		Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2015	11856289	EXPEDITED (15-DAY)		DE, OT	NO-BAYER-2015-491176		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Malignant Neoplasm Progression; Thrombocytopenia	Sorafenib (Raf Kinase Inhibitor)			S	Unknown			Bayer
	Denosumab			S	Subcutaneous	120 Mg, 4iw		Not Reported
	Sunitinib			S	Unknown	37.5 Mg, Qd		Not Reported
	Everolimus			S	Oral	7.5 Mg, Qd		Not Reported
	Everolimus			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Ipilimumab			S	Unknown			Not Reported
	Pazopanib			S	Unknown	800 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	10585571	NON-EXPEDITED			US-PFIZER INC-2014313814		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Duricef			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported

	Plaquenil	S		Unk		Not Reported
	Vioxx	S		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11314074	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1431591-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaemia; Blood Cholesterol Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Soft Tissue Swelling; Stomatitis; Synovitis; Tenderness	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Various Dosage, Years Ago		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Years Ago		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			C				Not Reported
	Benadryl			C				Not Reported
	Synthroid			C				Not Reported
	Lasix			C				Not Reported
	Enablex			C				Not Reported
	Ativan			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C				Not Reported
	Pantoloc			C				Not Reported
	Vagifem			C				Not Reported
	Dilaudid			C				Not Reported
	Rituxan			C		1000 Mg Day One And Day 15		Not Reported
	Kineret			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11781915	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-37		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma	Plaquenil			S	Unknown			Not Reported
	Risperidone			C				Not Reported
	Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11858428	EXPEDITED (15-DAY)		DE, HO, OT	US-WATSON-2015-16839		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mucormycosis; Septic Shock; Toxic Epidermal Necrolysis	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	Unk		Watson
	Phenytoin			C	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11859392	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-42		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Chest Pain; Dyspepsia; Flatulence; Skin Discolouration; Therapeutic Response Shortened	Plaquenil			S	Unknown			Not Reported
	Adalimumab			S				Not Reported
	Metformin			S				Not Reported
	Methotrexate			S				Not Reported
	Metoprolol			C				Not Reported
	Olmesartan Medoxomil			C				Not Reported
	Gabapentin			C				Not Reported
	Omeprazole			C				Not Reported
	Hydroxyzine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Atorvastatin			C				Not Reported
	Glyceryl Trinitrate			C				Not Reported

		Fluticasone			C					Not Reported
		Colecalciferol/Calcium Citrate			C					Not Reported
		Insulin			C					Not Reported
		Ergocalciferol/Ascorbic Acid/Tocopherol/Folic Acid/Retinol/Vitamin B Nos			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11860208	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-086627			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Drug Ineffective; Dyspnoea; Dysuria; Fibromyalgia; Headache; Hemiplegia; Hypersomnia; Hypertension; Idiopathic Intracranial Hypertension; Intervertebral Disc Degeneration; Kidney Infection; Knee Arthroplasty; Loss Of Consciousness; Meningitis; Migraine; Oral Disorder; Oropharyngeal Pain; Peripheral Swelling; Pharyngeal Swelling; Pharyngitis Streptococcal; Seizure; Sepsis; Swelling; Syncope; Transient Ischaemic Attack; Vision Blurred	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Unknown			Not Reported
	Vicodin			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Ms Contin			S	Unknown			Not Reported
	Oxycontin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2015	11861743	EXPEDITED (15-DAY)		OT	PHHY2015US165728			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ebstein'S Anomaly; Foetal Exposure During Pregnancy	Prednisone	S	Transplacental	2.5 Mg, Qd		Novartis
	Hydroxychloroquine	S	Transplacental	400 Mg, Qd		Not Reported
	Heparin	S	Transplacental			Not Reported
	Enoxaparin	S	Transplacental			Not Reported
	Belimumab	S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11723240	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015158932			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pyrexia; Throat Tightness; Urticaria	Benlysta			S	Intravenous (not otherwise specified)	590 Mg, Unk		Glaxosmithkline
	Plaquenil			S		200 Mg, Qd		Not Reported
	Prednisone			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11798469	EXPEDITED (15-DAY)		DS	CH-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CH-2015-39		70 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Mouth Syndrome; Pruritus; Pruritus Genital	Plaquenil			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11863378	EXPEDITED (15-DAY)		OT	TN-WATSON-2015-28160		33 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Prednisolone (Unknown)			S	Unknown	40 Mg/Day		Watson
	Hydroxychloroquine (Unknown)			S	Unknown	200 Mg/Day		Watson

	Chloroquine			C	Unknown	200 Mg/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11864138	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IT-2015-42		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cachexia; Fall; Gait Disturbance; Gait Disturbance; Gait Disturbance; Mononeuropathy; Nerve Conduction Studies Abnormal; Neuromyopathy; Paraesthesia	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11865312	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-42			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonia	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Etanercept			C				Not Reported
	Abatacept			C				Not Reported
	Rituximab			C				Not Reported
	Methotrexate			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11865313	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-42		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea Haemorrhagic	Plaquenil			S				Not Reported

Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S			Not Reported
Prednisone	S			Not Reported
Methotrexate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11865314	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-43		89 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Discolouration; Application Site Pain; Crystal Arthropathy; Dry Skin; Inappropriate Schedule Of Product Administration; Incorrect Dose Administered; Product Administered At Inappropriate Site; Product Use Issue; Skin Disorder; Swelling; Therapeutic Response Unexpected	Plaquenil			S	Unknown	Twice A Day		Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Diclofenac Sodium			S	Topical			Not Reported
	Diclofenac Sodium			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Ergocalciferol			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Colchicine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2015	11870083	DIRECT	Y	LT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Incorrect Product Administration Duration; Qrs Axis Abnormal; Ventricular Hypokinesia	Hydroxychloroquine 200mg			S	Oral	1 Tab		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11866435	EXPEDITED (15-DAY)		OT	CA-ROCHE-1571416		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Menopause; Peripheral Swelling; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown	On Therapy For 6 Months; Therapy Duration: 162 Day		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 323 Days		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 134 Days		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Ergocalciferol			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2015	11867270	EXPEDITED (15-DAY)		OT	US-ABBVIE-15P-163-1525404-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Basal Cell Carcinoma; Drug Ineffective; Headache; Malaise; Muscle Spasms; Pain; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Two Weeks		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2015	11577628	EXPEDITED (15-DAY)		OT	GR-JNJFOC-20150915065		83 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Psoriasis; Pulmonary Fibrosis; Rheumatoid Arthritis; Vasculitis	Simponi			S	Subcutaneous	50mg/0,5ml		Not Reported
	Arava			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported
	Cortisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2015	11847471	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015388082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Dyspepsia; Hernia; Nausea	Methotrexate Sodium			S	Subcutaneous	1 Ml/25 Mg Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2015	11747671	EXPEDITED (15-DAY)		OT	CA-SA-2015SA181197			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cartilage Injury; Depression; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Renal Function Test Abnormal	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Diclofenac			C				Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11877663	EXPEDITED (15-DAY)		OT	TN-MYLANLABS-2015M1047146			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine			S	Unknown	200 Mg/Day		Not Reported
	Prednisolone			S	Unknown	40 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11879760	EXPEDITED (15-DAY)		OT	NL-CONCORDIA		38 YR	Female	NLD

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulocytopenia; Leukopenia	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2015	11882641	DIRECT		DS, HO, LT, OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Pain; Rash; Rash; Skin Reaction	Hydroxychloroquine 200mg Zyd			S	Oral	2 Pills Once Daily Taken By Mouth	10 DAY	Zydus Pharm
	Oxycodone			C				Not Reported
	Calamine			C				Not Reported
	Clindamycin			C				Not Reported
	Diltiazem			C				Not Reported
	Metropolol			C				Not Reported
	Prednisone			C				Not Reported
	Ocular Lubricant			C				Not Reported
	Emollients			C				Not Reported
	Benadryl			C				Not Reported
	Apixaban			C				Not Reported
	Polyethylene Glycol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2016	11883962	EXPEDITED (15-DAY)		OT	US-ZYDUS-009858		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Leukopenia; Systemic Lupus Erythematosus	Azathioprine			S	Unknown	50mg Daily		Zydus Pharm
	Warfarin			S				Zydus Pharm
	Hydroxychloroquine			S	Unknown	400 Mg Daily		Zydus Pharm
	Belimumab			S		10mg/Kg		Not Reported
	Enoxaparin			S				Not Reported

	Mycophenolic Acid	C	Unknown		Not Reported
	Rituximab	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2016	11883971	EXPEDITED (15-DAY)		OT	US-ZYDUS-009877			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Ebstein'S Anomaly; Maternal Drugs Affecting Foetus	Hydroxychloroquine			S	Transplacental			Zydus Pharm
	Warfarin			S	Transplacental			Zydus Pharm
	Enoxaparin/Enoxaparin Sodium			S	Transplacental			Not Reported
	Prednisone/Prednisone Acetate			S	Transplacental			Not Reported
	Belimumab			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2016	11884591	NON-EXPEDITED			PT-LUPIN PHARMACEUTICALS INC.-2015-03634		65 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastric Disorder	Clarithromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Amoxicillin+Clavulanic Acid			S	Unknown			Not Reported
	Deflazacort			C	Unknown	6 Mg		Not Reported
	Bromazepam			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Alendronate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2016	11886611	NON-EXPEDITED			US-PFIZER INC-2015473929		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Celebrex	S	Unk	Pfizer
	Fentanyl	S	Unk	Not Reported
	Methotrexate	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	11778965	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-38			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cartilage Injury; Depression; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Renal Function Test Abnormal	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S				Not Reported
	Methotrexate			S				Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	11887516	EXPEDITED (15-DAY)		OT	PHHY2015IT170856		55 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Scleroderma	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			C	Unknown	1 Mg/Kg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2016	11889578	EXPEDITED (15-DAY)		OT	PHHY2015IT169654		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Mycobacterial Infection; Osteoporosis	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Novartis
	Mycophenolate Mofetil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11892119	EXPEDITED (15-DAY)		DE, LT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-43		< 1 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Great Vessel Anomaly; Foetal Exposure During Pregnancy	Plaquenil			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Warfarin Sodium			S	Transplacental			Not Reported
	Innohep			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11892226	EXPEDITED (15-DAY)		DE, OT	NO-BAYER-2015-497493		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Cell Carcinoma	Nexavar			S	Unknown			Bayer
	Everolimus			S	Unknown	10 Mg, Qd		Not Reported
	Everolimus			S	Oral	7.5 Mg, Qd		Not Reported
	Xgeva			S	Subcutaneous	120 Mg, Unk		Not Reported
	Xgeva			S	Unknown	400 Mg, Bid		Not Reported
	Xgeva			S	Unknown	200 Mg, Bid		Not Reported
	Pazopanib			S	Unknown	800 Mg, Qd For 5 Months		Not Reported
	Hydroxychloroquine			S		200 Mg, Bid		Not Reported
	Hydroxychloroquine			S		400 Mg, Bid		Not Reported
	Sunitinib			S	Unknown	37.5 Mg, Qd		Not Reported
	Ipilimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11893184	EXPEDITED (15-DAY)		OT	PHHY2015TW171860			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity	Cyclophosphamide			S	Unknown	50 Mg, Qd		Not Reported
	Cyclophosphamide			S				Not Reported
	Methotrexate			S	Unknown	50 Mg, Unk		Novartis
	Methotrexate			S				Novartis
	Cisplatin			S	Unknown	30 Unk, Unk		Not Reported
	Cisplatin			S				Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tegafur			S	Unknown			Not Reported
	Tegafur			S				Not Reported
	Uracil			S	Unknown			Not Reported
	Uracil			S				Not Reported
	Rapamycin			S	Unknown	2 Mg, Qd		Not Reported
	Rapamycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2016	11893286	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2016M1000044			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity	Methotrexate			S	Oral	50mg Every 2 Weeks		Not Reported
	Cisplatin			S	Intravenous (not otherwise specified)	30 Mg/M 2 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg/Day		Not Reported
	Cyclophosphamide			S	Oral	50mg Every Other Day		Mylan
	Sirolimus			S	Unknown	2 Mg/Day		Mylan
	Tegafur W/Uracil			S	Unknown	1 Dosage Form Thrice Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11856825	EXPEDITED (15-DAY)		DE, HO, OT	TW-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-080078		81 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cholangiocarcinoma; Hypokalaemia	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Qmo		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11861741	EXPEDITED (15-DAY)		OT	PHHY2015US161062			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Mass; Muscle Spasms; Pneumonia	Baclofen Intrathecal			S	Intrathecal	39.0176 Ug To 49.984 Ug/Day		Not Reported
	Baclofen Intrathecal			S	Intrathecal	0.049 Mg, Qd (Dose Reduced)		Not Reported
	Cilostazol			S	Unknown	2 Df, Bid		Novartis
	Omeprazole			S	Unknown	2 Df, Bid		Not Reported
	Ondansetron			S	Unknown	1 Df, Prn (1 Tablet Dispense Three Times Daily As Needed)		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	1 Df, 5qd		Not Reported
	Tizanidine			S	Unknown	1 Df, Tid		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	1 Df, Bid		Not Reported
	Diphenoxylate+Atropine			S	Unknown	1 Df, Prn (1 Four Times Daily As Needed)		Not Reported
	Alendronate			S	Unknown	1 Df, Qw		Not Reported

Diphenhydramine Hydrochloride	S	Unknown	1 Df, Q6h	Not Reported
Gabapentin	S	Unknown	1 Df, Tid	Not Reported
Hydroxyzine Hcl	S	Unknown	1 Df, Prn ((1 Tablet Every Four Hours As Needed))	Not Reported
Morphine	S	Intrathecal	24.386 Mg To 21.668 Mg/Day (50 Mg/Ml)	Not Reported
Morphine	S	Intrathecal	21.868 Mg, Qd (35 Mg/Ml) (Dose Reduced)	Not Reported
Bupivacaine	S	Intrathecal	0.24386 Mg To 0.3124 Mg/Day	Not Reported
Bupivacaine	S	Intrathecal	0.243 Mg, Qd	Not Reported
Aspirin	S	Unknown	81 Mg, Qd	Not Reported
Prednisone	S	Unknown	1 Df, Tid	Not Reported
Calcium 600 + D	S	Unknown	2 Df, Qd (Comcentration: 600 To 400 Mg Unit)	Not Reported
Asmanex	S	Respiratory (inhalation)	200 Ug, Unk (Asmanex 120 Metered Doses 220 Mcg/Inh Aerosol Powder, Breath Activated)	Not Reported
Fluticasone Propionate	S	Unknown	Unk Unk, Qd	Not Reported
Acetaminophen W/Hydrocodone	S	Unknown	1 Df, 5qd (Concentration: 7.5-325 Mg)	Not Reported
Tylenol	S	Unknown	3 Df, Prn (3 Tablets Every Six Hours As Needed)	Not Reported
Ventolin Hfa	S	Unknown	2 Df, Prn (108 (90 Base) Mcg/Act (1-2 Puffs Aerosol Soln Every 4-6 As Needed)	Not Reported
Hydrocodone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11894907	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-44			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Sarcoidosis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11894909	EXPEDITED (15-DAY)		DE, OT	NO-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NO-2015-44		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Progression	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200mg		Not Reported
	Afinitor			S	Oral	7.5 Mg		Not Reported
	Afinitor			S	Oral	10 Mg		Not Reported
	Sunitinib			S	Unknown	37.5 Milligram		Not Reported
	Ipilimumab			S	Unknown			Not Reported
	Sorafenib			S	Unknown			Not Reported
	Votrient			S		800 Milligram		Not Reported
	Denosumab			S	Unknown	120 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11895307	EXPEDITED (15-DAY)		HO, OT	PHHY2015ES171130		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Whipple'S Disease	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11896218	NON-EXPEDITED		OT	US-ROCHE-1478155		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Rituxan			S	Intravenous (not otherwise specified)	2 Doses		Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Oxycodone/Acetaminophen			C				Not Reported
	Prednisone			C	Oral	Am		Not Reported
	Norvasc			C				Not Reported
	Lipitor			C				Not Reported
	Omeprazole			C	Unknown			Not Reported
	Amlodipine			C	Oral			Not Reported
	Aspirin			C	Oral	Daily		Not Reported
	Atorvastatin			C	Oral	Nightly		Not Reported
	Maxipime			C	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin			C	Subcutaneous			Not Reported
	Eplerenone			C	Oral			Not Reported
	Filgrastim			C	Subcutaneous	480 Mcq		Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoprazole			C	Oral	30 Min Before Breakfast And Meal		Not Reported
	Potassium Chloride			C	Oral	120 Meq		Not Reported
	Prednisone			C	Oral			Not Reported
	Timolol Hemihydrate			C	Unknown	1 Drop Right Eye		Not Reported
	Hydroxychloroquine			C				Not Reported
	Acetaminophen			C				Not Reported
	Celecoxib			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2016	11896350	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2016M1000106			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Hepatitis B Reactivation	Etoposide			S	Oral	50mg Every Other Day	Not Reported
	Gemcitabine			S	Intravenous (not otherwise specified)	1400mg Every 2 Weeks	Not Reported
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	400 Mg/Day	Not Reported
	Sirolimus			S	Intravenous (not otherwise specified)	2 Mg/Day	Mylan
	Cyclophosphamide			S	Oral	50mg Every Other Day	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11431144	EXPEDITED (15-DAY)		OT	PHHY2015CA102257		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Movement Disorder; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Swelling	Voltaren			S	Unknown			Novartis
	Methotrexate Pfizer//Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral	1 Df, Bid (5 Mg Bid)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11898943	NON-EXPEDITED			US-PFIZER INC-2015445398			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		1 Unk, 2x/Day		Pfizer

	Cimzia	S	Unk, Cyclic (Every Other Week)		Not Reported
	Plaquenil	S	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11901958	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-44		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Staphylococcal Infection	Plaquenil			S	Oral			Not Reported
	Arava			S				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2016	11904708	NON-EXPEDITED			US-ROCHE-1647216		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Diazepam			S	Unknown			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Lorazepam			S	Unknown	Upto 3 Mg/Day		Not Reported
	Lorazepam			S	Unknown	Total Lorazepam Therapy Lasted 35 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Amantadine			S	Unknown	Maximum Dose		Not Reported

	Etomidate	C	Unknown			Not Reported
	Enoxaparin	C	Unknown			Not Reported
	Succinylcholine	C				Not Reported
	Succinylcholine	C				Not Reported
	Mycophenolate Mofetil	C	Unknown			Not Reported
	Risperidone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2016	11905538	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-009790		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Creatine Increased; Cardiac Failure Congestive; Chronic Kidney Disease; Eye Infection; Feeling Hot; Gout; Haematochezia; Haemoglobin Decreased; Hospitalisation; Hypokalaemia; Oedema Peripheral; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Hypertension; Respiratory Distress	Hydroxychloroquine			S	Oral			Zydus Pharm
	Sildenafil			S				Not Reported
	Furosemide			S	Oral			Not Reported
	Verapamil/Verapamil Hydrochloride			S				Not Reported
	Olmesartan			S				Not Reported
	Methotrexate			C		Four Tablets Given One Day Per Week		Not Reported
	Ranitidine			C				Not Reported
	Methotrexate/Methotrexate Sodium			C				Not Reported
	Chondroitin/Glucosamine			C		Two Given Daily		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Salbutamol/Salbutamol Sulfate			C				Not Reported
	Folate Sodium/Folic Acid			C				Not Reported
	Iron			C				Not Reported
	Fish Oil			C				Not Reported
	Colecalciferol			C				Not Reported
	Calcium Carbonate/Calcium Lactogluconate			C				Not Reported
	Lactobacillus Reuteri			C				Not Reported
	Pramipexole/Pramipexole Dihydrochloride			C				Not Reported
	Vitamins Nos			C				Not Reported
	Spironolactone			C				Not Reported
	Amlodipine			C				Not Reported

	Levothyroxine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2016	11839511	EXPEDITED (15-DAY)		DE	PHHY2015NO162969		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Malignant Neoplasm Progression; Thrombocytopenia	Votrient			S	Unknown	800 Mg, Qd		Not Reported
	Afinitor			S	Unknown	10 Unk, Qd		Novartis
	Afinitor			S	Unknown	7.5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Not Reported
	Xgeva			S	Subcutaneous	120 Mg, Qw4		Not Reported
	Sunitinib			S	Unknown	37.5 Mg, Qd		Not Reported
	Ipilimumab			S	Unknown			Not Reported
	Sorafenib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2016	11903212	EXPEDITED (15-DAY)		OT	PHHY2015TW172917		48 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Encephalopathy; Hepatic Failure; Hepatitis B Reactivation	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11860353	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015438108		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tooth Infection	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		200 Mg, 2x/Day		Not Reported

	Arava			S					Not Reported
	Cortisone			C		Shot			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11867096	EXPEDITED (15-DAY)		DE, OT	NO-AMGEN-NORSP2015136303		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Malignant Neoplasm Progression; Thrombocytopenia	Xgeva			S	Subcutaneous	120 Mg, Q4wk		Amgen
	Sunitinib			S	Unknown	37.5 Mg, Qd		Not Reported
	Pazopanib			S	Unknown	800 Mg, Qd		Not Reported
	Ipilimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Not Reported
	Sorafenib			S	Unknown	Unk		Not Reported
	Everolimus			S	Oral	7.5 Mg, Qd		Not Reported
	Afinitor			S	Oral	7.5 Mg, Qd		Not Reported
	Votrient			S	Unknown	800 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11906731	EXPEDITED (15-DAY)		DE	PHHY2015TW172672		60 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatic Encephalopathy; Hepatitis B Reactivation	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Methotrexate			S	Unknown	7.5 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11908568	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2016M1001044			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatic Encephalopathy; Hepatitis B Reactivation	Hydroxychloroquine			S	Unknown	200mg Twice Daily For Two Months And Then Once Daily For One Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2016	11908586	EXPEDITED (15-DAY)		DE, HO	TW-MYLANLABS-2016M1001049			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatic Encephalopathy; Hepatitis B Reactivation; Shock	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11911166	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-01			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Butterfly Rash; Cutaneous Lupus Erythematosus; Psoriasis; Rash; Vasculitis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Megastrength Fish Oil			C				Not Reported
	Dhea			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11911326	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-44			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11911327	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-44		60 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blister; Lip Oedema; Oedema Peripheral; Oedema Peripheral; Rash Maculo-Papular	Plaquenil	S	Oral	200 Mg Twice A Day		Not Reported
	Levothyrox	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2016	11911688	EXPEDITED (15-DAY)		OT	US-DSJP-DSJ-2015-113155AA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Fall; Loss Of Control Of Legs; Nerve Injury; Pain In Extremity	Baclofen Intrathecal			S	Intrathecal	149 Mg/Day		Not Reported
	Norvasc			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Vitamin B			S	Unknown	Unk		Not Reported
	Cevimeline Hydrochloride Hydrate			S	Unknown	Unk		Daiichi
	Colace			S	Unknown	Unk		Not Reported
	Premarin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Relafen			S	Unknown	Unk		Not Reported
	Melatonin			S	Unknown	Unk		Not Reported
	Miralax /00754501/			S	Unknown	Unk		Not Reported
	Requip			S	Unknown	Unk		Not Reported
	Valerian /01561601/			S	Unknown	Unk		Not Reported
	Neurontin			S	Unknown	Unk		Not Reported
	Tramadol /00599202/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11443497	EXPEDITED (15-DAY)		OT	DE-AMGEN-DEUNI2015085305		65 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Cough; Dyspnoea	Etanercept			S	Unknown	50 Mg, Qwk		Amgen

	Plaquenil /00072602/	S	Unknown	200 Mg, Daily		Not Reported
	Chloroquine	S	Unknown	200 Mg, Daily		Not Reported
	Azathioprin	S	Unknown	50 Mg, Weekly		Not Reported
	Formatris	C		Unk		Not Reported
	Novopulmon	C		Unk		Not Reported
	Singulair	C		Unk		Not Reported
	Salbutamol	C		Unk		Not Reported
	Omeprazole	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11911851	EXPEDITED (15-DAY)		OT	PHHY2015US049163		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Fall; Loss Of Control Of Legs; Nerve Injury; Pain In Extremity	Lioresal Intratecal			S	Intrathecal	149 Mcg/Day		Not Reported
	Tramadol			S	Unknown			Novartis
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Norvasc			S	Unknown	Unk		Not Reported
	Evoxac			S	Unknown			Not Reported
	Colace			S	Unknown			Not Reported
	Premarin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Relafen			S	Unknown	Unk		Not Reported
	Melatonin			S	Unknown			Not Reported
	Miralax			S	Unknown	Unk		Not Reported
	Requip			S	Unknown	Unk		Not Reported
	Valerian			S	Unknown			Not Reported
	Neurontin			S	Unknown			Not Reported
	Vitamin B			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11913534	EXPEDITED (15-DAY)		OT	IT-TEVA-624245ISR		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression; Lumbar Vertebral Fracture; Mycobacterial Infection; Osteoporosis	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11914286	EXPEDITED (15-DAY)		OT	TW-FRESENIUS KABI-FK201600182			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis B Reactivation	Etoposide (Manufacturer Unknown)			S	Oral			Fresenius Medical Care
	Gemcitabine (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide			S				Not Reported
	Sirolimus			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2016	11914293	EXPEDITED (15-DAY)		OT	TW-FRESENIUS KABI-FK201600177			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity	Methotrexate (Manufacturer Unknown)			S	Oral			Fresenius Medical Care
	Cisplatin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Tegafur/Uracil			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Sirolimus			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11849835	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2015-42			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ectopic Pregnancy; Exposure During Pregnancy	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11879855	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-37			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pain; Peripheral Swelling; Retinopathy; Sinusitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11916180	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2016002567			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dysphonia; Pruritus	Advair Diskus Inhalation Powder			S		2 Puff(S), 1d		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11918014	EXPEDITED (15-DAY)		OT	PHHY2016US001964		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Retinal Toxicity	Hydroxychloroquine			S	Unknown	20 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	9730624	EXPEDITED (15-DAY)		OT	CA-ROCHE-1279901		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Arthralgia; Arthralgia; Back Pain; Back Pain; Blood Pressure Diastolic Increased; Blood Pressure Increased; Blood Pressure Increased; Bronchitis; Cellulitis; Depression; Dizziness; Drug Ineffective; Fatigue; Fatigue; Fatigue; Fatigue; Haemorrhoids; Headache; Hepatic Enzyme Increased; Hot Flush; Impaired Healing; Infection; Influenza; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Ligament Sprain; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Oedema Peripheral; Oedema Peripheral; Oral Herpes; Pain; Pain In Extremity; Pneumonia; Scratch; Sinusitis; Skin Laceration; Skin Ulcer; Swelling; Throat Irritation; Tooth Fracture; Urticaria; Visual Field Defect; Visual Field Defect; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pneumonia Vaccine			S	Unknown			Not Reported
	Prometrium (Canada)			C				Not Reported
	Teveten Plus			C				Not Reported
	Adalat			C				Not Reported
	Crestor			C				Not Reported
	Andriol			C				Not Reported
	Estrogel			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	11790497	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-39			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Asthma; Colitis; Drug Ineffective; Dysstasia; Fatigue; Gait Disturbance; Hand Deformity; Joint Swelling; Joint Swelling; Joint Swelling; Musculoskeletal Pain; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	11856151	EXPEDITED (15-DAY)		OT	US-BAXALTA-2015BLT003211		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Eye Disorder; Hepatic Enzyme Increased; Hepatic Neoplasm; Procedural Pain; Pruritus; Urticaria	Gammagard			S	Subcutaneous	5 G, 2x A Week		Baxalta
	Gammagard			S	Subcutaneous	5 G, 2x A Week		Baxalta
	Plaquenil			S	Unknown	Unk		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Levaquin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	11922521	EXPEDITED (15-DAY)		OT	TW-HQ SPECIALTY-TW-2016INT000002			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Ejection Fraction Decreased	Cisplatin			S		30/M2 Q2wk		Hq Specialty
	Cyclophosphamide			S		50 Mg, Qd		Not Reported

	Methotrexate	S	50 Mg,Q2wk	Not Reported
	Tegafur W/Uracil	S	1 # Tid	Not Reported
	Rapamycin	S	2 Mg, Unk	Not Reported
	Hydroxychloroquine	S	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11569702	EXPEDITED (15-DAY)		OT	CA-SA-2015SA148055			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Operation; Tuberculosis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11879794	EXPEDITED (15-DAY)		OT	CA-SA-2015SA219682			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Nephrolithiasis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11890565	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1048003			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression; Lumbar Vertebral Fracture; Mycobacterial Infection; Osteoporosis; Thoracic Vertebral Fracture	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11923406	EXPEDITED (15-DAY)		OT	IT-ACCORD-037064		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Immunosuppression; Lumbar Vertebral Fracture; Mycobacterial Infection; Osteoporosis	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11924168	NON-EXPEDITED			US-PFIZER INC-2015473329			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Diflucan			S	Unknown	Unk		Pfizer
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Cipro			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11924754	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2015-000715		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Influenza; Nasopharyngitis; Stress	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Prednisone Tablets			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11924803	NON-EXPEDITED			US-ENDO PHARMACEUTICALS			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Erythema; Nerve Injury; Pain In Extremity	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Prednisone Tablets			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11925284	EXPEDITED (15-DAY)		DE	TW-CORDEN PHARMA LATINA S.P.A.-TW-2016COR000001			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Etoposide			S	Oral	50 Mg, Qod		Corden
	Cyclophosphamide			S	Oral	50 Mg, Qod		Not Reported
	Gemcitabine			S	Intravenous (not otherwise specified)	1400 Mg Per Body, Q2w		Not Reported
	Rapamycin			S		2 Mg, Qd		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2016	11925436	EXPEDITED (15-DAY)		DE, HO	TW-FRESENIUS KABI-FK201600254		54 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Brain Oedema; Coagulopathy; Hepatic Encephalopathy; Hepatitis B Reactivation; Hypotension; Multiple Organ Dysfunction Syndrome	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Leflunomide			S	Unknown					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported
	Etanercept			S	Unknown					Not Reported
	Andazathioprine			S	Unknown					Not Reported
	Rituximab			S	Unknown					Not Reported
	Adalimumab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11541790	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-25		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Wrist Deformity	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Enbrel			S				Not Reported
	Celebrex			S				Not Reported
	Celebrex			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Lyrica			S				Not Reported
	Arthrotec			S				Not Reported
	Prednisone			S				Not Reported
	Naprosyn			S				Not Reported
	Amitriptyline			S				Not Reported
	Voltaren			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11876671	EXPEDITED (15-DAY)		DE, OT	NO-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NO-2015-43		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Progression	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Afinitor			S	Unknown			Not Reported

		Afinitor			S	Oral				Not Reported
		Xgeva			S	Subcutaneous				Not Reported
		Sunitinib			S	Unknown				Not Reported
		Ipilimumab			S	Unknown				Not Reported
		Sorafenib			S	Unknown				Not Reported
		Votrient			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11926420	EXPEDITED (15-DAY)		OT	CA-ROCHE-1696476		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Naprosyn			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Crestor			C				Not Reported
	Folic Acid			C				Not Reported
	Naprelan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11927103	EXPEDITED (15-DAY)		OT	PHHY2016CA002531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes	Gold Sodium Thiomalate Sandoz			S	Unknown			Not Reported

Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Methotrexate	S	Unknown	25 Mg, Qw	Novartis
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Humira	S	Unknown	200 Mg, Bid	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Remicade	S	Unknown	200 Mg, Unk	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Benadryl /00647601/	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Cortison	C	Unknown		Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Enablex	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Kenalog /00806701/	C	Unknown		Not Reported
	Kineret	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Opioids	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported

	Rituxan			C	Unknown					Not Reported
	Synthroid			C	Unknown					Not Reported
	Trimethoprim			C	Unknown					Not Reported
	Urispas			C	Unknown					Not Reported
	Vagifem			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2016	11928227	EXPEDITED (15-DAY)		DE, HO	TW-FRESENIUS KABI-FK201600255		53 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Arrest; Death; Hepatic Encephalopathy; Hepatitis B Reactivation; Shock	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Entecavir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11880694	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-43		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hernia; Nausea	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11929281	EXPEDITED (15-DAY)		OT	CA-ROCHE-1695167		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Haematocrit Decreased; Haemoglobin Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Naproxen	S	Oral	Not Reported
	Co Atenolol	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Palafer Cf	S	Unknown	Not Reported
	Pantoloc	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11930290	EXPEDITED (15-DAY)		HO	TW-FRESENIUS KABI-FK201600329		60 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Coagulopathy; Hepatic Encephalopathy; Hepatitis B Reactivation; Hyperammonaemia; Hyperbilirubinaemia	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11930516	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Drug Ineffective; Nodule; Pain	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11931329	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cystoid Macular Oedema; Maculopathy; Optical Coherence Tomography Abnormal; Retinal Degeneration; Retinal Pigment Epitheliopathy; Retinopathy; Toxicity To Various Agents; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932009	NON-EXPEDITED			US-PFIZER INC-2016025327			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Flomax			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932134	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005381		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Meloxicam			S	Oral			Apotex
	Cetirizine Hydrochloride Tablets			S	Oral			Apotex
	Hydroxychloroquine			S	Oral			Not Reported

		Hydroxyzine			S	Oral					Not Reported
		Butalbital W/Caffeine/Paracetamol			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932136	EXPEDITED (15-DAY)		DE	US-APOTEX-2016AP005383		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tramadol Hydrochloride			S	Oral			Apotex
	Hydroxychloroquine			S	Oral			Not Reported
	Amitriptyline			S	Oral			Not Reported
	Cyclobenzaprin Hydrochloride			S	Oral			Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11932168	EXPEDITED (15-DAY)		OT	GB-WATSON-2015-18049			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Hydroxychloroquine (Unknown)			S	Oral	200 Mg, Unknown		Watson
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Q4h		Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported
	Lansoprazole			C	Oral	30 Mg, Unk		Not Reported
	Prednisolone			C	Oral	3 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2016	11933012	EXPEDITED (15-DAY)		OT	CA-ROCHE-1673197		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11471967	EXPEDITED (15-DAY)		OT	CA-SA-2015SA058442		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Lower Respiratory Tract Infection; Pain In Extremity; Parkinson'S Disease; Peripheral Swelling; Therapeutic Product Effect Incomplete	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Pregabalin			S	Oral	Form Is Pills		Not Reported
	Risedronate Sodium			S	Unknown	Form: Pill		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11905295	EXPEDITED (15-DAY)		OT	IT-ROCHE-1691102		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression; Lumbar Vertebral Fracture; Mycobacterium Abscessus Infection; Osteoporosis; Thoracic Vertebral Fracture	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11935859	NON-EXPEDITED			US-PFIZER INC-2015477324			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11937094	EXPEDITED (15-DAY)		DE	FR-MUNDIPHARMA DS AND PHARMACOVIGILANCE -GBR-2016-0		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Rigidity; Adrenal Insufficiency; Blood Triglycerides Abnormal; Cardiomegaly; Decreased Appetite; Erysipelas; Extrasystoles; Fungal Infection; General Physical Health Deterioration; Hepatosplenomegaly; Inflammation; Lung Disorder; Mobility Decreased; Pancytopenia; Purpura; Sepsis; Shock; Toxicity To Various	Oxycontin Lp 10 Mg, Comprime Pellicule A Liberation Prolongee			S	Oral	10 Mg, Bid		Purdue
	Oxynorm			S	Unknown	5 Mg, Tid		Purdue
	Methotrexat /00113801/			S	Oral	10 Mg, Weekly		Not Reported
	Salazopyrine			S	Oral	1 G, Tid		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Risedronat			S	Oral	35 Mg, Weekly		Not Reported
	Caltrate +Vit.D			S	Oral	1 Df, Bid		Not Reported
	Doliprane			S	Oral	1 G, Tid		Not Reported
	Lorazepam			S	Oral	2.5 Mg, Daily		Not Reported
	Amlodipine			S	Oral	10 Mg, Daily		Not Reported
	Lansoprazole			S	Oral	15 Mg, Daily		Not Reported

Agents; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11885671	EXPEDITED (15-DAY)		HO	IT-JUBILANT CADISTA PHARMACEUTICALS-2015JUB00445		85 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Alendronate And Cholecalciferol			S	Unknown	Unk		Jubilant
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Coumadin			C				Not Reported
	Levothyroxine			C				Not Reported
	Bisoprolol Hemifumarate			C				Not Reported
	Losartan Potassium/Hydrochlorothiazide			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11910823	EXPEDITED (15-DAY)		HO, OT	CHPA2016US000487		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Escherichia Infection; Escherichia Infection; Inappropriate Schedule Of Product Administration; Nephrolithiasis; Wrong Technique In Product Usage Process	Voltaren			S	Topical	Size Of A Pearl, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11938311	EXPEDITED (15-DAY)		OT	US-TEVA-626963USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Creatine Increased; Cardiac Failure Congestive; Cardiac	Furosemide			S	Unknown			Ivax
	Hydroxychloroquine			S	Unknown			Teva

Failure Congestive; Chronic Kidney Disease; Eye Infection; Gout; Haematochezia; Hypertension; Hypocalcaemia; Oedema; Peripheral Swelling; Pneumonia; Respiratory Distress; Skin Warm	Verapamil	S	Unknown		Barr
	Revatio	S	Unknown		Not Reported
	Benicar	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939312	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-01		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Plaquenil			S	Oral			Not Reported
	Doxycycline			S	Oral			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11939732	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IT-2016-01		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression; Lumbar Vertebral Fracture; Mycobacterial Infection; Osteoporosis	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisone			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11940101	EXPEDITED (15-DAY)		DS	CONCORDIA PHARMACEUTICALS INC.-CO-OR-KR-2016-002		25 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Enophthalmos	Prednisolone			S				Concordia
	Hydroxychloroquine Sulfate			S				Not Reported

	Acyclovir				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11940420	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-02			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11450775	EXPEDITED (15-DAY)		OT	CA-ROCHE-1626687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Naprosyn			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	(10 X 2.5 Mg), Weekly		Not Reported
	Pms-Sulfasalazine			S	Oral	1000 Mg (2 X 500 Mg), 2x/Day;		Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Co Atenolol			S	Unknown	25 Mg (Half Of 50 Mg)		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11894908	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-44			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Nephrolithiasis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Weekly		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11944805	NON-EXPEDITED			US-PFIZER INC-2016000120			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rabeprazole			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11948338	NON-EXPEDITED			US-PFIZER INC-2016030584		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Constipation; Mouth Swelling; Nausea; Swollen Tongue	Lyrica			S				Pfizer
	Plaquenil			S				Not Reported
	Pilocarpine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	8192839	EXPEDITED (15-DAY)		OT	CA-UCBSA-029901		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Skin; Fatigue; Pyrexia; Rash; Weight Decreased	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Plaquenil			S	Oral	400 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11191819	NON-EXPEDITED		HO, OT	US-AMGEN-USASL2014098197		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Carpal Tunnel Decompression; Cough; Fatigue; Mastitis; Pyrexia; Rheumatoid Arthritis; Skin Lesion; Somnolence; Tendon Sheath Incision	Enbrel	S	Unknown	50 Mg, Qwk		Amgen
	Enbrel	S	Unknown	Unk		Amgen
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Methotrexate	C		Low Dose Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11707423	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-36		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Fatigue; Hordeolum; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis; Stomatitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11949545	NON-EXPEDITED			US-ABBVIE-15K-163-1356917-00		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea Haemorrhagic	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11951089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015365972		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Disorder; Leukopenia; Retinal Toxicity; White Blood Cell Count Increased	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil /00072603/			S		200 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11956036	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2015-004856			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Sulfasalazine			S	Unknown			Not Reported
	Prednisone Tablets			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11958348	EXPEDITED (15-DAY)		HO	CA-ROCHE-1699443			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Naprosyn			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Motrin			S	Unknown					Not Reported
	Plaquenil			S	Unknown					Not Reported
	Tramadol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11958965	EXPEDITED (15-DAY)		OT	CA-ROCHE-1699447		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Naprosyn			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 6 Years		Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11962143	EXPEDITED (15-DAY)		OT	AR-WATSON-2016-00337			Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Coloboma; External Auditory Canal Atresia; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Hypertelorism Of Orbit; Microtia; Oesophageal Atresia; Patent Ductus Arteriosus; Spine Malformation	Mycophenolate Mofetil (Unknown)			S	Transplacental	1 G, Daily		Not Reported
	Azathioprine (Unknown)			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine (Unknown)			S	Transplacental	Unk		Watson
	Prednisolone (Unknown)			S	Transplacental	Unk		Watson
	Calcium Lactate (Unknown)			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11962662	EXPEDITED (15-DAY)		HO	CA-ROCHE-1697797		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11963782	NON-EXPEDITED			US-ABBVIE-15K-163-1383052-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diabetes Mellitus Inadequate Control; Drug Ineffective; Fatigue;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Headache; Musculoskeletal Pain; Nausea; Vertigo	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Novolog	C			Not Reported
	Levimir	C			Not Reported
	Altace	C			Not Reported
	Crestor	C			Not Reported
	Folic Acid	C			Not Reported
	Xanax	C			Not Reported
	Lexapro	C			Not Reported
	Enbrel	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11511093	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-22		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Lower Respiratory Tract Infection; Pain In Extremity; Parkinson'S Disease; Peripheral Swelling; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11617770	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-29			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Operation;	Plaquenil			S				Not Reported

Tuberculosis	Arava			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11965283	EXPEDITED (15-DAY)		OT	PHHY2016CA010046		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Pregabalin			S	Unknown			Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Misoprostol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11965383	EXPEDITED (15-DAY)		OT	CA-ROCHE-1699437		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haematocrit Decreased; Haemoglobin Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Naprosyn			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Atenolol			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Folic Acid				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11966250	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA010020			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11966973	EXPEDITED (15-DAY)		HO	FR-SA-2016SA013470		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Leukopenia; Pancytopenia; Thrombocytopenia	Plaquenil			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Imeth			S	Oral			Not Reported
	Speciafoldine			C				Not Reported
	Cortancyl			C				Not Reported
	Omeprazole			C				Not Reported
	Actonel			C				Not Reported
	Aldactone			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11967009	EXPEDITED (15-DAY)		DE	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-02		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Pancytopenia	Plaquenil			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Imeth			S	Oral			Not Reported
	Salazopyrine			S	Oral			Not Reported
	Risedronate			S	Oral			Not Reported
	Caltrate			S	Oral			Not Reported
	Oxycontin			S	Intravenous drip			Not Reported
	Oxynorm			S	Intravenous drip			Not Reported
	Lorazepam			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11967251	EXPEDITED (15-DAY)		OT	CA-DEP_13478_2016		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Etanercept (Etanercept)			S		Df		Not Reported
	Diclofenac (Dicofenac)			S		Df		Not Reported
	Methotrexate (Methotrexate)			S		Df		Not Reported
	Prednisone (Prednisone)			S		Df		Not Reported
	Xeljanz (Tofacitinib Citrate)			S	Oral			Unknown
	Pregabalin (Pregabalin)			S		Df		Not Reported
	Naproxen (Naproxen)			S		Df		Not Reported
	Amitriptyline (Amitriptyline)			S		Df		Not Reported

		Celecoxib (Celecoxib)			S		Df		Not Reported
		Diclofenac Sodium (Diclofenac Sodium)			S		Df		Not Reported
		Hydroxychloroquine (Hydroxychloroquine)			S		Df		Not Reported
		Misoprostol (Misoprostol) (Misoprostol)			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11967257	EXPEDITED (15-DAY)		HO, OT	CA-DEP_13480_2016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac (Diclofenac)			S		Df		Not Reported
	Tramadol			C		Df		Not Reported
	Enbrel (Etanercept)			S	Subcutaneous	Df		Unknown
	Humira (Adalimumab)			S	Subcutaneous	Df		Unknown
	Methotrexate (Methotrexate)			S		Df		Not Reported
	Motrin (Ibuprofen)			S		Df		Unknown
	Naprosyn (Naproxen)			S		Df		Unknown
	Plaquenil (Hydroxychloroquine Phospate)			S		Df		Unknown
	Arava (Leflunomide)			S		Df		Unknown
	Aspirin (Acetylsalicylic Acid)			S		Df		Not Reported
	Gold (Gold)			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2016	11967261	EXPEDITED (15-DAY)		HO, OT	CA-DEP_13481_2016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis;	Diclofenac			S		Df		Not Reported
	Enbrel (Etanercept)			S	Subcutaneous	Df		Unknown
	Hydroxychloroquine			S		Df		Not Reported

Vomiting; Weight Decreased	Motrin (Ibuprofen)	S		Df	Unknown
	Naprosyn (Naproxen)	S		Df	Unknown
	Aspirin (Acetylsalicylic Acid)	S		Df	Not Reported
	Arava (Leflunomide)	S		Df	Unknown
	Humira (Adalimumab)	S	Subcutaneous	Df	Unknown
	Methotrexate	S		Df	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	10733094	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015026574			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Pantoloc			S		Unk		Pfizer
	Folic Acid			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Aleve			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Synthroid			S		Unk		Not Reported
	Vitalux /00322001/			C		Unk		Not Reported
	Ascorbic Acid W/Betacarotene/Copper/01586901/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11634939	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-30		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Hyperkeratosis	Plaquenil			S	Oral			Not Reported
	Kardegic			C				Not Reported
	Esomeprazole			C				Not Reported
	Alfuzosin			C				Not Reported
	Lisinopril Dihydrate			C				Not Reported
	Clopidogrel			C				Not Reported

	Ferograd Vitamin C			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11780884	EXPEDITED (15-DAY)		HO	CA-ROCHE-1665904			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 210.0 Day(S)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 15.0 Day(S)		Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml Pen		Not Reported
	Methotrexate			S	Subcutaneous	25mg/Ml		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 6.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11967172	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA010026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Motrin			S	Unknown			Not Reported

		Naprosyn			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Tramadol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11968704	EXPEDITED (15-DAY)		OT	CA-ROCHE-1700106		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Naproxen			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Misoprostol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11968863	EXPEDITED (15-DAY)		HO	CA-ROCHE-1699445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis;	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported

Vomiting; Weight Decreased	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Motrin	S	Unknown	Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Voltaren	S	Unknown	Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11970892	NON-EXPEDITED			US-ABBVIE-15K-163-1389480-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Tinnitus	Humira			S	Unknown			Not Reported

	Plaquenil			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11970996	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-02		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Swelling Face	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Atenolol			C				Not Reported
	Atorvastatin			C				Not Reported
	Beconase			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Canesten			C				Not Reported
	Cetirizine			C				Not Reported
	Omeprazole			C				Not Reported
	Piroxicam			C				Not Reported
	Ramipril			C				Not Reported
	Sodium Cromoglicate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2016	11971195	NON-EXPEDITED			US-ABBVIE-15K-163-1392168-00		20 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Range Of Motion Decreased; Mobility Decreased	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ibuprofen			C		Two To Three 800s		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11634931	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Malaise; Osteomyelitis; Pleurisy; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Actemra			S				Not Reported
	Gold			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11948504	EXPEDITED (15-DAY)		OT	PHHY2016CA008164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Neoral			S	Oral	20 Mg, Unk		Novartis
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, (Qwk)		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11975716	EXPEDITED (15-DAY)		OT	CA-ROCHE-1702406		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide			S	Oral				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11976346	EXPEDITED (15-DAY)		OT	CA-ROCHE-1702303		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	For 107 Days		Not Reported
	Imuran			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative Free Prefilled Syringes		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11976459	EXPEDITED (15-DAY)		DE	US-JNJFOC-20151204453		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Cetrizine		Y	S	Oral			Not Reported
	Cetrizine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxyzine			S	Oral			Not Reported

	Butalbital, Acetaminophen & Caffeine			S	Oral					Not Reported
	Meloxicam			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2016	11976954	EXPEDITED (15-DAY)		OT	SG-UCBSA-2016002151		61 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Omeprazole			S		Unk		Kremers Urban
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2016	11981408	EXPEDITED (15-DAY)		DE, HO	IN-ACCORD-037322		28 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthamoeba Infection; Amoebic Lung Abscess; Meningoencephalitis Amoebic	Methotrexate			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2016	11981779	EXPEDITED (15-DAY)		OT	CA-ROCHE-1702380		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Apo-Hydroxyquine			C	Unknown				Not Reported
	Ergocalciferol			C	Unknown				Not Reported
	Leucovorin			C	Unknown				Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11004863	EXPEDITED (15-DAY)		HO	PHHY2015FR040553		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Cortancyl			C	Unknown	5 Mg, Unk		Not Reported
	Kardegic			C	Unknown	75 Mg, Unk		Not Reported
	Cardensiel			C	Unknown	5 Mg, Unk		Not Reported
	Tahor			C	Unknown	40 Mg, Unk		Not Reported
	Eupantol			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported
	Seroplex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11982030	EXPEDITED (15-DAY)		OT	CA-ROCHE-1702371		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Orencia			S	Intravenous (not otherwise specified)			Not Reported
		Plaquenil			S	Unknown			Not Reported
		Remicade			S	Intravenous (not otherwise specified)			Not Reported
		Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11982040	EXPEDITED (15-DAY)		OT	CA-ROCHE-1702385		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased; Haemoglobin Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Naprosyn			S	Oral			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pms-Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11982057	EXPEDITED (15-DAY)		HO	CA-ROCHE-1699439		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Decreased Appetite; Dizziness; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight	Naprosyn			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased	Motrin			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Voltaren			S	Unknown				Not Reported
	Tramadol Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11983944	EXPEDITED (15-DAY)		OT	PHHY2016PT008581			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Strongyloidiasis	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2016	11984523	EXPEDITED (15-DAY)		OT	US-TEVA-625078USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Neck Pain; Osteoporosis; Palpitations; Respiratory Tract Infection; Sinusitis; Wrist Fracture	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Lyrica			C				Not Reported
	Cymbalta			C				Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11913006	NON-EXPEDITED			US-ROXANE LABORATORIES, INC.-2016-RO-00058RO		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Methotrexate			S	Unknown			Roxane

	Celecoxib	S	Unknown	400 Mg		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11948298	EXPEDITED (15-DAY)		OT	IT-BAXTER-2016BAX002845		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Immunosuppression; Lumbar Vertebral Fracture; Multiple Fractures; Mycobacterial Infection; Osteomyelitis; Osteoporosis; Thoracic Vertebral Fracture	Endoxan Baxter			S	Intravenous (not otherwise specified)			Baxter
	Endoxan Baxter			S	Unknown			Baxter
	Endoxan Baxter			S				Baxter
	Endoxan Baxter			S				Baxter
	Endoxan Baxter			S				Baxter
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	Low Dose		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported
	Mycophenolic Acid			S				Not Reported
	Mycophenolic Acid			S				Not Reported
	Mycophenolic Acid			S				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11986102	NON-EXPEDITED			US-ABBVIE-15K-163-1336814-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Nail Discolouration; Nail Disorder; Nail Pitting; Nystagmus; Psoriasis; Therapeutic Response Unexpected; Visual Impairment	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11988149	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703947		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2016	11997678	DIRECT	Y	HO			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hydroxychloroquine			S	Oral	200 Mg Am Po		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11991076	EXPEDITED (15-DAY)		CA	FR-009507513-1602FRA000736			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pierre Robin Syndrome; Polyhydramnios	Losartan Potassium			S	Transplacental	100 Mg, Qd		Merck
	Cellcept			S	Transplacental	2 G Daily		Not Reported
	Cortancyl			S	Transplacental	30 Mg, Qd		Not Reported
	Plaquenil			S	Transplacental	400 Mg, Qd		Not Reported
	Lasilix			S	Transplacental	Unk		Not Reported
	Trandate			S	Transplacental	400 Mg, Qd		Not Reported
	Lovenox			S	Transplacental	1.2 Ml, Qd		Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Transplacental	100 Mg, Qd		Not Reported
	Imurel			S	Transplacental	125 Mg, Qd		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Transplacental	100 Mg, Qd		Not Reported
	Tamiflu			C	Transplacental	Unk		Not Reported
	Bactrim			C	Transplacental	Unk		Not Reported
	Rovamycine			C	Transplacental	Unk		Not Reported
	Clamoxyl (Amoxicillin)			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11992199	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703182		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Year(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Year(S)		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3.0 Month(S)		Not Reported

Sedimentation Rate Increased; Synovitis	Hydroxychloroquine		S	Unknown	Therapy Duration: 2.0 Month(S)	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Month(S)	Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral		Not Reported
	Infliximab		S	Unknown	Therapy Duration: 12.0 Month(S)	Not Reported
	Methotrexate		S	Unknown	Therapy Duration: 9.0 Year(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11992210	EXPEDITED (15-DAY)		OT	CA-ROCHE-1704002		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11992388	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703186		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11992393	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703948		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11992444	EXPEDITED (15-DAY)		OT	CA-ROCHE-1704009		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not			Not Reported

				otherwise specified)		
	Arava		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Methotrexate		S	Intramuscular	Therapy Duration: 6 Years	Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Oral	Therapy Duration: 6 Years	Not Reported
	Naprosyn		C	Unknown		Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11992727	EXPEDITED (15-DAY)		OT	CA-ROCHE-1700560		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11993158	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703137		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 5 Months	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 5 Months	Not Reported
	Humira	S	Subcutaneous	Therapy Duration:: 7 Months	Not Reported
	Plaquenil	S	Unknown	Therapy Duration: 3 Years	Not Reported
	Methotrexate	C			Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11995608	NON-EXPEDITED		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-03		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Amlodipine			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Bisoprolol			C				Not Reported
	Brinzolamide			C				Not Reported
	Cetirizine			C				Not Reported
	Fexofenadine			C				Not Reported
	Flucloxacillin			C				Not Reported
	Lumigan			C				Not Reported
	Omeprazole			C				Not Reported
	Ramipril			C				Not Reported
	Temazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2016	11996730	NON-EXPEDITED			US-ABBVIE-15K-163-1414026-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Aortic Arteriosclerosis; Aortic Valve Thickening; Arterial Occlusive Disease; Arteriosclerosis Coronary Artery; Cardiac Disorder; Cardiac Failure Congestive; Cardiac Murmur; Cardiomyopathy; Chest Pain; Congestive Cardiomyopathy; Drug Ineffective; Drug Ineffective; Fatigue; Feeling Abnormal; Fluid Retention; Hepatic Cyst; Hepatic Lesion; Left Atrial Dilatation; Left Ventricular Dysfunction; Malaise; Mitral Valve Incompetence; Musculoskeletal Discomfort; Myocardial Ischaemia; Myocardial Ischaemia; Pericardial Effusion; Pulmonary Valve Incompetence; Tricuspid Valve Incompetence	Humira	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Sterapred	S	Oral	As Directed	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prilosec	C	Oral		Not Reported
	Lipitor	C	Oral		Not Reported
	Ambien	C	Oral	Nightly As Needed	Not Reported
	Synthroid	C	Oral		Not Reported
	Ventolin Hfa	C		Actuation Inhaler/2 Puffs Into The Lungs Every 6	Not Reported
	Vicodin	C	Oral		Not Reported
	Valium	C	Oral	As Needed	Not Reported
	Prinivil	C	Oral		Not Reported
	Coreg	C	Oral		Not Reported
	Zestril	C	Oral		Not Reported
	Lasix	C	Oral		Not Reported
	Aspirin	C	Oral		Not Reported
	Citracal + D	C	Oral		Not Reported
	Celebrex	C	Oral		Not Reported
	Adenosine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	11201347	EXPEDITED (15-DAY)		DS	DE-ABBVIE-15K-062-1409800-00			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Cough; Infection; Nasopharyngitis; Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12002046	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000312		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydroxyzine Hydrochloride			S	Oral	Unk Df, Unk		Northstar
	Hydroxychloroquine			S	Oral	Unk Df, Unk		Not Reported
	Meloxicam			S	Oral	Unk Df, Unk		Not Reported
	Cetirizine			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12003653	NON-EXPEDITED			US-ABBVIE-15K-163-1424807-00		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burn Oral Cavity; Cyst; Cyst Rupture; Haemorrhagic Cyst; Impaired Healing; Oral Disorder; Oral Disorder; Oral Pain; Scar; Swelling	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Losartan			C				Not Reported
	Hctz			C				Not Reported
	Simvastatin			C				Not Reported
	Activella			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11753053	NON-EXPEDITED			US-AMGEN-USASL2015119539		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Chest Discomfort; Fatigue; Feeling Abnormal; Headache; Injection Site Erythema; Injection Site	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Reaction; Malaise;
Nasopharyngitis;
Oropharyngeal Pain; Pain;
Throat Irritation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11770058	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015396862		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Platelet Count Decreased	Xeljanz			S	Oral	10 Mg, Daily		Pfizer
	Xeljanz			S		Unk		Pfizer
	Plaquenil			S		30 Mg, 2x/Day		Not Reported
	Elmiron			C		Unk		Not Reported
	Bactrim			C		Unk		Not Reported
	Prosed			C		Unk		Not Reported
	Sectral			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	B12			C		Unk		Not Reported
	Armour Thyroid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12006338	EXPEDITED (15-DAY)		CA	FR-ROCHE-1704370			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pierre Robin Syndrome	Cellcept			S	Transplacental			Not Reported
	Losartan Potassium			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Imurel			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Loxen (France)			S	Transplacental			Not Reported
	Trandate			S	Transplacental			Not Reported

					Aspegic (France)		S	Transplacental		Not Reported
					Lovenox		S	Transplacental		Not Reported
					Lasilix		S	Transplacental		Not Reported
					Rovamycine		S	Transplacental		Not Reported
					Tamiflu		C	Unknown		Not Reported
					Bactrim		C	Transplacental		Not Reported
					Clamoxyl (France)		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12011400	EXPEDITED (15-DAY)		OT	FR-SA-2016SA021024			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enoxaparin Sodium			S	Unknown			Not Reported
	Immune Globulin Nos			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12011501	EXPEDITED (15-DAY)		OT	FR-SA-2016SA021039			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enoxaparin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12011505	EXPEDITED (15-DAY)		OT	FR-SA-2016SA021047			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enoxaparin Sodium			S	Unknown			Not Reported
	Rituximab			C		At Day 1 And Day 15		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12012769	EXPEDITED (15-DAY)		HO	CA-TEVA-632345ACC		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate			S	Unknown			Teva
	Humira			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atrovent			C				Not Reported
	Benztropine			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Folic Acid			C				Not Reported
	Methoprazine			C				Not Reported
	Pantoprazole			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Salbutamol			C				Not Reported
	Trifluoperazine			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12013941	EXPEDITED (15-DAY)		DE	PHHY2016NO010640		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

General Physical Health Deterioration; Malignant Neoplasm Progression; Thrombocytopenia	Votrient	S	Unknown	800 Mg, Qd		Not Reported
	Afinitor	S	Unknown	10 Mg, Qd		Not Reported
	Afinitor	S	Oral	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid		Novartis
	Hydroxychloroquine	S	Unknown	400 Mg, Bid		Novartis
	Sorafenib	S	Unknown			Not Reported
	Xgeva	S	Subcutaneous	120 Mg, Qw4		Not Reported
	Sunitinib	S	Unknown	3.75 Mg, Qd		Not Reported
	Ipilimumab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12017052	EXPEDITED (15-DAY)		CA	PHHY2016FR012503			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pierre Robin Syndrome; Polyhydramnios	Loxen Lp			S	Transplacental	2 Df, Qd		Not Reported
	Losartan			S	Transplacental	100 Mg, Qd		Novartis
	Cellcept			S	Transplacental	2 G, Qd		Not Reported
	Cortancyl			S	Transplacental	30 Mg, Qd		Not Reported
	Imurel			S	Transplacental	125 Mg, Qd		Not Reported
	Plaquenil			S	Transplacental	2 Df, Qd		Not Reported
	Trandate			S	Transplacental	2 Df, Qd		Not Reported
	Aspegic//Acetylsalicylate Lysine			S	Transplacental	100 Mg, Qd		Not Reported
	Lovenox			S	Transplacental	2 Df, Qd		Not Reported
	Lasilix			S	Transplacental	Unk		Not Reported
	Tamiflu			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported
	Rovamycine			S	Transplacental	Unk		Not Reported
	Clamoxyl//Amoxicillin			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	12017286	NON-EXPEDITED			US-ABBVIE-15K-163-1454449-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Depression; Diplopia; Rheumatoid Arthritis; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atenolol			C				Not Reported
	Omeprazole			C				Not Reported
	Levothyroxine			C				Not Reported
	Folic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Fish Oil			C				Not Reported
	Cholecalciferol			C				Not Reported
	Oxycodone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2016	12020446	NON-EXPEDITED			US-ABBVIE-15K-163-1465809-00		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Decreased Appetite; Dry Mouth; Headache; Hepatic Enzyme Abnormal; Lethargy	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xanax			C				Not Reported
	Valium			C				Not Reported
	Citalopram			C				Not Reported
	Lisinopril + Hidroclorotiazida			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2016	12020489	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-110897			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased	Hydroxychloroquine	S	Unknown	Unk		Ipca
	Folic Acid	S	Unknown	Unk		Mutual
	Methotrexate	S	Unknown	Unk		Not Reported
	Pantoloc	S	Unknown	Unk		Not Reported
	Aleve	S	Unknown	Unk		Not Reported
	Synthroid	S	Unknown	Unk		Not Reported
	Vitalux	C	Unknown	Unk		Not Reported
	Ascorbic Acid W/Betacarotene/Copper	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2016	12021381	EXPEDITED (15-DAY)		DE	US-NORTHSTAR HEALTHCARE HOLDINGS-US-2016NSR000366		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Tramadol Hydrochloride			S	Oral	Unk Df, Unk		Northstar
	Hydroxychloroquine			S	Oral	Unk Df, Unk		Not Reported
	Amitriptyline			S	Oral	Unk Df, Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk Df, Unk		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2016	12023402	NON-EXPEDITED			US-ABBVIE-15K-163-1475208-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Diarrhoea; Headache; Muscle Spasms	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2016	12025925	NON-EXPEDITED			US-ABBVIE-15K-163-1486197-00		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Restasis			C				Not Reported
	Atenolol			C				Not Reported
	Synthroid			C				Not Reported
	Celexa			C				Not Reported
	Iron			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Multivitamin			C				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2016	12028921	NON-EXPEDITED			US-ABBVIE-15K-163-1500007-00		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12036874	EXPEDITED (15-DAY)		CA	FR-ROCHE-1702288		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Polyhydramnios	Cellcept			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Cortancyl			S	Unknown			Not Reported
	Imurel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Loxen (France)			S	Unknown				Not Reported
	Trandate			S	Unknown				Not Reported
	Aspegic (France)			S	Unknown				Not Reported
	Lovenox			S	Unknown				Not Reported
	Lasilix			S	Unknown				Not Reported
	Rovamycine			S	Unknown				Not Reported
	Bactrim			C	Unknown				Not Reported
	Tamiflu			C	Unknown				Not Reported
	Clamoxyl (France)			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12037186	EXPEDITED (15-DAY)		OT	CA-ROCHE-1704049		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12039695	EXPEDITED (15-DAY)		DE, OT	NO-BAYER-2016-016337		42 YR	Male	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Renal Cell Carcinoma; Thrombocytopenia	Nexavar			S	Oral			Bayer
	Nexavar			S	Unknown			Bayer
	Sunitinib			S	Unknown	37.5 Mg, Qd		Not Reported
	Sunitinib			S	Endocervical	37.5 Mg, Qd		Not Reported
	Afinitor			S	Oral	7.5 Mg, Qd		Not Reported

	Afinitor	S	Unknown	7.5 Mg, Qd	Not Reported
	Afinitor	S	Unknown	200 Mg	Not Reported
	Afinitor	S		10 Unk, Unk	Not Reported
	Pazopanib	S	Unknown	800 Mg, Qd	Not Reported
	Xgeva	S	Subcutaneous	120 Mg, 4iw	Not Reported
	Xgeva	S	Subcutaneous	120 Mg, Unk	Not Reported
	Ipilimumab	S	Unknown		Not Reported
	Ipilimumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12044364	NON-EXPEDITED			US-ABBVIE-15P-163-1410788-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Asthenia; Confusional State; Drug Ineffective; Fatigue; Mobility Decreased	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Oxycontin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12045909	EXPEDITED (15-DAY)		CA	FR-SA-2016SA018535			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pierre Robin Syndrome; Polyhydramnios	Losartan Potassium			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Transplacental			Not Reported
	Lovenox			S	Transplacental			Not Reported
	Lasilix			S	Transplacental			Not Reported

	Cellcept		S	Transplacental		Not Reported
	Imurel		S	Transplacental		Not Reported
	Loxen (Nicardipine Hydrochloride)		S	Transplacental		Not Reported
	Trandate		S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12047844	EXPEDITED (15-DAY)		DS	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-03		65 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Cough; Dyspnoea	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Oral			Not Reported
	Formatris			C				Not Reported
	Novopulmon			C				Not Reported
	Singulair			C				Not Reported
	Salbutamol			C				Not Reported
	Omeprazole			C				Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12047845	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-03			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Ataxia; Complement Factor Decreased; Fatigue; Palpitations; Rebound Effect; Systemic Lupus Erythematosus; Tinnitus	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Quinacrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2016	12052099	DIRECT					77 YR	Female	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deafness; Dry Eye; Dry Mouth; Dysphonia; Muscular Weakness; Vision Blurred	Hydroxychloroquine 200 Mg			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	11036544	EXPEDITED (15-DAY)		OT	CA-ROCHE-1564095		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Malaise; Pain; Pharyngeal Oedema; Urticaria	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 34 Days		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 283 Days		Not Reported
	Methotrexate Sodium			S	Intra-arterial	Therapy Duration: 8 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	11729137	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-11		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Duodenitis; Musculoskeletal Stiffness; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Aluminium Hydroxide/Magnesium Trisilicate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12052035	EXPEDITED (15-DAY)		LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2015-39			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Eruption; Pruritus; Systemic Lupus Erythematosus	Plaquenil	S	Oral	1 Or 2 Tablets Daily Alternately		Not Reported
	Pravastatin	C				Not Reported
	Predonine	C				Not Reported
	Marzulene (Azulene Sodium Sulfonate\Levoglutamide)	C				Not Reported
	Depas (Etizolam)	C				Not Reported
	Thyradin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12054706	NON-EXPEDITED			US-ABBVIE-15P-163-1463350-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Depression; Diplopia; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12055185	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-03		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Cataract; Chest Pain; Corneal Lesion; Keratitis; Nausea; Pruritus; Tinnitus	Plaquenil			S	Oral			Not Reported
	Lasilix			C				Not Reported
	Furosemide			C				Not Reported
	Desloratadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12055394	EXPEDITED (15-DAY)		HO	FR-HQ SPECIALTY-FR-2016INT000042		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic	Methotrexate Sodium			S	Oral	Unk		Hq Specialty

Syndrome; Pancytopenia	Plaquenil /00072603/	S	Oral	Unk		Not Reported
	Diclofenac	S	Oral	Unk		Not Reported
	Irbesartan	S	Oral	Unk		Not Reported
	Speciafoldine	C		Unk		Not Reported
	Cortancyl	C		Unk		Not Reported
	Omeprazole	C		Unk		Not Reported
	Actonel	C		Unk		Not Reported
	Aldactone /00006201/	C		Unk		Not Reported
	Zopiclone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12055669	EXPEDITED (15-DAY)		OT	CA-ROCHE-1708268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12055842	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-15298680			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia; Pregnancy On Oral Contraceptive; Premature Delivery	Abatacept			S	Intravenous (not otherwise specified)	10 Mg/Kg, Q4wk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Oral	500 Mg, Bid		Bristol Myers Squibb
	External-Mycophenolate Mofetil			S	Oral	1000 Mg, Qd		Unknown

External-Prednisone	S	Oral	5 Mg, Qd		Unknown
External-Hydroxychloroquine Sulfate	S	Oral	200 Mg, Bid		Unknown
External-Ethinylestradiol+Desogestrel	S	Oral	20 Mg, Qd		Not Reported
External-Levothyroxine	S	Oral	150 Mg, Qd		Not Reported
External-Iron	S	Oral	1 Df, Qd		Not Reported
External-Esomeprazole	S	Oral	40 Mg, Qd		Not Reported
External-Escitalopram Oxalate	S	Oral	10 Mg, Qd		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2016	12058484	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Contusion; Gait Inability; Rash; Stomatitis	Hyoscyamine			S				Virtus Pharmaceuticals
	Lipitor			C				Not Reported
	Gabapentin			C				Not Reported
	Metformin Hcl			C				Not Reported
	Famotidine			C				Not Reported
	Irbesartan			C				Not Reported
	Claritin			C				Not Reported
	Lutein			C				Not Reported
	Fish Oil			C				Not Reported
	Omega 3			C				Not Reported
	Cinnamon			C				Not Reported
	Hydroxychloroquine 200mg			S				Zydus Pharm
	Tramadol Hcl			C				Not Reported
	Meloxicam			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Mystatin			C				Not Reported
	Premarin			C				Not Reported
	Voltaren Gel Diclofenac Sodium			C				Not Reported
	Triamcinolone			C				Not Reported
	Nystatin Powder			C				Not Reported
	Benadryl Itch Stopping Cream			C				Not Reported
	Clotrimazole Cream			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	10234816	EXPEDITED (15-DAY)		CA, DE, OT	DE-ROCHE-1415675			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hydrops Foetalis	Tocilizumab			S	Transplacental			Not Reported
	Quensyl			S	Transplacental			Not Reported
	Folic Acid			S	Transplacental			Not Reported
	Sulfasalazin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12057222	EXPEDITED (15-DAY)		OT	CA-ROCHE-1708270		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Injection			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral	25 Mg/Ml Therapy Duration: 730 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12059857	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-04		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Thrombotic Microangiopathy	Plaquenil			S	Oral			Not Reported
	Gemzar			S	Intravenous (not otherwise specified)			Not Reported

	Bromazepam	C	Oral			Not Reported
	Eupantol	C				Not Reported
	Repaglinide	C	Oral			Not Reported
	Paracetamol	C		1g 4x/Day If Required		Not Reported
	Eupressyl	C				Not Reported
	Diffu K	C		3 Capsules 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12059858	EXPEDITED (15-DAY)		OT	DK-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DK-2016-03		59 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Wound	Plaquenil			S				Not Reported
	Cimzia			S				Not Reported
	Cimzia			S				Not Reported
	Methotrexate			S				Not Reported
	Salazopyrin			S				Not Reported
	Hjertemagnyl [Acetylsalicylic Acid\Magnesium Oxide]			C				Not Reported
	Persantin R			C				Not Reported
	Folinsyre			C				Not Reported
	Alendronat			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12059860	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-03			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rheumatoid Arthritis; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12060671	EXPEDITED (15-DAY)		OT	US-TEVA-632763USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Liver Injury; Muscle Spasms	Leflunomide		S	Unknown		Barr
	Hydroxychloroquine		S	Unknown		Teva
	Xeljanz		C			Not Reported
	Sulfamethoxazole-Temp Ds		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12063254	EXPEDITED (15-DAY)		DE	CA-SA-2016SA021529		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Lasix			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Combivent			S	Unknown	Dosage Form-Metered-Dose (Aerosol)		Not Reported
	Flovent			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2016	12063982	NON-EXPEDITED			US-ABBVIE-15P-163-1530337-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	Two Years		Not Reported
	Enbrel			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	11895460	EXPEDITED (15-DAY)		DE, HO	CA-SA-2016SA001469		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hip Fracture; Pneumonia; Renal Tubular Necrosis; Respiratory Failure	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Atorvastatin			C				Not Reported
	Ventolin			C		Dose: 100-200 Mcg Every 4 Hours		Not Reported
	Spiriva			C				Not Reported
	Endocet			C		8-12 Hours		Not Reported
	Pantoloc			C				Not Reported
	Carvedilol			C				Not Reported
	Nitro-Dur			C		Frequency: Hour		Not Reported
	N-Acetylcysteine			C				Not Reported
	Advair			C		Dose:1 Puff(S)		Not Reported
	Adalat Xl			C				Not Reported
	Quinapril			C				Not Reported
	Alendronate			C				Not Reported
	Ferrous Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	11927769	EXPEDITED (15-DAY)		DE, HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-01		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hip Fracture; Pneumonia; Renal Tubular Necrosis; Respiratory Failure	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Atorvastatin			C				Not Reported
	Ventolin			C				Not Reported

	Spiriva	C		Not Reported
	Endocet	C		Not Reported
	Pantoloc	C		Not Reported
	Carvedilol	C		Not Reported
	Nitro-Dur	C		Not Reported
	N-Acetylcysteine	C		Not Reported
	Advair	C		Not Reported
	Adalat Xl	C		Not Reported
	Quinapril	C		Not Reported
	Alendronate	C		Not Reported
	Ferrous Fumarate	C		Not Reported
	Xeljanz	C		Not Reported
	Methotrexate Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	11995607	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CH-2016-03		15 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macula Thickness Measurement; Maculopathy; Maculopathy; Optical Coherence Tomography Abnormal; Visual Field Tests Abnormal	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cyclosporin			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12067561	EXPEDITED (15-DAY)		CA	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-05			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pierre Robin Syndrome; Polyhydramnios	Plaquenil			S	Transplacental			Not Reported
	Losartan Potassium			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Transplacental			Not Reported

	Lovenox	S	Transplacental	1.2 Millilitre		Not Reported
	Lasilix	S	Transplacental			Not Reported
	Cellcept	S	Transplacental			Not Reported
	Imurel	S	Transplacental			Not Reported
	Loxen (Nicardipine Hydrochloride)	S	Transplacental			Not Reported
	Trandate	S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2016	12067562	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-05		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Etanercept			S				Not Reported
	Cholecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	10235636	EXPEDITED (15-DAY)		OT	DE-ROCHE-1414243		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Tocilizumab			S	Intravenous drip			Not Reported
	Quensyl			S	Oral			Not Reported
	Folic Acid			S	Oral			Not Reported

	Sulfasalazin			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	11046753	EXPEDITED (15-DAY)		OT	CA-ROCHE-1564087		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Condition Aggravated; Dehydration; Depressed Mood; Dermatitis; Fall; Immobile; Peripheral Swelling; Rib Fracture; Scar; Vomiting	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 91 Days		Not Reported
	Celebrex			S	Unknown	Therapy Duration: 731 Days		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 882 Days		Not Reported
	Prednisone			S	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	12054210	EXPEDITED (15-DAY)		OT	FR-009507513-1602FRA001476		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Pneumocystis Jirovecii Pneumonia	Losartan Potassium			S	Oral	100 Mg, Qd		Merck
	Cortancyl			S		30 Mg, Qd		Not Reported
	Plaquenil			S		400 Mg, Qd		Not Reported
	Aspegic [Acetylsalicylate Lysine]			S		100 Mg, Qd		Not Reported
	Lovenox			S		1.2 Ml, Qd		Not Reported
	Lasilix			S		Unk		Not Reported
	Cellcept			S		2 G Daily		Not Reported
	Imurel			S		125 Mg, Qd		Not Reported
	Loxen (Nicardipine Hydrochloride)			S		100 Mg, Qd		Not Reported

	Trandate	S	400 Mg, Qd	Not Reported
	Tamiflu	C	Unk	Not Reported
	Bactrim	C	Unk	Not Reported
	Rovamycine	C	Unk	Not Reported
	Clamoxyl (Amoxicillin)	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2016	12072611	EXPEDITED (15-DAY)		DE	US-PERRIGO-16US001200		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Cetirizine Hydrochloride			S	Oral	Unk		Perrigo
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxyzine			S	Oral	Unk		Not Reported
	Butalbital, Acetaminophen & Caffeine			S	Oral	Unk		Not Reported
	Meloxicam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12079816	EXPEDITED (15-DAY)		OT	IT-IPCA LABORATORIES LIMITED-IPC201602-000223		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression;	Hydroxychloroquine Sulfate			S				Ipca
Multiple Fractures;	Hydroxychloroquine Sulfate			S				Ipca
Mycobacterial Infection;	Prednisone			S				Not Reported
Osteoporosis	Azathioprine			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Cyclophosphamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080226	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-04		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080227	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-04			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Aspirin			S				Not Reported
	Prednisone			S				Not Reported
	Enoxaparin Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080228	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-05			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Aspirin			S				Not Reported
	Prednisone			S				Not Reported
	Enoxaparin Sodium			S				Not Reported
	Immune Globulin Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12080229	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-05			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisone			S				Not Reported

	Aspirin			S						Not Reported
	Enoxaparin Sodium			S						Not Reported
	Rituximab			C						Not Reported
	Vitamin Supplementation			C						Not Reported
	Immune Globulin Nos			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12081385	EXPEDITED (15-DAY)		DE	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-05		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Plaquenil			S				Not Reported
	Lasix			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12081387	EXPEDITED (15-DAY)		HO, LT	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-04		75 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2016	12081388	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-04		84 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Abnormal	Plaquenil			S	Oral			Not Reported
	Omeprazole			C				Not Reported
	Colecalciferol			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Persantin			C				Not Reported
	Valsartan			C				Not Reported
	Simvastatin			C				Not Reported
	Vaseline			C				Not Reported
	Prednisolone			C				Not Reported
	Lormetazepam			C				Not Reported
	Mirtazapine			C				Not Reported
	Salbutamol			C				Not Reported
	Oculotect			C				Not Reported
	Movicolon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12080453	EXPEDITED (15-DAY)		HO, OT	EG-WATSON-2016-02900		28 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine (Unknown)			S	Unknown	400 Mg, Daily		Watson
	Prednisolone (Unknown)			S	Unknown	40 Mg, Daily		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12083329	NON-EXPEDITED			PHEH2016US003869		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis	Diovan			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Lovastatin			S	Unknown	Unk		Novartis

			Ambrisentan		S	Unknown	10 Mg, Qd		Not Reported
			Levothyroxine		S	Unknown	Unk		Not Reported
			Plaquenil		S	Unknown	Unk		Not Reported
			Pletal		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2016	12084428	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160202945		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use; Pancytopenia; Product Use In Unapproved Indication; Psychotic Disorder	Risperdal			S	Oral	6 Mg A Day.		Not Reported
	Haldol			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Imurel			S	Oral			Not Reported
	Chlorpromazine			S	Unknown			Not Reported
	Cortancyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	11154636	EXPEDITED (15-DAY)		HO, LT, OT	FR-AMGEN-FRASP2015051933		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bundle Branch Block Left; Cardio-Respiratory Arrest; Chest Pain; Diarrhoea; Electrocardiogram Qt Prolonged; Hypokalaemia; Lactic Acidosis; Malaise; Nausea; Torsade De Pointes; Ventricular Dyssynchrony	Procoralan			S	Oral	5 Mg, Bid		Amgen
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Seroplex			S	Oral	5 Mg, Qd		Not Reported
	Atacand			C		4 Mg, Daily		Not Reported
	Aldactone /00006201/			C		25 Mg, Unkevery Other Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12079731	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-04		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myalgia; Paresis	Plaquenil			S	Oral			Not Reported
	Ezetrol			S	Oral			Not Reported
	Seresta			C				Not Reported
	Bisoprolol			C				Not Reported
	Levothyrox			C				Not Reported
	Dafalgan			C				Not Reported
	Mirtazapine			C				Not Reported
	Lansoprazole			C				Not Reported
	Lormetazepam			C				Not Reported
	Lyrica			C				Not Reported
	Oxycontin			C				Not Reported
	Oxynorm			C				Not Reported
	Candesartan Cilexetil			C				Not Reported
	Calciparine			C				Not Reported
	Cetirizine			C				Not Reported
	Calcidose Vitamine D			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12088196	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712236		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 78 Days		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Fosamax			C				Not Reported

	Ibuprofen			C	Unknown					Not Reported
	Lisinopril			C						Not Reported
	Vitamin D3			C						Not Reported
	Alendronate Sodium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2016	12090817	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016097874		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Haematemesis	Sulfasalazine			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	11381043	EXPEDITED (15-DAY)		HO, OT	US-UNITED THERAPEUTICS-UNT-2014-013167		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Kidney Injury; Acute Kidney Injury; Blood Folate Decreased; Dizziness; Hypokalaemia; Hypotension; Impaired Healing; Infusion Site Discharge; Infusion Site Erythema; Infusion Site Haematoma; Infusion Site Haemorrhage; Infusion Site Infection; Infusion Site Pain; Infusion Site Pruritus; Infusion Site Swelling; Infusion Site Warmth; Malaise; Nasal Congestion; Oedema; Pancreatitis Acute;	Remodulin			S	Subcutaneous	0.038 Mg/Kg, Continuing		United Therapeutics
	Remodulin			S	Subcutaneous	0.038 Mg/Kg, Continuing		United Therapeutics
	Remodulin			S	Subcutaneous	0.060 Mg/Kg, Continuing		United Therapeutics
	Remodulin			S	Subcutaneous	0.056 Mg/Kg, Continuing		United Therapeutics
	Letairis			S	Oral	5 Mg, Qd		Not Reported
	Letairis			S		Unk		Not Reported
	Letairis			S				Not Reported
	Plaquenil Sulfate			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Tylenol /00020001/			C				Not Reported
	Lasix /00032601/			C	Oral	20 Mg, Bid		Not Reported
	Aspirin /00002701/			C	Oral	81 Mg, Qd		Not Reported

Pancytopenia; Pyrexia; Rash; Retroperitoneal Lymphadenopathy; Thrombocytopenia; Trichomoniasis; Urinary Tract Infection	Omeprazole	C	Oral	40 Mg, Qd		Not Reported
	Xanax	C		Unk		Not Reported
	Metoprolol	C				Not Reported
	Nystatin	C				Not Reported
	Protonix /01263204/	C				Not Reported
	Prochlorperazine	C				Not Reported
	Risperdal	C				Not Reported
	Simethicone	C				Not Reported
	Potassium Chloride	C				Not Reported
	Sucralfate	C				Not Reported
	Chlorpromazine	C				Not Reported
	Erythromycin	C				Not Reported
	Reglan /00041901/	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12094288	EXPEDITED (15-DAY)		HO	PHHY2016GB018782		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Folic Acid			S	Oral	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Novartis
	Etanercept			S	Unknown			Not Reported
	Cholecalciferol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12095456	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2016091615		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Pneumonia	Pristiq	S	Unk		Pfizer
	Mirtazapine	S	Unk		Not Reported
	Venlafaxine Hcl	S	Unk		Pfizer
	Bupropion	S	Unk		Not Reported
	Cyclobenzaprine	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12095657	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160209300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Acetaminophen		Y	S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12098324	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1712252			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12099712	EXPEDITED (15-DAY)		HO	GB-TEVA-634759ACC		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower	Folic Acid			S	Oral	Frequency: Six Days A Week		Ivax
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr

	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram Daily;		Not Reported
	Cholecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12103130	EXPEDITED (15-DAY)		OT	AE-ROCHE-1711505			Unknown	ARE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Chest Discomfort; Cough; Dizziness; Drug Intolerance; Infection; Injection Site Reaction; Liver Function Test Increased; Menorrhagia; Ocular Toxicity; Pigmentation Disorder; Psoriasis; Pulmonary Haemorrhage; Thyroid Neoplasm; Upper Gastrointestinal Haemorrhage; White Blood Cell Count Decreased	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	12103371	EXPEDITED (15-DAY)		HO	GB-HOSPIRA-3173741		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Etanercept	S	Unknown			Not Reported
	Folic Acid	S	Oral	Frequency: Six Days A Week		Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Cholecalciferol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12104745	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-06		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Hydroxychloroquine Sulfate			S				Not Reported
	Naproxen			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Folic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12104924	EXPEDITED (15-DAY)		OT	TR-IPCA LABORATORIES LIMITED-IPC201602-000249		73 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Hydroxychloroquine Sulfate			S				Ipca
	Insulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12105066	NON-EXPEDITED			US-PFIZER INC-2016071841		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Adrenaline			S				Unknown
	Neosporin			S				Pfizer
	Sulfasalazine			S				Pfizer
	Codeine			S				Not Reported
	Cymbalta			S				Not Reported
	Crestor			S				Not Reported
	Ceftin			S				Not Reported

	Plaquenil			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12107198	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-06			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Nexium			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12107199	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-05		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Foot Operation; Platelet Count Decreased	Plaquenil			S				Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Elmiron			C				Not Reported
	Sectral			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin B12			C				Not Reported
	Armour Thyroid			C				Not Reported
	Bactrim			C				Not Reported
	Prosed/Ds			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2016	12107242	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-11		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eyelid Oedema; Pruritus; Pustule; Pyrexia; Rash Papular; Vision Blurred	Plaquenil	S	Oral		Not Reported
	Altim//Cortivazol	C	Unknown		Not Reported
	Plavix	C	Unknown		Not Reported
	Bi-Tildiem	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Mianserine	C	Unknown		Not Reported
	Inexium	C	Unknown		Not Reported
	Colchimax (France)	C	Unknown		Not Reported
	Allopurinol	C	Unknown		Not Reported
	Cortancyl	C	Unknown		Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)	C	Unknown		Not Reported
	Klipal Codeine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	11314892	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-580566USA		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Back Pain; Infection; Pelvic Pain; Renal Failure; Sepsis	Indomethacin (Mah Unknown)			S	Unknown			Teva
	Prednisone (Mah Unknown)			S	Unknown			Not Reported
	Pfizer-Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Xeljanz			S		10 Milligram Daily;		Not Reported
	Xeljanz			S		5 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Fluconazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	11911787	EXPEDITED (15-DAY)		HO, OT	US-SA-2016SA003214		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Creatine Increased; Cardiac Failure Congestive; Chronic Kidney Disease; Contusion; Eye Infection; Fall; Feeling Hot; Gout; Haematochezia; Hypertension; Hypocalcaemia; Oedema; Oedema Peripheral; Pericardial Effusion; Pneumonia; Respiratory Distress	Hydroxychloroquine			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lasix			S	Oral	In Am		Not Reported
	Lasix			S	Oral	In Am		Not Reported
	Lasix			S	Oral	In Am		Not Reported
	Lasix			S	Oral	In Am		Not Reported
	Lasix			S	Oral	In Am		Not Reported
	Lasix			S	Oral	In Am		Not Reported
	Benicar			S	Oral			Not Reported
	Benicar			S	Oral			Not Reported
	Revatio			S	Oral			Not Reported
	Revatio			S	Unknown			Not Reported
	Verpamil			S	Oral	Modified Release Film-Coated Tablet		Not Reported
	Verpamil			S	Oral	Modified Release Film-Coated Tablet		Not Reported
	Verpamil			S	Oral	Modified Release Film-Coated Tablet		Not Reported
	Verpamil			S	Oral	Modified Release Film-Coated Tablet		Not Reported
	Verpamil			S	Oral	Modified Release Film-Coated Tablet		Not Reported
	Verpamil			S	Oral	Modified Release Film-Coated Tablet		Not Reported
	Ranitidine			C				Not Reported
	Protonix			C				Not Reported

	Methotrexate	C	Not Reported
	Plaquenil	C	Not Reported
	Chondroitin W/Glucosamine	C	Not Reported
	Aspirin	C	Not Reported
	Proair Hfa	C	Not Reported
	Folic Acid	C	Not Reported
	Ferrous Sulfate	C	Not Reported
	Omega 3	C	Not Reported
	Vitamin D/Calcium	C	Not Reported
	Mirapex	C	Not Reported
	Uloric	C	Not Reported
	Spironolactone	C	Not Reported
	Amlodipine Besilate	C	Not Reported
	L-Thyroxin	C	Not Reported
	Potassium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2016	12108446	EXPEDITED (15-DAY)		OT	CA-ROCHE-1714154		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Malaise; Movement Disorder; Muscle Spasms; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased	Naprosyn			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	For 6 Years		Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Xeljanz			S	Oral	1 Dosage Form		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	11533768	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3010143		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Muscle Spasms; Pain; Rheumatoid Arthritis	Arthrotec			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12113576	EXPEDITED (15-DAY)		HO	GB-ACCORD-037960		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower	Methotrexate			S	Subcutaneous	Orally 15 Mg Weekly From 22-May-2014, Increased On 05-Jun-2014 To 25 Mg, Decreased On 29-Jan-2015 To		Accord
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Oral	Frequency: Six Days A Week		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Colecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12114760	EXPEDITED (15-DAY)		HO	GB-WATSON-2016-03442		40 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Lower	Folic Acid (Unknown)	S	Oral	5 Mg, Frequency: Six Days A Week		Watson
	Methotrexate (Unknown)	S	Oral	15 Mg, 1/Week		Not Reported
	Methotrexate (Unknown)	S	Subcutaneous	25 Mg, 1/Week		Not Reported
	Methotrexate (Unknown)	S	Subcutaneous	15 Mg, 1/Week		Not Reported
	Methotrexate (Unknown)	S	Subcutaneous	20 Mg, 1/Week		Not Reported
	Methotrexate (Unknown)	S	Oral	15 Mg, 1/Week		Not Reported
	Methotrexate (Unknown)	S	Oral	25 Mg, 1/Week		Not Reported
	Hydroxychloroquine (Unknown)	S	Oral	200 Mg, Daily		Watson
	Etanercept	S	Unknown	Unk Unk, Unknown		Not Reported
	Cholecalciferol	C	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12115073	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-07		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Paraesthesia; Rheumatoid Arthritis	Plaquenil			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Celebrex			S				Not Reported
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12115074	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-06		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Eczema; Enterococcal Infection; Erythema; Fungal Infection; Hyperkeratosis; Local	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Imiquimod			S				Not Reported

Reaction; Neutrophil Count Increased; Papilloma Viral Infection; Skin Erosion; Skin Lesion; Skin Ulcer; Squamous Cell Carcinoma Of Skin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12115075	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-06			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Retention	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12115173	DIRECT	Y	HO			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Sepsis; Pneumonia Bacterial; Pneumothorax; Post Procedural Complication; Respiratory Failure	Hydroxychloroquine, 400 Mg			S	Oral			Prasco
	Prasco							
	Levothyroxine			C				Not Reported
	Aspirin			C				Not Reported
	Perosol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2016	12116678	EXPEDITED (15-DAY)		HO	PHHY2016GB023484		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Methotrexate			S	Unknown			Novartis
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen			S	Unknown	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2016	11809999	EXPEDITED (15-DAY)		OT	CA-ROCHE-1671718		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Incomplete; Abortion Spontaneous; Haemorrhage; Maternal Exposure During Pregnancy; Rheumatoid Arthritis	Naproxen			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	11927243	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL000076			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Creatinine Increased; Cardiac Failure Congestive; Chronic Kidney Disease; Contusion; Eye Infection; Fall; Feeling Hot; Gout; Haematochezia; Hypertension; Hypocalcaemia; Oedema; Pericardial Effusion; Peripheral Swelling; Pneumonia; Respiratory Distress	Lasix			S	Oral	40 Mg, Daily		Validus
	Lasix			S	Oral	20 Mg, Daily		Validus
	Lasix			S	Oral	Unk		Validus
	Lasix			S	Oral	80 Mg, Daily		Validus
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Benicar			S	Oral	10 Mg, Bid		Not Reported
	Benicar			S	Oral	0.5 Df, Bid		Not Reported
	Revatio			S		20 Mg, Tid		Not Reported
	Revatio			S		20 Mg, Tid		Not Reported
	Verapamil			S	Oral	200 Mg, Bid		Not Reported
	Verapamil			S	Oral	200 Mg, Daily		Not Reported
	Verapamil			S	Oral	200 Mg, Daily		Not Reported
	Ranitidine			C		Unk		Not Reported

Protonix /01263204/	C	Unk	Not Reported
Methotrexate	C	Unk	Not Reported
Plaquenil /00072602/	C	Unk	Not Reported
Chondroitin W/Glucosamine /02118501/	C	Unk	Not Reported
Aspirin /00002701/	C	Unk	Not Reported
Proair Hfa	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Ferrous Sulfate	C	Unk	Not Reported
Omega 3 /01334101/	C	Unk	Not Reported
Calcium/Vitamin D /01204201/	C	Unk	Not Reported
Mirapex	C	Unk	Not Reported
Uloric	C	Unk	Not Reported
Spironolactone	C	Unk	Not Reported
Amlodipine Besilate	C	Unk	Not Reported
L-Thyroxin	C	Unk	Not Reported
Potassium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	11937067	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-01		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Creatine Increased; Cardiac Failure Congestive; Chronic Kidney Disease; Contusion; Eye Infection; Fall; Feeling Hot; Gout; Haematochezia; Hypertension; Hypocalcaemia; Oedema; Oedema Peripheral; Pericardial Effusion;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Lasix			S	Oral			Not Reported
	Benicar			S	Oral			Not Reported
	Benicar			S	Oral			Not Reported
	Revatio			S	Oral			Not Reported
	Revatio			S	Unknown			Not Reported

Pneumonia; Respiratory Distress	Verpamil			S	Oral				Not Reported
	Verpamil			S	Oral				Not Reported
	Verpamil			S	Oral				Not Reported
	Ranitidine			C					Not Reported
	Protonix			C					Not Reported
	Methotrexate			C					Not Reported
	Plaquenil			C					Not Reported
	Chondroitin W/Glucosamine			C					Not Reported
	Aspirin			C					Not Reported
	Proair Hfa			C					Not Reported
	Folic Acid			C					Not Reported
	Ferrous Sulfate			C					Not Reported
	Omega 3			C					Not Reported
	Calcium/Vitamin D			C					Not Reported
	Mirapex			C					Not Reported
	Uloric			C					Not Reported
	Spironolactone			C					Not Reported
	Amlodipine Besilate			C					Not Reported
	L-Thyroxin			C					Not Reported
	Potassium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12123925	NON-EXPEDITED			US-PFIZER INC-2016060390			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12127840	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-07		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12127842	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-06			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2016	12127942	NON-EXPEDITED			US-PFIZER INC-2016119974		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	10642910	NON-EXPEDITED			US-PFIZER INC-2014337054		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ampicillin			S		Unk		Pfizer
	Bextra			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Levothyroxine Sodium			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Lyrica			S		Unk		Pfizer
	Meloxicam			S		Unk		Not Reported
	Skelaxin			S		Unk		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Trazodone Hcl			S		50 Mg, Unk		Unknown
	Spiriva			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Vytorin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Azelastine			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Voltaren			S		Unk		Not Reported
	Alor			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Sulindac			S		Unk		Not Reported
	Asmanex			S		Inhaler		Not Reported
	Iodine			S		Unk		Not Reported
	Lialda			S		Unk		Not Reported

Ator	S	Unk	Not Reported
Ultram	C	50 Mg, Daily	Not Reported
Synthroid	C	100 Ug, Daily (Morning)	Not Reported
Atenolol	C	100 Mg, Daily (1 Morning 1 Evening)	Not Reported
Donnatal	C	Unk	Not Reported
Effexor Xr	C	75 Mg, Daily (Evening)	Not Reported
Omeprazole	C	20 Mg, Daily (1 Evening)	Not Reported
Klor-Con M	C	20 Ug, Daily (1 Morning)	Not Reported
Amlodipine	C	5 Mg, Daily (1 Evening)	Not Reported
Crestor	C	10 Mg, Daily (1 Evening)	Not Reported
Epipen	C	0.3 Mg, As Needed	Not Reported
Oxygen	C	Unk ((3) %10; Daily: Evening)	Not Reported
Fluconazole	C	150 Mg, As Needed (Daily)	Not Reported
Fluticasone	C	50 Mg, As Needed (Daily)	Not Reported
B 12	C	1000 Mg, 2x/Day (1 Morning 1 Evening)	Not Reported
Coq 10	C	200 Mg, 1x/Day (1 Morning)	Not Reported
Zyrtec	C	10 Mg, Daily (Morning)	Not Reported
Baby Aspirin	C	81 Mg, 1x/Day (1 Morning)	Not Reported
Vitamin D Nos	C	1000 Mg, 1x/Day (1 Morning)	Not Reported
Vitamin C	C	Unk, 1x/Day (1 Morning)	Not Reported
Magnesium	C	100 Mg, 1x/Day (1 Morning)	Not Reported
Folic Acid	C	400 Mg, 1x/Day (1 Morning)	Not Reported
Benadryl	C	Unk, 1x/Day (1 Morning)	Not Reported
Blink Tears	C	1 Gtt, As Needed (1 Drop	Not Reported

			In Each Eye)	
	Neilmed Sinus Rinse	C	Unk, As Needed	Not Reported
	Refresh Optive	C	Unk, 4x/Day	Not Reported
	Restasis	C	Unk	Not Reported
	Flax Oil	C	Unk (1 Morning)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	12132144	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-02266		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse	Cyclobenzaprine			S	Unknown			Aurobindo
	Sertraline			S	Unknown			Aurobindo
	Morphine			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	12134739	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201602006471		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Cardiotoxicity; Congestive Cardiomyopathy; Haemolytic Anaemia; Hepatojugular Reflux; Oedema Peripheral; Pericardial Effusion; Pleural Effusion; Pulmonary Arterial Hypertension; Thrombotic Microangiopathy	Gemzar			S	Intravenous (not otherwise specified)	Unk		Unknown
	Plaquenil /00072602/			S	Oral	Unk Unk, Bid		Not Reported
	Bromazepam			C	Oral	1.25 Mg, Qd		Not Reported
	Repaglinide			C		1 Kiu, Qd		Not Reported
	Repaglinide			C	Oral	1 Mg, Qd		Not Reported
	Paracetamol			C		4 G, Qd		Not Reported
	Eupantol			C	Oral	20 Mg, Qd		Not Reported

	Eupressyl /00631801/			C		30 Mg, Tid				Not Reported
	Diffu K			C	Oral	3 Df, Tid				Not Reported
	Lasilix /00032601/			C		Unk, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2016	12135245	EXPEDITED (15-DAY)		HO	GB-TEVA-637505ACC		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Folic Acid			S	Unknown			Ivax
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2016	11465382	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1602717		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Hand Deformity; Joint Swelling; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Peripheral Swelling; Physical Disability; Thrombocytosis	Naprosyn			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	Prescribed At 20 Mg A Day To Taper 2.5 Mg Weekly To Discontinue		Not Reported
	Orencia			S	Subcutaneous	Powder For Solution Intravenous		Not Reported
	Cimzia			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Gabapentin			C				Not Reported

	Lovastatin	C		Not Reported
	Pantoprazole	C		Not Reported
	Tramadol	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2016	11779296	EXPEDITED (15-DAY)		DS, OT	US-BAXALTA-2015BLT002899		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthralgia; Drug Specific Antibody Present; Exfoliative Rash; Fatigue; Hypersensitivity; Pruritus; Rash; Rash; Skin Burning Sensation; Skin Exfoliation; Swelling; Vomiting	Hyqvia			S	Subcutaneous	30 G, 1x A Month		Baxalta
	Hyqvia			S	Subcutaneous	7.5 Mg, Week 1		Baxalta
	Hyqvia			S		15 G, Week 2		Baxalta
	Hyqvia			S		22.5 G, Week 4		Baxalta
	Plaquenil			S	Unknown	Unk		Not Reported
	Vitamin B12			C	Unknown	Unk Unk, 1x A Month		Not Reported
	Premarin			C	Unknown	2 Dosage Forms, 1x A Day		Not Reported
	Norvasc			C	Unknown	Unk Unk, 1x A Day		Not Reported
	Prilosec			C	Unknown	Unk Unk, As Needed		Not Reported
	Calcium + Vit D			C	Unknown	Unk Unk, 1x A Day		Not Reported
	Hydroxyzine			C	Unknown	10 Mg, 3x A Day		Not Reported
	Proair Hfa			C	Unknown	2 Dosage Forms, 6x A Day As Needed		Not Reported
	Venlafaxine			C		37.5 Mg, 2x A Day		Not Reported
	Vesicare			C		Unk		Not Reported
	Xopenex Hfa			C		As Directed Every 4-6 Hours, As Needed		Not Reported
	Promethazine			C	Rectal	12.5 Mg, 3x A Day, As Needed		Not Reported
	Hizentra			C	Unknown	6 G, Mostly 1x A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2016	12137179	NON-EXPEDITED		HO	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-06		70 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urosepsis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Allopurinol			C				Not Reported
	Simvastatin			C				Not Reported
	Atacand			C				Not Reported
	Irbesartan			C				Not Reported
	Chlorthalidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2016	12137180	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-07		51 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Rash Papular	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	11684729	NON-EXPEDITED			US-AMGEN-USASP2015109720		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Device Issue; Eye Disorder; Gait Disturbance; Inappropriate Schedule Of Product Administration; Injection Site Pain; Pain; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12124072	EXPEDITED (15-DAY)		OT	PHHY2016BA023582		4 YR	Female	BIH

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Disease Recurrence; Erythema; Eyelid Rash; Myositis; Nasal Oedema; Product Use In Unapproved Indication; Skin Atrophy; Ulcer	Ciclosporin			S	Unknown			Novartis
	Methylprednisolone			S	Unknown	30 Mg/Kg, Three Boluses		Not Reported
	Methylprednisolone			S	Unknown	2 Mg/Kg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg/M2, Unk		Not Reported
	Apotex Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12139623	EXPEDITED (15-DAY)		HO	GB-ACCORD-038276		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Syncope	Methotrexate			S	Unknown			Accord
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen Pfizer			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2016	12142115	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2016131943		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardioplegia; Multiple Organ Dysfunction Syndrome; Poisoning Deliberate	Xanax	S	Oral	Unk		Pfizer
	Plaquenil /00072603/	S	Oral	Unk		Not Reported
	Oxycontin Lp	S	Oral	20 Mg, Unk		Not Reported
	Oxynorm	S	Oral	5 Mg, Unk		Not Reported
	Oxynorm	S	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	11927810	NON-EXPEDITED			US-PFIZER INC-2016025245		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Not Reported
	Terazosin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12131140	NON-EXPEDITED			US-PFIZER INC-2016120075		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Amira			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12144271	EXPEDITED (15-DAY)		HO	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-112564			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Folic Acid			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Ipca
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12144380	NON-EXPEDITED			US-PFIZER INC-2016081927		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Minocycline			S		Unk		Not Reported
	Cefdinir			S		Unk		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Chlorhexidine			S		Unk		Not Reported
	Thimerosal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12146267	EXPEDITED (15-DAY)		HO, LT	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-08		55 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Cardiac Arrest; Cardiomyopathy; Ventricular Tachycardia	Plaquenil			S	Oral			Not Reported
	Omeprazole			C				Not Reported
	Paracetamol			C				Not Reported
	Gemfibrozil			C				Not Reported
	Sulfasalazine			C				Not Reported
	Paroxetine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Etoricoxib			C				Not Reported
	Meloxicam			C				Not Reported
	Nadroparin Calcium			C				Not Reported

	Butrans			C						Not Reported
	Desloratadine			C						Not Reported
	Metoprolol Succinate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12147013	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2016-08		79 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage	Plaquenil			S				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12147259	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-07			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12147750	EXPEDITED (15-DAY)		HO	GB-WATSON-2016-04114		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Folic Acid			S	Oral	Unk		Watson
	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Oral	Unk		Watson
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Naproxen			S	Oral	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12150957	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016135351		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea;	Methotrexate Sodium			S				Pfizer

Vomiting; Weight Decreased	Sulfasalazine	S		Pfizer
	Plaquenil /00072603/	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2016	12153017	EXPEDITED (15-DAY)		OT	BR-ABBVIE-16K-020-1569697-00		21 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Anxiety; Exposure During Pregnancy; Gastric Disorder; Gastrooesophageal Reflux Disease	Humira			S	Subcutaneous			Not Reported
	Reuquinol			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Escitalopram			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2016	12156989	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2016-03273		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Respiratory Arrest	Zolpidem			S	Unknown			Aurobindo
	Hydroxychloroquine			S	Unknown			Not Reported
	Bupropion			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12160594	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-08			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fasciitis	Plaquenil			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Indocid			S	Oral			Not Reported
	Chrono-Indocid			S	Oral			Not Reported
	Cortancyl			C				Not Reported

		Hydrocortisone			C						Not Reported
		Metoject			C						Not Reported
		Speciafoldine			C						Not Reported
		Lansoprazole			C						Not Reported
		Orocal D(3)			C						Not Reported
		Oxycontin Lp			C						Not Reported
		Oxynormoro			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12160595	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-TR-2016-08		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiacetylcholine Receptor Antibody Positive; Asthenia; Extraocular Muscle Paresis; Muscular Weakness; Myasthenia Gravis; Somnolence	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12161430	EXPEDITED (15-DAY)		OT	IT-HOSPIRA-3196294		78 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purulence	Roactemra			S	Intravenous (not otherwise specified)	Every 28 Days		Not Reported
	Actonel			C				Not Reported
	Samyr /00882301/			C				Not Reported
	Dibase			C				Not Reported
	Folina /00024201/			C				Not Reported
	Cacit Vitamin D3			C				Not Reported
	Lansoprazole			C				Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Cardioaspirin			C				Not Reported
	Medrol /00049601/			C				Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2016	12162657	DIRECT					45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Rash	Hydroxychloroquine			S	Oral	1 Pill		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2016	11100044	EXPEDITED (15-DAY)		HO, OT	US-DSJP-DSU-2015-113826		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Anaemia; Cardiac Failure Congestive; Chronic Kidney Disease; Diarrhoea; Eye Infection; Fall; Gout; Haematochezia; Hypertension; Hypocalcaemia; Melaena; Oedema; Pericardial Effusion; Peripheral Swelling; Pneumonia	Benicar			S	Oral	10 Mg, Bid		Daiichi
	Benicar			S		1/2 (20 Mg) Tablet, Bid		Daiichi
	Revatio			S	Oral	20 Mg, Tid		Not Reported
	Revatio			S	Oral	20 Mg, Tid		Not Reported
	Revatio			S		20 Mg, Tid		Not Reported
	Revatio			S	Oral	20 Mg, Bid		Not Reported
	Verapamil Hcl			S	Oral	200 Mg, Bid		Not Reported
	Verapamil Hcl			S	Oral	200 Mg, Qd		Not Reported
	Verapamil Hcl			S		200 Mg, Qd		Not Reported
	Verapamil Hcl			S		400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported
	Lasix /00032601/			S	Oral	80 Mg, Qd		Not Reported
	Lasix /00032601/			S		40 Unk (1 In Am)		Not Reported
	Lasix /00032601/			S		Unk		Not Reported
	Lasix /00032601/			S	Oral	20 Mg, Qd In Am		Not Reported
	Lasix /00032601/			S		40 Unk, Unk (On Hold 40)		Not Reported
	Ranitidine			C		150 Mg, Bid		Not Reported
	Protonix			C	Oral	40 Mg, Qd In Pm		Not Reported

Methotrexate	C	Oral	2.5 Mg, (4 Tablets) Once Every 1 Wk On Thursday	Not Reported
Plaquenil /00072602/	C	Oral	200 Mg, Bid	Not Reported
Plaquenil /00072602/	C			Not Reported
Chondroitin Glucosamin	C	Oral	1500 Mg, Bid	Not Reported
Aspirin /00002701/	C		Unk	Not Reported
Proair Hfa	C	Oral	2 Puffs 4 Times A Day Prn	Not Reported
Folic Acid	C	Oral	800 Mg, Bid Am And Pm	Not Reported
Ferrous Sulfate	C		65 Mg, Qd 1 Am	Not Reported
Omega 3 Fish Oil /01334101/	C	Oral	2 Day Triple Strength 860 Epa/ 580 Dha	Not Reported
Calcium & Vitamin D /01483701/	C	Oral	Unk, Qd	Not Reported
Probiotics /07325001/	C	Oral	Unk, Qd	Not Reported
Mirapex	C		0.5 Mg, Qd 1 1/2 Pm	Not Reported
Uloric	C	Oral	40 Mg, Qd	Not Reported
Multivitamin /00097801/	C	Oral	Unk, Qd	Not Reported
Spironolactone	C		1/4 Tab Qam	Not Reported
Amlodipine Besylate	C		5 Mg, Bid	Not Reported
L-Thyroxin	C		75 Mg, Qd	Not Reported
Metoprolol	C		50 Mg, Bid	Not Reported
Potassium	C		Unk	Not Reported
Amlodipine Besilate	C		Unk	Not Reported
Plaquenil /00072602/	C		Unk	Not Reported
Rocephin	C			Not Reported
Synthroid	C			Not Reported
Tylenol /00020001/	C			Not Reported
Zithromax	C			Not Reported
Omeprazole	C			Not Reported
Polymyxin B -Trimethoprim Ophtha.	C			Not Reported
Restasis	C			Not Reported
Systane Balance	C			Not Reported
Vitamin C /00008001/	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2016	12162925	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-08		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Plaquenil			S	Oral			Not Reported
	Doxycycline			S	Oral			Not Reported
	Kayexalate			C				Not Reported
	Valium			C				Not Reported
	Movicol			C				Not Reported
	Uvedose			C				Not Reported
	Doliprane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	10867025	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2015066201		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Anaemia; Blood Creatine Increased; Cardiac Failure Congestive; Chronic Kidney Disease; Condition Aggravated; Diarrhoea; Eye Infection; Fall; Fatigue; Feeling Hot; Gastrooesophageal Reflux Disease; Gout; Haematochezia; Hypertension; Hypocalcaemia; Melaena; Oedema; Pericardial Effusion; Peripheral Swelling; Pneumonia; Pulmonary Oedema; Skin Abrasion; Skin Abrasion; Weight Increased	Benicar			S	Oral	10 Mg, 2x/Day		Not Reported
	Benicar			S		10 Mg (1/2 20 Mg Tablet), 2x/Day		Not Reported
	Revatio			S	Oral	20 Mg, 3x/Day		Pfizer
	Revatio			S	Oral	20 Mg, 3x/Day		Pfizer
	Revatio			S		20 Mg, 3x/Day		Pfizer
	Revatio			S	Oral	20 Mg, 2x/Day		Pfizer
	Verapamil Hcl			S	Oral	200 Mg, 2x/Day		Pfizer
	Verapamil Hcl			S	Oral	200 Mg, 1x/Day		Pfizer
	Verapamil Hcl			S		200 Mg, 1x/Day ((Pl X Cp 4864 200 Mg)		Pfizer
	Verapamil Hcl			S	Oral	400 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Lasix			S	Oral	80 Mg, 1x/Day		Not Reported

Lasix	S		40 One In Am	Not Reported
Lasix	S		40 Mg, 1x/Day	Not Reported
Lasix	S	Oral	20 Mg, 1x/Day (In Am)	Not Reported
Lasix	S		40 Mg, Unk (On Hold 40)	Not Reported
Ranitidine	C	Oral	150 Mg, 1x/Day	Not Reported
Ranitidine	C		150, 2 A Day	Not Reported
Protonix	C		40 Mg, 1x/Day	Not Reported
Methotrexate	C		4 Df, Weekly (4 Tab. 1 Day A Week)	Not Reported
Methotrexate	C		Unk (On Hold,Stop)	Not Reported
Methotrexate	C		2.5 Mg, Weekly (4 Tabs Weekly)	Not Reported
Plaquenil	C	Oral	200 Mg, 1x/Day	Not Reported
Plaquenil	C	Oral	200 Mg, 2x/Day	Not Reported
Plaquenil	C	Oral	200 Mg, Daily	Not Reported
Chondroitin Glucosamin	C	Oral	1500 Mg, 2x/Day	Not Reported
Aspirin	C		81 Mg, Unk	Not Reported
Aspirin	C		81 Unk, 1x/Day	Not Reported
Aspirin	C	Oral	81 Mg, Daily	Not Reported
Proair Hfa	C		2 Puffs, 4x A Day As Needed	Not Reported
Proair Hfa	C		2 Df, 4x/Day	Not Reported
Proair Hfa	C		90 Ug, 4x/Day (As Needed)	Not Reported
Folic Acid	C		1 A Day 800 Mcg Am. Pm	Not Reported
Folic Acid	C		Unk Unk, 1x/Day	Not Reported
Folic Acid	C	Oral	1 Mg, Daily	Not Reported
Ferrous Sulfate	C		Unk, 1x/Day	Not Reported
Ferrous Sulfate	C		65 Mg, Unk (Take With Food)	Not Reported
Omega 3 Fish Oil	C		Unk, 2x/Day (Triple	Not Reported

			Streanth 860 Epa /580dha)	
Calcium & Vitamin D	C		Unk, 1x/Day	Not Reported
Probiotics	C		Unk, 1x/Day	Not Reported
Mirapex	C		0.5 Mg Take 1/1/2pm	Not Reported
Mirapex	C	Oral	0.5 Mg, 1x/Day	Not Reported
Uloric	C		On Hold; Still Taking	Not Reported
Multivitamin	C	Oral	1 Df, Daily	Not Reported
Spironolactone	C		150 Mg, 2x/Day (6 Tab 2x A Day)	Not Reported
Spironolactone	C		Unk (Decreased To ¼ Tab)	Not Reported
Amlodipine Besilate	C		8 Mg, 2x/Day	Not Reported
Amlodipine Besilate	C		5 Mg, 2x/Day	Not Reported
Amlodipine Besilate	C		5 Mg, 1x/Day Hs	Not Reported
L-Thyroxin	C		75 Mg, 1x/Day	Not Reported
L-Thyroxin	C		75 Mg, 5 Days 1x/Day, 2 Days 1/2 Tab	Not Reported
Metoprolol	C	Oral	50 Mg, 2x/Day	Not Reported
Potassium	C		Unk	Not Reported
Rocephin	C	Intravenous (not otherwise specified)	1 G, Daily (1 Ea, 100 Ml/Hr)	Not Reported
Synthroid	C	Oral	75 Ug, Daily	Not Reported
Tylenol	C	Oral	650 Mg, 4x/Day	Not Reported
Tylenol	C			Not Reported
Zithromax	C	Intravenous (not otherwise specified)	500 Mg, Daily (250 Ml/Hr)	Not Reported
Omeprazole	C	Oral	20 Mg, Daily	Not Reported
Polymyxin B -Trimethoprim Ophtha.	C	Ophthalmic	Unk, 3x/Day ? (1 Drop)	Not Reported
Fish Oil	C	Oral	Unk	Not Reported
Restasis	C	Ophthalmic	Unk, Daily (1 Drop)	Not Reported

Systane Balance	C		Unk, 3x/Day (1 Drop Both Eyes)	Not Reported
Vitamin C /00008001/	C		Unk	Not Reported
Furosemide	C		10 Mg, Daily	Not Reported
Lutein	C		20 Mg, 2x/Day	Not Reported
Pantoprazole	C	Oral	40 Mg, Daily	Not Reported
Norvasc	C	Oral	5 Mg, Daily	Not Reported
Allopurinol	C		Unk	Not Reported
Augmentin	C	Oral	125 Mg, 2x/Day (Every 12 Hours)	Not Reported
Proventil	C		25 Mg, Every 6 Hours	Not Reported
Levothyroxine	C	Oral	75 Ug, Daily (Every Morning Before Breakfast)	Not Reported
Lopresor	C	Oral	50 Mg, Daily	Not Reported
Aldactone	C		6.25 Mg, Daily (1/4 Of 25mg Tablet)	Not Reported
Isoptin	C	Oral	100 Mg, Daily	Not Reported
Calan	C	Oral	100 Mg, Daily	Not Reported
Amlodipine Besilate	C		Unk	Not Reported
Synthroid	C		Unk	Not Reported
Tylenol /00020001/	C		Unk	Not Reported
Omeprazole	C		Unk	Not Reported
Polymyxin B -Trimethoprim Ophtha.	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	11718877	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015201342		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Large Intestine Polyp; Ligament Rupture;	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer

Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Weight Increased	Plaquenil	S	400 Mg, Daily		Not Reported
	Leflunomide	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Invokana	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12167299	EXPEDITED (15-DAY)		HO, LT	FR-MUNDIPHARMA DS AND PHARMACOVIGILANCE -GBR-2016-0		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardioplegia; Multiple Organ Dysfunction Syndrome; Poisoning Deliberate	Oxycontin Lp 20 Mg, Comprime Pellicule A Liberation Prolongee			S	Oral	Unk		Purdue
	Oxynorm, Gelule			S	Oral	Unk		Purdue
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Xanax			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12169462	EXPEDITED (15-DAY)		CA, DE	FR-PFIZER INC-2016147263			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Dandy-Walker Syndrome; Maternal Exposure During Pregnancy	Xanax			S	Transplacental	0.75 Mg, 1x/Day At Bedtime		Pfizer
	Coumadine			S	Transplacental	Unk		Not Reported
	Plaquenil /00072602/			S	Transplacental	100 Mg, 2x/Day		Not Reported
	Cortancyl			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Aspegic Baby			S	Transplacental	100 Mg, 1x/Day		Not Reported
	Mopral /00661201/			S	Transplacental	1 Df, 2x/Day		Not Reported
	Cacit /00944201/			S	Transplacental	1 Df, 1x/Day		Not Reported
	Clareal			C	Transplacental	0.075 Mg, Unk		Not Reported

Lovenox	C	Transplacental	"0.6" Twice Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2016	12171014	DIRECT		DS, HO			71 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Cellulitis; Type 2 Diabetes Mellitus; Wound Secretion	Plaquenil			S	Oral	2 Per Day Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	11473478	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-20		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Kidney Injury; Acute Kidney Injury; Blood Folate Decreased; Dehydration; Diarrhoea; Dizziness; Gastroenteritis; Hypokalaemia; Hypotension; Impaired Healing; Infusion Site Erythema; Infusion Site Haematoma; Infusion Site Haemorrhage; Infusion Site Infection; Infusion Site Pain; Infusion Site Pruritus; Infusion Site Swelling; Infusion Site Warmth; Injection Site Discharge; Malaise; Nasal Congestion; Nausea; Oedema; Pancreatitis Acute; Pancytopenia; Pyrexia; Rash; Retroperitoneal	Plaquenil			S	Oral			Not Reported
	Remodulin			S	Subcutaneous			Not Reported
	Remodulin			S	Subcutaneous			Not Reported
	Remodulin			S	Subcutaneous			Not Reported
	Remodulin			S	Subcutaneous			Not Reported
	Letairis			S	Oral			Not Reported
	Letairis			S				Not Reported
	Letairis			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Xanax			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Nystatin			C	Unknown			Not Reported
	Protonix			C	Unknown			Not Reported

Lymphadenopathy; Thrombocytopenia; Trichomoniasis; Urinary Tract Infection; Vomiting	Prochlorperazine			C	Unknown	Not Reported
	Risperdal			C	Unknown	Not Reported
	Simethicone			C	Unknown	Not Reported
	Potassium Chloride			C	Unknown	Not Reported
	Sucralfate			C	Unknown	Not Reported
	Chlorpromazine			C	Unknown	Not Reported
	Erythromycin			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	11832604	EXPEDITED (15-DAY)		OT	US-ROXANE LABORATORIES, INC.-2015-RO-02070RO			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Chronic Kidney Disease; Glomerular Filtration Rate Decreased	Furosemide Tablets Usp, 80 Mg			S	Oral	80 Mg		Roxane
	Revatio			S	Unknown	60 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Verapamil			C	Unknown			Not Reported
	Benicar			C	Unknown	20 Mg		Not Reported
	Amlodipine Besilate			C	Unknown	10 Mg		Not Reported
	Ranitidine			C	Unknown	300 Mg		Not Reported
	Plaquenil			C	Unknown			Not Reported
	Chondroitin Glucosamin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Proair Hfa			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ferrous Sulfate			C	Unknown			Not Reported
	Omega 3 Fish Oil			C	Unknown			Not Reported
	Calcium And Vitamin D			C	Unknown			Not Reported
	Probiotics			C	Unknown			Not Reported

	Mirapex	C	Unknown	0.75 Mg		Not Reported
	Uloric	C	Unknown	100 Mg		Not Reported
	Multivitamin	C	Unknown			Not Reported
	Spironolactone	C	Unknown	25 Mg		Not Reported
	L-Thyroxin	C	Unknown	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12171404	EXPEDITED (15-DAY)		HO, LT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-09		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardioplegia; Multiple Organ Dysfunction Syndrome; Poisoning Deliberate	Plaquenil			S	Oral			Not Reported
	Oxycontin Lp			S	Oral			Not Reported
	Oxynorm			S	Oral			Not Reported
	Xanax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12171728	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-08			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dizziness; Drug Ineffective; Fatigue; Hypertension; Nasopharyngitis; Palpitations; Peripheral Swelling; Rheumatoid Arthritis; Throat Irritation	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12171730	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-09		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Unevaluable Event	Plaquenil			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Sulfasazine			S	Unknown	Not Reported
	Methotrexate Sodium			S	Subcutaneous	Not Reported
	Humira			S	Unknown	Not Reported
	Rituxan			S	Unknown	Not Reported
	Azathioprine			S	Unknown	Not Reported
	Minocycline			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12172092	EXPEDITED (15-DAY)		OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-061		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Naproxen			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Misoprostol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12172094	EXPEDITED (15-DAY)		OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-063		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Incomplete; Abortion Spontaneous; Exposure During Pregnancy; Haemorrhage; Rheumatoid Arthritis	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2016	12172100	EXPEDITED (15-DAY)		HO, OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-069		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen			S	Unknown			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

		Triamcinolone			S	Unknown				Not Reported
		Triamcinolone			S	Unknown				Not Reported
		Triamcinolone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2016	12174445	EXPEDITED (15-DAY)		HO, OT	AU-CIPLA LTD.-2013AU00814			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Disease Progression; Lung Adenocarcinoma; Myositis; Recall Phenomenon; Therapeutic Response Decreased	Gemcitabine			S	Unknown	Unk		Cipla
	Carboplatin			S	Unknown	Unk		Cipla
	Fluorouracil			S	Unknown	Unk		Cipla
	Prednisolone			S	Unknown	50 Mg, Qd		Cipla
	Prednisolone			S	Unknown	10 Mg, Qd		Cipla
	Prednisolone			S	Unknown	50 Mg, Qd		Cipla
	Prednisolone			S	Unknown	10 Mg, Qd		Cipla
	Mytomicin C			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	11624375	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477186-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Erythema; Fatigue; Malaise; Pharyngeal Oedema; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12175303	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-09		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Skin Burning Sensation; Skin Exfoliation; Swelling Face	Plaquenil			S	Oral			Not Reported
	Orocal D(3)			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12179561	EXPEDITED (15-DAY)		CA, DE	FR-ASTRAZENECA-2016SE27165			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Dandy-Walker Syndrome	Mopral			S	Transplacental			Not Reported
	Aspegic Nourrissons			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Xanax			S	Transplacental			Not Reported
	Cacit [Calcium Carbonate]			S	Transplacental			Not Reported
	Coumadine			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2016	12180403	DIRECT		OT			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain	Hydroxychloroquine 200mg Tabs			S	Oral	2 Pills Twice Daily Mouth		Mylan
	Tamsulosin			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	11624377	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477043-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Herpes Zoster; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Pneumonia Viral; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Day 1, Day 15		Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Ativan			C				Not Reported
	Benadryl			C				Not Reported
	Dilaudid			C				Not Reported
	Enablex			C				Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C		Metered Dose		Not Reported
	Pantoprazole Sodium			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C	Vaginal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	11898851	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2015-44		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Drug Monitoring Procedure Incorrectly Performed; Neutropenia; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Zaponex		S	Oral	Not Reported
	Zaponex		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12160462	NON-EXPEDITED			US-PFIZER INC-2016118902		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12179594	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-09			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Valve Calcification; Pericardial Effusion; Vascular Calcification	Plaquenil			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2016	12181081	NON-EXPEDITED		HO	DE-JNJFOC-20160210576		85 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Haemorrhage	Imbruvica			S	Oral			Not Reported
	Imbruvica			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported

	Quensyl			S	Oral	Not Reported
	Allopurinol			C	Oral	Not Reported
	Metoprolol			C	Oral	Not Reported
	Madopar			C	Oral	Not Reported
	Ramipril			C	Oral	Not Reported
	Amlodipine			C	Oral	Not Reported
	Furosemide			C	Oral	Not Reported
	Pantozol			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	11843677	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015134316		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Fluid Drainage; Psoriatic Arthropathy; Rheumatoid Arthritis; Sjogren'S Syndrome; Synovial Cyst; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Qwk		Not Reported
	Plaquinol			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported
	Arava			C	Oral	10 Mg, Unk		Not Reported
	Marijuana			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12183662	NON-EXPEDITED			US-PFIZER INC-2016132685		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12185272	EXPEDITED (15-DAY)		HO	PHHY2016CA033835		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Novartis
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12185377	EXPEDITED (15-DAY)		HO	CA-MYLANLABS-2016M1011046			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Mylan
	Sulfasalazine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2016	12185381	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2016M1011250			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Incomplete; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	400 Mg/Day		Not Reported
	Prednisolone			S	Unknown	2.5 Mg/Day		Not Reported
	Acetylsalicylic Acid			S	Unknown	100 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2016	12190731	DIRECT	Y	HO			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angioedema	Hydroxychloroquine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12191038	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-09		14 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphangioma	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12191052	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-09		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomegaly; Cardiomyopathy; Dilatation Ventricular; Dyspnoea Exertional; Ejection Fraction Decreased; Left Atrial Enlargement; Left Ventricular Hypertrophy; Myocardial Oedema; Right Atrial Enlargement; Troponin Increased; Ventricular Hypertrophy; Ventricular Hypokinesia	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12191053	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-10			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Viral Infection	Plaquenil			S	Oral			Not Reported

	Enbrel			S						Not Reported
	Enbrel			S						Not Reported
	Actemra			S						Not Reported
	Xeljanz			C						Not Reported
	Methotrexate			C						Not Reported
	Cymbalta			C						Not Reported
	Folic Acid			C						Not Reported
	Simponi			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12191055	EXPEDITED (15-DAY)		HO, LT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-10		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Decreased; Blood Calcium Decreased; Blood Chloride Decreased; Blood Sodium Decreased; Dizziness; Dyspnoea; Electrolyte Imbalance; Lethargy; Loss Of Consciousness; Palpitations; Rash; Skin Burning Sensation; Skin Exfoliation; Somnolence; Swelling; Vision Blurred	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12191056	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-10		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Tinnitus; Visual Impairment	Hydroxychloroquine Sulfate			S				Not Reported
	Asa			C				Not Reported
	Oxyneo			C				Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12191923	NON-EXPEDITED			US-PFIZER INC-2016109022			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Pruritus; Rash	Lomotil			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2016	12192007	EXPEDITED (15-DAY)		DS, OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-09		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinitis; Visual Impairment	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12139296	EXPEDITED (15-DAY)		OT	CA-ROCHE-1719415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Drug Hypersensitivity; Drug Ineffective; Furuncle; Hand Deformity; Ovarian Neoplasm; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12167427	NON-EXPEDITED			US-PFIZER INC-2016119707		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196024	EXPEDITED (15-DAY)		DE	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Pneumonia	Hydroxychloroquine Sulfate			S				Not Reported
	Bupropion			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Mirtazapine			S				Not Reported
	Pristiq			S				Not Reported
	Venlafaxine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196025	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine Sulfate			S				Not Reported
	Aleve			S				Not Reported
	Folic Acid			S				Not Reported
	Methotrexate			S				Not Reported
	Pantoloc			S				Not Reported
	Synthroid			S				Not Reported

	Vitalux			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196026	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Myfortic			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196027	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis; Headache; Pneumonia; Psoriasis	Plaquenil			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196295	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201603-000332		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity	Hydroxychloroquine Sulfate			S				Ipca
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12196300	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC201603-000333		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Joint Tuberculosis; Sjogren'S Syndrome	Hydroxychloroquine Sulfate			S						Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12197764	DIRECT	Y	DE, HO			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Sepsis; Bronchial Secretion Retention; Pneumonia Bacterial; Pneumothorax; Post Procedural Complication; Respiratory Failure	Hydroxychloroquine, 400 Mg Prasco			S	Oral			Prasco
	Levothyroxine			C				Not Reported
	Aspirin			C				Not Reported
	Ferosul			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2016	12199510	DIRECT	Y	HO			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Test Positive; Diarrhoea	Hydroxychloroquin Sulfate			S				Not Reported
	Ertapenem			S				Not Reported
	Pantoprazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	9090876	EXPEDITED (15-DAY)		OT	DE-ROCHE-1183980		71 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Influenza; Rheumatoid Arthritis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Quensyl			S	Unknown			Not Reported
	Prednisolon			S	Unknown			Not Reported
	Prednisolon			S	Unknown			Not Reported
	Nebivolol			C	Unknown			Not Reported
	Simva			C				Not Reported
	Gabapentin			C				Not Reported

		Forair (Germany)			C					Not Reported
		Iscover			C					Not Reported
		Provas (Germany)			C					Not Reported
		Levomepromazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12198903	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-052130		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S		Unk		Bayer
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Tocilizumab			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Every Two Days		Not Reported
	Prednisone			S				Not Reported
	Methotrexate			C				Not Reported
	Plaquenil			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200054	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-10			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cyclobenzaprine			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

		Naproxen			C						Not Reported
		Sulfasalazine			C						Not Reported
		Synthroid			C						Not Reported
		Tylenol W/Codeine No. 3			C						Not Reported
		Vitamin B Complex			C						Not Reported
		Garlic			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200055	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-10		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm Malignant; Lymphadenopathy; Rheumatoid Arthritis; Vision Blurred	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin B6			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200057	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Nicoderm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200058	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Methotrexate			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Humira			S	Unknown				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200059	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-10		23 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Rupture Of Membranes	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Prednisolon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12200060	EXPEDITED (15-DAY)		DE	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-10			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Dandy-Walker Syndrome; Foetal Exposure During Pregnancy	Plaquenil			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Aspegic Nourrissons			S	Transplacental			Not Reported
	Mopral			S	Transplacental			Not Reported
	Cacit [Calcium Carbonate]			S	Transplacental			Not Reported
	Xanax			S	Unknown			Not Reported
	Coumadine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12201847	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2016034217		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Asthenia; Back Pain; Blindness; Constipation; Dyspepsia; Fatigue; Headache; Joint Injury; Joint Swelling; Malaise; Muscle Spasms; Photosensitivity Reaction; Synovitis; Treatment Failure	Enbrel		S	Unknown	Unk		Amgen
	Plaquenil /00072602/		S	Oral	200 Mg, Qwk		Not Reported
	Humira		S	Unknown			Not Reported
	Sulfasalazine		S	Unknown			Not Reported
	Naproxen		C	Oral	500 Mg, Bid		Not Reported
	Prednisone		C	Oral	5 Mg, Bid		Not Reported
	Depo Medrol		C	Intramuscular	120 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2016	12202083	EXPEDITED (15-DAY)		OT	GXKR2016DE001438			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small For Dates Baby	Citalopram			S	Transplacental	40 [Mg/D]		Novartis
	Quensyl			S	Transplacental	200 [Mg/D]; Gw 15 - 41.1		Not Reported
	Clexane			C	Transplacental	40 [Mg/D]; Gw 4-41.1		Not Reported
	L-Thyroxine//Levothyroxine			C	Transplacental	75 [Mg/D]/ In The Beginning 25 Mg/D Later Dosage Increased To 75 Mg/D		Not Reported
	Fluomizin			C	Transplacental	10 [Mg/D]; Gw 26-27		Not Reported
	Biofanal			C	Transplacental	Unk; Gw 37-38		Not Reported
	Amoxihexal			C	Transplacental	3000 [Mg/D]; Gw 37-39		Not Reported
	Folsaeure			C	Transplacental	0.4 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12127841	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-07			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diabetic Neuropathy; Drug Ineffective; Finger	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Amputation; Pain; Pain	Simponi			C					Not Reported
	Methotrexate			C					Not Reported
	Alendronate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12203660	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Drug Intolerance; Gastrointestinal Disorder; Impaired Self-Care; Nausea; Nausea; Rheumatoid Arthritis; Sedation; Somnolence	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cortisone			C				Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12203662	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204232	EXPEDITED (15-DAY)		OT	BR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-BR-2016-14		54 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S					Not Reported
	Prednisone			S					Not Reported
	Prednisone			S					Not Reported
	Ibuprofen			S					Not Reported
	Methotrexate			S					Not Reported
	Naproxen			S					Not Reported
	Adalimumab			S					Not Reported
	Tocilizumab			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204233	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204234	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Levothyroxine			C				Not Reported
	Mobicox			C				Not Reported
	Nexium			C				Not Reported
	Nortriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204235	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Vision Blurred	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204236	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-13		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Disorder; Leukopenia; Retinal Toxicity; White Blood Cell Count Decreased	Plaquenil			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204237	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-12		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Myalgia	Plaquenil			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Triatec (Ramipril)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204239	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-13			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Glomerulonephritis;	Plaquenil			S				Not Reported
	Dilantin			C				Not Reported

Seizure; Systemic Lupus Erythematosus	Keppra			C		Not Reported
	Depakote			C		Not Reported
	Neurontin			C		Not Reported
	Cytoxan			C		Not Reported
	Prednisone			C		Not Reported
	Imuran			C		Not Reported
	Clinoril			C		Not Reported
	Cellcept			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204371	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Gammagard			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204372	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Maternal Exposure Before Pregnancy; Placental Insufficiency; Premature Delivery	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204373	NON-EXPEDITED		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-13		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Erythropoietin Antibody Negative; Drug Ineffective; Haemoglobin Decreased	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Mycophenolate Mofetil		S	Unknown	Not Reported
	Eprex		S	Subcutaneous	Not Reported
	Eprex		S		Not Reported
	Eprex		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204376	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-13		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Infusion Related Reaction; Migraine; Off Label Use; Post-Traumatic Neck Syndrome; Road Traffic Accident	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zoplicone			C				Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Diflucan			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Euro-D			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Methylprednisolone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204377	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-13		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12204378	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-13		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Diarrhoea	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cortisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2016	12205758	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1011654			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Diarrhoea; Drug Interaction; Flatulence; Muscle Spasms; Nausea; Pollakiuria	Ranitidine Mylan 150 Mg			S		150 Mg, Unk		Mylan
	Hydroxychloroquine Sulphate			S	Oral	400 Mg, Bid		Mylan
	Sertraline Actavis			C		Unk		Mylan
	Propranolol Actavis			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	11917052	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Folic Acid	C			Not Reported
	Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12206389	NON-EXPEDITED			US-AMGEN-USASP2016034131		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg,Bid		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12208155	EXPEDITED (15-DAY)		CA	GXKR2016DE001580			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect	Lamotrigine			S	Transplacental	350 [Mg/D (Bis 150)]		Novartis
	Metoprolol			S	Transplacental	100 [Mg/D (2 X 50)]		Not Reported
	Quensyl			S	Transplacental	200 [Mg/D]		Not Reported
	Marcumar			C	Transplacental	Unk Ukn, Unk		Not Reported
	Enoxaparin			C	Transplacental	80 [Mg/D (2 X 40)]		Not Reported
	Ass			C	Transplacental	100 [Mg/D]		Not Reported
	Folsaeure			C	Transplacental	5 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12208180	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-14		42 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Diarrhoea; Drug Interaction; Flatulence; Muscle Spasms; Nausea; Pollakiuria	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Ranitidine			S	Unknown			Not Reported
	Sertraline			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12208292	EXPEDITED (15-DAY)		HO, OT	ES-BAYER-2016-053403			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystic Fibrosis; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Acetylsalicylic Acid (> 100 Mg)			S	Transplacental			Bayer
	Acetylsalicylic Acid (> 100 Mg)			S	Transplacental			Bayer
	Hydroxychloroquine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2016	12208410	EXPEDITED (15-DAY)		OT	DE-TEVA-645072GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Citalopram			S	Transplacental	40 Milligram Daily;		Pliva
	Quensyl			S	Transplacental	200 Milligram Daily;		Not Reported
	Clexane 40			C	Transplacental	40 Milligram Daily;		Not Reported
	L-Thyroxin			C	Transplacental	75 Microgram Daily; In The Beginning 25 Microgram/D Later Dosage Increased To 75 Microgram/D		Not Reported

	Fluomizin	C	Transplacental	10 Milligram Daily;		Not Reported
	Biofanal	C	Transplacental			Not Reported
	Amoxihexal	C	Transplacental	3000 Milligram Daily;		Not Reported
	Folio	C	Transplacental	.4 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12211919	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016035088		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Bone Erosion; C-Reactive Protein Abnormal; Fear Of Disease; Gait Inability; Infection; Osteitis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Enbrel			S	Subcutaneous	25 Mg, Twice Per Week		Amgen
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	1.5 G, Twice A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12212150	EXPEDITED (15-DAY)		CA, DE, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-019466			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Dandy-Walker Syndrome; Foetal Exposure During Pregnancy	Coumadine			S	Transplacental	Unk		Bristol Myers Squibb
	Plaquenil /00072603/			S	Transplacental	100 Mg, Bid		Not Reported
	Cortancyl			S	Transplacental	10 Mg, Qd		Not Reported
	Aspegic /00002703/			S	Transplacental	100 Mg, Qd		Not Reported
	Mopral /00661201/			S	Transplacental	1 Df, Bid		Not Reported
	Cacit /00944201/			S	Transplacental	1 Df, Qd		Not Reported
	Xanax			S	Transplacental	0.75 Mg, Qd		Not Reported
	Lovenox			S	Transplacental	1 Df, Bid		Not Reported
	Clareal			S	Transplacental	0.075 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12213219	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3214252		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Methotrexate			S	Unknown	11 Years		Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown	3 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Vagifem			C	Vaginal			Not Reported
	Darifenacin Hydrobromide			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Cortisone			C	Intramuscular			Not Reported
	Cortisone			C	Intra-articular			Not Reported
	Norflex /00018303/			C				Not Reported
	Remicade			S	Unknown			Not Reported
	Omnaris			C				Not Reported
	Arava			C		Every 1 Day		Not Reported
	Furosemide			C				Not Reported
	Synthroid			C				Not Reported
	Ativan			C		Every 1 Day		Not Reported
	Dilaudid			C		Every 1 Day		Not Reported
	Loperamide			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12213757	NON-EXPEDITED			US-AMGEN-USASL2016035898		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Treatment Failure	Enbrel		S	Unknown	50 Mg, Qwk	Amgen
	Methotrexate		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Hcq		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12214224	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2016M1012390			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Foetal Exposure During Pregnancy; Small For Dates Baby	Citalopram Mylan			S	Transplacental	40 [Mg/D]		Mylan
	Hydroxychloroquine Sulfate			S	Transplacental	200 [Mg/D]		Not Reported
	Clexane			C	Transplacental	40 [Mg/D]		Mylan
	L-Thyroxin			C	Transplacental	75 [Mg/D]/ In The Beginning 25 Mg/D Later Dosage Increased To 75 Mg/D		Mylan
	Fluomizin			C	Transplacental	10 [Mg/D]		Mylan
	Biofanal			C	Transplacental	Unk		Mylan
	Amoxihexal			C	Transplacental	3000 [Mg/D]		Mylan
	Folio			C	Transplacental	0.4 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2016	12214230	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2016M1012389			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Azathioprine Mylan			S	Transplacental	50 Mg, Qd (50 [Mg/D])		Mylan
	Quensyl			S	Transplacental	400 [Mg/D]/ Maybe Higher Dosage (2 X 400 Mg/D) For Several Weeks		Mylan
	Prednisolon /00016201/			C	Transplacental	5 Mg, Qd (5 [Mg/D])		Mylan

	Vigantoletten	C	Transplacental	500 Iu, Qd (500 [I.E./D]/ Unknown When And How Long)		Mylan
	Folic Acid	C	Transplacental	Unk		Mylan
	Clexane	C	Transplacental	40 Mg, Qd (40 [Mg/D])		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	11645423	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-31		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Hyperlipasaemia; Rash Pustular	Plaquenil			S	Oral			Not Reported
	Cortancyl			C				Not Reported
	Logimax			C				Not Reported
	Imeth			C				Not Reported
	Eucreas			C				Not Reported
	Rilmenidine			C				Not Reported
	Speciafoldine			C				Not Reported
	Telmisartan			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12212048	NON-EXPEDITED			US-PFIZER INC-2016162175		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Treatment Noncompliance	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Daily (200 Mg, Take 2 Tablets By Oral Route Every Day)		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12217764	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/16/0078137		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Citalopram			S	Transplacental			Not Reported
	Quensyl			S	Transplacental			Not Reported
	Clexane 40			C	Transplacental			Not Reported
	Levothyroxine Sodium			C	Transplacental			Not Reported
	Fluomizin			C	Transplacental			Not Reported
	Biofanal			C	Transplacental			Not Reported
	Amoxihexal			C	Transplacental			Not Reported
	Folio			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12217969	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/16/0078268		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Vaginosis; Exposure During Pregnancy; Sinusitis	Citalopram			S	Oral			Not Reported
	Quensyl			S	Oral			Not Reported
	Clexane 40			C	Subcutaneous			Not Reported
	Levothyroxine Sodium			C	Oral			Not Reported
	Fluomizin			C	Vaginal			Not Reported
	Biofanal			C	Vaginal			Not Reported
	Amoxihexal			C	Oral			Not Reported
	Folio			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12218843	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2016M1013043			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiotoxicity	Hydroxychloroquine	S	Unknown	600mg/Day		Not Reported
	Doxycycline	C	Unknown	200mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12224209	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000131		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S	Oral			Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg, Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	11871704	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015463093		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Large Intestine Polyp	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S				Pfizer
	Omeprazole			S		40 Mg, 2x/Day		Not Reported
	Lisinopril			S		1x/Day (5/6.25 Mg)		Not Reported
	Hydroxychloroquine			S		450 Mg, 1x/Day (1½ Tab A Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12199444	NON-EXPEDITED			US-PFIZER INC-2016162162			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

	Plaquenil	S	Unk		Not Reported
	Arava	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12225462	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-15		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small For Dates Baby	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Citalopram			S	Transplacental			Not Reported
	Clexane			C	Transplacental			Not Reported
	L-Thyroxin			C	Transplacental			Not Reported
	Fluomizin			C	Transplacental			Not Reported
	Biofanal			C	Transplacental			Not Reported
	Amoxihexal			C	Transplacental			Not Reported
	Folio			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2016	12225463	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-15		36 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Sinusitis; Vaginal Infection	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Citalopram			S	Oral			Not Reported
	Clexane			C				Not Reported
	L-Thyroxin			C				Not Reported
	L-Thyroxin			C				Not Reported
	Fluomizin			C				Not Reported
	Biofanal			C				Not Reported
	Amoxihexal			C				Not Reported
	Folio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12184683	EXPEDITED (15-DAY)		OT	CA-SA-2016SA047230		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cough; Ear Infection; Fatigue; Headache; Migraine; Nasopharyngitis; Nausea; Non-Cardiac Chest Pain; Pneumonia	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12213928	EXPEDITED (15-DAY)		OT	DE-WATSON-2016-06242		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Citalopram (Unknown)			S	Transplacental	40 Mg, Daily		Watson
	Quensyl			S	Transplacental	200 Mg, Daily		Not Reported
	Clexan			C	Transplacental	40 Mg, Daily		Not Reported
	L-Thyroxin			C	Transplacental	75 Mg, Daily		Not Reported
	Fluomizin			C	Transplacental	10 Mg, Daily		Not Reported
	Biofanal			C	Transplacental	Unk Unk, Unknown		Not Reported
	Amoxihexal			C	Transplacental	3 Df, Daily		Not Reported
	Folio			C	Transplacental	0.4 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12228228	EXPEDITED (15-DAY)		CA, OT	DE-DRREDDYS-GER/GER/16/0078236		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During	Metoprolol			S	Transplacental			Not Reported

Pregnancy; Foetal Growth Restriction	Lamotrigine		S	Transplacental		Not Reported
	Quensyl		S	Transplacental		Not Reported
	Marcumar		C	Transplacental		Not Reported
	Clexane 40		C	Transplacental		Not Reported
	Ass 100		C	Transplacental		Not Reported
	Folsaeure		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12228584	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-114152		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small For Dates Baby	Citalopram			S	Transplacental	40 Mg, Daily, From 0-41.1 Gestational Week		Sun
	Quensyl			S	Transplacental	200 Mg, Daily, From 15-41.1 Gestational Week		Not Reported
	Clexane 40			C	Transplacental	40 Mg, Daily, From 4-41.1 Gestational Week		Not Reported
	L-Thyroxin			C	Transplacental	75 Mg, Daily, From 0-41.1 Gestational Week		Not Reported
	Fluomizin			C	Transplacental	10 Mg, Daily, From 26-27 Gestational Week		Not Reported
	Biofanal			C	Transplacental	From 37-38 Gestational Week		Not Reported
	Amoxihexal			C	Transplacental	1000 Mg, Tid, From 37-39 Gestational Week		Not Reported
	Folio			C	Transplacental	0.4 Mg, Daily, From 0-14.4 Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12231466	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000129		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Treatment Failure	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Cimzia			S		Unk		Not Reported
	Remicade			S		Unk, Powder For Solution		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2016	12232628	EXPEDITED (15-DAY)		CA	DE-VALIDUS PHARMACEUTICALS LLC-DE-2016VAL000655		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect	Metoprolol Tartrate			S	Transplacental	100 [Mg/D (2 X 50)]		Validus
	Lamotrigine			S	Transplacental	350 [Mg/D (Bis 150)]		Not Reported
	Quensyl			S	Transplacental	200 [Mg/D]		Not Reported
	Marcumar			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Ass			C		Unk		Not Reported
	Folsaeure			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2016	12233033	NON-EXPEDITED			US-AMGEN-USASL2016036866		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Issue; Device Leakage; Incorrect Dose Administered; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2016	12233055	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2016M1012765			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy	Metoprolol			S	Transplacental	50 Mg, Bid (100 [Mg/D (2 X 50)])		Not Reported
	Lamotrigine			S	Transplacental	175 Mg, Bid (350 [Mg/D (Bis 150)])		Not Reported
	Quensyl			S	Transplacental	200 Mg, Qd		Mylan
	Marcumar			C	Transplacental	Unk		Mylan
	Clexane			C	Transplacental	40 Mg, Bid, 80 [Mg/D (2 X 40)]		Mylan
	Ass			C	Transplacental	100 Mg, Qd		Mylan
	Folic Acid			C	Transplacental	5 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	11511123	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-21		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Drug Ineffective; Fatigue; Limb Injury	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12179886	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-09			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12234282	EXPEDITED (15-DAY)		CA	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-16		28 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anterior Chamber Cleavage Syndrome; Maternal Exposure During Pregnancy	Hydroxychloroquine Sulfate	S	Transplacental		Not Reported
	Methotrexate	S	Transplacental		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12234284	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-15		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12234285	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-15		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12234657	EXPEDITED (15-DAY)		HO	TR-MYLANLABS-2016M1013844			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12235286	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-16			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Gait Disturbance; Joint Stiffness; Pain; Peripheral	Plaquenil			S				Not Reported
	Aspirin			C				Not Reported
	Coumadin			C				Not Reported

Swelling	Coversyl			C						Not Reported
	Atenolol			C						Not Reported
	Hydrochlorothiazide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12235697	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2016SE35122		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delusion; Fatigue	Omeprazen			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Airtal			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2016	12235842	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000151		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Pneumonia Viral; Stomatitis; Tenderness	Methotrexate Sodium			S		3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	7.1429 Mg (25 Mg, 2 In 1 W)		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S		25 Mg (750 Mg, 1 In 1 Mo)		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Remicade			S		10 Mg (300 Mg, 1 In 1 Mo)		Not Reported
	Arava			C		20 Mg, 1 D		Not Reported
	Ativan			C		1 Mg, 1 D		Not Reported
	Cortisone			C	Intramuscular	Unk		Not Reported
	Cortisone			C	Intra-articular	Unk		Not Reported
	Darifenacin Hydrobromide			C		Unk		Not Reported
	Dilaudid			C		4 Mg, 1 D		Not Reported

	Diphenhydramine Hydrochloride	C		Unk, Prn	Not Reported
	Furosemide	C		13.3333 Mg (40 Mg, 1 In 3 D)	Not Reported
	Loperamide	C		2 D	Not Reported
	Norflex /00018303/	C		2 D	Not Reported
	Omnaris	C		Unk	Not Reported
	Pantoprazole Sodium	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Vagifem	C	Vaginal	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12202455	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cough; Ear Infection; Fatigue; Headache; Migraine; Nasopharyngitis; Nausea; Non-Cardiac Chest Pain; Pneumonia	Plaquenil			S	Oral			Not Reported
	Arava			S				Not Reported
	Xeljanz			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Celebrex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12237642	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2016-04134		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Foetal Heart Rate Deceleration Abnormality	Metoprolol			S	Transplacental	50 Mg, Two Times A Day		Aurobindo
	Lamotrigine			S		175 Mg, Two Times A Day		Aurobindo
	Quensyl			S	Transplacental	200 Mg, Once A Day		Not Reported
	Marcumar			C	Transplacental	Unk		Not Reported
	Clexane			C	Transplacental	40 Mg, Two Times A Day		Not Reported
	Ass			C	Transplacental	100 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12238241	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016192350		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Has Been On For 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12238571	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-16		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Gold			S				Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12238572	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-16		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder	Plaquenil			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2016	12239590	EXPEDITED (15-DAY)		CA	DE-GLAXOSMITHKLINE-DE2016GSK044525		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Foetal Exposure During Pregnancy	Lamotrigine	S	Transplacental	175 Mg, Bid		Glaxosmithkline
	Quensyl	S	Transplacental	200 Mg, Qd		Not Reported
	Metoprolol	S	Transplacental	50 Mg, Bid		Not Reported
	Marcumar	C	Transplacental	Unk		Not Reported
	Clexane 40	C	Transplacental	40 Mg, Bid		Not Reported
	Ass 100	C	Transplacental	100 Mg, Qd		Not Reported
	Folic Acid	C	Transplacental	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2016	12241086	EXPEDITED (15-DAY)		CA	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-114410			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect	Metoprolol			S	Transplacental	50 Mg, Bid, 0.-30.3. Gestational Week		Sun
	Lamotrigine			S	Transplacental	175 Mg, Bid, 0.30.3. Gestational Week		Taro
	Quensyl			S	Transplacental	200 Mg, Qd, 0.-30.3. Gestational Week		Not Reported
	Marcumar			C	Transplacental	Unk, 0.-3.5. Gestational Week		Not Reported
	Clexane 40			C	Transplacental	40 Mg, Bid, 3.6.-30.3. Gestational Week		Not Reported
	Ass 100			C	Transplacental	100 Mg, Qd, 0.-30.3. Gestational Week		Not Reported
	Folic Acid			C	Transplacental	5 Mg, Qd, 0.-4.3. Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2016	12243790	EXPEDITED (15-DAY)		HO, OT	GXBR2016US001117		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Cough; Eye Disorder; Fatigue; Left Ventricular End-Diastolic Pressure Increased; Lung Disorder; Myocardial Infarction; Night Sweats; Orthopnoea; Restrictive Cardiomyopathy	Hydroxychloroquine Sulfate Tablets Usp	S	Oral	400 Mg, Qd		Novartis
	Ranexa	C	Oral	1000 Mg, Bid		Not Reported
	Zetia	C	Oral	10 Mg, Qd		Not Reported
	Lipitor	C	Oral	80 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Carvedilol	C	Oral	18.2 Mg, Bid		Not Reported
	Hydrochlorothiazide	C	Oral	5 Mg, Qd		Not Reported
	Nature Throid	C	Oral	32.5 Mg, Qd		Not Reported
	Baby Aspirin	C	Oral	5 Mg, Qd		Not Reported
	Nitroglycerin	C	Sublingual	Unk Df, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	11982789	NON-EXPEDITED		OT	US-AMGEN-USASL2016008626		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Blindness; Device Issue; Grip Strength Decreased; Hand Deformity; Injection Site Bruising; Injection Site Swelling; Musculoskeletal Disorder; Osteoporosis; Visual Impairment	Enbrel			S	Unknown	50 Mg, Weekly		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	12246438	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-15		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Remicade				S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz				S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	12246439	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-15		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Nasopharyngitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	12246440	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-16		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	12246441	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-17		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Nasopharyngitis; Therapeutic Product Effect Incomplete	Plaquenil			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2016	12246442	EXPEDITED (15-DAY)		CA	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-16		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Lamotrigine			S	Transplacental			Not Reported
	Metoprolol			S	Oral			Not Reported
	Marcumar			C	Transplacental			Not Reported
	Clexane			C	Transplacental			Not Reported
	Ass			C	Transplacental			Not Reported
	Folsaure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12089585	NON-EXPEDITED			US-PFIZER INC-2016101405		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Advil			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Pamelor			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

	Aspirin			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12100138	EXPEDITED (15-DAY)		CA, HO, OT	DE-ACTELION-A-CH2016-131573			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Chondrodystrophy; Congenital Musculoskeletal Anomaly; Cyanosis; Foetal Growth Restriction; Hypotonia; Neonatal Respiratory Distress Syndrome; Posture Abnormal; Premature Baby	Opsumit			S	Transplacental	10 Mg, Qd		Actelion
	Ventavis Bayer Schering			S	Transplacental	Unk		Bayer
	Sildenafil			S	Transplacental	20 Mg, Tid		Not Reported
	Azathioprin			S	Transplacental	50 Unk, Qd		Not Reported
	Tinzaparin			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Treprostinil			S	Transplacental			Not Reported
	Apixaban			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12248606	NON-EXPEDITED			US-PFIZER INC-2016194113		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Xeljanz			S		Unk		Pfizer
	Rituxan			S				Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2016	12253061	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective	Hydroxychloroquine 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12251932	EXPEDITED (15-DAY)		HO	CA-ABBVIE-16K-028-1600482-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Type 2 Diabetes Mellitus	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12252317	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600368-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Sleep Disorder	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12252332	EXPEDITED (15-DAY)		CA	DE-LUPIN PHARMACEUTICALS INC.-E2B_00005204		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Foetal Exposure During Pregnancy	Quensyl			S	Transplacental	Not Reported
	Metoprolol			S	Transplacental	Not Reported
	Lamotrigine			S	Transplacental	Not Reported
	Marcumar			C	Transplacental	Not Reported
	Clexane 40			C	Transplacental	Not Reported
	Ass 100			C	Transplacental	Not Reported
	Folsaure			C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12252605	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600462-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12252756	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600543-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cyclosporine			S	Oral			Not Reported

	Enbrel		S	Unknown	Not Reported
	Imuran		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2016	12253832	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600607-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Quality Of Life Decreased; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	10778860	NON-EXPEDITED		OT	US-AMGEN-USASP2015011394		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Product Dose Omission	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072603/			S	Oral	400 Mg, Unk		Not Reported
	Methotrexate			S	Oral	7.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, 6 Times/Wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	11640342	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA161831			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bursitis; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Dry Mouth; Fall; Hypoaesthesia; Hypoaesthesia; Intervertebral Disc Operation; Malaise; Movement Disorder; Nausea; Neck Deformity; Nerve Injury; Pain; Staphylococcal Infection; Tracheostomy	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	11778963	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-37			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache; Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Rheumatoid Arthritis; Weight Fluctuation	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12171729	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-08		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Plaquenil		S		Not Reported
	Plaquenil		S		Not Reported
	Gabapentin		S	Unknown	Not Reported
	Gabapentin		S	Unknown	Not Reported
	Folic Acid		S		Not Reported
	Folic Acid		S		Not Reported
	Prednisone		S		Not Reported
	Prednisone		S	Unknown	Not Reported
	Nexium		S		Not Reported
	Nexium		S		Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12256285	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600633-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Specific Antibody Present; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12256307	NON-EXPEDITED			US-PFIZER INC-2016162862		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cortisone			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Promus Stent			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257071	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2016M1014852			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Maternal Exposure During Pregnancy	Ramipril			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Torasemide			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Metamizole			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown			Mylan
	Aliskiren			S	Unknown			Mylan
	Heparin			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257073	EXPEDITED (15-DAY)		CA, DE, OT	DE-MYLANLABS-2016M1014839			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy	Ramipril			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Torasemide			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Salbutamol			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Metamizole			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Mylan
	Aliskiren			S	Transplacental			Mylan
	Heparin			S	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257168	EXPEDITED (15-DAY)		CA	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-17			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Transposition; Foetal Exposure During Pregnancy	Plaquenil			S	Transplacental			Not Reported
	Aspegic Nourrissons			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257169	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IT-2016-17		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Fatigue	Plaquenil			S	Oral			Not Reported
	Airtal			S				Not Reported
	Omeprazen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257713	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-17			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12257957	EXPEDITED (15-DAY)		HO	GB-ABBVIE-16K-167-1561960-00		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Ketoacidosis; Diarrhoea; Exposure During Pregnancy; Hypertension; Infection; Normal Newborn; Pre-Eclampsia	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2016	12261580	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600488-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Swelling; Soft Tissue Disorder; Synovitis	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Ativan	C		Not Reported
	Benadryl	C		Not Reported
	Codeine	C		Not Reported
	Cortisone	C		Not Reported
	Dilaudid	C		Not Reported
	Dexamethasone	C		Not Reported
	Enablex	C		Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog	C		Not Reported
	Kineret	C		Not Reported
	Lasix	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoloc	C		Not Reported
	Restasis	C		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12263409	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600546-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dysgeusia; Hypertension; Sinus Congestion; Sinusitis; Synovitis; Urinary Tract Infection	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Xeljanz		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2016	12264121	NON-EXPEDITED			US-JNJFOC-20160318638			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Pruritus; Rash	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Aspirin		Y	S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Lomotil			S	Unknown			Not Reported
	Iodine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12270535	DIRECT					47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Pruritus; Therapy Non-Responder	Plaquenil			S	Oral	50 Tablet(S) Twice A Day Taken By Mouth		Not Reported
	Effexor			C				Not Reported
	Trazodone			C				Not Reported
	Quinacrine			C				Not Reported
	Silica			C				Not Reported
	Selenium			C				Not Reported
	Zinc			C				Not Reported
	Biotin			C				Not Reported
	Iron			C				Not Reported
	Omega-3 Fa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12213542	NON-EXPEDITED			US-PFIZER INC-2016131663		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12275782	EXPEDITED (15-DAY)		HO	US-STRIDES ARCOLAB LIMITED-2016SP002426			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutrophil Pelger-Huet Anomaly Present; Night Sweats; Pyrexia	Ibuprofen			S	Unknown	600 Mg, Qid		Unknown
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12277427	EXPEDITED (15-DAY)		DS, HO	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-17		58 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Eosinophilia	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12277428	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-CO-PL-ES-2016-18			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12277429	EXPEDITED (15-DAY)		DS	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-17		57 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Feeling Hot; Pustule; Rash; Skin Exfoliation	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Clenil Modulite			C				Not Reported
	Esomeprazole			C				Not Reported
	Salmeterol			C				Not Reported
	Depo-Medrone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2016	12279853	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1602986-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	11678874	NON-EXPEDITED		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-32			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bursitis; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Dry Mouth; Fall; Hypoaesthesia; Hypoaesthesia; Intervertebral Disc Operation; Malaise; Movement Disorder; Nausea; Neck Deformity; Nerve Injury; Pain; Staphylococcal Infection; Tracheostomy	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12047086	NON-EXPEDITED			US-PFIZER INC-2016011860		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flatulence	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12114823	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-06			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Resistance; Inflammation; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			C				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Actemra			C				Not Reported

	Prednisone			C						Not Reported
	Indocin			C						Not Reported
	Tramadol			C						Not Reported
	Sulfasalazine			C						Not Reported
	Amoxicillin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12280608	EXPEDITED (15-DAY)		OT	US-ZYDUS-010642		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Toxicity To Various Agents; Visual Field Defect	Hydroxychloroquine			S	Unknown	6.0 Mg/Kg Actual Body Weight (8.0 Mg/Kg Ideal Body Weight)		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12280611	EXPEDITED (15-DAY)		OT	US-ZYDUS-010637		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Toxicity To Various Agents; Visual Field Defect	Hydroxychloroquine			S	Unknown	8.3 Mg/Kg Actual Body Weight (10.1 Mg/Kg Ideal Body Weight) Daily Dose		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12280917	NON-EXPEDITED			US-AMGEN-USASP2016049009		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2016	12281191	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-18			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	11391753	NON-EXPEDITED			US-PFIZER INC-2015270409			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium			S	Unknown	Unk		Unknown
	Neurontin			S	Unknown	Unk		Pfizer
	Neosporin			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Epinephrine			S	Unknown	Unk		Unknown
	Erythromycin			S	Unknown	Unk		Pfizer
	Bacitracin			S	Unknown	Unk		Pfizer
	Motrin			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S				Not Reported
	Dexilant			S				Not Reported

	Savella			S						Not Reported
	Aldara			S						Not Reported
	Methadone			S						Not Reported
	Arava			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12286473	EXPEDITED (15-DAY)		HO, OT	CN-ACTAVIS-2016-08424		27 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Prednisone (Unknown)			S	Unknown	5 Mg, Daily For More Then 10 Years		Watson
	Hydroxychloroquine (Unknown)			S	Unknown	200 Mg, Daily For More Then 10 Years		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	10642235	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSL2014095031		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myeloid Leukaemia; Infection; Pneumonia	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	50 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12293878	EXPEDITED (15-DAY)		OT	PHHY2016RU050909		13 YR	Male	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bone Marrow Transplant Rejection; Treatment Failure	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S				Not Reported
	Methotrexate	S				Not Reported
	Hydroxychloroquine	S	Unknown			Novartis
	Antithymocyte Immunoglobulin	C	Unknown	60 Mg/Kg, Unk		Not Reported
	Thiotepa	C	Unknown	42 G/M2, Unk		Not Reported
	Thiotepa	C	Unknown	10 Mg/Kg, Unk		Not Reported
	Fludarabine	C	Unknown	150 Mg/M2, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12297230	EXPEDITED (15-DAY)		HO	CN-MYLANLABS-2016M1016665			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12299213	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Urticaria	Hydroxychloroquine 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	10067267	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014005419		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm Malignant; Lymphadenopathy; Ocular Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Vision Blurred	Enbrel			S	Unknown	50 Mg Once Weekly		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C		1 Mg Daily		Not Reported
	Methotrexate			C		0.4ml Once Weekly		Not Reported
	Vitamin B6			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

	Folic Acid			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	10400025	EXPEDITED (15-DAY)		HO	CA-SA-2014SA109346			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Dyspnoea; Lung Disorder	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12122100	EXPEDITED (15-DAY)		OT	RU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-RU-2016-07		28 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12203661	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-12		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Abnormal; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			C				Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12304459	EXPEDITED (15-DAY)		OT	CA-ROCHE-1746972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12305552	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-20			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Swelling; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain; Peripheral Swelling; Stevens-Johnson Syndrome	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12305553	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-20		77 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin G Increased; Hypocomplementaemia; Nephropathy; Protein Urine Present; Renal Impairment	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12305632	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-18			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction; Restrictive Cardiomyopathy	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12305633	EXPEDITED (15-DAY)		OT	IN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IN-2016-20		1 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photosensitivity Reaction; Porphyria Non-Acute; Porphyrins Urine Increased; Product Use Issue; Product Use Issue; Transaminases Increased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Vincristine			S	Unknown			Not Reported
	Daunorubicin			S	Unknown			Not Reported
	L-Asparaginase			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Mercaptopurine			S	Unknown			Not Reported
	Cytarabine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12305805	EXPEDITED (15-DAY)		HO, OT	FR-ASTELLAS-2016US015710		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Vesicare			S	Unknown	Unk, Unknown Freq.		Astellas
	Cortancyl			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

	Ditropan			S	Oral	Unk, Unknown Freq.			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12306114	EXPEDITED (15-DAY)		HO	TR-IPCA LABORATORIES LIMITED-IPC201604-000380		29 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2016	12306354	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAXTER-2016BAX020349		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	822 (Further Not Specified)		Baxter
	Azathioprine			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported

	Methylprednisolone Sodium Succinate			C	Unknown				Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	11965022	EXPEDITED (15-DAY)		OT	CA-ROCHE-1699434		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Naprosyn			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12266820	NON-EXPEDITED			US-AMGEN-USASL2016044356		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12309609	NON-EXPEDITED			US-PFIZER INC-2016188431			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Fentanyl Citrate			S				Unknown
	Naproxen Sodium			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Reglan /00041901/			S		Unk		Not Reported
	Ancef /00288502/			S		Unk		Not Reported
	Asprin			S		Unk		Not Reported
	Lortab /00607101/			S				Not Reported
	Percocet /00867901/			S				Not Reported
	Dilaudid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12310352	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-19		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Leukocytosis; Pyrexia; Rash	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Seroplex			C				Not Reported
	Imovane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12310638	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-19			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Loss Of	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Personal Independence In Daily Activities; Myocardial Infarction; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12311133	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016052748		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Headache; Joint Swelling; Mobility Decreased; Pain	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2016	12314429	DIRECT	Y				59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis	Hydroxychloroquine 200 Mg			S	Oral	Mg Qd Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12200056	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-11		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Musculoskeletal Pain; Pain In Extremity; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12313724	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-19		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Plaquenil			S	Oral			Not Reported
	Abilify			C				Not Reported
	Xeroquel			C				Not Reported
	Cymbalta			C				Not Reported
	Theralene			C				Not Reported
	Lasilix			C				Not Reported
	Aldactone			C				Not Reported
	Ramipril			C				Not Reported
	Metoject			C				Not Reported
	Speciafoldine			C				Not Reported
	Disulone			C				Not Reported
	Cortancyl			C				Not Reported
	Paracetamol			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12316520	EXPEDITED (15-DAY)		OT	US-ZYDUS-010845		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Arthralgia; Butterfly Rash; Gait Disturbance; Joint Effusion; Osteonecrosis; Thrombocytopenia; Tuberculosis	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Levofloxacin/Levofloxacin Mesylate			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown	Gradually Increase The Dose To 100 -125 Mg		Zydus Pharm
	Methylprednisolone			S	Intravenous (not otherwise specified)	Methyl Prednisolone Iv Pulse Therapy, Followed By Oral Taper Dose, Then Maintenance Dose Of 7.5 Mg.		Not Reported
	Kanamycin			S	Unknown			Not Reported
	Aminosalicylic Acid			S	Unknown			Not Reported

	Cycloserine	S	Unknown		Not Reported
	Pyrazinamide	S	Unknown		Not Reported
	Clofazimine	S	Unknown		Not Reported
	Calcium Gluconate	C	Unknown		Not Reported
	Alendronic Acid	C	Unknown		Not Reported
	Colecalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2016	12317858	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745545			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Subcutaneous	Solution		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2016	12321928	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2016M1018024			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2016	12324848	EXPEDITED (15-DAY)		HO	CN-ENDO PHARMACEUTICALS INC-2016-002951		27 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Prednisone Tablets 5mg			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	10768490	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014100252		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspepsia; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Hypoaesthesia; Joint Swelling; Migraine; Nausea; Pharyngeal Swelling; Rheumatoid Factor Positive; Swelling	Enbrel			S	Subcutaneous	50 Mg, One Every One Week		Amgen
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15-20-25 Mg		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400- 300 Mg Die		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Prednisone			C				Not Reported

Face; Synovitis; Uveitis	Arthrotec	C	75 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	11393035	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014105912		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate /00113802/			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Arava			S	Oral	50 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12326339	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2016055468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mortin			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12327980	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201604-000397			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12327982	EXPEDITED (15-DAY)		HO	FR-IPCA LABORATORIES LIMITED-IPC201604-000398		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis; Respiratory Failure	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2016	12328299	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-21		59 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Lichen Planus; Parosmia; Taste Disorder	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Naproxen			C				Not Reported
	Omeprazole			C				Not Reported
	Dutasteride			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	11614170	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-29		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Joint Swelling; Joint Swelling; Migraine; Nasal Congestion; Pain;	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Sulfasalazine			S	Unknown	Not Reported
	Leflunomide			S	Oral	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Enbrel			S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	11761895	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-37		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Celebrex			S				Not Reported
	Sulfasalazine			S	Rectal			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12330236	EXPEDITED (15-DAY)		OT	TR-ROCHE-1751367		51 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aura; Dizziness; Heart Rate Decreased; Hypotension; Infusion Related Reaction; Loss Of Consciousness; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methyl Prednisolone Sodium Succinate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12330299	EXPEDITED (15-DAY)		HO, OT	CL-ROCHE-1696955		57 YR	Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthma; Bone Pain; Fall; Fractured Coccyx; Immune System Disorder; Malaise; Muscular Weakness; Product Dose Omission; Wrist Fracture	Actemra			S	Subcutaneous			Not Reported
	Celecoxib			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12331293	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-21		32 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Plaquenil			S	Oral			Not Reported
	Adalimumab			C				Not Reported
	Mtx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12331440	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-115211		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Foot Fracture; Hypertension; Weight Increased	Prednisone			S	Unknown	Unk		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12331441	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL		53 YR	Female	USA

INDUSTRIES LTD-
2016US-115225

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Osteonecrosis	Minocycline			S	Unknown	Unk		Ranbaxy
	Prednisone			S	Oral	Unk		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Not Reported
	Mycophenolate Mofetil			S	Unknown	4 G, Daily		Not Reported
	Tacrolimus			S	Topical	Unk		Not Reported
	Imiquimod			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12332518	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016054582		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Eye Disorder	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2016	12334405	EXPEDITED (15-DAY)		HO	PHHY2016FR059552		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Glivec			S	Oral	400 Mg, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported

	Plaquenil			S	Oral	200 Mg, Qd				Not Reported
	Coumadine			C	Oral	8.5 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12335985	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016056564		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12335999	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/16/0079260		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Butterfly Rash; Drug Interaction; Gait Disturbance; Haemoglobin Decreased; Osteonecrosis; Pain In Extremity; Platelet Count Decreased; Rash; Systemic Lupus Erythematosus; Toxicity To Various Agents	Levofloxacin Tablets			S	Unknown			Not Reported
	Kanamycin			S				Not Reported
	Para-Aminosalicylic Acid			S				Not Reported
	Cycloserine			S				Not Reported
	Pyrazinamide			S				Not Reported
	Clofazimine			S				Not Reported
	Methyl Prednisolone			S	Unknown			Not Reported
	Methyl Prednisolone			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12336849	EXPEDITED (15-DAY)		HO	CH-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CH-2016-		22 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Drug-Induced Liver Injury	Plaquenil			S				Not Reported
	Minac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12336850	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-20		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Plaquenil			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Ditropan			S	Oral			Not Reported
	Vesicare			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12337586	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016055539		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2016	12338329	EXPEDITED (15-DAY)		HO	CA-ABBVIE-16K-028-1618188-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Oral Mucosal Eruption; Rash; Skin Exfoliation; Therapeutic Response Shortened	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	11289156	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015071349		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Malaise; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	11749106	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015072358		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Pain; Drug Ineffective; Drug Intolerance; Dyspepsia; Infection; Joint Swelling; Malaise; Mobility Decreased; Rheumatoid Arthritis; Therapeutic	Enbrel			S	Subcutaneous	25 Mg, Cyclical		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Orencia			S	Intravenous (not	750 Mg, Qmo		Not Reported

Product Effect Decreased						otherwise specified)				
	Prednisone			C		Unk				Not Reported
	Myochrysine			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12208179	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-14		23 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhegmatogenous Retinal Detachment	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12341259	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-21		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small For Dates Baby	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Boostrix			C				Not Reported
	Montelukast			C				Not Reported
	Folic Acid			C				Not Reported
	Euphorbium Comp			C				Not Reported
	Fenistil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12341262	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2016-21		73 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Pain In Extremity	Plaquenil			S	Unknown			Not Reported
	Arimidex			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Calcium			C						Not Reported
	Panadol			C						Not Reported
	Vitamin D Nos			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12341263	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-21			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Dyspnoea; Lung Disorder	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12341264	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-21			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small For Dates Baby	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Boostrix			C				Not Reported
	Montelukast			C				Not Reported
	Femibion [Minerals Nos;Vitamins Nos]			C				Not Reported
	Euphorbium Comp			C				Not Reported
	Fenistil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12342857	EXPEDITED (15-DAY)		HO, OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-090		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug	Naproxen			S	Unknown			Not Reported

Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Humira			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Xeljanz			S	Oral	Not Reported
	Methotrexate			C	Unknown	Not Reported
	Folic Acid			C		Not Reported
	Hcq			C		Not Reported
	Plaquenil			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12342859	EXPEDITED (15-DAY)		OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-092		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12342863	EXPEDITED (15-DAY)		HO, OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-096		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug	Naproxen			S	Unknown			Not Reported
	Abatacept			S	Intravenous drip			Not Reported
	Adalimumab			S	Unknown			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction; Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Anakinra	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Gammagard S/D	S	Intravenous drip		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12342864	EXPEDITED (15-DAY)		OT	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-097			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Diarrhoea; Hepatic Function Abnormal; Renal Impairment; Therapeutic Product Effect Delayed; Tooth Loss	Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12342866	EXPEDITED (15-DAY)		HO	CA-PEDIAPHARM INC.-PD-NAP-CA-2016-099		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Eruption; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Naproxen			S	Unknown				Not Reported
	Actemra			S	Unknown				Not Reported
	Adalimumab			S	Subcutaneous				Not Reported
	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2016	12342953	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016055315		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2016	12341465	EXPEDITED (15-DAY)		OT	PHHY2016CA062109		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Cortisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2016	12341474	EXPEDITED (15-DAY)		OT	PHHY2016CA062015		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Voltaren			S	Oral	75 Mg, Bid		Novartis
	Lisinopril			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Tecta			S	Unknown			Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Synthroid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2016	12343707	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-032450			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Flatulence	Abatacept			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12305635	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-19		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Salazopyrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12346370	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-087416			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Aleve			S				Bayer
	Synthroid			S				Not Reported
	Pantoprazole Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Folic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12348605	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245582		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Eye Disorder	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12348852	EXPEDITED (15-DAY)		HO	CN-IPCA LABORATORIES LIMITED-IPC201604-000409		27 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Hydroxychloroquine Sulfate			S				Ipca
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12349777	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2016056815		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angiopathy; Condition Aggravated; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	8.0 Mg, 1 Every 1 Day		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12350364	NON-EXPEDITED			US-PFIZER INC-2016226695			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ibuprofen			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2016	12352386	NON-EXPEDITED			US-PFIZER INC-2016246260		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pustular Psoriasis	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 1x/Day		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	11634942	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-15			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankle Operation; Localised Infection; Renal Failure; Sepsis	Plaquenil		S	Oral	Not Reported
	Arava		S	Unknown	Not Reported
	Methotrexate		C		Not Reported
	Xeljanz		C		Not Reported
	Xeljanz		C		Not Reported
	Xeljanz		C		Not Reported
	Xeljanz		C		Not Reported
	Xeljanz		C	Oral	Not Reported
	Indomethacin		C		Not Reported
	Prednisone		C		Not Reported
	Fluconazole		C		Not Reported
	Enbrel		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12354564	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK062660		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Voltaren			S	Unknown	Unk		Glaxosmithkline
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Amitriptyline			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12354836	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-22		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Plaquenil			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported

	Amoxicillin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12355292	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016246802		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12355827	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016056600		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Arava			S	Oral	50 Mg, Qd		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2016	12356934	NON-EXPEDITED			US-PFIZER INC-2016252064			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

	Humira			S		Unk				Not Reported
	Prednisone			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2016	12362334	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-21		72 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12364860	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-087411			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Aleve			S	Unknown			Bayer
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12364987	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-087412			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Aleve			S	Unknown			Bayer
	Synthroid			S	Unknown			Not Reported
	Pantoprazole Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Folic Acid			S	Unknown				Not Reported
		Calcium D Pantothenate			C					Not Reported
		Nicotinamide			C	Unknown				Not Reported
		Pyridoxine Hydrochloride			C					Not Reported
		Riboflavin			C					Not Reported
		Thiamine Hydrochloride			C					Not Reported
		Vitamin B12			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12367067	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-087556			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Aleve			S	Unknown			Bayer
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12367972	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-36		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; General Physical Health Deterioration; Hypersensitivity; Oedema; Pyrexia; Rash Maculo-Papular	Plaquenil			S	Oral			Not Reported
	Cortancyl			C				Not Reported
	Skenan			C				Not Reported
	Actiskenan			C				Not Reported
	Melaxose			C				Not Reported
	Solumedrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2016	12368844	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016252838		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angiopathy; Condition Aggravated; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Visual Impairment	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	8.0 Mg, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2016	12369903	EXPEDITED (15-DAY)		OT	US-TEIKOKU PHARMA USA-TPU2016-00285			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Cataract; Depressed Mood; Pain In Extremity; Pain In Jaw; Systemic Lupus Erythematosus; Toothache	Lidoderm			S	Topical	One Patch On Each Hip And One On Cervical Spine Applied Topically Daily As Needed		Teikoku
	Lidoderm			S				Teikoku
	Lidoderm			S				Teikoku
	Lidoderm			S				Teikoku
	Lidoderm			S				Teikoku
	Lidocaine Patch 5% (Qualitest)			S	Topical	One Patch On Each Hip And One On Cervical Spine Applied Topically Daily As Needed		Teikoku
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Singulair			S				Not Reported
	Metoprolol			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Glipizide			C	Oral			Not Reported

	Metformin			C	Oral					Not Reported
	Metformin			C	Oral					Not Reported
	Aspirin			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	11935191	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-01		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dyspnoea; Fibromyalgia; Kidney Infection; Musculoskeletal Stiffness; Pain In Extremity	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12374794	NON-EXPEDITED			US-PFIZER INC-2016258786			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ampicillin Sodium			S		Unk		Unknown
	Amoxicillin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2016	12376751	NON-EXPEDITED			US-MALLINCKRODT-T201502732		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Testosterone Decreased; Infection;	Repository Corticotropin Injection			S	Subcutaneous	80 Units/Twice Per Week		Mallinckrodt

Malaise; Product Dose Omission	Repository Corticotropin Injection	S	Subcutaneous	80 Units/Twice Per Week		Mallinckrodt
	Imuran	S				Not Reported
	Plaquenil	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12351027	EXPEDITED (15-DAY)		OT	CA-SA-2016SA090873		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis; Liver Disorder	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12380428	NON-EXPEDITED			US-PFIZER INC-2016231052		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Compazine			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Kapidex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12382229	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-22			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling;	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

Pharyngitis Streptococcal;
Rheumatoid Arthritis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2016	12382230	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-22			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Arthropathy; Arthropathy; Drug Hypersensitivity; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Remicade			C				Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Celebrex			C				Not Reported
	Relafen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12385289	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-089485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S				Bayer
	Aspirin			S				Bayer
	Aspirin			S				Bayer
	Aspirin			S				Bayer
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported

	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Voltaren	S		Not Reported
	Tramadol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12385706	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-089574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S	Unknown			Bayer
	Arava			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin			S				Not Reported
	Naprosyn			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2016	12386903	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016261798		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Polyarthritis; Treatment Failure	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Plaquenil /00072602/			S		200 Mg, 2x/Day		Not Reported
	Humira			S		40 Mg, Every 2 Weeks		Not Reported
	Humira			S		40 Mg, Weekly		Not Reported
	Simponi			S		50 Mg, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12191037	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-09		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cough; Ear Infection; Fatigue; Headache; Migraine; Nasopharyngitis; Nausea; Non-Cardiac Chest Pain; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12339738	NON-EXPEDITED			US-AMGEN-USASL2016054109		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Injection Site Erythema; Injection Site Recall Reaction; Injection	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

Site Swelling; Injection
Site Urticaria; Pain

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12388985	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK063913		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Voltaren			S	Oral	75 Mg, Bid		Glaxosmithkline
	Methotrexate			S	Subcutaneous	20 Mg, We		Glaxosmithkline
	Lisinopril			S	Unknown	Unk		Not Reported
	Tecta (Pantoprazole Magnesium)			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12389104	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-22		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis; Liver Disorder	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12389105	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-22		47 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390601	EXPEDITED (15-DAY)		OT	AR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AR-2016-23			Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Maculopathy	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390602	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-22		54 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B; Hepatitis B Dna Increased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390603	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-23		45 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B; Hepatitis B Dna Increased; Product Use Issue	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390604	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-23		36 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatitis B;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hepatitis B; Viral Load Increased	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390605	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-23		51 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatic Cirrhosis; Hepatitis; Hepatitis B; Hepatitis B Dna Increased; Jaundice; Product Use Issue	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390606	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-23		54 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Hepatitis B; Hepatitis B; Hepatitis B Dna Increased; Product Use Issue	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lamivudine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390607	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-23		39 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B; Hepatitis B Dna Increased; Product Use Issue	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2016	12390608	NON-EXPEDITED		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-22		75 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Psoriasis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Bendroflumethiazide			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Folic Acid			C				Not Reported
	Innovace			C				Not Reported
	Lamictal			C				Not Reported
	Letrozole			C				Not Reported
	Methotrexate			C				Not Reported
	Omeprazole			C				Not Reported
	Qvar			C				Not Reported
	Salamol			C				Not Reported
	Simvastatin			C				Not Reported
	Calcium D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12290255	EXPEDITED (15-DAY)		HO	JP-ACTELION-A-CH2016-133272		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haemoglobin Decreased; Platelet Count Decreased; White Blood Cell Count Decreased	Macitentan			S	Oral	10 Mg, Qd		Actelion
	Plaquenil			S	Oral	400 Mg, Qod		Not Reported
	Plaquenil			S	Oral	200 Mg, Qod		Not Reported
	Ciclosporin			C				Not Reported
	Daikentyuto			C				Not Reported
	Rabeprazole			C				Not Reported
	Senna Leaf			C				Not Reported
	Mosapride Citrate			C				Not Reported
	Beraprost Sodium			C				Not Reported
	Losartan Potassium			C				Not Reported
	Prednisolone			C				Not Reported
	Clonazepam			C				Not Reported

		Diazepam			C					Not Reported
		Mirtazapine			C					Not Reported
		Eszopiclone			C					Not Reported
		Magnesium Oxide			C					Not Reported
		Lactulose			C					Not Reported
		Clostridium Butyricum			C					Not Reported
		Ursodeoxycholic Acid			C					Not Reported
		Sulfamethoxazole\Trimethoprim			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12374814	NON-EXPEDITED			US-PFIZER INC-2016260381			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2016	12375889	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2016GSK067623			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Lymphopenia; Neutropenia	Benlysta			S		10 Mg/Kg, Unk		Glaxosmithkline
	Benlysta			S		5 Mg/Kg, Unk		Glaxosmithkline
	Acetylsalicylic			S		100 Mg, Qd		Glaxosmithkline
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Levothyroxine			C		75 Unk, Qd		Not Reported
	Omeprazole			C		20 Mg, Qd		Not Reported
	Alendronate			C		70 Mg, Unk		Not Reported
	Methotrexate			C		15 Mg, Unk, Per Week		Not Reported
	Prednisone			C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12366810	EXPEDITED (15-DAY)		OT	EG-AMGEN-EGYSP2016060687		61 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Leukopenia; Product Use Issue; Thrombocytopenia	Enbrel			S	Unknown	50 Mg, One Every Other Week For Two Weeks		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg Alternating With 200 Mg Daily		Not Reported
	Eltroxin			S	Unknown	75 Mg, Daily		Not Reported
	Methotrexate Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12398491	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-24		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Glivec			S	Oral			Not Reported
	Coumadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12398492	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-24		31 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oligospermia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2016	12398800	NON-EXPEDITED			US-PFIZER INC-2015427972		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Methotrexate Sodium	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	11372130	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ABBVIE-15P-163-1442521-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Pain Upper; Abnormal Behaviour; Abnormal Behaviour; Agitation; Allergic Oedema; Allergic Respiratory Symptom; Amnesia; Anxiety; Aspiration; Asthenia; Back Pain; Cardiac Arrest; Chest Discomfort; Confusional State; Constipation; Depression; Dermatitis Allergic; Diarrhoea Haemorrhagic; Dizziness; Dry Mouth; Dyspepsia; Electrolyte Depletion; Faecaloma; Fatigue; Feeling Abnormal; Flatulence; Gastrooesophageal Reflux Disease; Headache; Immunodeficiency; Impaired Quality Of Life; Insomnia; Irritability; Large Intestine Perforation; Memory Impairment; Mental Disorder; Mental Impairment; Mental Status Changes; Mood Altered; Nausea; Nervousness;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Atenolol			S	Unknown	In The Morning		Not Reported
	Klonopin			S	Unknown	In The Morning		Not Reported
	Omeprazole			S	Unknown	Before Meals		Not Reported
	Oxycodone And Acetaminophen			S	Unknown	5 Mg/325 Mg		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Seroquel			S	Unknown	At Bedtime		Not Reported
	Zoloft			S	Unknown	Alternating With 37.5 Mg Dose, In The Morning		Not Reported
	Zoloft			S	Unknown	Alternating With 25 Mg Dose, In The Morning		Not Reported
	Oxycodone			S	Unknown			Not Reported

Panic Attack; Sepsis; Sexual Dysfunction; Somnolence; Urinary Tract Infection; Urticaria; Vision Blurred; Visual Impairment; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	11600396	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-29		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Lymph Node Calcification; Nausea; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	12404393	EXPEDITED (15-DAY)		HO	DK-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DK-2016-24		85 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dehydration; General Physical Health Deterioration; Nausea; Weight Decreased	Plaquenil			S	Oral			Not Reported
	Marevan			C				Not Reported
	Alendronate			C				Not Reported
	Amlodipine			C				Not Reported
	Cosopt			C				Not Reported
	Folimet			C				Not Reported
	Furix (Furosemide)			C				Not Reported
	Kaleorid			C				Not Reported
	Lumigan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2016	12405041	NON-EXPEDITED			US-CELGENEUS-USA-2016054722		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment; Nausea	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported
	Losartan			C	Unknown	400 Milligram		Not Reported
	Hctz			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Prozac			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	11969776	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016025057			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Cervical Cord Compression; Nephrolithiasis; Renal Pain; Rheumatoid Arthritis	Sulfasalazine			S		Unk		Pfizer
	Folic Acid			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Carvedilol			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Xarelto			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12407453	NON-EXPEDITED			US-PFIZER INC-2015464692		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Rash Pruritic	Celecoxib			S		Unk		Pfizer
	Celecoxib			S		200 Mg, 1x/Day		Pfizer
	Celecoxib			S		200 Mg, 2x/Day		Pfizer
	Methotrexate			S		6 Df, Weekly (6 Pills Once		Not Reported

				A Week),	
	Remicade		S	Unk (Taking The Minimum Dose Of Remicade)	Not Reported
	Remicade		S	Unk (They Increased The Dose 50%)	Not Reported
	Hydroxychloroquine		S	200 Mg, Unk	Not Reported
	Folic Acid		C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2016	12407850	NON-EXPEDITED		OT	US-MDT-ADR-2015-02300		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Mass; Magnetic Resonance Imaging Abnormal; Muscle Spasms; Pneumonia	Compounded Baclofen			S	Intrathecal	49.984 Mcg/Day		Not Reported
	Morphine			S	Intrathecal	24.386 Mg/Day		Not Reported
	Bupivacaine			S	Intrathecal	0.24386 Mg/Day		Not Reported
	Cilostazol			S				Not Reported
	Omeprazole			S				Not Reported
	Calcium 600 Plus D			S	Oral	600-400 Mg, 2 Tablets Per Day		Not Reported
	Asmanex			S	Respiratory (inhalation)			Not Reported
	Diphenoxylate Atropine Generic For Lomotil			S				Not Reported
	Hydroxyzine Hcl			S	Oral			Not Reported
	Metoclopramide Hcl			S	Oral			Not Reported
	Tylenol Extra Strength			S	Oral	500 Mg, 3 Tablets Every 6 Hours As Needed		Not Reported
	Ventolin Hfa			S	Respiratory (inhalation)	108 (90 Base) Mcg/Act (1-2 Puffs Aerosol Solution Every 4-6 As Needed		Not Reported
	Compounded Baclofen			S	Intrathecal	39.0176 Mcg/Day		Not Reported
	Morphine			S	Intrathecal	21.668 Mg/Day		Not Reported
	Bupivacaine			S	Intrathecal	0.3124 Mg/Day		Not Reported

	Morphine Sulfate	S	Intrathecal		Not Reported
	Aspirin	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Prednisone	S			Not Reported
	Tizanidine Hcl	S			Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Diphenhydramine Hcl	S	Oral		Not Reported
	Fluticasone Propionate	S	Nasal		Not Reported
	Acetaminophen\Hydrocodone Bitartrate	S	Oral	7.5-325 Mg, 1 Tablet Every 4 To 6 Hours As Needed	Not Reported
	Ondansetron	S	Oral		Not Reported
	Gabapentin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12336851	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-21		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12410531	EXPEDITED (15-DAY)		OT	FR-ROCHE-1765085		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Atrophy; Neuromyopathy	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Metoject			S	Oral			Not Reported
	Nolvadex			S	Oral			Not Reported
	Decapeptyl (Triptorelin Acetate)			C	Unknown			Not Reported
	Speciafoldine			C	Unknown			Not Reported

	Ixprim			C	Unknown	As Required				Not Reported
	Cortancyl			C	Unknown	In The Morning				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2016	12411885	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-24		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Clostridium Difficile Colitis; Nausea; Vomiting	Plaquenil			S	Oral			Not Reported
	Rovamycine			S	Intravenous (not otherwise specified)			Not Reported
	Rocephin			S	Intravenous (not otherwise specified)			Not Reported
	Benemide			S	Oral			Not Reported
	Doliprane			C				Not Reported
	Esomeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414347	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-06932		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxyzine			S	Oral			Aurobindo
	Meloxicam			S	Oral			Aurobindo
	Acetaminophen			S	Oral			Not Reported
	Cetrizine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2016	12414368	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR-APL-2016-06937		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cyclobenzaprine			S	Oral			Aurobindo

	Amitriptyline	S	Oral		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Oral		Not Reported
	Hydroxychloroquine	S			Not Reported
	Tramadol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2016	12415266	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-00		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunodeficiency; Infection; Off Label Use	Hydroxychloroquine			S	Unknown			Hikma
	Doxycycline			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2016	12415556	NON-EXPEDITED			US-PFIZER INC-2016277300		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12182072	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2016030716		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Herpes Zoster; Infection; Musculoskeletal Stiffness; Nephrolithiasis; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Rosacea; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12388182	EXPEDITED (15-DAY)		OT	CA-SA-2016SA096563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gait Disturbance; Impaired Work Ability; Insomnia; Joint Swelling; Meniere'S Disease; Pain; Peripheral Swelling; Therapeutic Response Decreased; Vertigo	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Tylenol			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12418032	NON-EXPEDITED			US-AMGEN-USASP2016068581		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Eye Disorder; Eye Pain; Feeling Abnormal; Feeling Cold; Vision Blurred	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Oral	5 Mg, Qd M-F, Sat Sun Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12418321	NON-EXPEDITED			US-PFIZER INC-2016261101		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer

	Septra	S	Unk	Pfizer
	Vantin	S	Unk	Pfizer
	Baclofen	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Trimox	S	Unk	Not Reported
	Ultram	S	Unk	Not Reported
	Haldol	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12418789	EXPEDITED (15-DAY)		CA	DE-STRIDES ARCOLAB LIMITED-2016SP003964			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Tacrolimus			S	Transplacental	Unk		Strides
	Ramipril			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Rivaroxaban			S	Transplacental	Unk		Not Reported
	Torasemide			S	Transplacental			Not Reported
	Ezetimibe			S		Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Dipyrone			S	Transplacental	Unk		Not Reported
	Aliskiren			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12421038	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-24			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2016	12421766	NON-EXPEDITED			US-PFIZER INC-2016260405		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2016	12426078	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000319		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Polyarthritis; Synovitis	Methotrexate Sodium			S		3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Plaquenil /00072602/			S		400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Humira			S		40 Mg, 2 W		Not Reported
	Humira			S		40 Mg, 1 W		Not Reported
	Simponi			S		50 Mg, 1 Mo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2016	12428656	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-25		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State	Plaquenil			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Tranxene			S	Oral			Not Reported

	Lepticur	S	Oral			Not Reported
	Loxapac	S	Oral	50 Drops		Not Reported
	Theralene	S	Oral	50 Drops		Not Reported
	Noctamide	S	Oral			Not Reported
	Abilify	S	Oral			Not Reported
	Dafalgan Codeine	S	Oral			Not Reported
	Imeth	S	Oral			Not Reported
	Speciafoldine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12318331	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-20		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Condition Aggravated; Drug Ineffective; Fatigue; Flatulence; Headache; Inflammation; Pain In Extremity; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Euro-Folic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12432056	EXPEDITED (15-DAY)		HO, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-042052		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Reumaflex /00113802/			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Unk		Not Reported
	Naproxene /00256201/			C	Oral	500 Mg, Unk		Not Reported
	Deltacortene			C	Oral	7.5 Mg, Unk		Not Reported

	Patrol			C	Oral	2 U, Unk			Not Reported
	Ideos			C	Oral	1 U, Unk			Not Reported
	Cardirene			C	Oral	75 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12433164	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-25			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12434609	EXPEDITED (15-DAY)		OT	FR-MEDAC PHARMA, INC.-1053246		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Atrophy; Neuromyopathy	Metoject			S				Medac
	Nolvadex			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Decapeptyl (Triptorelin Acetate)			C				Not Reported
	Folic Acid			C				Not Reported
	Tramadol Hydrochloride And Acetaminophen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12435245	EXPEDITED (15-DAY)		HO	FR-HQ SPECIALTY-FR-2016INT000326		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Product	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg, 1 In 1 W)		Hq Specialty

Use In Unapproved Indication	Fluoxetine Hydrochloride	S	Oral	30 Mg (1.5 Dosage Form, In Morning)	Not Reported
	Loxapac /00401801/	S	Oral	250 Gtt Drop (S) (50 Gtt Drop (S), 5 In 1 D)	Not Reported
	Theralene	S	Oral	50 Gtt Drop (S), At Bedtime	Not Reported
	Tranxene	S	Oral	1 Dosage Form, 4 In 1 D	Not Reported
	Noctamide	S	Oral	1 Dosage Form, Evening	Not Reported
	Abilify	S	Oral	10 Mg (1 Dosage Form, Evening)	Not Reported
	Lepticur	S	Oral	2 Dosage Form, Morning	Not Reported
	Dafalgan Codeine	S	Oral	6 Dosage Form (2 Dosage Form, Morning, Midday And Evening)	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, 2 In 1 D	Not Reported
	Speciafoldine	C	Oral	4 Dosage Form, On Wednesdays	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12435804	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000333		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Drug Ineffective; Fatigue; Flatulence; Headache; Hypoaesthesia; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg, 1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Oral	1.4286 Mg (10 Mg, 1 In 1 W)		Hq Specialty
	Plaquenil /00072602/			S	Oral	300 Mg, 1 D		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Euro Folic			C		6 In 1 W		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2016	12437942	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis	Hydroxychloroquine S 200mg Mylan Pharmaceuticals Inc			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	10585563	EXPEDITED (15-DAY)		HO, OT	CA-GSKJP-KK201408067GSK1550188SC003		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Eye Laser Surgery; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Knee Operation; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome;	Benlysta			S	Intravenous (not otherwise specified)	At Week 0, 2, 4 Than Every 4 Weeks		Glaxosmithkline
	Benlysta			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Benlysta			S	Intravenous (not otherwise specified)	810 Mg At Week 0, 2, 4 Than Every 4 Weeks		Glaxosmithkline
	Benlysta			S	Intravenous (not otherwise specified)	810 Mg, Unk		Glaxosmithkline
	Methotrexate			S		Unk		Glaxosmithkline
	Cellcept			S		Unk		Glaxosmithkline
	Prednisone			S		50 Mg, Unk, At Bedtime(Hs)		Not Reported
	Prednisone			S		50 Mg, Unk, Am		Not Reported
	Prednisone			S		50 Mg, Unk, Am		Not Reported
	Plaquenil			S		Unk		Not Reported
	Fentanyl Teva			S		9 Mg, Unk		Not Reported
	Cortisone			S		Unk		Not Reported
	Neurontin			C	Oral	400 Mg, 1d		Not Reported
	Neurontin			C		Unk, 500mg In The Morning And 500mg In The Afternoon And 800mg At Night		Not Reported
	Neurontin			C		Unk, 600 Mg Morning 400 Afternoon 800 Mg Night		Not Reported

Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Impairment; Visual Impairment; Weight Decreased	Gravol	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	11638520	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-30		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bronchitis; Cystitis; Diarrhoea; Dizziness; Nausea; Pneumonia; Urinary Tract Infection	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Esbriet			S	Unknown			Not Reported
	Esbriet			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	11882400	EXPEDITED (15-DAY)		OT	CA-SA-2015SA219662		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nodule; Pain; Peripheral Swelling; Rheumatoid Arthritis;	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Therapeutic Product Effect Variable; Urinary Tract Infection	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported
	Cortisone	C			Not Reported
	Cortisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12155798	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-042092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Aleve			S				Bayer
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12384293	NON-EXPEDITED			US-AMGEN-USASP2016062976		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash; Swelling Face	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Actemra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2016	12439818	EXPEDITED (15-DAY)		OT	DE-FRI-1000083872		< 1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Citalopram			S	Transplacental	40 Mg		Forest
	Quensyl			S	Transplacental	200 Mg		Not Reported
	Clexane			C	Transplacental	40 Mg		Not Reported
	L-Thyroxin			C	Transplacental	25 Ug		Not Reported
	L-Thyroxin			C	Transplacental	75 Ug		Not Reported
	Fluomizin			C	Transplacental	10 Mg		Not Reported
	Biofanal			C	Transplacental			Not Reported
	Amoxihexal			C	Unknown	3000 Mg		Not Reported
	Folio			C	Transplacental	0.4 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12441385	NON-EXPEDITED			US-PFIZER INC-2016265133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Clindamycin Hcl			S		Unk		Pfizer
	Neosporin			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12443242	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016285034			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nodule	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer

Hydroxychloroquine	S	400 Mg, Unk		Not Reported
Cortisone	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	11656356	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-31			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Mobility Decreased; Neck Pain; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown	Unknown		Not Reported
	Methotrexate			C				Not Reported
	Cortisone			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12404392	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-24			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12447326	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-26		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Joint Swelling; Joint Swelling; Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Treatment Failure	Plaquenil			S		Not Reported
	Arava			S		Not Reported
	Gold			S		Not Reported
	Enbrel			S		Not Reported
	Methotrexate Sodium			S		Not Reported
	Lyrica			S	Oral	Not Reported
	Sulfasalazine			S		Not Reported
	Orencia			S		Not Reported
	Simponi			S		Not Reported
	Cellcept			S		Not Reported
	Actemra			S		Not Reported
	Rituxan			S		Not Reported
	Remicade			S		Not Reported
	Humira			S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12447327	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IT-2016-26		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis	Plaquenil			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reumaflex [Methotrexate Sodium]			S	Subcutaneous			Not Reported
	Pantoprazole			C				Not Reported
	Naproxen			C				Not Reported
	Deltacortene			C				Not Reported
	Patrol			C				Not Reported
	Ideos			C				Not Reported
	Cardirene			C				Not Reported
	Mtx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12447328	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-25		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Liver	Plaquenil			S				Not Reported

Function Test Increased; Pain	Methotrexate	S				Not Reported
	Exemestane	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12448527	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-25		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Fibrosis; Liver Function Test Increased; Nausea	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12448529	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-25		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Blood Potassium Decreased; Bradycardia; Condition Aggravated; Confusional State; Diarrhoea; Disorientation; Long Qt Syndrome; Mental Disorder; Nausea; Slow Response To Stimuli; Torsade De Pointes; Toxicity To Various Agents; Troponin I Increased; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting	Plaquenil			S	Unknown			Not Reported
	Quinine Sulfate			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12449179	NON-EXPEDITED			US-PFIZER INC-2015427441		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12449222	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Malaise; Peripheral Swelling; Product Complaint	Methotrexate Sodium			S	Oral	15 Mg, 1 W		Hq Specialty
	Plaquenil /00072602/			S	Oral	1 Dosage Form (1 Dosage Form, 1 In 1 D)		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Sulfasalazine			S	Oral	1 D		Not Reported
	Sulfasalazine			S	Oral	1000 Mg (500 Mg, 2 In 1 D)		Not Reported
	Retinol			C	Oral	1 In 1 D		Not Reported
	Leflunomide			C	Oral	1 Dosage Form (1 Dosage Form, 1 In 1 D)		Not Reported
	Prednisone			C	Oral	1 Dosage Form (1 Dosage Form, 1 In 1 D)		Not Reported
	Hydroxychloroquine			C	Oral	1 Dosage Form (1 Dosage Form, 1 In 1 D)		Not Reported
	Hydrothiazide			C	Oral	1 Dosage Form (1 Dosage Form, 1 In 1 D)		Not Reported
	Folic Acid			C	Oral	1 Dosage Form (1 Dosage Form, Except The Day		Not Reported

				Patient Takes Methotrexate)		
	Glucosamine	C	Oral	1 In 1 D		Not Reported
	Multivitamins	C	Oral	1 In 1 D		Not Reported
	Vitamin C /00008001/	C	Oral	1 In 1 D		Not Reported
	Vitamin D /00107901/	C	Oral	1 In 1 D		Not Reported
	Tylenol Arthritis	C		As Necessary		Not Reported
	Sulfathalidine	C	Oral	1 D		Not Reported
	Nicotinamide	C	Oral	1 In 1 D		Not Reported
	Panthenol	C	Oral	1 In 1 D		Not Reported
	Riboflavin	C	Oral	1 In 1 D		Not Reported
	Toviaz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2016	12384733	NON-EXPEDITED			US-PFIZER INC-2016260239		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Ibuprofen			S		Unk		Pfizer
	Methotrexate			S		2.5 Mg, Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2016	12421678	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-24			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gait Disturbance; Impaired Work Ability; Insomnia; Joint Swelling; Meniere'S	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Celebrex			C				Not Reported
	Humira			C				Not Reported

Disease; Pain; Peripheral Swelling; Therapeutic Response Decreased; Vertigo	Methotrexate	C		Not Reported
	Tylenol	C		Not Reported
	Omeprazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2016	12455543	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12456048	EXPEDITED (15-DAY)		OT	EG-CONCORDIA PHARMACEUTICALS INC.-CO-PL-EG-2015-03		28 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Abdomen; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Diarrhoea; Hepatitis Toxic; Nausea; Vomiting	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12456049	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2015-03			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Diabetes Mellitus; Drug Dependence; Drug Ineffective; Hypertension; Off Label Use; Unevaluable Event	Plaquenil			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclosporin			S				Not Reported
	Dapsone			S				Not Reported
	Methotrexate			S				Not Reported
	Montelukast			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12456050	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2015-04		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Drug Dependence; Hypertension; Ill-Defined Disorder; Off Label Use; Steroid Diabetes; Treatment Failure	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclosporin			S				Not Reported
	Cyclosporin			S				Not Reported
	Dapsone			S				Not Reported
	Dapsone			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Montelukast			S				Not Reported
	Montelukast			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12456051	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-00		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blepharospasm; Depressed Mood; Drug Ineffective; Ocular Hyperaemia; Vision Blurred	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2016	12456538	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-26			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12388200	EXPEDITED (15-DAY)		OT	CA-SA-2016SA096542			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Cirrhosis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12459602	EXPEDITED (15-DAY)		OT	GB-WATSON-2016-11915		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemoglobin Decreased; Nausea; Neutrophil Count Decreased; Periorbital Oedema; White Blood Cell Count Decreased	Hydroxychloroquine (Unknown)			S	Unknown	800 Mg, Qd		Watson
	Imatinib (Unknown)			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460289	NON-EXPEDITED		OT	US-AMGEN-USASL2016074104		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Infection; Insomnia; Limb Discomfort; Malaise;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

Musculoskeletal Pain; Pain; Pain In Extremity; Urinary Tract Infection	Methotrexate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460547	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-03		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Pigment Epitheliopathy; Retinogram Abnormal; Retinopathy; Visual Field Defect; Visual Field Tests Abnormal	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460548	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-13			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460549	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-13			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460550	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-14			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460551	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-17		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Urticaria	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460552	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-17			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nervous System Disorder	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460553	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-27			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Depression; Diplopia; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed; Therapeutic Product Effect Delayed	Plaquenil			S	Unknown			Not Reported
	Humira			S				Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460554	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-29			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Dyschromicum Perstans	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460555	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-31		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Decreased Appetite; Diarrhoea; Dyspepsia; Dyspnoea; Gastroenteritis Viral; Malaise; Nasopharyngitis; Nausea; Oedema Peripheral; Vomiting	Plaquenil			S	Unknown			Not Reported
	Juxtapid			S	Oral			Not Reported
	Juxtapid			S	Oral			Not Reported
	Geodon			C				Not Reported
	Sulfasalazine			C				Not Reported
	Metoprolol			C				Not Reported
	Nexium			C				Not Reported
	Avapro			C				Not Reported
	Buspar			C				Not Reported
	Lipitor			C				Not Reported
	Pristiq			C				Not Reported
	Trazodone			C				Not Reported
	Lortab			C				Not Reported
	Ziprasidone			C				Not Reported
	Probiotic			C				Not Reported
	Ginger			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460556	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-32			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Skin Disorder	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460557	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-32			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Plaquenil			S				Not Reported

Ineffective; Gastrooesophageal Reflux Disease; Joint Stiffness	Plaquenil			S						Not Reported
	Adalimumab			S						Not Reported
	Meloxicam			S						Not Reported
	Meloxicam			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460558	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-41			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Opacity; Eye Disorder	Plaquenil			S				Not Reported
	Metoprolol Tartrate			C		Breaks It In Half And Takes Half A Day		Not Reported
	Amlodipine Besilate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460559	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-41			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460560	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-41		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deposit Eye	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460561	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-41			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Colour Changes; Pigmentation	Plaquenil			S	Oral			Not Reported

Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460562	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2015-43		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460900	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460901	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460902	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Vomiting	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460903	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-00		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Plaquenil			S				Not Reported
	Nexium			C				Not Reported
	Xyzal			C				Not Reported
	Clobetasol			C				Not Reported
	Symbicort			C				Not Reported
	Singulair			C				Not Reported
	Prednisone			C				Not Reported
	Betamethasone			C				Not Reported
	Macrodantin			C				Not Reported
	Xolair			C				Not Reported
	Inderal			C				Not Reported
	Maxidex			C				Not Reported
	Klor-Con			C				Not Reported
	Estrace			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460904	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Back Pain; Diarrhoea	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460905	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Not Reported
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460906	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-02		24 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Plaquenil			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460907	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-04			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460908	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-18			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Decreased; Palpitations; Pruritus	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460909	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-18			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Madarosis	Plaquenil			S				Not Reported
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460910	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-18		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Texture Abnormal	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460911	NON-EXPEDITED			US-CONCORDIA			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460912	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-19			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Discolouration	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Metformin			C				Not Reported
	Singulair			C				Not Reported
	Hyzzar			C				Not Reported
	Requip			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460913	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-20		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia	Plaquenil			S				Not Reported
	Celebrex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460914	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-20			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis	Plaquenil			S				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460915	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-21		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S	Oral			Not Reported
	Cevimeline			C				Not Reported
	Cozar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460916	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-23			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460917	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-23			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460918	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-23			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered; Eye Disorder; Pain; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Not Reported
	Plaquenil			S		200 Mg Bid		Not Reported
	Synthroid			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Restasis			C	Ophthalmic	One Drop In Each Eye Twice A Day		Not Reported

	Lutein			C						Not Reported
	Vitamin B Complex Supplement			C						Not Reported
	Fish Oil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460919	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-08			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Plaquenil			S				Not Reported
Abdominal Distension;	Actemra			C				Not Reported
Abdominal Pain; Pain;	Dexilant			C				Not Reported
Product Substitution Issue	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460920	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-08			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460921	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-10		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Plaquenil			S	Unknown			Not Reported
	Ambrisentan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460922	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-11			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460923	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-12		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460924	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-13			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460925	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-14			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460926	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-14			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460927	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-14			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460928	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-14			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460929	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-16			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460930	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-17			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460931	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-17			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12460932	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-17			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12461950	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000362		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Gait Disturbance; Insomnia; Joint Swelling; Malaise; Pain; Peripheral Swelling	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Plaquenil /00072602/			S		400 Mg, 1 D		Not Reported
	Tylenol W/Codeine No. 3			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2016	12464279	DIRECT		OT			24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Erythema; Pharyngeal Swelling; Throat Irritation	Hydroxychloroquine Sul, 200 Mg Zydus			S	Oral	160 Tablet(S) Every 12 Hours Taken By Mouth		Zydus Pharm
	Trilafon			C				Not Reported
	Fetzima			C				Not Reported
	D3			C				Not Reported
	Pepcid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12305634	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-19		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Feeling Abnormal; Loss Of Personal Independence In Daily Activities;	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Musculoskeletal Stiffness; Nausea; Pain; Pneumonia; Rash; Sinusitis; Somnolence	Xeljanz	S	Oral	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2016	12464410	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-28			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Disability; Drug Ineffective; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling	Plaquenil			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2016	12468921	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016283087		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Decreased Appetite; Diabetes Mellitus; Fatigue; Impaired Work Ability; Nausea; Pancreatitis; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Plaquenil /00072603/			S		200 Mg Twice A Month In One Day		Not Reported
	Cortisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	11620202	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478113-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Asthenia; Depression; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Dependence; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Headache; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Variable Doses 10 To 20 Mg		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Dexamethasone	C		Cortisone		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	11896639	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-44		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nodule; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Variable; Urinary Tract Infection	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12471498	NON-EXPEDITED			US-MYLANLABS-2015M1035832			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12471500	NON-EXPEDITED			US-MYLANLABS-2016M1015649			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutrophil Count Decreased; Platelet Count Decreased; Therapeutic Product Effect Delayed; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Qd		Mylan
	Hydroxychloroquine Sulfate Tablets, Usp			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12471501	NON-EXPEDITED			US-MYLANLABS-2016M1012138			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen Positive	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12471858	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-27		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemoglobin Decreased; Nausea; Neutrophil Count Decreased; Periorbital Oedema; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imatinib			S				Not Reported
	Imatinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12473151	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-27		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Biopsy Heart Abnormal; Cardiac Failure; Cardiomyopathy; Chest Pain; Dyspnoea; Left Ventricular Hypertrophy; Magnetic Resonance Imaging Abnormal; Troponin Increased	Plaquenil	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12473152	EXPEDITED (15-DAY)		HO	IN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IN-2016-28		36 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cutaneous Lupus Erythematosus; Epidermolysis; Hypocomplementaemia; Inappropriate Schedule Of Product Administration; Red Blood Cell Sedimentation Rate Increased; Skin Exfoliation; Skin Lesion; Stomatitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12473153	EXPEDITED (15-DAY)		HO	IN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IN-2016-28		25 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cutaneous Lupus Erythematosus; Epidermolysis; Inappropriate Schedule Of Product Administration; Pyrexia; Rash; Skin Exfoliation; Skin Lesion; Stomatitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2016	12473154	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-28		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	11620201	EXPEDITED (15-DAY)		DS	CA-ABBVIE-15K-028-1477565-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspnoea; Joint Swelling; Joint Swelling; Musculoskeletal Stiffness	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2016	12477263	NON-EXPEDITED			US-PFIZER INC-2016304458		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S				Not Reported
	Xeljanz			C		5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2016	11621522	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477279-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Drug Intolerance; Fatigue; Haemoptysis; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Joint Swelling; Multimorbidity; Multiple Sclerosis; Nausea; Rheumatoid Arthritis; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Flagyl			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Cefaclor			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	8798822	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GLAXOSMITHKLINE-A0990806A		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Catheter Site Discharge; Catheterisation Cardiac; Complication Associated With Device; Death; Diarrhoea; Dizziness; Ear Infection; Ejection Fraction Decreased; Emergency Care; Endotracheal Intubation; Flushing; Herpes Zoster; Hospitalisation; Hypertension; Hypoaesthesia; Left Ventricular Dysfunction; Oedema Peripheral; Right Ventricular Heave; Syncope; Tachycardia; Upper Respiratory Tract Infection	Flolan			S	Intravenous (not otherwise specified)	28 Ng/Kg/Min Continuously With A Concentration Of 45,000 Ng/Ml.28 Ng/Kg/Min Continuously With A[...]		Glaxosmithkline
	Flolan			S		Unk		Glaxosmithkline
	Flolan			S		Unk		Glaxosmithkline
	Flolan			S		Unk		Glaxosmithkline
	Flolan			S		Unk		Glaxosmithkline
	Flolan			S	Intravenous (not otherwise specified)	28 Ng/Kg/Min		Glaxosmithkline
	Flolan			S	Intravenous (not otherwise specified)	28 Ng/Kg/Min Continuous		Glaxosmithkline
	Cellcept			S	Oral	500 Mg Tablets500 Mg Daily X 3 Days, Then 500 Mg Twice Daily X 2 Weeks, Then 1000 Mg Twice Daily		Glaxosmithkline
	Plaquenil			S	Oral	200 Mg Tablet		Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Lasix			C	Oral			Not Reported
	Claritin			C	Oral			Glaxosmithkline
	Ocuvite Preservision			C				Not Reported
	Klor-Con			C				Not Reported
	Adcirca			C	Oral			Not Reported
	Tracleer			C				Not Reported
	Deltasone			C				Not Reported
	Veletri			C				Not Reported
	Imuran			C				Not Reported
	Baby Aspirin			C				Not Reported
	Flonase			C				Not Reported
	Ultram			C				Not Reported

	Kenalog			C						Not Reported
	Ambien			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	11748148	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015384009		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthenia; Cartilage Atrophy; Condition Aggravated; Depression; Diarrhoea; Drug Intolerance; Dysgeusia; Lethargy; Malaise; Nausea; Panic Attack; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Arava			S		10 Mg, Daily		Not Reported
	Arava			S		10 Mg, Daily		Not Reported
	Tamsulosin Hcl			C	Oral	0.4 Unk, Unk		Not Reported
	Diclofenac Potassium			C	Oral	50 Mg, 1 Tablet Two Times Daily As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	11966306	EXPEDITED (15-DAY)		LT, OT	DK-PFIZER INC-2016041064		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Dyspnoea; Ejection Fraction Decreased; Left Ventricular Dilatation; Left Ventricular Failure; Systolic Dysfunction; Ventricular Hyperkinesia	Salazopyrin En-Tabs			S	Oral	1 G, 2x/Day		Pfizer
	Ercoquin			S	Oral	200 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Plaquenil /00072603/			S	Oral	200 Mg, 1x/Day		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	12428270	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US06003			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hallucination,	Gabapentin			S	Oral	300 Mg Orally Four Times		Invagen

Visual; Somnolence; Treatment Noncompliance					Daily Plus 600 Mg At Bedtime (Total Daily Dose 1800 Mg)	
	Gabapentin	S	Oral	300 Mg, Qd		Invagen
	Warfarin	S	Oral	5 To 10 Mg Daily		Invagen
	Pravastatin	S	Oral	20 Mg, Daily		Cipla
	Metoprolol	S	Oral	50 Mg, Bid		Cipla
	Doxycycline	S	Oral	20 Mg, Bid		Cipla
	Lansoprazole	S	Oral	30 Mg, Daily		Not Reported
	Teriparatide	S	Subcutaneous	20 Mg, Daily		Not Reported
	Insulin Aspart	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Daily		Not Reported
	Tramadol	S	Oral	100 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2016	12481899	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000389		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Musculoskeletal Stiffness; Nodule; Synovitis	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Hydroxychloroquine			S		400 Mg		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	11837318	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-40		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diabetes Mellitus; Joint Swelling; Lower Respiratory Tract Infection; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12421037	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-24			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Cirrhosis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12483270	EXPEDITED (15-DAY)		DE, OT	US-STRIDES ARCOLAB LIMITED-2016SP006878			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Meloxicam			S	Oral	Unk		Strides
	Cetirizine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxyzine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12485339	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015322505		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2016	12485341	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016288489		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count Decreased	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer
	Voltaren			S				Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Arava			S		20 Mg, Every 2 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	11518952	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-24		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Cerebrovascular Accident; Deformity; Dry Eye; Dyspnoea; Gait Disturbance; Nodule	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12327586	EXPEDITED (15-DAY)		OT	RU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-RU-2016-20		35 YR	Male	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pigmentation Disorder; Poisoning	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12488522	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016307526		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue	Methotrexate Sodium			S	Oral	25 Mg, Weekly (More Than 6 Months Ago)		Pfizer
	Hydroxychloroquine			S		200 Mg, Daily, More Than 6 Months		Not Reported
	Leflunomide			S		10 Mg, Daily, For More Than 3 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12488816	NON-EXPEDITED			US-AMGEN-USASL2016077964		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Pain; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072603/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2016	12490089	EXPEDITED (15-DAY)		HO, LT, OT	TR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-TR-2016-28		71 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anger; Blindness; Brain Oedema; Cerebrovascular Accident; Cognitive Disorder; Diarrhoea; Hallucination; Toxicity To Various Agents; Vomiting	Plaquenil			S	Oral			Not Reported
	Beloc [Metoprolol]			C				Not Reported
	Messina Combi			C				Not Reported
	Doxium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	11952665	EXPEDITED (15-DAY)		LT	DK-ABBVIE-16K-044-1545885-00		43 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Ejection Fraction Decreased; Left Ventricular Dilatation; Left Ventricular Failure; Systolic Dysfunction; Ventricular Hyperkinesia	Humira			S	Subcutaneous			Not Reported
	Ercoquin			S	Oral			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexat			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12491029	NON-EXPEDITED			US-AMGEN-USASP2016078944		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Malaise; Nausea; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12492239	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016023006		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Rash	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Ucb
	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 4 Weeks		Ucb
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2016	12493029	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-28			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Musculoskeletal Stiffness; Skin Mass	Hydroxychloroquine Sulfate	S				Not Reported
	Methotrexate	C				Not Reported
	Cortisone	C				Not Reported
	Zostavax	C				Not Reported
	Arava	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12495313	NON-EXPEDITED			US-PFIZER INC-2016195392		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfadiazine Silver			S		Unk		Pfizer
	Gentamicin Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12496958	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000405		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		50 Mg, Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		1 Df, Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Estrogel			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Xalatan			C		Unk		Not Reported
	Cosopt			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Valsartan			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2016	12496964	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000418		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Constipation; Crying; Dyspepsia; Emotional Disorder; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Porphyria Acute	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Arava			S	Oral	(10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2016	12498067	EXPEDITED (15-DAY)		OT	TW-BAXTER-2016BAX031680		79 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Back Pain; Compression Fracture; Disease Progression; Mitral Valve Incompetence; Osteoporosis; Pain In Extremity; Pulmonary Arterial Hypertension; Tricuspid Valve Incompetence	Endoxan Injection			S	Unknown	1#, Qod		Baxter
	Endoxan Injection			S	Unknown	Qod		Baxter
	Prednisolone			S	Unknown	1.5#		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Plaquenil			S	Unknown	1#		Not Reported
	Coumadin			S	Unknown			Not Reported
	Sildenafil			S	Unknown	Qid - Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12250357	NON-EXPEDITED		HO, LT, OT	PHHY2015US033784			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Back Pain; Bronchitis; Candida Infection; Chest Discomfort; Diabetes Mellitus; Gait Inability; Hand Deformity; Headache; Hypoglycaemia; Inflammation; Malaise; Nasal Obstruction; Nodule; Rheumatoid Arthritis; Rhinorrhoea; Sinus Disorder; Spontaneous Haemorrhage	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, 1 In 3 Week	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Unknown		Novartis
	Prednisone	S			Novartis
	Coreg	S	Oral	6.25 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid (Currently On Hold Due To Hypoglycemia)	Not Reported
	Leflunomide	C	Oral	20 Mg, Qd	Not Reported
	Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C			Not Reported
	Cortisone	C	Unknown		Not Reported
	Spiriva	C	Nasal	18 Ug, Qd	Not Reported
	Levothyroxine	C	Oral	75 Ug, Qd	Not Reported
	Prilosec	C	Oral	40 Mg, Qd	Not Reported
	Lexapro	C	Oral	20 Mg, Qd	Not Reported
	Albuterol	C	Unknown	Tid (As Needed)	Not Reported
	Ventolin	C	Unknown	108 Ug, Tid (2 Puffs, As Needed)	Not Reported
	Xanax	C	Oral	2 Mg, Tid (As Required)	Not Reported
	Diflucan	C	Unknown	150 Mg, Unk	Not Reported
	Carvedilol	C	Oral	6.25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12267046	NON-EXPEDITED			US-PFIZER INC-2016194628		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Sulfasalazine	S	1500 Mg (500mg, Three Tablets), 2x/Day	Pfizer
	Hydroxychloroquine	S	200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12362333	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-22		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12500223	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-29			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Plaquenil			S				Not Reported
	Lyrica			C				Not Reported
	Asa			C				Not Reported
	Rabeprazole			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12501087	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000415		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Methotrexate Sodium			S		Unk		Hq Specialty
	Plaquenil /00072602/			S		200 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Humira			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

	Celecoxib		C	Oral	400 Mg, (200 Mg, 2 In 1 Day)				Not Reported
	Prednisone		C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	11993525	EXPEDITED (15-DAY)		LT	DK-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DK-2016-03		42 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Dyspnoea; Ejection Fraction Decreased; Left Ventricular Dilatation; Left Ventricular Failure; Systolic Dysfunction; Ventricular Hyperkinesia	Plaquenil			S	Oral			Not Reported
	Ercoquin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Methotrexat			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12483780	NON-EXPEDITED			US-PFIZER INC-2016307202			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S				Pfizer
	Hydroxychloroquine			S				Not Reported
	Sulfazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505823	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505824	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Nausea; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505825	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Gastrointestinal Disorder; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505826	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Intestinal	Plaquenil			S				Not Reported
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505903	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition	Hydroxychloroquine Sulfate			S				Not Reported

Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hepatic Enzyme Increased; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Delayed	Arava		S			Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S			Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505904	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Therapeutic Product Effect Incomplete	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12505905	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Rheumatoid Arthritis; Synovitis	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Cortisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508050	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Enbrel "Immunex"			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508051	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Hypophagia; Urinary Incontinence; Viral Infection	Hydroxychloroquine Sulfate			S				Not Reported
	Azathioprine			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Nexium			C				Not Reported

	Rosuvastatin Calcium			C						Not Reported
	Tylenol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508052	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-33		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Invasive Ductal Breast Carcinoma; Pleural Effusion	Plaquenil			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ativan			C				Not Reported
	Calcium Carbonate/Calcium Lactogluconate			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported
	Diclofenac Diethylamine			C				Not Reported
	Elavil			C				Not Reported
	Ergocalciferol			C				Not Reported
	Escitalopram Oxalate			C				Not Reported
	Fosamax			C				Not Reported
	Lipitor			C				Not Reported
	Prednisone Acetate			C				Not Reported
	Rivotril			C				Not Reported
	Tenormin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508295	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2015GSK139770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Benlysta			S		900 Mg, Unk		Glaxosmithkline
	Benlysta			S		900 Unk, Unk		Glaxosmithkline
	Benlysta			S		900 Unk, Unk		Glaxosmithkline
	Benlysta			S		900 Mg, Unk		Glaxosmithkline
	Chloroquine Phosphate			S				Glaxosmithkline
	Plaquenil			S				Not Reported
	Methotrexate			S				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508814	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-33		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Incomplete; Abortion Spontaneous; Exposure During Pregnancy; Haemorrhage; Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508815	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-33		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Joint Swelling; Movement Disorder; Musculoskeletal Stiffness; Peripheral Swelling	Plaquenil			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508816	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-33		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Asthenia; Decreased Appetite; Drug Ineffective; Influenza Like Illness; Infusion Related Reaction; Nasal Congestion; Pruritus; Upper Respiratory Tract Congestion; Weight Decreased; Weight	Hydroxychloroquine Sulfate			S				Not Reported
	Arava			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Increased					otherwise specified)				
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Diphenhydramine			C					Not Reported
	Methylprednisolone			C					Not Reported
	Tylenol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12508817	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-36		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Plaquenil			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Actemra			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509031	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Decreased Appetite; Diabetes Mellitus; Fatigue; Impaired Work Ability; Pancreatitis; Therapeutic Product Effect Incomplete; Vomiting	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cortisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509032	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Plaquenil			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Humira			S	Unknown	Not Reported
	Gold			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509033	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Drug Ineffective; Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509034	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Lung Disorder; Pericardial Effusion; Pulmonary Oedema; Renal Disorder; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509035	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509036	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sinusitis	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509037	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Disorder	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509038	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509039	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-31		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Feeling Hot; Fine Motor Skill Dysfunction; Mobility Decreased; Paraesthesia	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509041	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Plaquenil	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	12509042	NON-EXPEDITED		OT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-26		75 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Bepricor			C				Not Reported
	Eliquis			C				Not Reported
	Teprenone			C				Not Reported
	Digosin			C				Not Reported
	Onealfa			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	11879856	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2015-43		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Pain	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Predonine			C				Not Reported
	Nexium			C				Not Reported
	Salagen			C				Not Reported
	Baktar			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12421010	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2016075982		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Infusion Related Reaction; Product Complaint; Pruritus; Pruritus	Benlysta Powder For Infusion			S	Intravenous (not otherwise specified)	760 Mg, Cyc		Glaxosmithkline
	Benlysta Powder For Infusion			S		Unk		Glaxosmithkline
	Benlysta Powder For Infusion			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Benadryl (Diphenhydramine Hydrochloride)			C				Not Reported
	Citalopram			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Leflunomide			C				Not Reported
	Medrol Dose Pack			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol			C				Not Reported
	Arava			C				Not Reported
	Wellbutrin			C				Glaxosmithkline
	Nexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12516614	NON-EXPEDITED			US-JAZZ-2015-US-022077		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4 G, Bid		Jazz
	Hydroxychloroquine			S		Unk		Not Reported
	Benadryl Allergy			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Magnesium Chelate			C		Unk		Not Reported
	Zinc Acetate			C		Unk		Not Reported
	Albuterol Sulfate Hfa			C		Unk		Not Reported
	Coq10			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported

	Singulair	C	Unk		Not Reported
	Vitamin D3	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12517087	NON-EXPEDITED			US-PFIZER INC-2016085499			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12517818	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-34		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Plaquenil			S				Not Reported
Increased; Drug	Arava			S				Not Reported
Ineffective; Drug	Arava			S				Not Reported
Intolerance; Dyspepsia;	Arava			S				Not Reported
Liver Function Test	Arava			S				Not Reported
Abnormal; Nausea; Red	Arava			S				Not Reported
Blood Cell Sedimentation	Arava			S				Not Reported
Rate Increased;	Arava			S				Not Reported
Rheumatoid Arthritis;	Arava			S				Not Reported
Therapeutic Response	Enbrel			S				Not Reported
Decreased	Humira			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Methotrexate Sodium		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518655	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Plaquenil			S				Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Indomethacin			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Actemra			S				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518656	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-35		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Red Blood Cell Sedimentation Rate	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Folic Acid			S				Not Reported
	Methotrexate Sodium			S				Not Reported

Increased; Treatment Failure	Cortisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518658	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-35		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Plaquenil			S				Not Reported
	Celebrex			S				Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518659	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-35		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis	Plaquenil			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518661	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-36		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Nausea; Vomiting	Plaquenil			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	0.6 Millilitre(S)		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518828	EXPEDITED (15-DAY)		OT	PHHY2016FR088044		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518920	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518922	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		35 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methorexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518923	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-30		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Atrovent			C				Not Reported
	Benzatropine			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrimeprazine			C				Not Reported
	Pantoprazole			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Salbutamol			C				Not Reported
	Trifluoperazine			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518924	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-33			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Folic Acid			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518925	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-33			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518927	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-34		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Disability; Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Plaquenil		S	Oral	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518929	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-34		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518931	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-34			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518933	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		62 YR	Male	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518935	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-34		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Arthritis; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518937	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-35		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Dizziness; Drug Ineffective; Eye Disorder; Inflammation	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12518938	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-36		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Nausea; Retinitis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12519304	EXPEDITED (15-DAY)		DS, HO, OT	GB-PFIZER INC-2016322354		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Liver Function Test Abnormal; Pancytopenia	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Hydroxychloroquine			S	Oral	200mg (Monday To Friday At Two Doses Daily)		Not Reported
	Amitriptyline			C		Unk		Not Reported

Co-Codamol	C	Unk	Not Reported
Folic Acid	C	10 Mg, Weekly	Not Reported
Ibuprofen	C	Unk	Not Reported
Prednisolone	C	Reducing Course.	Not Reported
Proton Pump Inhibitors	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2016	12520013	NON-EXPEDITED			US-PFIZER INC-2016292993		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S				Pfizer
	Etodolac			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Imuran /00001501/			S				Not Reported
	Lactose			S				Not Reported
	Nabumetone			S				Not Reported
	Seldane			S				Not Reported
	Sulindac			S				Not Reported
	Terfenadine			S				Not Reported
	Azathioprine			S				Not Reported
	Clinoril			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12522592	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000425		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Discharge; Fatigue;	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty

Headache; Nasopharyngitis; Nausea; Oropharyngeal Pain; Rhinorrhoea; Sinus Pain	Methotrexate Sodium	S	Oral	0.8571 Mg (6 Mg, 1 In 1 W)	Hq Specialty
	Plaquenil /00072602/	S		400 Mg (200 Mg, 2 In 1 D)	Not Reported
	Sulfasalazine	S		2 G	Not Reported
	Xeljanz	S	Oral	10 Mg (5 Mg, 2 In 1 D)	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12522819	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000433		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Nausea	Methotrexate Sodium			S		More Than 20 Mg (1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G (1 G, 2 In 1 D)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		20 Mg, 1 D		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Stelara			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2016	12522826	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000424		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pneumonitis; Pyelonephritis	Methotrexate Sodium			S		25 Mg, Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

Actemra	S	Unk	Not Reported
Orencia	S	Unk	Not Reported
Plaquenil /00072602/	S	Unk	Not Reported
Mirtazapine	S	15 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2016	12523909	NON-EXPEDITED			US-JAZZ-2015-US-022313			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Fibromyalgia; Migraine	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3.75 G, Qd		Jazz
	Plaquenil			S		200 Mg, Bid		Not Reported
	Gabapentin			C		Unk		Not Reported
	Motrin Ib			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported
	Armour Thyroid			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Metoprolol Tartrate			C		Unk		Not Reported
	Modafinil			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Proair			C		Unk		Not Reported
	Ritalin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	10252256	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ROCHE-1418176		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Bilirubin Increased; Catheter Site	Cellcept			S	Oral	500mg Qd X 3 Days, 500mg Bid X 3 Week,		Not Reported

Discharge; Catheterisation Cardiac; Complication Associated With Device; Death; Diarrhoea; Dizziness; Ear Infection; Ejection Fraction Decreased; Flushing; Herpes Zoster; Hypertension; Hypoaesthesia; Left Ventricular Dysfunction; Liver Function Test Increased; Loss Of Consciousness; Oedema Peripheral; Right Ventricular Heave; Syncope; Tachycardia; Upper Respiratory Tract Infection				1000mg Bid		
	Flolan	S	Unknown	28 Ng/Kg/Min		Not Reported
	Flolan	S	Intravenous (not otherwise specified)	28 Ng/Kg/Min		Not Reported
	Flolan	S	Intravenous (not otherwise specified)	28 Ng/Kg/Min		Not Reported
	Flolan	S	Intravenous (not otherwise specified)	28 Ng/Kg/Min		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Lasix	C				Not Reported
	Claritin	C				Not Reported
	Ocuvite Preservision	C				Not Reported
	Potassium Chloride	C				Not Reported
	Adcirca	C				Not Reported
	Tracleer	C				Not Reported
	Epoprostenol Sodium	C				Not Reported
	Aspirin	C				Not Reported
	Fluticasone Propionate	C				Not Reported
	Tramadol Hcl	C				Not Reported
	Triamcinolone Acetonide	C				Not Reported
	Zolpidem Tartrate	C				Not Reported
	Prednisone	C				Not Reported
	Imuran	C				Not Reported
	Baby Aspirin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	11755044	EXPEDITED (15-DAY)		HO	CA-SA-2015SA184343		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Diabetes Mellitus; Infection; Localised Infection; Pain	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C				Not Reported

	Advil				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	11888905	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-44			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cartilage Injury; Depression; Dizziness; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Palpitations; Panic Attack; Renal Function Test Abnormal; Tremor	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Diclofenac			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported
	Tamsulosin Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12277426	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-18			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Fatigue; Foot Fracture; Joint Swelling; Malaise; Nausea; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Cortisone			C				Not Reported
	Cortisone			C		2.5 Mg Every Other Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12486421	NON-EXPEDITED			US-PFIZER INC-2016306079		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

	Humira			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12490087	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-28		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Estrogel			C				Not Reported
	Calcium			C				Not Reported
	Xalatan			C				Not Reported
	Cosopt			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12495524	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-29		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil			S	Oral	Dose Alternated Between 200 Mg/Day And 400 Mg/Day Each Day		Not Reported
	Bayaspirin			C				Not Reported
	Procylin			C				Not Reported
	Crestor			C				Not Reported
	Predonine			C				Not Reported
	Nexium			C				Not Reported
	Prograf			C				Not Reported

		Bonalon			C						Not Reported
		Zolpidem			C						Not Reported
		Prednisolone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12526876	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-051815			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12527535	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-36			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Joint Stiffness; Joint Swelling; Joint Swelling; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12528303	EXPEDITED (15-DAY)		DS	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-35		75 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspepsia; Palpitations	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12528790	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015179918		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Diarrhoea; Drug Ineffective; Interstitial Lung Disease; Mycobacterium Tuberculosis Complex Test Positive; Pain; Synovitis	Methotrexate Sodium			S	Oral	15 Mg (6 Tablets Of 2.5 Mg), Weekly		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg (7 Tablets Of 2.5 Mg) , Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg (8 Tablets Of 2.5 Mg), Weekly		Pfizer
	Arava			S		20 Mg, Daily		Not Reported
	Plaquenil			S		200 Mg Tablet Take 2 Tablets Daily From Monday To Friday Then 1 Tablet Daily Saturday And Sunday		Not Reported
	Plaquenil			S		400 Mg (200 Mg X 2 Tablets), 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, Daily (6 Days Per Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12528792	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015325834		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Pain; Cough; Drug Ineffective; Eosinophilia; Gait Disturbance; Oedema; Pain; Paraesthesia; Post Procedural Infection; Productive Cough; Swelling Face; Synovitis	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil /00072603/			S		400 Mg, 1x/Day		Not Reported
	Leflunomide			S		10 Mg, Unk		Not Reported
	Prednisone			C		Tapering Course		Not Reported
	Cymbalta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12528800	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015080773		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Hepatic Enzyme Increased; Nasopharyngitis; Platelet Count Decreased; Pneumonia; Rheumatoid Arthritis; Weight Increased; White Blood Cell Count Decreased	Methotrexate Sodium			S	Oral	25 Mg		Pfizer
	Methotrexate Sodium			S		12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		7.5 Mg, Unk		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S		Decreasing Dose		Not Reported
	Plaquenil			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2016	12530608	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Urticaria	Hydroxychloroquine 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12530225	NON-EXPEDITED			US-PFIZER INC-2016292322		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methylprednisolone			S				Pfizer
	Morphine Sulfate			S				Pfizer
	Erythromycin			S				Pfizer
	Atenolol			S				Pfizer
	Etodolac			S				Pfizer
	Omeprazole			S				Not Reported
	Ceclor			S				Not Reported
	Keflex			S				Not Reported
	Hydrocodone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

	Januvia			S						Not Reported
	Vioxx			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12530261	NON-EXPEDITED			US-PFIZER INC-3106455		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Headache; Malaise; Muscle Spasms; Product Dose Omission; Weight Increased	Methotrexate Sodium			S		6 Mg, Weekly		Unknown
	Plaquenil /00072602/			S				Not Reported
	Prednisone			S				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Ibuprofen			C		600 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12531524	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000468		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest X-Ray Abnormal; Dental Caries; Drug Ineffective; Lower Respiratory Tract Infection; Malaise; Nausea	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	Unk		Hq Specialty
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12531567	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000446		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Neutropenia; White Blood Cell Count Decreased	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate Sodium			S		Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	Unk		Hq Specialty
	Sulfasalazine			S	Oral	2000 Mg (1000 Mg, 2 In 1		Not Reported

							D)		
		Voltaren /00372301/			S		Unk		Not Reported
		Plaquenil Sulfate			S		400 Mg (200 Mg, 2 In 1 D)		Not Reported
		Leflunomide			S		10 Mg (20 Mg, 1 In 2 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12531763	NON-EXPEDITED			US-PFIZER INC-2016293557		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Joint Swelling; Musculoskeletal Stiffness; Peripheral Swelling; Therapeutic Product Effect Incomplete	Xeljanz			S		5 Mg, Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12532014	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK095847		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count Decreased	Voltaren			S				Glaxosmithkline
	Methotrexate			S		Unk		Glaxosmithkline
	Methotrexate			S	Oral	Unk		Glaxosmithkline
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Plaquenil			S		200 Mg, Bid		Not Reported
	Arava			S		20 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2016	12535615	DIRECT		DS			66 YR	Male	NGA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tinnitus	Hydroxychloroquine Hcqs, 200 Mg			S	Oral			Alpha Therapeutic

	Methotrexate			C						Not Reported
	Prednisolone			C						Not Reported
	Calcium D3			C						Not Reported
	Folic Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12423083	NON-EXPEDITED			US-PFIZER INC-2016280258		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		12.5 Mg, Weekly (5 Pills Weekly 2.5 Mg)		Pfizer
	Methotrexate Sodium			S				Pfizer
	Plaquenil			S		40 Mg, 1x/Day (2 Pill Per Day 20mg)		Not Reported
	Plaquenil			S				Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12536759	EXPEDITED (15-DAY)		DS, HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201606-003318		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Liver Function Test Abnormal; Pancytopenia	Hydroxychloroquine			S	Oral	Two Doses Daily (Monday To Friday)		Concordia
	Methotrexate			S	Oral			Not Reported
	Amitriptyline			C				Not Reported
	Co-Codamol			C				Not Reported
	Folic Acid			C				Not Reported
	Ibuprofen			C				Not Reported
	Prednisolone			C		Reducing Course.		Not Reported
	Proton Pump Inhibitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12537587	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000467		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	50 Mg, 1 W		Not Reported
	Plaquenil /00072602/			S		200 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg (500 Mg, 2 In 1 D)		Not Reported
	Sulfasalazine			S		2000 Mg (1000 Mg, 2 In 1 D)		Not Reported
	Humira			S		2.8571 Mg (40 Mg, 1 In 2 W)		Not Reported
	Rituxan			S		0.0111 G (2 G, 1 In 6 Mo)		Not Reported
	Leflunomide			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Prednisone			S		20 Mg, 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2016	12537898	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000470		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Hydroxychloroquine			S		200 Mg (200 Mg, 1 In 1 D)		Not Reported
	Leflunomide			S		10 Mg (10 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	11985225	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

INC.-CO-PL-CA-2016-02

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Infection; Pain; Rheumatoid Arthritis; Therapy Non-Responder	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported
	Celebrex			S				Not Reported
	Toradol			S				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12541755	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000483			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Mycophenolate Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12541833	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-37		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral; Skin Hyperpigmentation	Plaquenil			S	Oral			Not Reported
	Dermoval (Clobetasol Propionate)			S	Cutaneous			Not Reported
	Lodoz			C				Not Reported
	Coversyl			C				Not Reported
	Inegy			C				Not Reported
	Plavix			C				Not Reported
	Seroplex			C				Not Reported

	Seresta			C						Not Reported
	Atarax			C						Not Reported
	Dafalgan			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12541835	EXPEDITED (15-DAY)		DS, HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-37		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Liver Function Test Abnormal; Pancytopenia	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Amitriptyline			C				Not Reported
	Co-Codamol			C				Not Reported
	Folic Acid			C				Not Reported
	Ibuprofen			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12541836	EXPEDITED (15-DAY)		HO, LT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-37		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Intentional Product Misuse; Pain; Pancytopenia; Pyrexia; Sepsis	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Dapsone			S	Oral			Not Reported
	Fish Oil			C				Not Reported
	Methotrexate			C				Not Reported
	Vitamin B Compound Strong			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2016	12542143	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000478		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Carpal Tunnel Syndrome; Drug Ineffective; Fibromyalgia; General	Methotrexate Sodium			S	Unknown	17.5 To 25 Mg (1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Unknown	17.5 To 25 Mg (1 In 1 W)		Hq Specialty

Physical Health Deterioration; Liver Function Test Increased; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Radicular Pain; Rheumatoid Arthritis; Spinal Stenosis	Arava	S	Unknown	20 Mg (20 Mg, 1 In 1 D)	Not Reported
	Arava	S			Not Reported
	Plaquenil	S		400 Mg (400 Mg, 1 In 1 D)	Not Reported
	Plaquenil	S		Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Sulfasalazine	S	Oral	(2 G, 1 D)	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S			Not Reported
	Tramacet	S		Unk	Not Reported
	Aclasta	S	Intravenous (not otherwise specified)	Unk, Single	Not Reported
	Nortriptyline	C	Unknown	At Bedtime (20 Mg)	Not Reported
	Nortriptyline	C	Unknown	Bedtime (2 Dosage Form, 1 D)	Not Reported
	Metformin	C	Unknown	(5 Mg,1 D)	Not Reported
	Metformin	C	Unknown	1000 Mg (500 Mg, 2 In 1 D)	Not Reported
	Lorazepam	C	Unknown	Once Nightly (1 Mg)	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported
	Lyrica	C	Oral	300 Mg (150 Mg, 2 In 1 D)	Not Reported
	Premarin	C	Unknown	(3.6 Mg)	Not Reported
	Vitamin D Nos	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Depomedrol	C	Intramuscular	1.3333 Mg (40 Mg, 1 In 1 Mo)	Not Reported
	Depomedrol	C	Subcutaneous	(1 Mo)	Not Reported
	Depomedrol	C	Subcutaneous	Unk	Not Reported
	Tylenol Arthritis	C		Unk	Not Reported
	Actonel Once-A-Week	C	Unknown	5 Mg (35 Mg, 1 In 1 W)	Not Reported

	Ergocalciferol			C	Unknown	Unk				Not Reported
	Methylprednisolone Acetate			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12544167	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-119838		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Antiphospholipid Syndrome	Hydroxychloroquine			S	Unknown	600 Mg, Daily		Ipca
	Methotrexate			S	Unknown	20 Mg Weekly		Not Reported
	Prednisone			S	Unknown	10 Mg, Daily		Mutual
	Calcium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Vitamin D3			S	Unknown	Unk		Not Reported
	Prednisolone			S	Intravenous (not otherwise specified)	120mg(2mg/Kg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12544387	NON-EXPEDITED			US-PFIZER INC-2016305963			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Altace			S		Unk		Pfizer
	Demerol			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Avapro			S		Unk		Not Reported
	Fluarix 2015/2016			S		Unk		Not Reported
	Kombiglyze Xr			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

	Meloxicam	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Pravachol	S	Unk		Not Reported
	Sular	S	Unk		Not Reported
	Tekturna	S	Unk		Not Reported
	Toprol	S	Unk		Not Reported
	Tussionex Pennkinetic	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12546498	NON-EXPEDITED			US-PFIZER INC-2016333064			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12546523	EXPEDITED (15-DAY)		DS, HO, OT	GB-WATSON-2016-14689		37 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aplastic Anaemia; Liver Function Test Abnormal; Pancytopenia	Hydroxychloroquine (Unknown)			S	Oral	200 Mg, 10 Dosages A Week, Two Doses Daily (Monday To Friday)		Watson
	Methotrexate Sodium			S	Oral	10 Mg, 1/Week		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Co-Codamol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	10 Mg, 1/Week		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk; Reducing Course.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2016	12547893	DIRECT	Y				40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Macular Hole	Enbrel Sureclick 50mg/Ml			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	11781914	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-38		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Diabetes Mellitus; Infection; Localised Infection; Pain	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12081386	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-05			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Lower Respiratory Tract Infection; Rheumatoid Arthritis; Urinary Tract Infection	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Actemra			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Prednisone			C				Not Reported
	Orencia			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12235285	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-15		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fall; Gait Disturbance; Gait Inability; Pain; Swelling	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12444950	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2016080083		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Hepatic Failure; Hepatitis; Hyperbilirubinaemia; Jaundice; Ocular Icterus; Transaminases Increased	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S				Not Reported
	Cell Cept			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12473150	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-27		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema	Plaquenil			S	Oral			Not Reported
	Octagam			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			S	Oral			Not Reported
	Levothyrox			C				Not Reported
	Lercan			C				Not Reported
	Cardensiel			C				Not Reported
	Folic Acid			C				Not Reported
	Kaleorid			C				Not Reported
	Esidrex			C				Not Reported

	Micardis			C						Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			C						Not Reported
	Elisor			C						Not Reported
	Rivotril			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12497008	EXPEDITED (15-DAY)		HO	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-29		54 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Logorrhoea	Plaquenil			S	Oral			Not Reported
	Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12547717	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016088032		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis	Enbrel			S	Subcutaneous	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported
	Celebrex			C	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2016	12550218	EXPEDITED (15-DAY)		HO, LT	GB-WATSON-2016-15023		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Pain; Pancytopenia; Pyrexia; Sepsis	Dapsone (Unknown)			S	Oral	100 Mg, Daily		Not Reported
	Hydroxychloroquine (Unknown)			S	Oral	400 Mg, Daily (Prescribed 200mg Twice A Day But Patient Was Taking 400mg Once A Day.)		Watson

	Vitamin B Compound /00171501/	C	Unknown	1 Df, Daily		Not Reported
	Fish Oil	C	Oral	1 Df, Daily		Not Reported
	Methotrexate	C	Unknown	Unk Unk, Unknown (This Had Been Discontinued 2 Weeks Prior To Admission.)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12484209	EXPEDITED (15-DAY)		OT	FR-ROCHE-1777299			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Infection; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12536665	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016330706		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Maculopathy; Pulmonary Toxicity; Thrombocytopenia	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Eliquis			C	Oral	5 Mg, 2x/Day		Not Reported
	Amlodipine			C		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12552572	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-CO-PL-DE-2016-37		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Dyspnoea; Ejection Fraction Decreased; Fibrosis; Left Ventricular End-Diastolic Pressure Increased; Left Ventricular End-Diastolic Pressure Increased; Left Ventricular Hypertrophy; N-Terminal Prohormone Brain Natriuretic Peptide Increased; Peripheral Swelling	Hydroxychloroquine Sulfate			S				Not Reported
	Sildenafil			C				Not Reported
	Iloprost			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12552730	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000501		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Methotrexate Sodium			S		7.5 To 12.5 Mg (1 In 1 W)		Hq Specialty
	Plaquenil /00072602/			S		400 Mg (200 Mg,2 In 1 D)		Not Reported
	Simponi			S		1.6667 Mg (50 Mg,1 In 1 Mo)		Not Reported
	Arava			S		10 Mg (20 Mg,1 In 2 D)		Not Reported
	Arava			S		10 Mg (20 Mg,1 In 2 D)		Not Reported
	Imuran /00001501/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12553062	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015415931		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Myocardial Infarction; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2016	12553960	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000522		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Plaquenil			S	Unknown	400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Leflunomide			S	Unknown	20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Humira			S	Subcutaneous	2.8571 Mg (40 Mg, 1 In 2 W)		Not Reported
	Imuran			S	Unknown	100 Mg Every Morning And 50 Mg Every Evening		Not Reported
	Sulfasalazine			S	Oral	1500 Mg (500mg 3 Tabs) Twice A Day, Took More Than 6 Months		Not Reported
	Naprosyn			C	Unknown	1000 Mg (500 Mg, 2 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	10688866	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-BMS-2014-004599		30 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Caesarean Section; Maternal Exposure During Pregnancy; Normal Newborn; Pre-Eclampsia; Premature Delivery	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Aspirin /00002701/			S	Unknown	100 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Enoxaparin			S	Unknown	60 Mg, Bid		Not Reported

	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	12556864	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201607-003543		50 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nodular Vasculitis; Product Use In Unapproved Indication; Rebound Effect	Orapred			S	Oral			Concordia
	Orapred			S	Oral			Concordia
	Orapred			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Colchicine			S	Oral			Not Reported
	Rifampicin			C				Not Reported
	Isoniazid			C				Not Reported
	Ethambutol			C				Not Reported
	Pyrazinamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2016	12557581	EXPEDITED (15-DAY)		HO, OT	MX-CONCORDIA PHARMACEUTICALS INC.-CO-PL-MX-2016-37		39 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Plaquenil			S	Oral			Not Reported
	Rantudil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	11656374	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-32		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fungal Infection; Herpes Zoster; Lower Respiratory Tract	Plaquenil			S	Oral			Not Reported
	Oxycodone			C				Not Reported
	Methotrexate			C				Not Reported

Infection; Pneumonia; Staphylococcus Test Positive; Wheezing

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12265976	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016204841		91 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Drug Intolerance; Gait Inability; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Sulfasalazine			S				Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil /00072603/			S	Oral	400 Mg, 1x/Day		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12537783	EXPEDITED (15-DAY)		DE, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-36		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiac Hypertrophy; Cardiomyopathy; Myocardial Fibrosis; Myopathy; Ventricular Hypertrophy	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12561488	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-38			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung Disease; Vomiting	Plaquenil			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S				Not Reported

	Methotrexate			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2016	12562326	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000574		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fungal Infection; Herpes Zoster; Joint Swelling; Lower Respiratory Tract Infection; Pneumonia; Staphylococcus Test Positive	Methotrexate Sodium			S	Oral	1.4286 Mg (10 Mg,1 In 1 W)		Hq Specialty
	Plaquenil /00072602/			S	Oral	200 Mg (200 Mg,1 In 1 D)		Not Reported
	Oxycodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12564176	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000535		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Product Dose Omission	Methotrexate Sodium			S		3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Folic Acid			S		Unk		Not Reported
	Arava			S	Oral	20 Mg (20 Mg, 1 In 1 D)		Not Reported
	Plaquenil /00072602/			S		Everday Besides Sunday (200 Mg, 1 In 1 D)		Not Reported
	Cimzia			S		14.2857 Mg (200 Mg, 1 In 2 W)		Not Reported
	Humira			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	10.0357 Mg (281 Mg,1 In 4 W)		Not Reported
	Actemra			S	Subcutaneous	162 Mg,1 W		Not Reported
	Prednisone			S		Alternate Day (Every Second For Next 2 Weeks) (2 Dosage Form)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12564177	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000536		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Normal; Hepatotoxicity	Methotrexate Sodium			S		Unk		Hq Specialty
	Sulfasalazine			S		Single (1 Dosage Form)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Every Morning (20 Mg, 1 In 1 D)		Not Reported
	Xeljanz			C	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12566264	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000549		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Diarrhoea; Drug Ineffective; Interstitial Lung Disease; Mycobacterium Tuberculosis Complex Test Positive; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	6 Dosage Form, 1 In 1 W		Hq Specialty
	Methotrexate Sodium			S	Oral	7 Dosage Form, 1 In 1 W		Hq Specialty
	Methotrexate Sodium			S	Oral	8 Dosage Form, 1 In 1 W		Hq Specialty
	Arava			S		Various (1 D)		Not Reported
	Arava			S		Various (2 Dosage Form, 1 D)		Not Reported
	Plaquenil /00072602/			S		2 Tabs Daily From Monday To Friday, 1 Tab Daily On		Not Reported
	Plaquenil /00072602/			S		2 Dosage Form,1 In 1 D		Not Reported
	Folic Acid			C	Oral	6 Days Per Week Except Day Of Methotrexate		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12566277	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000542		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate Sodium			S		3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Celebrex			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg,1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12566290	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000546		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Fibrosis; Therapeutic Response Unexpected	Methotrexate Sodium			S		Unk		Hq Specialty
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12566294	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000547			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Pain; Cough; Gait Disturbance; Oedema; Paraesthesia; Post Procedural Infection; Productive Cough; Swelling Face; Synovitis	Methotrexate Sodium			S		Unk		Hq Specialty
	Methotrexate Sodium			S		2.1429 Mg (15 Mg,1 In 1 W)		Hq Specialty
	Actemra			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Leflunomide			S		10 Mg, Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg,1 In 1 D		Not Reported
	Humira			C		Unk		Not Reported
	Prednisone			C		Unk, Tapering		Not Reported

	Cymbalta			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2016	12567211	EXPEDITED (15-DAY)		OT	CA-SA-2016SA102314		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	11497873	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-21		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	11502717	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-21		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Bone Disorder; Condition Aggravated; Fall; Lower Limb Fracture; Osteoarthritis; Osteoporosis; Pain In	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete; Tibia Fracture; Wrist Fracture

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	11651426	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015110145		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Bone Disorder; Drug Ineffective; Hip Arthroplasty; Infection; Lower Limb Fracture; Osteonecrosis; Post Procedural Infection; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	11774354	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-37			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Joint Swelling; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported
	Invokana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	11776321	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2015124500		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Eye Disorder; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Bid		Not Reported
	Humira			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12448528	EXPEDITED (15-DAY)		LT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-25			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12527054	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE-IL2016GSK094975			Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Benlysta			S	Intravenous (not otherwise specified)	10 Mg/Kg, Once A Month		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12541834	EXPEDITED (15-DAY)		HO, LT	NL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-NL-2016-37		25 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apnoea; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactic Acid Increased; C-Reactive Protein Increased; Cardiomyopathy; Conduction Disorder; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Overdose; Pleural Effusion; Vomiting	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Diazepam			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12570445	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CN-2016-38		56 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema; Rash	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12570446	EXPEDITED (15-DAY)		HO, LT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-38		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Failure	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12570450	EXPEDITED (15-DAY)		OT	SK-CONCORDIA PHARMACEUTICALS INC.-CO-PL-SK-2016-38		60 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571084	EXPEDITED (15-DAY)		DS, OT	US-BAYER-2016-138031		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Ear Pain; Gait Disturbance; Gait Inability; Hyperacusis; Hypergeusia; Insomnia; Limb Discomfort; Mitochondrial Toxicity; Muscle Twitching; Muscular Weakness; Muscular Weakness; Myalgia; Nervous System Disorder; Nervousness; Neurotoxicity; Pain In Extremity; Palpitations; Parosmia; Photophobia; Retinal Disorder; Taste Disorder; Thirst; Weight Bearing Difficulty	Cipro			S		5 Pills		Bayer
	Levaquin			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571133	EXPEDITED (15-DAY)		HO	NL-MYLANLABS-2016M1029524			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose; Suicide	Hydroxychloroquine			S	Oral	5g		Not Reported
	Codeine			C	Unknown			Mylan

Attempt; Toxicity To Various Agents; Vomiting	Domperidone	C	Unknown	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571136	EXPEDITED (15-DAY)		HO	NL-MYLANLABS-2016M1029523			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apnoea; Drug Interaction; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Myocardial Necrosis Marker Increased; Pleural Effusion; Sedation; Suicide Attempt; Toxicity To Various Agents; Vomiting	Hydroxychloroquine			S	Oral	17.5 G		Not Reported
	Diazepam			S	Oral	550mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571606	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000552		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Haematemesis; Jaundice; Nausea; Rheumatoid Arthritis; Vomiting	Methotrexate Sodium			S	Oral	1.4286 Mg (10 Mg,1 In 1 W)		Hq Specialty
	Sulfasalazine			S		Unk		Not Reported
	Arava			S	Oral	20 Mg (20 Mg,1 In 1 D)		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Remicade			S		3 Mg/Kg, Unk		Not Reported
	Rituxan			S		1000 Mg, Unk		Not Reported
	Actemra			S		8 Mg/Kg, Unk		Not Reported

	Ascorbic Acid			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571610	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000558		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Interstitial Lung Disease	Methotrexate Sodium			S		2.8571 Mg (20 Mg, 1 In 1 W)		Hq Specialty
	Sulfasalazine			S		2 G (1 G, 2 In 1 D)		Not Reported
	Xeljanz			S		Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg (20 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12571621	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000563		87 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration	Methotrexate Sodium			S	Oral	Strenght: 2.5 Mg (10 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg (200 Mg,2 In 1 D)		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			C	Oral	20 Mg (10 Mg,2 In 1 D)		Not Reported
	Tylenol Arthritis			C	Oral	(3 Dosage Form,1 D)		Not Reported
	Lucentis			C		(1 Mo)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2016	12574347	DIRECT	Y				17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Rash	Hydroxychloroquine 200 Mg Tabs Ranbaxy		S	Oral		Ranbaxy
	Hydroxychloroquine 200 Mg Tabs Zydus		S	Oral		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	11689624	EXPEDITED (15-DAY)		OT	CA-SA-2015SA173079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastric Disorder; Haematemesis; Hepatitis; Jaundice; Joint Stiffness; Joint Swelling; Nausea; Rheumatoid Arthritis; Vomiting	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			C	Unknown	Start Date: Over The Past Four Years Infusion		Not Reported
	Vitamin C			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12404394	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-24		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Pyrexia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12490088	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-28		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gamma-Glutamyltransferase Increased; Hepatitis; Transaminases Increased	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apranax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12528302	EXPEDITED (15-DAY)		DE, HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-35		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Mitral Valve Incompetence	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Doxycycline			S	Oral			Not Reported
	Doxycycline			S	Oral			Not Reported
	Previscan (Fluindione)			C				Not Reported
	Lasilix			C				Not Reported
	Bisoce			C				Not Reported
	Kardegic			C				Not Reported
	Pantoprazole			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12573434	EXPEDITED (15-DAY)		OT	PHHY2016CA095695			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Gold Sodium Thiomalate Sandoz			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Novartis
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Unknown	200 Mg, Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Endocervical	200 Mg, Bid		Not Reported

Humira	S	Unknown	200 Mg, Bid	Not Reported
Enbrel	S	Unknown	25 Mg, Qw2	Not Reported
Actemra	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Ativan	C	Unknown		Not Reported
Benadryl /01563701/	C	Unknown	Unk	Not Reported
Codeine	C	Unknown		Not Reported
Cortisone	C	Unknown		Not Reported
Dexamethasone	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Enablex//Darifenacin	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog /00806701/	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lasix	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoloc//Pantoprazole Sodium Sesquihydrate	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Rituxan	C	Unknown		Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12573580	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2016SP002661			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Strides
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Not Reported
	Lisinopril			S		40 Mg, Qd		Not Reported
	Atorvastatin			S		20 Mg, Qd		Not Reported
	Atorvastatin			S				Not Reported
	Metoprolol			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S		5 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12574607	NON-EXPEDITED		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-39		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Plaquenil			S	Oral			Not Reported
	Colchicine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12574670	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016348160		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		0.08 Ml, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Actemra			S		162 Mg, Weekly		Not Reported
	Simponi			S				Not Reported
	Arava			S				Not Reported
	Plaquenil			S		Unk		Not Reported

	Hydroxychloroquine			S		Unk				Not Reported
	Prednisone			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12575863	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000570		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Sulfasalazine			S		500 Mg (500 Mg,1 In 1 D)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Amlodipine			C	Oral	5 Mg (5 Mg,1 In 1 D)		Not Reported
	Eliquis			C	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2016	12578026	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoacusis; Visual Impairment	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	11652656	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015351696		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Bone Disorder; Drug Ineffective; Infection; Lower Limb Fracture; Osteonecrosis; Post Procedural Infection; Therapeutic Product Effect	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

Decreased	Leflunomide	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Prednisone	C	Unk		Not Reported
	Hydromorphone	C	Unk		Not Reported
	Methotrexate	C			Not Reported
	Gold	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	11712922	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015117077		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Unk, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Unk, Qd		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Unk, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12577836	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016092369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cortisone			C	Oral	Unk		Not Reported
	Diclofenac			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2016	12578800	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2015SP002193			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Mycophenolate Mofetil			S		1500 Mg, Bid		Strides
	Prednisolone			S		30 Mg, Qd		Not Reported
	Hydroxychloroquine			S		200 Mg, Bid		Not Reported
	Warfarin			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	11560361	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015310269		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Joint Swelling; Pain In Extremity	Salazopyrin			S	Oral	1 G, 2x/Day		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Leflunomide			S		20 Mg, Daily		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12519852	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016313545		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Insomnia; Multiple Sclerosis	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1500mg (500mg 3 Tabs), Twice A Day		Pfizer
	Imuran			S		100mg Every Morning And 50mg Every Evening		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported

Leflunomide	S		20 Mg, 1x/Day		Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks, More Than 3 Months		Not Reported
Naprosyn	C		500 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12581656	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2015SP002546			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Strides
	Prednisolone			S		1 Mg, 4 Tablets A Day		Not Reported
	Plaquenil /00072602/			S		200 Mg, Bid		Not Reported
	Lisinopril			S		20 Mg, Every 12 Hrs		Not Reported
	Methyldopa			S		500 Mg, Bid		Not Reported
	Prenatal Vitamins /02014401/			S		1 Tablet		Not Reported
	Diflucan			S		150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12582063	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2016SP001201			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Strides
	Prednisolone			S		15 Mg, Qd		Not Reported
	Plaquenil /00072602/			S		400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12582903	NON-EXPEDITED			US-AMGEN-USASP2016093640		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12583763	NON-EXPEDITED		OT	US-AMGEN-USASP2016093658			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Pneumonia; Sepsis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Quantity 60 (30 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12584279	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016355397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Cortisone			C	Oral	Unk		Not Reported
	Diclofenac			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2016	12584301	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015375987		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Df, Weekly		Pfizer
	Leflunomide			S		20 Df, 1x/Day		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Humira			S				Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12224214	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000130		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg,2 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12526215	NON-EXPEDITED			US-PFIZER INC-2016307831		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Gabapentin			S				Pfizer
	Cymbalta			S				Not Reported
	Hydroxychlor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12580236	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016093623		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Drug Intolerance; Faeces Soft; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12580718	EXPEDITED (15-DAY)		OT	PHHO2016US010154		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase; Aspartate Aminotransferase; Blood Alkaline Phosphatase	Dabrafenib			S	Oral	150 Mg, Bid		Novartis
	Trametinib			S	Oral	2 Mg, Bid (Qam)		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd (250 Mgd) 2-5		Not Reported
	Tylenol			S	Oral	650 Mg, Q6h		Not Reported
	Tylenol			S	Oral	325 Mg, Prn (Q12h)		Not Reported
	Coq10			C	Unknown			Not Reported
	Vitamiin C			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12586018	NON-EXPEDITED			US-JAZZ-2016-US-001995			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Muscle Spasms	Xyrem	S	Oral	2.25 G, Bid	Jazz
	Xyrem	S	Oral	Dose Adjustments	Jazz
	Xyrem	S	Oral	4.5 G, Bid	Jazz
	Xyrem	S	Oral	3 G, Bid	Jazz
	Xyrem	S	Oral	4.5 G, Bid	Jazz
	Plaquenil	S		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Effexor	C		Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Xanax	C		Unk	Not Reported
	Multivitamins	C		Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Trazodone	C		Unk	Not Reported
	Norco	C		10-325	Not Reported
	Prozac	C		Unk	Not Reported
	Prenatal Formula	C		Unk	Not Reported
	Ortho Micronor	C		Unk	Not Reported
	Cymbalta	C		Unk	Not Reported
	Norco	C		10-325	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12586833	NON-EXPEDITED			US-PFIZER INC-2016352510		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Calcium			S		Unk		Pfizer
	Geodon			S		Unk		Pfizer
	Cipro /00697201/			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Abilify			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12587474	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2016345994		64 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pancytopenia	Salazopirina En			S		1 Df, 1x/Day		Pfizer
	Hydroxychloroquine			S		1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12589592	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000597		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Oral	(2 G,1 D)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Prednisone			C		(10 Mg,1 D)		Not Reported
	Vimovo			C		(2 In 1 D)		Not Reported
	Lorazepam			C	Oral	At Bedtime At Night (1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12589598	EXPEDITED (15-DAY)		HO	CA-HQ SPECIALTY-CA-2016INT000599		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Urinary Tract Infection	Methotrexate Sodium			S		Unk		Hq Specialty
	Xeljanz			S	Oral	10 Mg (5 Mg,2 In 1 D)		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12589621	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000591		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Feeling Abnormal; Memory Impairment	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	Unk		Hq Specialty
	Enbrel			S		50 Mg, Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	2.8571 Mg (40 Mg,1 In 2 W)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	26.7857 Mg (750 Mg,1 In 4 W)		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Naprelan			C		Unk		Not Reported
	Effexor			C		Unk		Not Reported
	Reactine /00884302/			C		Unk		Not Reported
	Benadryl /00000402/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12589974	EXPEDITED (15-DAY)		HO, LT	PHHY2016NL097310		25 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Suicide Attempt	Diazepam			S	Unknown	550 Mg,		Novartis
	Hydroxychloroquine			S	Unknown	17.5 G,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12590530	NON-EXPEDITED			US-AMGEN-USASP2016093601			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Infection; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2016	12590542	EXPEDITED (15-DAY)		OT	CA-ROCHE-1627133		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Arava			S	Oral	Frequency: Every 1 Day		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Every Day Besides Sunday		Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	10742007	EXPEDITED (15-DAY)		DE, OT	CA-MYLANLABS-2015M1001431			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Myopathy	Hydroxychloroquine			S	Unknown	200mg Daily For More Than 14 Years		Not Reported

	Methotrexate	C	Unknown	25 Mg, Qw		Mylan
	Atenolol	C	Unknown			Mylan
	Hydrochlorothiazide	C	Unknown			Mylan
	Clobazam	C	Unknown			Mylan
	Phenytoin	C	Unknown			Mylan
	Valproate Semisodium	C	Unknown			Mylan
	Nitrazepam	C	Unknown			Mylan
	Levetiracetam	C	Unknown			Mylan
	Citalopram	C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12517191	NON-EXPEDITED			US-PFIZER INC-2016320598		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred; Weight Increased	Lyrica			S	Oral	50 Mg At Bedtime		Pfizer
	Lyrica			S	Oral	50 Mg, 2x/Day		Pfizer
	Lyrica			S	Oral	75 Mg, Unk		Pfizer
	Hydroxychloroquine			S	Oral	25mg, Tablet, One In The Morning And 2 At Night		Not Reported
	Hydroxychloroquine			S				Not Reported
	Pennsaid			C		2%		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12593943	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000593		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Musculoskeletal Disorder; Toxicity To Various Agents	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12593962	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000592		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Methotrexate Sodium			S		2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	(50 Mg,1 W)		Not Reported
	Simponi			S	Subcutaneous	(50 Mg,1 Mo)		Not Reported
	Hydroxychloroquine			S		(300 Mg,1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12594092	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000608		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Pneumonia; Vomiting	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Xeljanz			S		10 Mg, (5 Mg,2 In 1 D)		Not Reported
	Cimzia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12596023	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-39			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Pneumonia	Plaquenil			S	Unknown					Not Reported
	Methotrexate Sodium			S	Unknown					Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2016	12598908	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-060034			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Orencia			S	Unknown	Unavailable		Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12059859	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-03		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Haemorrhage; Herpes Zoster; Hypoaesthesia; Joint Lock; Joint Swelling; Mobility Decreased; Peripheral Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Not Reported
	Naproxen			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12282710	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-19			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Plaquenil			S	Oral			Not Reported

Rheumatoid Arthritis	Leflunomide	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12517819	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-34			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naproxen			C				Not Reported
	Bupropion Hydrochloride			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12599025	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-40		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatitis	Plaquenil			S				Not Reported
	Cellcept			S				Not Reported
	Benylysta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12599616	EXPEDITED (15-DAY)		OT	PHHY2015CA172344		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cataract; Cellulitis; Gastric Ulcer	Voltaren	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	0.9 Ml, Qw	Novartis
	Plaquenil	S	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown	20 Mg, Prn (As Needed)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12599758	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000620		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Back Disorder; Blood Albumin Decreased; Diverticulum; Drug Ineffective; Headache; Intestinal Perforation; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Neck Mass; Rheumatoid Arthritis; Thrombocytosis	Methotrexate Sodium			S		Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Enbrel			S		7.1429 Mg, (50 Mg,1 In 1 W)		Not Reported
	Naproxyn			S		1000 Mg, (500 Mg,2 In 1 D)		Not Reported
	Orencia			S	Subcutaneous	17.8571 Mg, (125 Mg,1 In 1 W)		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		20 Mg, (20 Mg,1 D)		Not Reported
	Prednisone			S		2.5 Mg, 1 W		Not Reported
	Folic Acid			C		4 Days A Week (5 Mg)		Not Reported
	Gabapentin			C		Unk		Not Reported

	Lovastatin	C		Unk	Not Reported
	Metoprolol	C		Unk	Not Reported
	Vitamin D /00107901/	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Tramadol	C		Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Naprelan	C		Unk	Not Reported
	Xeljanz	C	Oral	10 Mg (5 Mg, 2 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600580	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000605		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Fat Disorder; Drug Ineffective; Mass; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Sulfasalazine			S	Oral	2000 Mg, 1 D		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Unk		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg,2 In 1 D)		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Leflunomide			S		20 Mg, 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600600	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000624		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Sinusitis; Treatment Failure	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

	Orencia	S		Unk	Not Reported
	Simponi	S		Unk	Not Reported
	Gold	S		Unk	Not Reported
	Cellcept /01275102/	S		Unk	Not Reported
	Arava	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600606	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000621		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypoaesthesia	Methotrexate Sodium			S	Oral	2.8571 Mg, (20 Mg,1 In 1 W)		Hq Specialty
	Arava			S	Oral	20 Mg (20 Mg,1 In 1 D)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg (400 Mg, 1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2016	12600613	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000615		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis; Interstitial Lung Disease; Pruritus; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	25 Unk, Unk		Hq Specialty
	Plaquenil /00072602/			S		400 Mg (200 Mg,2 In 1 D)		Not Reported

Plaquenil /00072602/	S	Unk	Not Reported
Plaquenil /00072602/	S	200 Mg, 1 D	Not Reported
Sulfasalazine	S	(1 G,1 D)	Not Reported
Folic Acid	C	(5 Mg,1 W)	Not Reported
Naprosyn /00256201/	C	Unk	Not Reported
Tylenol /00020001/	C	Unk	Not Reported
Vimovo	C	Unk	Not Reported
Meloxicam	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	11752352	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015120608		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Chondropathy; Drug Ineffective; Dysphonia; Erythema; Hernia Repair; Hyperhidrosis; Influenza Like Illness; Joint Swelling; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Pyrexia; Swelling Face	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Methotrexate			S	Subcutaneous	1 Ml, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	11849878	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015134910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Musculoskeletal Stiffness; Pain; Therapeutic Product	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported

Effect Decreased	Plaquenil /00072603/		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone		S	Unknown	3 Mg, Unk	Not Reported
	Methotrexate Sodium		S	Unknown	20 Mg, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12424857	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016282055		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Blood Potassium Decreased; Bradycardia; Condition Aggravated; Confusional State; Diarrhoea; Disorientation; Long Qt Syndrome; Mental Disorder; Nausea; Slow Response To Stimuli; Torsade De Pointes; Toxicity To Various Agents; Troponin I Increased; Ventricular Extrasystoles; Ventricular Tachycardia; Vomiting	Amiodarone Hcl			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Quinine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12578335	EXPEDITED (15-DAY)		OT	US-ROCHE-1798633		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatitis	Cellcept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Benlysta			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12603893	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000625		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Prednisone			C		5 Mg, (5 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12604454	NON-EXPEDITED			GXBR2015US002549		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pruritus; Rash Papular	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	400 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S				Novartis
	Apap			C	Unknown	Unk Df, Prn		Not Reported
	Apap Night			C	Unknown	Unk Df, Prn		Not Reported
	Sumatriptan			C	Unknown	Unk Df, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2016	12604897	EXPEDITED (15-DAY)		OT	CA-BEH-2016060125		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Peripheral Sensory Neuropathy	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	2000 Mg/Kg, Qmt		Csl Behring
	Intravenous Immunoglobulin	S				Csl Behring
	Intravenous Immunoglobulin	S				Csl Behring
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	S	Unknown	Low Dose		Not Reported
	Natural Tears	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	11729146	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-35			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastric Disorder; Haematemesis; Hepatitis; Jaundice; Joint Stiffness; Joint Swelling; Nausea; Rheumatoid Arthritis; Vomiting	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rituxan			C				Not Reported
	Vitamin C			C				Not Reported
	Remicade			C				Not Reported
	Actemra			C				Not Reported
	Rosuvastatin			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12234283	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-16		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder;	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Pollakiuria; Product Dose Omission			otherwise specified)		
	Actemra	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Leucovorin	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Folic Acid	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12238218	EXPEDITED (15-DAY)		HO, LT	US-ELI_LILLY_AND_COMPANY-US201603009730		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cellulitis; Multiple Organ Dysfunction Syndrome; Panniculitis; Septic Shock; Staphylococcal Infection	Adcirca			S	Oral	Unk, Unknown		Eli Lilly And Co
	Tyvaso			S	Respiratory (inhalation)	Unk, Qid		Not Reported
	Beraprost Sodium			S	Oral	30 Ug, Qd		Not Reported
	Beraprost Sodium			S	Unknown	120 Ug, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Opsumit			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12452309	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000346		91 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Arava			S	Oral	20 Mg (20 Mg,1 In 1 D)		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg (400 Mg,1 In 1 D)		Not Reported
	Sulfasalazine			S		Unk		Not Reported

	Prednisone			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12531731	NON-EXPEDITED			US-PFIZER INC-2016298523			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Celebrex			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Mysoline			S		Unk		Not Reported
	Ridaura			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12605603	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014039289		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Condition Aggravated; Nodule; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12605965	NON-EXPEDITED			US-PFIZER INC-2016334737			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12606710	EXPEDITED (15-DAY)		HO	NL-TEVA-679210ISR		25 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apnoea; Drug Interaction; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Loss Of Consciousness; Myocardial Necrosis Marker Increased; Overdose; Pleural Effusion; Sedation; Suicide Attempt; Toxicity To Various Agents; Vomiting	Diazepam			S	Oral	550mg		Barr
	Hydroxychloroquine			S	Oral	17.5 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12606763	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-40		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Cell Death; Hepatocellular Injury; Iatrogenic Injury; Middle Insomnia; Proteinuria; Synovitis; Systemic Lupus Erythematosus	Plaquenil			S	Oral			Not Reported
	Doliprane			S	Oral			Not Reported
	Biprofenid			S	Oral			Not Reported
	Zamudol			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Monoalgic Lp (200 Mg, Gastro-Resistant Tablet) (Tramadol)			S	Oral			Not Reported
	Twynsta			C				Not Reported
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12607299	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000594		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Avapro			C		Unk		Not Reported
	Aspirin /00002701/			C		Unk		Not Reported
	Gluconorm /00082702/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12607327	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000632		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; White Blood Cell Disorder	Methotrexate Sodium			S	Oral	1.7857 Mg (2.5 Mg,5 In 1 W)		Hq Specialty
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg (200 Mg,2 In 1 D)		Not Reported
	Prednisone			S		Unk		Not Reported
	Arava			S		(..2007)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12608721	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-38		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catheterisation Cardiac; Diarrhoea; Ejection Fraction Decreased; Left Ventricular Dysfunction; Tachycardia	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Flolan			S		28 Ng/Kg/Min		Not Reported
	Flolan			S				Not Reported
	Flolan			S				Not Reported
	Cellcept			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Baby Aspirin			C				Not Reported
	Flonase			C				Not Reported
	Ultram			C				Not Reported
	Kenalog			C				Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2016	12608728	EXPEDITED (15-DAY)		DE, HO	CA-HQ SPECIALTY-CA-2016INT000636		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Demyelination; Fall; Focal Dyscognitive Seizures; Pericardial Effusion; Pleural Effusion; Seizure	Methotrexate Sodium			S		15-25 Mg (1 In 1 W)		Hq Specialty
	Hydroxychloroquine			S		200-400 Mg (1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	11866589	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015134484		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12553908	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000531		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Intolerance; Treatment Failure	Methotrexate Sodium			S		2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S		15 Mg, Unk		Hq Specialty
	Salazopyrin			S	Oral	2 G (1 G, 2 In 1 D)		Not Reported
	Salazopyrin			S		Unk		Not Reported
	Leflunomide			S		20 Mg, 1 D		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Rituxan			S	Subcutaneous	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	1.6667 Mg (50 Mg, 1 In 1 Mo)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12582731	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016094340		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Gait Disturbance; Infection; Lung Disorder; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Q Weekly		Amgen
	Humira			S	Unknown	40 Mg, Every Two Weeks		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Od		Not Reported
	Calcium			C		Unk		Not Reported
	Folic Acid			C	Oral	5 Mg, Qd (Six Days Per Week)		Not Reported
	Xeljanz			C	Oral	50 Mg, Bid (2x/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12585380	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016093962		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Arthroplasty; Hip Surgery; Infection; Knee Arthroplasty; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611159	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000663		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Insomnia; Pneumonia; Rheumatoid Arthritis; Weight Increased	Methotrexate Sodium			S		Unk		Hq Specialty
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611815	NON-EXPEDITED			US-PFIZER INC-3025760			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Pfizer
	Alprazolam			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Minocycline			S		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611827	NON-EXPEDITED			US-PFIZER INC-3054908		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pregnancy	Methotrexate Sodium			S	Unknown			Pfizer
	Etanercept			S	Unknown	Unk		Not Reported

		Etanercept		S	Unknown	50 Mg, Freq: 1 Week ; Interval : 1			Not Reported
		Etanercept		S					Not Reported
		Plaquenil /00072602/		S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611828	NON-EXPEDITED			US-PFIZER INC-3071775		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Asthenia; Dizziness; Drug Ineffective; Hypertension; Malaise; Walking Disability	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S				Not Reported
	Prednisone			S		0.5 In The Morning And Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611857	NON-EXPEDITED		OT	US-PFIZER INC-3194265		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil/00072602/			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611858	NON-EXPEDITED		OT	US-PFIZER INC-3192564			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611864	NON-EXPEDITED			US-PFIZER INC-3206523			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Texture Abnormal	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil/00072602/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611886	NON-EXPEDITED			US-PFIZER INC-2015470459			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Cellcept			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Macrobid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611887	NON-EXPEDITED			US-PFIZER INC-2016003385		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611900	NON-EXPEDITED			US-PFIZER INC-2016015871			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Avelox Abc Pack			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Erythromycin Base			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611907	NON-EXPEDITED		OT	US-PFIZER INC-3192071			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611976	NON-EXPEDITED			US-PFIZER INC-3240102			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Unknown
	Meperidine Hcl			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611977	NON-EXPEDITED			US-PFIZER INC-2016192942			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Demerol			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12611990	NON-EXPEDITED		OT	US-PFIZER INC-3219322		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	0.8 Ml, Weekly		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Promus Stent			S		Unk		Not Reported
	Cortisone Acetate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2016	12612329	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014145746		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Condition Aggravated; Nodule; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	11803689	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-40			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Nausea; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	11825743	EXPEDITED (15-DAY)		OT	CA-AMGEN-KDL369309		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Disability; Drug Ineffective; Drug Intolerance; Joint Stiffness; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk, 2 Times/Wk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Mg, Od, 1 Every 1 Day.		Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Naprosyn			C	Oral	500 Mg, Bid		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12281117	NON-EXPEDITED		OT	US-PFIZER INC-2016218579		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

	Methotrexate Sodium	S	Unk		Pfizer
	Humira	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Remicade	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12597526	NON-EXPEDITED			US-PFIZER INC-2016349912		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12616622	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-40			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	11798419	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-40		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Cataract; Diarrhoea;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Dizziness; Drug Ineffective; Headache; Hypertension; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Malaise; Myalgia; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Viral Infection; White Blood Cell Count Decreased	Xeljanz	C	Oral		Not Reported
	Orencia	C			Not Reported
	Enbrel	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12537590	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000471		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epicondylitis; Malaise; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Tetanus Vaccine			C		Unk		Not Reported
	Haemophilus Influenza Type B Vaccine			C		Unk		Not Reported
	Prevnar			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12566244	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000541		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg,1 In 1		Hq Specialty

Rheumatoid Arthritis; Sensitivity To Weather Change				W)	
	Methotrexate Sodium	S	Subcutaneous	25 Mg/Ml (1 In 1 W)	Hq Specialty
	Xeljanz	S	Oral	10 Mg (5 Mg, 2 In 1 D)	Not Reported
	Arava	S	Oral	20 Mg (20 Mg,1 In 1 D)	Not Reported
	Plaquenil /00072602/	S		(400 Mg,1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12618353	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-41		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Castleman'S Disease; Granuloma; Histology Abnormal; Lymphadenopathy Mediastinal; Night Sweats; Obstructive Airways Disorder; Retroperitoneal Mass	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Fluticasone/Salmeterol			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported
	Loperamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12618493	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK108987		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Cellulitis; Gastric Ulcer	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Methotrexate			S		0.9 Ml, Qw		Glaxosmithkline
	Plaquenil			S				Not Reported
	Amitriptyline			C				Not Reported
	Prednisone			C				Not Reported
	Metformin			C				Not Reported
	Folic Acid			C				Not Reported
	Ergocalciferol			C				Not Reported
	Oxyneo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619148	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000660		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Rheumatoid Arthritis	Methotrexate Sodium			S		2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	50 Mg, 1 W		Not Reported
	Sulfasalazine			S	Oral	2 G (1 G,2 In 1 D)		Not Reported
	Plaquenil /00072602/			S		400 Mg, 1 D		Not Reported
	Arava			S		20 Mg, 1 D		Not Reported
	Humira			S		2.8571 Mg (40 Mg,1 In 2 W)		Not Reported
	Prednisone			S	Oral	Tapering Down		Not Reported
	Prednisone			S		Dose Increased		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619161	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000658		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Unknown	0.0114 Ml (0.08 Ml,1 In 1 W)		Hq Specialty
	Sulfasalazine			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	(162 Mg, 1 W)		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619218	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000654		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Specific Antibody Present; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619318	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-40			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus; Therapeutic Response Decreased	Plaquenil			S				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619395	EXPEDITED (15-DAY)		OT	US-WATSON-2016-16260		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Overdose; Retinal Toxicity	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	8.3 Mg/Kg, Daily		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619396	EXPEDITED (15-DAY)		OT	US-WATSON-2016-16261		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Retinal Toxicity	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	6.0 Mg/Kg, Daily		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619591	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-CA-WYE-H11835709		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S		Unk Unk, 2 Times/Wk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S	Oral	10 Mg, Od, 1 Every 1 Day.		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Kineret			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Naprosyn			C	Oral	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	12619700	EXPEDITED (15-DAY)		HO, LT	IR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IR-2016-40		15 YR	Male	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic	Hydroxychloroquine Sulfate			S				Not Reported

Seizure; Magnetic Resonance Imaging Brain Abnormal; Posterior Reversible Encephalopathy Syndrome	Cyclophosphamide	S				Not Reported
	Cyclophosphamide	S				Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)			Not Reported
	Prednisolone	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12374819	NON-EXPEDITED			US-PFIZER INC-2016260333		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12570447	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-38			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Hepatic Cirrhosis; Hepatic Steatosis	Plaquenil			S	Oral			Not Reported
	Endoxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12609246	NON-EXPEDITED			CA-AMGEN-CANSP2016097119		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Gait Disturbance; Joint Swelling; Pain In Extremity; Rash	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Tylenol			C		Unk		Not Reported

	Iron	C	Unk, At Night		Not Reported
	Metoprolol	C	Unk, At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12621140	NON-EXPEDITED			US-PFIZER INC-2016345097			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz			S	Oral	11 Mg, Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12621945	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan			S	Unknown	Unk			Not Reported
	Sulfathalidine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12621949	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cortisone Acetate			S		25 Mg, Unk		Not Reported
	Folic Acid			S		1 Mg, Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine /00884302/			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12622247	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015444509		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer

Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Methotrexate Sodium	S	Subcutaneous	Unk	Pfizer
	Plaquenil	S		Unk	Not Reported
	Simponi	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Arava	S		20 Mg, 1x/Day	Not Reported
	Prednisone	S		10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12622797	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000668		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Nausea; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S	Oral	2.857 Mg,(20 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	7.142 Mg, (50 Mg,1 In 1 W)		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Leflunomide			S		20 Mg, (20 Mg,1 In 1 D)		Not Reported
	Plaquenil			S		400 Mg, (200 Mg, 2 In 1 D)		Not Reported
	Simponi			S	Subcutaneous	Cyclical, (50 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12622798	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000682		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Vomiting	Methotrexate Sodium			S		25 Mg,		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		1500 Mg		Not Reported
	Hydroxychloroquine			S		200 Mg, 1 D		Not Reported
	Arava			S		(10 Mg,1 D)		Not Reported

	Remicade			S		Unk			Not Reported
	Orencia			S		Unk			Not Reported
	Actemra			S		Unk			Not Reported
	Kineret			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12622815	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000681		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12622846	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000669		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lower Limb Fracture; Osteonecrosis; Post Procedural Infection; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2016	12623305	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-40		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Staphylococcal Infection	Hydroxychloroquine			S				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Leucovorin			C				Not Reported
	Meloxicam			C				Not Reported
	Protonix			C				Not Reported
	Montelukast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12313465	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-USA/GER/16/0079142			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Thrombosis; Vena Cava Thrombosis	Ramipril			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Torasemide			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Metamizole			S	Unknown			Not Reported
	Aliskiren			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Heparin			S				Not Reported
	Rituximab			S				Not Reported

	Cyclophosphamide			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12313735	EXPEDITED (15-DAY)		CA, OT	DE-DRREDDYS-USA/GER/16/0079143			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy	Ramipril			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Simvastatin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Torasemide			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Metamizole			S	Unknown			Not Reported
	Aliskiren			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Heparin			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12624378	EXPEDITED (15-DAY)		DE, OT	CA-ACCORD-042858		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Demyelination; Fall; Seizure	Methotrexate			S		15-25 Mg		Accord
	Hydroxychloroquine			S		200-400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12624671	NON-EXPEDITED			US-PFIZER INC-2016350820		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12624672	NON-EXPEDITED			US-PFIZER INC-2016350062		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12624734	NON-EXPEDITED			US-PFIZER INC-2016350127		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12625096	NON-EXPEDITED			US-PFIZER INC-2016350301		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626046	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000689		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Intolerance	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	10-20 Mg		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Prolia			S	Unknown	Unk		Not Reported
	Cymbalta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626059	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported

Erythematosus	Fosamax			S		Unk	Not Reported
	Humira			S	Subcutaneous	Unk	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole			S		Unk	Not Reported
	Plaquenil /00072602/			S		Unk	Not Reported
	Prednisone			S		Unk	Not Reported
	Reactine /00884302/			S		Unk	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi			S	Subcutaneous	Unk	Not Reported
	Arava			S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626177	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Reactine (Cetirizine Hydrochloride)			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626178	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000691		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Procytox			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626237	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000688		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Decreased Immune Responsiveness; Lyme Disease	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626238	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000696		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Inability; Knee Arthroplasty; Pain In Extremity; Retinal Vascular Thrombosis; Sensitivity To Weather Change	Methotrexate Sodium			S	Oral	2.857 Mg, (20 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Zostavax			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626248	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Factor Positive; Synovitis	Methotrexate Sodium			S		2.8571 Mg (20 Mg, 1 In 1 W)		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk, Daily		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg, 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626311	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000703		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Arava		S	Unknown	Unk			Not Reported
	Humira		S	Subcutaneous	Unk			Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
	Leflunomide		S		Unk			Not Reported
	Orencia		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626325	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000714		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Imuran			S				Not Reported
	Neoral			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626327	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000705		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present; Gait Inability; Nausea; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Orencia	S	Unk		Not Reported
	Plaquenil /00072602/	S	Unk		Not Reported
	Remicade	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626870	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000713		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	2.857 Mg, (20 Mg,1 In 1 W)		Hq Specialty
	Plaquenil /00072602/			S		Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626872	EXPEDITED (15-DAY)		DS, OT	CA-HQ SPECIALTY-CA-2016INT000715		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Peripheral Swelling	Methotrexate Sodium			S	Oral	25 Mg		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Xeljanz			S	Oral	10 Mg, (5 Mg,2 In 1 D)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	0.2667 Mg, (8 Mg,1 In 1 Mo)		Not Reported
	Arava			S	Oral	(20 Mg,1 D)		Not Reported
	Hydroxychloroquine			S	Oral	(400 Mg, 1 D)		Not Reported
	Humira			S	Subcutaneous	2.8571 Mg (40 Mg,1 In 2 W)		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626873	EXPEDITED (15-DAY)		DS, OT	CA-HQ SPECIALTY-CA-2016INT000704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Cortisone			C		Unk		Not Reported
	Diclofenac			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2016	12626919	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Methotrexate Sodium			S	Unknown	3.5714 Mg (25 Mg, 1 In 1 W)		Hq Specialty
	Enbrel			S	Unknown	7.1429 Mg (25 Mg, 2 In 1 W)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	(1 D)		Not Reported
	Humira			S	Unknown	400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg (200 Mg, 2 In 1 D)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	(200 Mg)		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Benadryl			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Cortisone			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported

Dilaudid	C	Unknown	Unk	Not Reported
Enablex	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Norflex	C	Unknown	Unk	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituxan	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12628422	EXPEDITED (15-DAY)		HO, OT	US-ALVOGEN-2016-ALVOGEN-027195			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Overdose; Somnolence; Ventricular Fibrillation	Oxycodone/Apap			S		35 Tabs Of Oxycodone/ Acetaminophen, 5/325 Mg		Not Reported
	Hydroxychloroquine			S		60 Tabs Of Hydroxychloroquine, 200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629335	NON-EXPEDITED			US-AMGEN-USASP2016093276		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629406	EXPEDITED (15-DAY)		LT	CA-SA-2016SA144136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Drug Ineffective	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629464	NON-EXPEDITED		OT	US-AMGEN-USASL2016099370		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Hypertension; Mobility Decreased; Muscle Spasms; Osteoporosis; Rheumatoid Arthritis; Sjogren'S Syndrome; Skin Discolouration; Vision Blurred	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629837	EXPEDITED (15-DAY)		HO	NL-IPCA LABORATORIES LIMITED-IPC201607-000650		25 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Apnoea; Cardiomyopathy; Conduction Disorder; Hypokalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Pleural Effusion; Sedation; Toxicity To Various Agents; Vomiting	Hydroxychloroquine Sulfate			S	Oral			Ipca
	Diazepam			S	Oral			Not Reported
	Diazepam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12629845	EXPEDITED (15-DAY)		HO	NL-IPCA LABORATORIES LIMITED-IPC201607-000651		25 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Toxicity To Various Agents; Vomiting	Hydroxychloroquine Sulfate			S				Ipca
	Codeine			S				Not Reported
	Domperidone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12630123	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000721		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Joint Dislocation; Stomatitis	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

	Humira	S		Unk	Not Reported
	Voltaren /00372301/	S		Unk	Not Reported
	Cortisone	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12630138	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000729		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Coccydynia; Hyperhidrosis; Influenza; Laryngitis; Rheumatoid Arthritis; Therapeutic Product Effect Delayed	Methotrexate Sodium			S		Unk		Hq Specialty
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S		20 Mg (20 Mg,1 In 1 D)		Not Reported
	Prednisone			C	Oral	1 In 1 D		Not Reported
	Prednisone			C	Oral	Weaning Off 20 Mg Once Daily		Not Reported
	Cortisone			C		Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12630688	EXPEDITED (15-DAY)		CA	FR-ELI_LILLY_AND_COMPANY-FR201607012116			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly; Foetal Exposure During Pregnancy	Humalog Lispro			S	Transplacental	Unk, Unknown		Eli Lilly And Co
	Lantus			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Trandate			C				Not Reported
	Aspegic /00002703/			C				Not Reported
	Lovenox			C		0.4 Ml, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12630701	EXPEDITED (15-DAY)		OT	FR-ELI_LILLY_AND_COMPANY-FR201607012689			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus Inadequate Control; Exposure During Pregnancy; Glycosylated Haemoglobin Increased; Haematuria; Hypertension; Proteinuria; Renal Disorder	Humalog Lispro			S	Subcutaneous	Unk, Unknown		Eli Lilly And Co
	Lantus			S	Subcutaneous	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Qd		Not Reported
	Aspegic /00002703/			C		Unk		Not Reported
	Levonox			C		0.4 Ml, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12634903	EXPEDITED (15-DAY)		DS, OT	CA-HQ SPECIALTY-CA-2016INT000727		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Limb Deformity	Methotrexate Sodium			S	Oral	Lower Doses, Unk		Hq Specialty
	Methotrexate Sodium			S	Subcutaneous	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G (1 G,2 In 1 D)		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	25 Mg (25 Mg,1 In 1 D)		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Indocid			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg (400 Mg,1 In 1 D)		Not Reported
	Leflunomide			S	Unknown	(20 Mg,1 D)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Cymbalta			C	Oral	Nightly (30 Mg,1 In 1 D)		Not Reported
	Folic Acid			C	Unknown	Unk, (1 In 1 W)		Not Reported

Xeljanz	C	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2016	12635512	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-064411			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Peripheral Swelling; Pneumonia; Product Storage Error; Weight Decreased	Abatacept			S	Subcutaneous	125 Mg/Ml, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	11778964	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-38		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Glomerular Filtration Rate Decreased; Pain In Extremity; Pain In Extremity; Renal Failure; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12467211	EXPEDITED (15-DAY)		HO	AU-ROCHE-1775724			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Hypertension; Impaired Healing; Mitral Valve Incompetence; Osteoporosis; Polymyalgia Rheumatica; Rash; Skin Lesion; Syncope; Tricuspid Valve Incompetence; Wound	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Pramipexole Hydrochloride			S	Unknown			Not Reported

Secretion	Monohydrate					
	Flaminal Hydro	C	Topical			Not Reported
	Flecainide Acetate	C	Unknown			Not Reported
	Ganfort	C	Unknown	0.3mg/5mg Per 1 Ml Eye Drops		Not Reported
	Hiprex	C	Unknown			Not Reported
	Magmin	C	Unknown			Not Reported
	Megafol	C	Unknown			Not Reported
	Nexium	C	Unknown	1 Tablet		Not Reported
	Norvasc	C	Unknown			Not Reported
	Noten	C	Unknown			Not Reported
	Ostevit-D	C	Oral	25mcg/0.2ml, Oral Drops		Not Reported
	Panadol Osteo	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Prolia	C	Unknown	60mg/Ml		Not Reported
	Rosuzet Composite Pack	C	Unknown	10mg/40mg, 1 Of Each Daily		Not Reported
	Temaze	C	Unknown			Not Reported
	Xalatan	C	Unknown	50mcg/Ml, 1 Drop Each Eye		Not Reported
	Xarelto	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12473149	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-28		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Hydroxychloroquine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12518939	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-29		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lymphadenopathy; Myalgia; Oedema; Pain; Pruritus; Pustular Psoriasis; Pyrexia; Rash Pustular	Plaquenil			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Tacrolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12547369	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000485		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; General Physical Health Deterioration; Lower Respiratory Tract Infection; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12570448	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-38		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12574608	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS		40 YR	Female	JPN

INC.-CO-PL-JP-2016-39

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12633615	NON-EXPEDITED			US-IPCA LABORATORIES LIMITED-IPC201602-000286			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Dizziness; Nervousness; Vomiting	Hydroxychloroquine Sulfate			S	Oral			Ipca
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12634817	EXPEDITED (15-DAY)		CA	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-42			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Central Nervous System Anomaly	Plaquenil			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Plaquenil			S				Not Reported
	Lantus			S	Transplacental			Not Reported
	Humalog			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12635508	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000730		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		2.1429 Mg (15 Mg,1 In 1		Hq Specialty

							W)			
		Sulfasalazine			S		1000 Mg (500 Mg,2 In 1 D)			Not Reported
		Arava			S		20 Mg (20 Mg,1 In 1 D)			Not Reported
		Plaquenil /00072603/			S		400 Mg (400 Mg,1 In 1 D)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12635521	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Intolerance; Treatment Failure	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		(50 Mg, 1 W)		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7.1429 Mg, (300 Mg,1 In 6 W)		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Imuran /00001501/			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Cyclosporine			S		Unk		Not Reported
	Cimzia			S		14.2857 Mg, (200 Mg,1 In 2 W)		Not Reported
	Humira			S		2.8571 Mg, (40 Mg,1 In 2 W)		Not Reported
	Actemra			S		22.8571 Mg, (640 Mg,1 In 4 W)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2016	12637679	NON-EXPEDITED		HO, OT	US-ABBVIE-16P-163-1562359-00		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Ineffective;	Depakote			S	Unknown			Not Reported

Seizure	Lamictal	S	Unknown	Over The Last Two Years	Not Reported
	Lamictal	S	Unknown		Not Reported
	Dilantin	S	Unknown		Not Reported
	Keppra	S	Unknown		Not Reported
	Neurontin	S	Unknown		Not Reported
	Cytoxin	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Clinoril	S	Unknown		Not Reported
	Cellcept	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12592695	NON-EXPEDITED			US-PFIZER INC-2016349961		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12642196	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2016378216			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Myocardial Infarction; Angina Unstable; Musculoskeletal Stiffness;	Methotrexate			S		15 Mg, Weekly		Pfizer
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Prednisolone			S		7 Mg, Daily		Not Reported

Polyarthritis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2016	12642366	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000751		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fibromyalgia; Hepatitis; Myocardial Infarction	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cortisone			C	Unknown	Unk		Not Reported
	Cyclobenzaprine			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Prednisone Acetate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	11703150	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-34		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Arthritis; Fatigue; Musculoskeletal Pain; Rheumatoid Arthritis; Sciatica; Swelling	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	11920971	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2015US045716		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Back Pain; Bladder Pain; Constipation; Constipation; Cystitis; Cystitis; Dizziness; Ear Congestion; Eye Pain; Feeling Abnormal; Lip Swelling; Malaise; Rash Erythematous; Urine Abnormality	Myrbetriq			S	Oral			Astellas
	Myrbetriq			S				Astellas
	Biotene /03475601/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hctz			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Diltiazem			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Diltiazem			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Pravacol			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Avapro			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Kelpivia			C	Unknown	Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12577673	EXPEDITED (15-DAY)		DS, HO	CA-ABBVIE-16K-028-1619192-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Rheumatoid Arthritis; Urinary Tract Infection;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Two Doses		Not Reported
	Abatacept			S	Unknown			Not Reported
	Omegavit			C				Not Reported
	Prednisone			C				Not Reported
	Actonel			C				Not Reported
	Advair			C				Not Reported
	Spiriva			C				Not Reported

Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Senokot	C				Not Reported
	Vitamin B12	C				Not Reported
	Ascorbic Acid	C	Oral			Not Reported
	Rabeprazole	C				Not Reported
	Zinc Gluconate	C				Not Reported
	Ferrous Gluconate	C	Oral			Not Reported
	Citalopram	C				Not Reported
	Calcium	C				Not Reported
	Amlodipine	C				Not Reported
	Vitamin D Nos	C				Not Reported
	Tylenol	C		As Needed		Not Reported
	Aspirin	C				Not Reported
	Zopiclone	C				Not Reported
	Hydrochlorothiazide	C				Not Reported
	Olmetec	C				Not Reported
	Oxybutynin	C				Not Reported
	Folic Acid	C	Oral			Not Reported
	Advair	C				Not Reported
	Spiriva Handihaler	C				Not Reported
	Senokot S	C		Form Strength: 8.6mg/50mg		Not Reported
	Vitamin B12	C				Not Reported
	Omega-3 Fatty Acid/Dha/Epa/Fish Oil/Coenzyme Q-10	C		1960mg / 710mg / 930mg / 4530mg / 50mg Per 5ml Of Oral Liquid		Not Reported
	Rabeprazole Sodium	C	Oral			Not Reported
	Hydroxychloroquine Sulfate	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12645027	EXPEDITED (15-DAY)		HO, OT	CA-HQ SPECIALTY-CA-2016INT000731		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Knee Arthroplasty; Lower	Methotrexate Sodium			S	Oral	2.1429 Mg (15 Mg,1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Oral	2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty

Respiratory Tract Infection; Nasopharyngitis; Nephrolithiasis; Rheumatoid Arthritis	Methotrexate Sodium	S		Unk	Hq Specialty
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Plaquenil /00072602/	S		Unk	Not Reported
	Gold	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Actemra	S		(8 Mg/Kg)	Not Reported
	Prednisone	S		(50 Mg,1 D)	Not Reported
	Prednisone	S	Oral	5 Mg (5 Mg,1 In 1 D)	Not Reported
	Prednisone	S	Oral	(3 Mg,1 D)	Not Reported
	Naprosyn /00256201/	S		Unk	Not Reported
	Losec /00661201/	C		Unk	Not Reported
	Celexa /00582602/	C		Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Citalopram Hydrobromide	C		Unk	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Ketoprofen	C		200 Mg (100 Mg,2 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12645073	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000716		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Gastric Ulcer	Methotrexate Sodium			S	Unknown	(20 Dosage Form,1 W)		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported

	Leflunomide	S		20 Dosage Form (20 Dosage Form,1 In 1 D)		Not Reported
	Plaquenil	S	Unknown	400 Mg (400 Mg,1 In 1 D)		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12645298	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-42		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12645299	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-42		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram Qt Prolonged; Electrocardiogram U-Wave Abnormality; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Oxycodone/Paracetamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2016	12645748	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2015-002908			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Increased Tendency To Bruise; Skin Laceration	Prednisone Tablets			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12455015	NON-EXPEDITED			US-PFIZER INC-2016289940		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		6 Df, Weekly (6 Once Weekly)		Pfizer
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Sulfasalazine			S		20 Mg, 1x/Day		Pfizer
	Orencia			S		4 Df, Unk (4 Infusions)		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Rituxan			S		4 Df, Unk (4 Infusions)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12648732	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1696804-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Failure; Treatment Failure; Treatment Failure	Arava		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Cortisone		C			Not Reported
	Tylenol Arthritis		C		1 To 2 Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12648926	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000764		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Treatment Failure	Methotrexate Sodium			S	Oral	20 Mg		Hq Specialty
	Methotrexate Sodium			S	Oral	20 Mg		Hq Specialty
	Enbrel			S	Subcutaneous	7.1429 Mg (50 Mg,1 In 1 W)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Cyclosporin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2016	12649233	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000763		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty

Rheumatoid Arthritis	Enbrel	S	Subcutaneous	7.1429 Mg (25 Mg, 2 In 1 W)		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Imuran	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2016	12650417	NON-EXPEDITED			US-AMGEN-USASL2016103164		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Rash Pruritic	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2016	12645935	NON-EXPEDITED			US-PFIZER INC-2015442326			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Mtx			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2016	12652762	EXPEDITED (15-DAY)		DE, OT	CA-IPCA LABORATORIES LIMITED-IPC201608-000667		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Fibrillation; Cardiac Failure; Cardiomyopathy; Demyelination; Myopathy	Hydroxychloroquine Sulfate	S		Ipca
	Methotrexate	C		Not Reported
	Clobazam	C		Not Reported
	Phenytoin	C		Not Reported
	Divalproex Sodium	C		Not Reported
	Nitrazepam	C		Not Reported
	Levetiracetam	C		Not Reported
	Atenolol	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Citalopram	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2016	12653120	NON-EXPEDITED			US-PFIZER INC-2016209159			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash; Urticaria	Diclofenac Sodium			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Vimovo			S		Unk		Not Reported
	Nortriptyline			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Curcumin			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Etodolac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12067558	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-04		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Cough; Drug Ineffective; Eye Disorder; Gait Disturbance; Malaise;	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Nasopharyngitis; Pain; Peripheral Swelling; Peripheral Swelling; Pneumonia; Rheumatoid Arthritis	Xeljanz		S	Oral		Not Reported
	Actonel		C			Not Reported
	Ibuprofen		C			Not Reported
	Ergocalciferol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12427240	NON-EXPEDITED			US-AMGEN-USASL2016068158		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12570449	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-CO-PL-JP-2016-39		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Plaquenil			S	Oral			Not Reported
	Tacrolimus			S				Not Reported
	Predonine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12645937	NON-EXPEDITED			US-PFIZER INC-2016018565			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12655564	EXPEDITED (15-DAY)		HO, LT, OT	US-MALLINCKRODT-T201603494			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U-Wave Abnormality; Hypokalaemia; Hypomagnesaemia; Hypotension; Overdose; Somnolence; Torsade De Pointes; Toxicity To Various Agents	Oxycodone/Acetaminophen			S	Unknown	35 Tablets		Mallinckrodt
	Hydroxychloroquine			S	Unknown	60 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12655784	NON-EXPEDITED			US-PFIZER INC-2016376157			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Butorphanol Tartrate			S		Unk		Unknown
	Codeine			S		Unk		Not Reported
	Acetaminophen W/Propoxyphene Napsylate			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Hydrocodone/Acetaminophen			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Quinacrine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12657425	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy;	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		50 Mg, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Therapeutic Product Effect Incomplete	Plaquenil	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2016	12657543	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-43		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Plaquenil			S	Oral			Not Reported
	Advagraf			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Bactrim			S	Unknown			Not Reported
	Temerit			S	Unknown			Not Reported
	Cortancyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	11879430	NON-EXPEDITED			US-AEGERION PHARMACEUTICAL INC.-AEGR000279		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Decreased Appetite; Diarrhoea; Dyspepsia; Dyspnoea; Gastroenteritis Viral; Influenza; Malaise; Nasopharyngitis; Nausea; Oedema Peripheral; Vomiting	Juxtapid			S	Oral	5 Mg, Qd		Aegerion
	Juxtapid			S	Oral	5 Mg, Qd		Aegerion
	Plaquenil			S		200 Mg, Unk		Not Reported
	Geodon			C	Oral	20 Mg, Unk		Not Reported
	Sulfasalazine			C	Oral	500 Mg, Unk		Not Reported
	Metoprolol			C	Oral	100 Mg, Unk		Not Reported
	Nexium			C	Oral	10 Mg, Unk		Not Reported
	Avapro			C	Oral	150 Mg, Unk		Not Reported
	Buspar			C	Oral	5 Mg, Unk		Not Reported
	Lipitor			C	Oral	10 Mg, Unk		Not Reported
	Pristiq			C	Oral	100 Mg, Unk		Not Reported
	Trazodone			C	Oral	100 Mg, Unk		Not Reported

	Lortab			C	Oral	Unk				Not Reported
	Ziprasidone			C		Unk				Not Reported
	Probiotic			C		Unk				Not Reported
	Ginger			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12213669	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016162659		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Coronary Artery Disease; Deformity; Disease Progression; Dry Eye; Essential Hypertension; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Sjogren'S Syndrome; Tremor	Sulfasalazine			S	Oral	1000 Mg, 2x/Day (500 Mg 2 Tabs 2x Per Day)		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Combigan			C	Ophthalmic	Brimonidine Tartrate: 0.2%, Timolol Maleate: 0.5 %		Not Reported
	Dorzolamide Hcl			C	Ophthalmic	2 %, Unk		Not Reported
	Leflunomide			C	Oral	20 Mg, Unk		Not Reported
	Losartan Potassium			C	Oral	25 Mg, Unk		Not Reported
	Montelukast Sodium			C	Oral	10 Mg, Unk		Not Reported
	Trazodone Hcl			C	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12659041	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000765		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Nephrolithiasis; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate Sodium			S	Unknown	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, As Necessary		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg (400 Mg,1 In 1 D)		Not Reported

	Hydromorph			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12659063	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Methotrexate Sodium			S	Unknown	12.5 Mg (12.5 Mg,1 In 1 D)		Hq Specialty
	Methotrexate			S	Intramuscular	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1.7857 Mg (12.5 Mg,1 In 1 W)		Not Reported
	Enbrel			S	Unknown	7.1429 Mg (50 Mg,1 In 1 W)		Not Reported
	Arava			S	Unknown	5 Mg (10 Mg,1 In 2 D)		Not Reported
	Arava			S	Unknown	57.1429 Mg (200 Mg,2 In 1 W)		Not Reported
	Arava			S	Unknown	5 Mg (10 Mg,1 In 2 D)		Not Reported
	Arava			S	Unknown	2.8571 Mg (10 Mg,2 In 1 W)		Not Reported
	Arava			S	Unknown	10 Mg (10 Mg,1 In 1 D)		Not Reported
	Arava			S		4.2857 Mg (10 Mg,3 In 1 W)		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	200 Mg, Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12659070	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000769		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Sarcoidosis	Methotrexate Sodium	S	Oral	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Enbrel	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	2000 Mg (1000 Mg,2 In 1 D)		Not Reported
	Morphine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12662087	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000786		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Joint Destruction; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2016	12662274	EXPEDITED (15-DAY)		HO	DE-ABBVIE-16K-062-1698232-00		51 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Escherichia Urinary Tract Infection	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Azathioprin			S	Unknown	75 - 300 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 - 400 Mg		Not Reported

	Leflunomid	C	Not Reported
	Leflunomid	C	Not Reported
	Sulfasalazin	C	Not Reported
	Mtx	C	Not Reported
	Mabthera	C	Not Reported
	Mabthera	C	Not Reported
	Mabthera	C	Not Reported
	Mabthera	C	Not Reported
	Mabthera	C	Not Reported
	Mabthera	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	9106705	EXPEDITED (15-DAY)		OT	ES-UCBSA-068938		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Photosensitivity Reaction; Rash	Cimzia			S	Subcutaneous	200 Mg, Ev 15 Days		Ucb
	Dolquine			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Dacortin			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	11517816	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2015272087		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Death; Drug Intolerance; Localised Infection; Nausea; Pain; Purulent Discharge; Treatment Failure; Vomiting	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Daily		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12496633	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016311785		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Diarrhoea; Drug Intolerance; Eye Disorder; Infection; Lower Respiratory Tract Infection; Tongue Injury; Tuberculosis	Methotrexate Sodium	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Leflunomide	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12664258	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000783		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Enbrel			S	Unknown	2 In 1 W		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Mg (10 Mg,1 In 1 D)		Not Reported
	Naprosyn /00256201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12664370	EXPEDITED (15-DAY)		HO, LT, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Overdose; Somnolence; Torsade De	Hydroxychloroquine			S	Unknown			Hikma
	Oxycodone/Paracetamol			S	Unknown			Roxane

Pointes; Ventricular Fibrillation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12664526	NON-EXPEDITED			US-PFIZER INC-2016389181		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12664568	NON-EXPEDITED			US-PFIZER INC-2016390716		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Doxycycline Hyclate			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12665364	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2016M1033977			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Mylan-Hydroxychloroquine			S		400 Mg, Qd		Mylan
	Mylan-Hydroxychloroquine			S		200 Mg, Qod Alternating With 400mg Qod		Mylan
	Eltroxin			C		Unk		Mylan
	Symbicort			C		Unk		Mylan
	Lorazepam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2016	12665665	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015298444		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Lymph Node Calcification; Malaise; Nausea; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Oral	25 Mg		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12467387	NON-EXPEDITED			US-PFIZER INC-2016297913			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Advil			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Feldene			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Methotrexate			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Acetylsalicylic Acid			S		Unk		Pfizer
	Indomethacin			S		Unk		Unknown
	Naproxen Sodium			S		Unk		Pfizer
	Etodolac			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported

	Motrin	S	Unk	Not Reported
	Nabumetone	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Tylenol	S	Unk	Not Reported
	Vioxx	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12562308	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000534			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Squamous Cell Carcinoma Of Skin; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, 1 D		Not Reported
	Celexa /00582602/			C	Unknown	40 Mg, 1 D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12619183	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000659		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Peripheral Swelling	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	1 Df, Unk		Not Reported
	Sulfasalazine			S	Oral	(1 In 1 W)		Not Reported

	Prednisone			S	Oral	5 Mg (5 Mg,1 In 1 D)				Not Reported
	Plaquenil			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12626219	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000676		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12634971	NON-EXPEDITED			US-PFIZER INC-2016353746			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Feldene			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Dilanid			S		Unk		Not Reported
	Indocin			S		Unk		Not Reported
	Darvon			S		Unk		Not Reported
	Fectrim			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported

			Plaquenil		S		Unk		Not Reported
			Naprosyn		S		Unk		Not Reported
			Imuran		S		Unk		Not Reported
			Keflex		S		Unk		Not Reported
			Valium		S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12667819	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000809		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S		Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12668002	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000805		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Insomnia; Loss Of Personal Independence In Daily Activities; Malaise; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12668004	EXPEDITED (15-DAY)		HO, LT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-43		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Condition Aggravated; Electrocardiogram Qt Prolonged; Fall; Head Injury; Loss Of Consciousness; Palpitations; Syncope	Hydroxychloroquine Sulfate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12668006	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000797		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg (20 Mg,1 In 1 D)		Not Reported
	Prednisone			S	Unknown	10 Mg (10 Mg,1 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12668154	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-43			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Toxicity To Various Agents; Visual Impairment	Plaquenil			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12668228	EXPEDITED (15-DAY)		HO	CA-MYLANLABS-2016M1033936			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Peripheral Swelling; Pruritus; Skin Exfoliation; Swelling Face	Mylan-Hydroxychloroquine			S	Oral	400 Mg, Qd		Mylan
	Pregabalin			C				Mylan
	Metformin			C				Mylan
	Asa			C				Mylan
	Ciprofloxacin			C				Mylan
	Prednisone			C				Mylan
	Famotidine			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2016	12668745	NON-EXPEDITED		OT	US-AMGEN-USASP2016106766		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Optic Neuritis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasal			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	11529008	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0580		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Localised Infection; Nausea; Pain; Product Complaint; Purulent Discharge; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	11966654	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2012046460		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Totalis; Alopecia Universalis; Condition Aggravated; Drug Ineffective; Ear Infection; Herpes Zoster; Pain; Sinusitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Mefenamic Acid			C		Unk Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	12600508	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2013058842		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Pain; Pruritus; Rash; Swelling	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Every 2 Weeks		Not Reported
	Rituxan			S	Unknown	1 G, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	12671992	NON-EXPEDITED			US-PFIZER INC-2016390939			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2016	12673213	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0571		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; General Physical Health Deterioration; Lower Respiratory Tract Infection; Rheumatoid Arthritis; Tongue Injury	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	11070979	EXPEDITED (15-DAY)		HO	CA-AMGEN-CANSP2015039900		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Back Pain; Cough; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hypersensitivity; Injection Site Reaction; Lung Disorder; Muscle Disorder; Musculoskeletal Disorder; Pharyngitis Streptococcal; Psychomotor Hyperactivity; Skin Discolouration; Skin	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

Disorder; Viral Pharyngitis;
Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12398643	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015300227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Disorder; Cystitis; Malaise; Peripheral Swelling; Pollakiuria; Retinal Toxicity	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	6 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk, Daily		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Plaquenil /00072603/			S	Oral	1 Df, 1x/Day		Not Reported
	Plaquenil /00072603/			S	Oral	200 Mg, 2x/Day		Not Reported
	Prednisone			C	Oral	1 Df, 1x/Day		Not Reported
	Leflunomide			C	Oral	1 Df, 1x/Day		Not Reported
	Hydrothiazide			C	Oral	1 Df, 1x/Day		Not Reported
	Folic Acid			C	Oral	1 Df Once Daily Except On Days When Patient Takes Methotrexate		Not Reported
	Glucosamine			C	Oral	Unk, 1x/Day		Not Reported
	Multivitamins			C	Oral	Unk, 1x/Day		Not Reported
	Vitamin C			C	Oral	Unk, 1x/Day		Not Reported
	Vitamin D Nos			C	Oral	Unk, 1x/Day		Not Reported
	Tylenol Arthritis			C		Unk, As Needed		Not Reported
	Toviaz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12589589	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000600		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Constipation; Fall; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection; Wrist Fracture	Methotrexate Sodium	S	Oral	20 Mg, Unk	Hq Specialty
	Xeljanz	S	Oral	10 Mg (5 Mg,2 In 1 D)	Not Reported
	Xeljanz	S	Oral	10 Mg(5 Mg, 2 In 1 D)	Not Reported
	Xeljanz	S	Oral	10 Mg, (5 Mg, 2 In 1 D)	Not Reported
	Xeljanz	S	Oral	10 Mg (5 Mg,2 In 1 D)	Not Reported
	Celebrex	S	Unknown	400 Mg, (200 Mg, 2 In 1 D)	Not Reported
	Celebrex	S	Unknown	As Necessary	Not Reported
	Celebrex	S	Oral	(2 In 1 D)	Not Reported
	Celebrex	S	Oral	Once Per Day And Eventually As Needed	Not Reported
	Celebrex	S	Oral	(2 In 1 D)	Not Reported
	Celebrex	S	Oral	(1 In 1 D)	Not Reported
	Celebrex	S	Oral	200 Mg (200 Mg,1 In 1 D)	Not Reported
	Celebrex	S	Oral	200 Mg (200 Mg,1 In 1 D)	Not Reported
	Plaquenil /00072602/	S	Unknown	(200 Mg, 1 D)	Not Reported
	Prednisone	S		(2.5 Mg, 1 D)	Not Reported
	Prednisone	S		1.25 Mg (2.5 Mg, 1 In 2 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12619209	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000699		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Oral	25 Mg		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G (1 G,2 In 1 D)		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

	Humira	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg (400 Mg,1 In 1 D)	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Fosamax	C	Unknown	Unk	Not Reported
	Reactine (Cetirizine Hydrochloride)	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12677731	EXPEDITED (15-DAY)		OT	AU-HQ SPECIALTY-AU-2016INT000832			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Myocardial Infarction; Angina Unstable; Polyarthritis	Methotrexate Sodium			S	Unknown	2.1429 Mg (15 Mg,1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Unknown	(20 Mg,1 In 1 W)		Hq Specialty
	Methotrexate Sodium			S	Unknown	1.4286 Mg (10 Mg,1 In 1 W)		Hq Specialty
	Hydroxychloroquine			S	Unknown	400 Mg (200 Mg,2 In 1 D)		Not Reported
	Prednisolone			S	Unknown	7 Mg,1 D		Not Reported
	Prednisolone			S	Unknown	Dose Reduced (3.5 Mg,1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2016	12677734	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000833		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Fall; Joint Effusion; Weight Increased; Wrist Fracture	Methotrexate Sodium			S	Unknown	25 Mg		Hq Specialty
	Prednisone			S	Unknown	On And Off		Not Reported
	Humira			S	Unknown	40 Mg		Not Reported
	Simponi			S	Unknown	50 Mg		Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12001412	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016035890		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Totalis; Alopecia Universalis; Drug Ineffective; Herpes Zoster	Enbrel			S		50 Mg, Once Weekly		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Advil			C		Unk Unk, As Necessary		Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12137178	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-07			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

	Tylenol			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12329253	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000251		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Interaction; Joint Range Of Motion Decreased; Muscle Spasms; Pain; Pain In Jaw; Product Complaint; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Xeljanz			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Naprosyn /00256201/			S		Unk		Not Reported
	Apo-Amitriptyline			S		Unk		Not Reported
	Voltaren /00372301/			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12406718	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015146909		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Back Pain; Cough; Drug Ineffective; Fatigue; Hypersensitivity; Injection Site Reaction; Lung Disorder; Muscle Disorder; Musculoskeletal Disorder; Pharyngitis Streptococcal; Psychomotor	Enbrel			S		Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Hyperactivity; Skin Discolouration; Skin Disorder; Viral Pharyngitis; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12566272	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000548		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Back Pain; Fall; Influenza; Muscle Spasms; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	2.1429 Mg (15 Mg,1 In 1 W)		Hq Specialty
	Xeljanz			S	Oral	10 Mg (5 Mg, 2 In 1 D)		Not Reported
	Xeljanz			S	Oral	5 Mg (5 Mg,1 In 1 D)		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Prednisone			S	Unknown	2.5 Mg, 1 D		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12626889	EXPEDITED (15-DAY)			CA-HQ SPECIALTY-CA-2016INT000706		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate Sodium			S	Oral	Unk		Hq Specialty
	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12678892	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1405		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Leukopenia; Nausea; Treatment Failure; Vomiting; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12678919	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1187		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Migraine	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Kineret			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12680178	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-43			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Myocardial Infarction	Plaquenil			S				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported
	Symbicort Inhaler			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681233	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000848		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Celebrex			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg,1 D		Not Reported
	Plaquenil /00072603/			S	Unknown	400 Mg,1 D		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	6 Mg (6 Mg,1 In 1 D)		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Tylenol Arthritis			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2016	12681682	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000846		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate Sodium			S	Oral	3.5714 Mg (25 Mg,1 In 1 W)		Hq Specialty
	Arava			S	Unknown	10 Mg		Not Reported
	Plaquenil			S	Oral	200 Mg,1 D		Not Reported
	Tylenol			C	Unknown	As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	11699119	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-34		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; C-Reactive Protein Increased; Joint Swelling; Kidney Infection; Nephrolithiasis; Urinary Tract Infection	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	11999564	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016011295		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Osteoarthritis; Pneumonia; Pruritus; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12556210	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015268970		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axillary Mass; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Dry Mouth; Interstitial Lung Disease; Ocular Hyperaemia; Photophobia; Rash; Rash Pruritic; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Unk, Unk		Unknown
	Sulfasalazine			S	Oral	1 G, Daily		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S		200 Mg, Daily		Not Reported
	Folic Acid			C		5 Mg, Weekly		Not Reported
	Naprosyn			C	Oral	500 Mg, 2x/Day		Not Reported
	Tylenol No. 3			C		Unk		Not Reported
	Vimovo			C		500/20 Mg (1 Tablet) Two Times Daily		Not Reported
	Meloxicam			C		150 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12635482	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000735		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Intervertebral Disc	Methotrexate Sodium			S	Unknown	3.5714 Mg, (25 Mg,1 In 1 W)		Hq Specialty
	Enbrel			S	Subcutaneous	25 Mg,1 W		Not Reported
	Xeljanz			S	Oral	10 Mg, (5 Mg,2 In 1 D)		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	2.8571 Mg, (40 Mg,1 In 2 W)		Not Reported

Degeneration; Peripheral Swelling	Rituxan	S	Unknown	1 G		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Arava	S	Oral	20 Mg, (20 Mg 1 In 1 D)		Not Reported
	Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12664461	NON-EXPEDITED			US-PFIZER INC-2016388541		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Pantoprazole			C	Oral	40 Mg, Daily (1 Tablet By Oral Route Every Day)		Not Reported
	Prednisone			C	Oral	5 Mg, Daily (1 Tablet By Oral Route Every Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12682718	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1135		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Intervertebral Disc	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Degeneration; Peripheral Swelling	Actemra		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Gold		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683248	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000860		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Count Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Hq Specialty
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg (200 Mg,2 In 1 D)		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg,1 D		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	15 Mg,1 D		Not Reported
	Lyrica			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12683372	NON-EXPEDITED			US-PFIZER INC-2016396671			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684437	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-43		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fundoscopy Abnormal; Retinogram Abnormal; Visual Acuity Reduced	Plaquenil			S	Oral			Not Reported
	Lamisil			S	Oral			Not Reported
	Aprovel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12684438	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-43		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Flushing; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cetirizine			C				Not Reported
	Fucibet			C				Not Reported
	Hypromellose			C				Not Reported
	Meloxicam			C				Not Reported
	Paracetamol			C				Not Reported
	Sertraline			C				Not Reported
	Vagifem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2016	12685918	EXPEDITED (15-DAY)		OT	CA-HQ SPECIALTY-CA-2016INT000779		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Drug Intolerance; Dysuria; Malaise; Myalgia; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	2.8571 Mg (20 Mg,1 In 1 W)		Hq Specialty
	Xeljanz			S	Oral	10 Mg (5 Mg,2 In 1 D)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg (500 Mg,2 In 1 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12112417	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016021891		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Drug Ineffective; Fatigue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12687192	EXPEDITED (15-DAY)		OT	AU-CIPLA LTD.-2016AU17572			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Injection Site Reaction	Meloxicam			S	Unknown	7.5 Mg, Daily		Cipla
	Cetirizine			S	Unknown	Unk		Cipla
	Prednisolone			S	Unknown	Unk		Cipla
	Prednisolone			S	Unknown	Unk, Low Dose		Cipla
	Methotrexate			S	Unknown	Unk		Cipla
	Leflunomide			S	Unknown	200 Mg, Bid		Cipla
	Etanercept			S	Unknown	Unk, 7 Injections		Cipla
	Etanercept			S	Unknown	0.25 Mg, Days 1 To 2 Began With A Very Low Dose Of Etanercept With Increasing Doses (30-120minutes)		Cipla

	Etanercept		S	Unknown	Day 3 Was Similar But Had Slightly Higher Doses	Cipla
	Etanercept		S	Unknown	25 Mg, Day 4	Cipla
	Etanercept		S	Unknown	25 Mg, Subsequent Dosing, Biweekly	Cipla
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, Bid	Not Reported
	Adalimumab		S	Unknown	Unk	Not Reported
	Certolizumab		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12687203	EXPEDITED (15-DAY)		CA, OT	CH-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-122616			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Trisomy 21	Pregabalin			S	Transplacental			Not Reported
	Fluoxetine			S	Transplacental			Sun
	Duloxetine			S	Unknown			Sun
	Hydroxychloroquine			S	Transplacental			Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12687212	EXPEDITED (15-DAY)		OT	CH-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-122642			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Pregabalin			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Sun
	Duloxetine			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12687221	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0707		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Back Pain; Fall; Influenza; Muscle Spasms; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12687233	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0726			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Malaise; Peripheral Swelling; Product Complaint	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Leflunomide	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Hydrothiazide	C	Oral		Not Reported
	Folic Acid	C	Oral	Except The Day Patient Takes Methotrexat	Not Reported
	Glucosamine	C	Oral		Not Reported
	Multivitamins	C	Oral		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Sulfathalidine	C	Oral		Not Reported
	Toviaz	C	Unknown		Not Reported
	Vitamin D Nos	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12687500	EXPEDITED (15-DAY)		CA, OT	CH-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-122640			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Foetal Exposure During Pregnancy; Heart Valve Incompetence	Citalopram			S	Transplacental	0-40 Gw		Sun
	Chlorpromazine			S	Transplacental	From 0 Gw		Not Reported
	Hydroxychloroquine			S	Transplacental	From 0 Gw		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12689350	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1438		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Totalis; Alopecia Universalis; Drug Ineffective; Ear Infection; Herpes Zoster; Sinusitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Advil			C	Unknown					Not Reported
	Naproxen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2016	12691372	EXPEDITED (15-DAY)		DS	FR-FRI-1000087023		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Vestibular Syndrome; Deafness Unilateral	Nebivolol			S	Oral			Forest
	Advagraf			S	Oral	5 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Cellcept			S	Oral	1000 Mg		Not Reported
	Cellcept			S	Oral	500 Mg		Not Reported
	Cortancyl			S	Oral	10 Mg		Not Reported
	Bactrim			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	12694273	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016106983		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Gold			S		Injections		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2016	12695621	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose; Seizure; Unresponsive To Stimuli	Meloxicam			S	Oral	450 Mg, Unk		Corepharma
	Hydroxychloroquine			S	Oral	6 G, Unk		Not Reported
	Tramadol			S	Oral	1.5 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	11617747	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-03			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Cough; Dysphonia; Fatigue; Limb Discomfort; Lower Respiratory Tract Infection; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Plantar Fasciitis; Rheumatoid Arthritis; Sciatica; Sputum Discoloured; Tendon Injury; Tendon Pain	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Tens Therapy			C				Not Reported
	Cortisone			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	11748454	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2015-36		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Arthralgia; Constipation; Cough; Depressed Mood;	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Fatigue; Gait Inability; Inflammation; Irritability; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis	Xeljanz			S	Oral	Not Reported
	Celebrex			S	Oral	Not Reported
	Celebrex			S	Oral	Not Reported
	Prednisone			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Advil			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12509040	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-32		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Xeljanz			C				Not Reported
	Hydromorphone			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Cymbalta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12660433	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016377387		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Diarrhoea; Drug Ineffective; Drug Intolerance; Fatigue; Menorrhagia; Nausea;	Methotrexate Sodium			S		10 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Unk		Pfizer

Tinnitus	Sulfasalazine	S	500 Mg, 3x/Day	Pfizer
	Sulfasalazine	S	1.5 G, 2x/Day	Pfizer
	Gold	S	50 Mg, Cyclic (Every 3 Weeks)	Not Reported
	Gold	S	10 Mg, Unk	Not Reported
	Plaquenil	S	200 Mg, 2x/Day	Not Reported
	Leflunomide	S	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699263	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-44		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Cortisone			S	Oral			Not Reported
	Folic Acid			S				Not Reported
	Prednisone			S				Not Reported
	Sulfathalidine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S				Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Reactine (Cetirizine Hydrochloride)			S				Not Reported
	Fosamax			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699264	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-44		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tonic Clonic Movements	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699819	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-45			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			C				Not Reported
	Celebrex			C				Not Reported
	Hydromorph			C				Not Reported
	Tamsulosin			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699820	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-45		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Heart Abnormal; Blood Creatine Phosphokinase; Bundle Branch Block Left; Cardiac Septal Hypertrophy; Cardiomegaly; Chest Discomfort; Chest Pain; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Ejection Fraction Decreased; Electrocardiogram Abnormal; Endocardial	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisone			C				Not Reported
	Warfarin			C				Not Reported
	Ramipril			C				Not Reported
	Amlodipine			C				Not Reported
	Atenolol			C				Not Reported
	Levothyroxine			C				Not Reported

Fibrosis; Hypertrophic Cardiomyopathy; Left Ventricular Dysfunction; Left Ventricular Dysfunction; Left Ventricular Hypertrophy; Magnetic Resonance Imaging Abnormal; Mitral Valve Incompetence; Myocardial Fibrosis; N-Terminal Prohormone Brain Natriuretic Peptide Increased; Oedema Peripheral; Right Ventricular Hypertrophy; Troponin T Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2016	12699824	EXPEDITED (15-DAY)		LT, OT	US-MYLANLABS-2016M1036614			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12310637	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-19		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Calcium			C				Not Reported
	Tylenol Arthritis			C				Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported

	Metformin			C							Not Reported
	Hydroxychloroquine			C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12701201	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016110456		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Fall; Gait Disturbance; Gait Inability; Pain; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12701561	EXPEDITED (15-DAY)		OT	US-ZYDUS-011990		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma	Hydroxychloroquine			S	Oral			Zydus Pharm
	Methotrexate/Methotrexate Sodium			C		7.5 Mg Weekly		Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12701570	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1497		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumonia; Pruritus; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12702991	EXPEDITED (15-DAY)		HO, LT	PHHY2016US117861		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Injury; Syncope	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704149	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-44		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Celebrex			C				Not Reported
	Remicade			C				Not Reported
	Orencia			C				Not Reported
	Rituxan			C				Not Reported
	Arava			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704150	EXPEDITED (15-DAY)		LT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-44		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Amitriptyline			C				Not Reported
	Dexamethasone			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704175	EXPEDITED (15-DAY)		DS	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-44			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704608	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2016M1036887			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Drug Ineffective; Nodule; Pain	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Enbrel			S	Parenteral	50 Mg, Unk		Mylan
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Mylan
	Orencia			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2016	12704747	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2016M1036911			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Folic Acid			S		2 Df, Qw		Mylan
	Gabapentin			S		Unk		Mylan
	Nexium /01479302/			S		40 Mg, Qd		Mylan
	Plaquenil /00072602/			S		400 Mg, Qd		Mylan
	Prednisone			S		5 Mg, Qd		Mylan
	Sulfasalazine			C				Mylan
	Xeljanz			S	Oral	10 Mg, Qd		Mylan
	Xeljanz			S	Oral	10 Mg, Qd		Mylan
	Xeljanz			S	Oral	5 Mg, Qd		Mylan

	Xeljanz			S	Oral	Unk				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	10753841	EXPEDITED (15-DAY)		HO	FR-ROCHE-1350320		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Leukopenia; Thrombocytopenia; Treatment Failure	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	4th Cycle		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Day 15 Of 4th Cycle		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Levothyrox			C	Oral			Not Reported
	Speciafoldine			C	Oral			Not Reported
	Uvedose			C	Oral	Treatment Duration = 1 Day		Not Reported
	Solu-Medrol			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	11410704	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014265155		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Increased; Pharyngeal Swelling; Rash; Swelling; Wheezing	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Cimzia			S		Unk, Single		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk, Single		Not Reported
	Prednisone			S	Oral	20 Mg, Daily		Not Reported
	Prednisone			S	Oral	5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12566790	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016334077		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pneumonia; Weight Increased	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12705590	EXPEDITED (15-DAY)		HO	CA-ROCHE-1822907		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue;	Tocilizumab			S	Unknown			Not Reported

Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Prednisone			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			C					Not Reported
	Plaquenil			C					Not Reported
	Folic Acid			C					Not Reported
	Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12705639	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1517		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12705822	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1547		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Celebrex	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12707338	EXPEDITED (15-DAY)		DE	IL-CONCORDIA PHARMACEUTICALS INC.-CO-PL-IL-2016-45		27 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Condition Aggravated; Drug Ineffective; Dyspnoea; Interstitial Lung Disease; Pneumonia; Pulmonary Function Test Abnormal	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12708299	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2016M1037059			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U-Wave Abnormality; Hypokalaemia; Hypotension; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	60 Tabs Of 200 Mg		Not Reported
	Oxycodone And Acetaminophen			S	Unknown	35 Tabs Of 5/325 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2016	12708775	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA046516		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Increased; Pharyngeal Oedema; Rash; Swelling; Wheezing	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12710042	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASL2016112682		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Abscess; Diverticulitis; Feeling Abnormal; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12710273	EXPEDITED (15-DAY)		OT	CA-ROCHE-1824394		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Non-Hodgkin'S Lymphoma				otherwise specified)		
	Arava		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Minocycline		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12710283	EXPEDITED (15-DAY)		OT	CA-ROCHE-1824410		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 2.0 Day(S)		Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Bacillus Calmette Guerin			C	Unknown			Not Reported
	Clavulin			C	Unknown			Not Reported
	Amoxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12710417	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1553		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2016	12710459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1340		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Diarrhoea; Drug Intolerance; Fatigue; Menorrhagia; Nausea; Therapeutic Response Decreased; Tinnitus	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2016	12713602	NON-EXPEDITED			US-AMGEN-USASP2016110528		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Infection	Enbrel			S	Unknown				Amgen
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2016	12724005	DIRECT		DS			36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Substitution Issue	Plaquenil/Hydroxychloroquine Mylan Pharmaceuticals			S	Oral			Mylan
	Multivitamins			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12714176	NON-EXPEDITED			US-PFIZER INC-2016411159			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2016	12725159	DIRECT		DS			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Retinal Toxicity	Hydroxychloroqu- Ine			S	Oral			Prasco
	Acetaminophen With Codeine (Generic Of Norvast)			C				Not Reported
	Amlodipine Besylate Generic Of			C				Not Reported

	Norvast		
	Atorvastatin Generic Of Lipitor	C	Not Reported
	Triamcinolone Steroid Ointment	C	Not Reported
	Quinacrine	C	Not Reported
	Aspirin	C	Not Reported
	Vitamin D-3	C	Not Reported
	Coq10	C	Not Reported
	Preservision Areds2	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12131393	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016118176		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Ineffective; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	0.8 Ml, Weekly Injection		Unknown
	Sulfasalazine			S	Oral	1000 Mg (2x 500 Mg Tablets), 2x/Day		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Plaquenil /00072603/			S	Oral	400 Mg, 2x/Day: 2 Tablets Twice Daily		Not Reported
	Prednisone			S		Dose Changed Over Years		Not Reported
	Prednisone			S	Oral	20 Mg, Daily For Two Weeks At Which Time She Will Start Weaning		Not Reported
	Actemra			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12286931	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016210618		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cardiac Aneurysm; Drug	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer

Ineffective; Joint Swelling; Pain In Extremity	Hydroxychloroquine	S	400 Mg, 1x/Day	Not Reported
	Trazodone	C	Unk	Not Reported
	Warfarin	C	Unk	Not Reported
	Plaquenil	C	Unk	Not Reported
	Folic Acid	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Cortisone	C	Unk, As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12657546	EXPEDITED (15-DAY)		LT	RU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-RU-2016-43		42 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Lip Oedema	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12684436	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-CO-PL-AU-2016-43		72 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Sodium Decreased; Lower Respiratory Tract Infection	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported
	Oroxine			C				Not Reported
	Karvea			C				Not Reported
	Somac			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12702954	EXPEDITED (15-DAY)		HO	DE-GLAXOSMITHKLINE-DE2016GSK123827		25 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Herpes Zoster	Belimumab	S			Glaxosmithkline
	Azathioprine	S	150 Mg, Qd		Glaxosmithkline
	Prednisolone	S	5 Mg, Qd		Glaxosmithkline
	Hydroxychloroquine	S	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12715464	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1010		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal; Insomnia; Pneumonia; Rheumatoid Arthritis; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12717288	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-45			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Erythema; Lymphopenia; Pruritus; Rash; Transaminases Increased	Plaquenil			S	Oral			Not Reported
	Previscan (Fluindione)			C				Not Reported
	Kardegic			C				Not Reported
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12717291	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-CO-PL-UK-2016-45			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Burning Sensation; Chills; Choking Sensation; Confusional State; Disorientation; Dysgeusia; Dyspnoea; Feeling Abnormal; Head Discomfort; Insomnia; Lacrimation Increased; Nasal Congestion; Nasopharyngitis; Nausea; Pain; Paraesthesia; Photophobia; Product Quality Issue; Skin Tightness; Throat Irritation; Throat Tightness; Unevaluable Event; Vision Blurred	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Quinine			C				Not Reported
	Lansoprazole			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Mepacrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12717712	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-45		68 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Plaquenil			S	Oral			Not Reported
	Tenormine			C				Not Reported
	Crestor			C				Not Reported
	Fludex (Indapamide)			C				Not Reported
	Aerius (Desloratadine)			C				Not Reported
	Stilnox			C				Not Reported
	Doliprane			C				Not Reported
	Inipomp			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2016	12718104	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015472901		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Diarrhoea; Drug Intolerance; Fatigue; Feeling Abnormal; Headache; Insomnia; Rheumatoid Arthritis; Sinusitis; Stress; Therapeutic Product Effect Incomplete; Tinnitus	Methotrexate Sodium	S	25 Mg, Weekly	Pfizer
	Sulfasalazine	S	1 G, 2x/Day	Pfizer
	Plaquenil /00072603/	S	400 Mg, 1x/Day	Not Reported
	Simponi	S	50 Mg, Monthly	Not Reported
	Prednisone	S	10 Mg, 1x/Day	Not Reported
	Leflunomide	S	20 Mg, 1x/Day	Not Reported
	Folic Acid	C	Unk	Not Reported
	Amitriptyline	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	9671686	EXPEDITED (15-DAY)		HO	PHHY2013US122583		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypotension; Overdose; Somnolence; Ventricular Fibrillation	Hydroxychloroquine			S		60 Df, Unk		Novartis
	Oxycodone+Paracetamol			S		35 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	11127325	EXPEDITED (15-DAY)		OT	PR-ABBVIE-15K-131-1392920-00		57 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Blood Triglycerides Abnormal; Cataract; Cataract; Diplopia; Diplopia; Eye Disorder; Eye Disorder; Inflammation; Ophthalmoplegia; Retinal Detachment; Tooth Extraction; Vision Blurred	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	1 Am And 1 Pm		Not Reported
	Cymbalta			C	Oral			Not Reported
	Protonix			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Neurontin			C	Oral			Not Reported
	Cataflam			C	Oral			Not Reported

	Cataflam	C				Not Reported
	Reclaf	C	Oral			Not Reported
	Caltrate	C				Not Reported
	Vitamin D Nos	C	Oral			Not Reported
	Norvasc	C		Daily		Not Reported
	Atorvastatin	C	Oral			Not Reported
	Tramadol	C	Oral	37.5 / 325 Mg		Not Reported
	Benzonatate	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12694993	EXPEDITED (15-DAY)		OT	CA-SA-2016SA144144		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12722048	EXPEDITED (15-DAY)		HO	CH-ELI_LILLY_AND_COMPANY-CH201609000243		52 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Chest Discomfort; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Amplitude Decreased;	Cymbalta			S	Oral	30 Mg, Qd		Eli Lilly And Co
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Aspirin Cardio			C	Oral	100 Mg, Unknown		Not Reported
	Esomep /01479301/			C	Oral	40 Mg, Unknown		Not Reported

General Physical Health Deterioration; Off Label Use	Dafalgan	C	Oral	1000 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2016	12722747	NON-EXPEDITED			US-GILEAD-2016-0232006			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Interaction; T-Lymphocyte Count Decreased	Stribild			S	Unknown	Unk		Gilead
	Prezista			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12661537	NON-EXPEDITED			US-PFIZER INC-2016379825			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12687454	EXPEDITED (15-DAY)		OT	GXBR2016US002643		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma; Nausea; Renal Impairment	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	1 Df, Qd		Novartis
	Ibuprofen Tablets Usp			S	Unknown	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12700814	NON-EXPEDITED			US-AMGEN-USASP2016106882		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased;	Enbrel			S	Unknown	Unk		Amgen

Drug Ineffective; Heart Rate Decreased; Hypersensitivity	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12723950	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1659		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Insomnia; Rheumatoid Arthritis; Sinusitis; Stress; Tinnitus	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12724899	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004461		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Increased; Pharyngeal Oedema; Rash; Swelling; Wheezing	Plaquenil			S	Unknown			Concordia
	Arava			S				Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Cimzia			S	Unknown	Once			Not Reported
	Rituxan			S	Unknown	Once			Not Reported
	Prednisone			S	Oral				Not Reported
	Prednisone			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2016	12726419	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1037774			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Letrozole			S		Unk		Not Reported
	Palbociclib			S		Unk		Mylan
	Fulvestrant			S		Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	11790489	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2015-39		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Decreased; Blood Immunoglobulin A Increased; Glare; Visual Field Defect	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12364347	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-22		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Burning Sensation; Condition Aggravated; Diarrhoea; Fatigue; Limb Mass;	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Xeljanz			S	Oral			Not Reported

Malaise; Peripheral Embolism; Peripheral Swelling; Peripheral Swelling; Sciatica; Urinary Tract Infection	Methotrexate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12425678	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-CO-PL-FR-2016-25		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatocellular Injury; Toxic Skin Eruption	Plaquenil			S	Oral			Not Reported
	Cortancyl			C				Not Reported
	Levothyrox			C				Not Reported
	Mopral			C				Not Reported
	Daflon (Diosmin/Hesperidin)			C				Not Reported
	Dermoval (Clobetasol Propionate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12699262	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-44			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Influenza Like Illness; Pain In Extremity; Pain In Extremity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12727000	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1666		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Aneurysm; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Trazodone		C	Unknown	Not Reported
	Warfarin		C	Unknown	Not Reported
	Plaquenil		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Cortisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12730052	EXPEDITED (15-DAY)		DE, HO	AU-ABBVIE-04P-008-0281694-00		60 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Adrenal Insufficiency; Adrenocortical Insufficiency Acute; Brain Death; Encephalomyelitis; Malaise; Memory Impairment; Ophthalmoplegia; Wrong Product Administered	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported
	D-Penicillamine			C				Not Reported
	Azathioprine			C				Not Reported
	Salazopyrin			C				Not Reported
	Myocrisin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2016	12730270	EXPEDITED (15-DAY)		OT	CA-SA-2016SA163879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	12661651	NON-EXPEDITED			US-PFIZER INC-2016388547		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Hypersensitivity; Heart Rate Decreased	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2016	12731458	NON-EXPEDITED			US-AMGEN-USASL2016112934		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12736115	EXPEDITED (15-DAY)		DS	CA-ROCHE-1681491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Dyspnoea; Hypersensitivity; Mobility Decreased; Neutropenia; Synovitis	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Up To 20 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12737246	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-CO-PL-CA-2016-45		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Kineret			S				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12739255	EXPEDITED (15-DAY)		OT	EG-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004543		61 YR	Female	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Leukopenia; Thrombocytopenia	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Etanercept			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12739266	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004565		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Peripheral T-Cell	Hydroxychloroquine			S	Unknown			Concordia

Lymphoma Unspecified; Skin Lesion; Skin Mass	Hydroxychloroquine	S	Unknown		Concordia
	Fluocinonide	C	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12741747	DIRECT	Y	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Pain; Paraesthesia; Product Quality Issue	Hydroxychloroqu- Ine			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12711073	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016410428		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S				Not Reported
	Humira			S		Unk		Not Reported
	Rituxan			S				Not Reported
	Gabapentin			C		200 Mg, 2x/Day		Not Reported
	Prednisone			C		10 Mg, Daily		Not Reported
	Norvasc			C		2.5 Mg, Daily		Not Reported
	Atasol /00020001/			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12736153	EXPEDITED (15-DAY)		OT	CA-ROCHE-1827899			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S				Not Reported
	Anakinra			S	Unknown			Not Reported

Arava	S	Oral			Not Reported
Enbrel	S	Unknown	Therapy Duration: 6 Years		Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate Sodium	S	Oral			Not Reported
Methotrexate Sodium	S	Subcutaneous			Not Reported
Orencia	S	Unknown			Not Reported
Vioxx	S	Unknown			Not Reported
Leflunomide	C				Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12742907	EXPEDITED (15-DAY)		OT	NL-TEVA-691721ACC		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Haematochezia; Malaise; Nausea	Methotrexate Tablet 10mg			S	Oral	20 Mg Once Weekly		Not Reported
	Hydroxychloroquine Dragee 200mg			S	Oral	400 Milligram Daily; 200 Mg Twice A Day		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12745116	EXPEDITED (15-DAY)		HO, LT, OT	US-ZYDUS-012050		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrioventricular Block First Degree; Chest Discomfort; Electrocardiogram Qt Prolonged; Fall; Injury; Loss Of Consciousness; Palpitations; Syncope; Toxicity To Various Agents	Hydroxychloroquine			S	Oral			Zydus Pharm
	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12745299	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004574		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Haematochezia; Malaise; Nausea	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12745869	EXPEDITED (15-DAY)		HO, OT	US-TEVA-691604USA		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U-Wave Abnormality; Hypokalaemia; Hypotension; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Acetaminophen W/Oxycodone			S	Unknown	35 Tabs Of 5/325 Mg		Actavis
	Hydroxychloroquine			S	Unknown	60 Tabs Of 200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12746508	DIRECT		OT			66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Contraindicated Product Administered; Gastrointestinal Disorder	Plaquenil			S	Oral			Not Reported
	Atenolol			C				Not Reported
	Ace Inhibitor			C				Not Reported
	Escotaliphram			C				Not Reported
	Victoza			C				Not Reported
	Lantus			C				Not Reported
	Aspirin			C				Not Reported
	Restates			C				Not Reported
	Alpha-Lipoid Acid			C				Not Reported

	Multi-Vitamin			C					Not Reported
	Coq10			C					Not Reported
	Turmeric			C					Not Reported
	Magnesium			C					Not Reported
	Vitamin D3			C					Not Reported
	Potassium			C					Not Reported
	Zinc			C					Not Reported
	B-Complex Supplement			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2016	12747577	NON-EXPEDITED			US-JAZZ-2016-US-009774			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Plaquenil			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Synthroid			C				Not Reported
	Premarin			C				Not Reported
	Humira			C				Not Reported
	Norco			C				Not Reported
	Methotrexate			C				Not Reported
	Citalopram Hbr			C				Not Reported
	Zyrtec			C				Not Reported
	Astelin			C				Not Reported
	Claritin			C				Not Reported
	Evista			C				Not Reported
	Fosinopril Sodium			C				Not Reported
	Multivitamins			C				Not Reported
	Nasonex			C				Not Reported
	Nexium			C				Not Reported
	Norvasc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2016	12719321	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1613		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Haemorrhage	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Norvasc			C	Unknown			Not Reported
	Atasol (Acetaminophen)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2016	12755813	EXPEDITED (15-DAY)		OT	AU-009507513-1503AUS005971		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushing'S Syndrome; Drug Dependence; Hypertension; Ill-Defined Disorder; Off Label Use; Steroid Diabetes; Treatment Failure	Montelukast Sodium			S		Unk		Merck
	Montelukast Sodium			S				Merck
	Cyclosporine			S				Not Reported
	Cyclosporine			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Dapsone			S				Not Reported
	Dapsone			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S		At A Variable Dose Of 10 To 25 Mg Daily		Merck
	Prednisone			S				Merck
	Globulin, Immune			C				Not Reported
	Globulin, Immune			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12487411	NON-EXPEDITED			US-AMGEN-USASL2016078844		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Injection Site Erythema; Injection Site Inflammation; Injection Site Pain; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Injection Site Warmth; Malaise; Pain; Therapeutic Response Unexpected; Visual Acuity Reduced	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Flexeril			C		9 Qd Unk		Not Reported
	Flexeril			C		9 One Or Two Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12757230	NON-EXPEDITED			US-AMGEN-USASL2016120079		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Dose Administered; Pain; Product Dose Omission; Visual Impairment; Wrong Technique In Product Usage Process	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12757345	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004609		80 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Dyspepsia	Hydroxychloroquine			S	Oral			Concordia
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12757354	EXPEDITED (15-DAY)		DS, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004611		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Prednisolone			C				Not Reported
	Fluoxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12286629	NON-EXPEDITED			US-TEVA-644475USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present	Carvedilol			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12654632	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2016-10423		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Oxycodone And Acetaminophen Tablets Usp, 5 Mg/325 Mg			S	Unknown	35 Tablets		Aurobindo
	Hydroxychloroquine			S	Unknown	200 Mg, 60 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12711230	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1554		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Rheumatoid Arthritis; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naprosyn			C	Unknown	Once Daily As Needed		Not Reported
	Losec			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12739212	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Actonel			C				Not Reported
	Folic Acid			C				Not Reported
	Amlodipine Besilate			C				Not Reported
	Atenolol			C				Not Reported
	Salbutamol Sulfate			C				Not Reported
	Zenhale			C				Not Reported

	Methotrexate			C						Not Reported
	Calcium			C						Not Reported
	Vitamin D Nos			C						Not Reported
	Avamys			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12761396	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2016124549		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Arthralgia; Arthroscopy; Back Pain; Bunion Operation; Burning Sensation; Bursitis; Cellulitis; Drug Ineffective; Fatigue; Haemorrhage; Hyperhidrosis; Hypertension; Intervertebral Disc Degeneration; Knee Arthroplasty; Lumbar Radiculopathy; Muscle Spasms; Neuropathy Peripheral; Osteoarthritis; Osteomyelitis; Osteotomy; Pain In Extremity; Post Procedural Infection; Procedural Pain; Pruritus; Rash; Red Blood Cell Sedimentation Rate Increased; Staphylococcal Infection; Swelling Face; Tendonitis; Toe Operation; Weight Decreased; Weight Increased	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Clindamycin			S				Not Reported
	Clindamycin			S				Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Bactrim			S				Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Duloxetine			S	Unknown	60 Mg, Qd		Not Reported
	Duloxetine			S	Unknown	30 Mg, Unk		Not Reported
	Amlodipine			C		10 Mg, Qd		Not Reported
	Lipitor			C		20 Mg, Unk		Not Reported
	Celebrex			C		200 Mg, Unk		Not Reported
	Celebrex			C		100-200, Bid		Not Reported
	Atorvastatin			C		10 Mg, Qd		Not Reported
	Potassium Chloride			C		10 Meq, Tid		Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12763666	EXPEDITED (15-DAY)		HO, LT	US-IPCA LABORATORIES LIMITED-IPC201609-000755		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Head Injury; Syncope; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S	Oral			Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2016	12763760	EXPEDITED (15-DAY)		HO	US-CELGENEUS-USA-2016093895		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Abraxane			S	Intravenous drip			Not Reported
	Gemcitabine			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Glipizide			C	Oral			Not Reported
	Glipizide			C	Oral	50 Milligram		Not Reported
	Fentanyl			C	Transdermal			Not Reported
	Furosemide			C	Oral	50 Microgram		Not Reported
	Hydromorphone			C	Oral	16 Milligram		Not Reported
	Lansoprazole			C	Oral	60 Milligram		Not Reported
	Loperamide			C	Oral			Not Reported
	Ondansetron			C	Oral			Not Reported
	Prochlorperazine			C	Oral			Not Reported
	Spironolactone			C	Oral			Not Reported
	Valsartan			C	Oral	25 Milligram		Not Reported
	Zolpidem			C	Oral	12.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12098603	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016019575		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Weekly		Amgen
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Folic Acid			C		5 Mg, Qd		Not Reported
	Naprosyn			C		500 Mg, As Necessary		Not Reported
	Losec			C		20 Mg, Qd		Not Reported
	Citalopram			C		20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12106136	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-011636		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12430785	EXPEDITED (15-DAY)		OT	US-AMGEN-		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Nervous System Disorder; Peripheral Swelling; Rheumatoid Arthritis; Sleep Apnoea Syndrome; Therapeutic Product Effect Delayed; Vertigo	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	11 Mg One Tablet, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	100 Mg, Unk		Not Reported
	Remicade			S	Unknown	700 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	700 Unk, Unk		Not Reported
	Coumadin			C		3 Mg, Qd		Not Reported
	Sotalol			C		80 Mg, One Half Tablet Tid		Not Reported
	Prednisone			C		10 Mg, As Necessary		Not Reported
	Folic Acid			C		1 Mg, Qwk		Not Reported
	Tylenol			C		Unk Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12764798	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076418		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12764911	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004659		67 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Macular	Hydroxychloroquine			S	Unknown			Concordia
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Bisoprolol			C				Not Reported
	Cetirizine			C				Not Reported
	Co-Codamol			C				Not Reported
	Dapagliflozin			C				Not Reported
	Metformin			C				Not Reported
	Ramipril			C				Not Reported
	Sitagliptin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12764917	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photosensitivity Reaction	Plaquenil			S	Unknown			Concordia
	Celebrex			C				Not Reported
	Tylenol			C				Not Reported
	Magnesium			C				Not Reported

	Vitalux				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12765398	NON-EXPEDITED			US-PFIZER INC-2016438802			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12766489	EXPEDITED (15-DAY)		HO, LT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-01		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Condition Aggravated; Electrocardiogram Qt Prolonged; Syncope	Hydroxychloroquine			S	Oral			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12767802	EXPEDITED (15-DAY)		HO	US-IPCA LABORATORIES LIMITED-IPC201311-000464		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram U Wave Present; Hypokalaemia; Hypotension; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydroxychloroquine Sulfate			S		60 Tablets Of 200 Mg		Ipca
	Oxycodone/Paracetamol			S		35 Tablets Of 5/325 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2016	12767859	EXPEDITED (15-DAY)		HO, OT	ES-IPCA LABORATORIES LIMITED-IPC201609-000778		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Detachment; Maculopathy; Rhegmatogenous Retinal Detachment; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12769913	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004627		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S				Concordia
	Mycophenolate Mofetil			S				Not Reported
	Methotrexate			C		25 Mg/Cc Liquid		Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Prilosec			C				Not Reported
	Nifedipine			C				Not Reported
	Sildenafil			C				Not Reported
	Calcium			C		In The Morning		Not Reported
	Proair Hfa Aerosol			C		2 Puffs 4 Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12769932	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004702		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block	Hydroxychloroquine			S	Oral			Concordia

Complete; Bradycardia; Circulatory Collapse; Torsade De Pointes	Amitriptyline	S	Oral		Not Reported
	Calcichew D3 Forte	C			Not Reported
	Clopidogrel	C			Not Reported
	Colecalciferol	C			Not Reported
	Ferrous Fumarate	C			Not Reported
	Folic Acid	C			Not Reported
	Lansoprazole	C			Not Reported
	Memantine	C			Not Reported
	Methotrexate	C			Not Reported
	Paracetamol	C			Not Reported
	Prednisolone	C			Not Reported
	Sodium Pidolate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12769935	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004715		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Plaquenil			S				Concordia
	Avelox			S				Not Reported
	Ceftin			S				Not Reported
	Enbrel			S				Not Reported
	Factlve			S				Not Reported
	Humira			S				Not Reported
	Hydrocodone			S				Not Reported
	Latex Natural Rubber			S				Not Reported
	Remicade			S				Not Reported
	Flagyl			C				Not Reported
	Augmentin			C				Not Reported
	Arthrotec 50			C				Not Reported
	Amrix			C				Not Reported
	Albuterol Hfa Inhaler			C		90 Mcg/Actuation		Not Reported
	Albuterol			C				Not Reported
	Intal			C				Not Reported
	Benadryl			C				Not Reported
	Folvite			C				Not Reported
	Anaspaz Levsin			C				Not Reported
	Claritin D 24 Hour			C				Not Reported
	Lyrica			C				Not Reported

	Magnesium Oxide	C		Not Reported
	Mobic	C		Not Reported
	Robaxin	C		Not Reported
	Methotrexate	C		Not Reported
	Gas X Oral	C		Not Reported
	Ultram	C		Not Reported
	Ultram Er	C		Not Reported
	Desyrel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2016	12769947	EXPEDITED (15-DAY)		HO	GB-ACCORD-044129		84 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bradycardia; Circulatory Collapse; Torsade De Pointes	Amitriptyline			S	Oral	At Night		Accord
	Hydroxychloroquine			S	Oral	In The Morning.		Not Reported
	Calcichew D3 Forte			C				Not Reported
	Clopidogrel			C				Not Reported
	Colecalciferol			C				Not Reported
	Iron			C				Not Reported
	Folate Sodium/Folic Acid			C				Not Reported
	Lansoprazole			C				Not Reported
	Memantine Hydrochloride			C				Not Reported
	Methotrexate			C				Not Reported
	Paracetamol			C				Not Reported
	Prednisolone			C				Not Reported
	Sodium Pidolate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12773985	EXPEDITED (15-DAY)		OT	IT-ACCORD-044182		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Off Label Use; White Blood Cell Analysis Abnormal	Mycophenolic Acid			S				Accord
	Plaquenil			S	Oral			Not Reported
	Deltacortene			C	Oral	Strength: 5 Mg		Not Reported
	Bactrim			C	Oral	160 Mg + 800 Mg		Not Reported
	Ramipril			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12774024	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004722		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; White Blood Cell Analysis Abnormal	Plaquenil			S	Oral			Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Ramipril			C				Not Reported
	Deltacortene			C				Not Reported
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12774027	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004746		35 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Syndrome; Epilepsy; Meningitis Tuberculous; Migraine; Weight Decreased	Plaquenil			S	Oral			Concordia
	Imuran			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12774033	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004748		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Etanercept			S	Subcutaneous			Not Reported
	Sulfasalazine Tablet 500mg			S	Oral			Not Reported
	Methotrexate Tablet			S	Oral			Not Reported

	Lisinopril	C	Not Reported
	Bisoprolol	C	Not Reported
	Pantozol	C	Not Reported
	Dyazide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12774108	EXPEDITED (15-DAY)		OT	CA-ROCHE-1833329		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12774241	EXPEDITED (15-DAY)		HO	NL-TEVA-693422ACC		57 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia	Sulfasalazine Tablet 500mg			S	Oral	1000 Milligram Daily; 2 Times Per Day 4 Piece(S), Additional Info: 500mg		Actavis
	Methotrexat Tablet 10mg			S	Oral	1 Time Per Week 1 Piece(S), Additional Info: 25mg Weekly		Barr
	Plaquenil Tablet Omhuld 200mg			S	Oral	200 Milligram Daily; 1 Time Per Day 1 Piece(S), Additional Info: 200mg		Not Reported

	Etanercept Injvlst 50mg/Ml	S	Subcutaneous	1 Time Per Week 1 Piece(S), Additional Info: 50mg	Not Reported
	Lisinopril Tablet 10mg	C	Oral	10 Milligram Daily; 1 Time Per Day 1 Piece(S), Additional Info: 10mg	Not Reported
	Bisoprolol Tablet 10mg	C	Oral	10 Milligram Daily; 1 Time Per Day 1 Piece(S), Additional Info: 10mg	Not Reported
	Pantozol Tablet Msr 40mg	C	Oral	40 Milligram Daily; 1 Time Per Day 1 Piece(S), Additional Info: 40mg	Not Reported
	Triamtereen/Hydrochloorthiazide Tablet 50/25mg	C	Oral	1 Dosage Forms Daily; 1 Time Per Day 1 Piece(S), Additional Info: 50/4	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2016	12775354	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076360		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Naprosyn /00256201/			S	Unknown	500 Mg, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2016	12777264	NON-EXPEDITED		OT	US-AMGEN-USASL2016126802		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Product Dose Omission; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Allegra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2016	12779998	DIRECT		DS, LT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Constipation; Dysuria; Faeces Discoloured; Fatigue; Hair Texture Abnormal; Muscular Weakness; Nausea; Oral Discomfort; Oral Mucosal Blistering; Palpitations; Parosmia; Tinnitus; Tongue Discomfort; Tooth Discolouration; Visual Impairment; Vomiting; Weight Decreased	Hydroxychloroquine Sulfate			S	Oral	Other Strength:;Other Dose:;Other Frequency:Weekly;Other Route:		Not Reported
	Norrco			C				Not Reported
	Omeprazole			C				Not Reported
	Probiotics			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Miralax			C				Not Reported
	Promethazine			C				Not Reported
	Ondansetron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12764918	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004719		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Photosensitivity Reaction; Purpura	Plaquenil	S	Oral		Concordia
	Previscan (Fluindione)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12779397	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004791		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hand Deformity; Rheumatoid Arthritis; Walking Disability	Plaquenil Tablet			S	Oral	At Bedtime		Concordia
	Sulfasalazine			C				Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12780377	DIRECT	Y	OT			33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dry Eye; Dry Mouth; Fatigue; Product Substitution Issue; Sjogren'S Syndrome	Hydroxychloroquine 200mg			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2016	12781453	EXPEDITED (15-DAY)		OT	PHHY2016BR130281			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Decreased Immune Responsiveness; Joint Swelling; Pain; Rheumatoid Arthritis	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Q12mo (Between Jun And Jul)		Novartis
	Meticorten			S	Unknown			Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Reuquinol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12745361	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12781947	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004792			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Myocardial Infarction; Angina Unstable; Musculoskeletal Stiffness; Polyarthritis	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12782470	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004665		49 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Quality Issue; Rash Pruritic	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12782986	NON-EXPEDITED			US-PFIZER INC-2016446601		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2016	12784017	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK140433		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Voltarene Lp			S	Oral	75 Mg, Unk		Glaxosmithkline
	Plaquenil			S	Oral	Unk		Not Reported
	Inexium			S	Oral	40 Mg, Unk		Not Reported
	Ixprim			S	Oral	4 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12133402	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016022884		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Foot Deformity; Grip Strength Decreased; Hip Arthroplasty; Hypoaesthesia; Joint Swelling; Knee Arthroplasty; Musculoskeletal Disorder;	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported

Pain In Extremity; Red Blood Cell Sedimentation Rate Abnormal; Treatment Noncompliance	Folic Acid	C		Unk		Not Reported
	Perindopril	C		Unk		Not Reported
	Celebrex	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12767459	NON-EXPEDITED			US-PFIZER INC-2016437834			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Neomycin Sulfate			S		Unk		Pfizer
	Neosporin Gu			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Amoxicillin And Clavulanate Potassium			S		Unk		Not Reported
	Antivert			S		Unk		Not Reported
	Bleph-10			S		Unk		Not Reported
	Hydrocodone Bitartrate			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12786910	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016130708		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphoma	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787071	EXPEDITED (15-DAY)		HO, OT	LT-MYLANLABS-2016M1041150			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787731	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004845			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Malaise; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787966	NON-EXPEDITED			US-TEVA-642138USA		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787968	NON-EXPEDITED			US-TEVA-604448USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown			Teva
	Tylenol			C	Oral			Not Reported
	Baclofen			C	Oral			Not Reported

Baclofen	C		Not Reported
Bupropion	C	Oral	Not Reported
Vitamin D3	C	Oral	Not Reported
Folvite	C		Not Reported
Lasix	C		Not Reported
Magnesium Oxide	C	Oral	Not Reported
Metoprolol Succinate	C		Not Reported
Potassium Chloride	C		Not Reported
Aldactone	C		Not Reported
Azulfidine	C		Not Reported
Coumadin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787970	NON-EXPEDITED			US-TEVA-642148USA		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787972	NON-EXPEDITED			US-TEVA-642497USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787973	NON-EXPEDITED			US-TEVA-636816USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Glossitis	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787974	NON-EXPEDITED			US-TEVA-593353USA		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Hypersensitivity; Heart Rate Increased; Product Dose Omission	Hydroxychloroquine			S	Unknown			Teva
	Metoprolol			S	Unknown			Teva
	Sutent			S		37.5mg Alt 25mg Daily ; 2 Wks On/1 Wk Off		Not Reported
	Zometa			C				Not Reported
	Desonide			C				Not Reported
	Claritin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787976	NON-EXPEDITED			US-TEVA-627081USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787978	NON-EXPEDITED			US-TEVA-620563USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787983	NON-EXPEDITED			US-TEVA-592959USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective; Gait Disturbance; Skin Laceration	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12787985	NON-EXPEDITED			US-TEVA-642047USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12789020	NON-EXPEDITED			US-PFIZER INC-2016449920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12789094	NON-EXPEDITED			US-PFIZER INC-2016451980		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Compazine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12790391	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004867		4 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteomyelitis Bacterial; Q Fever	Hydroxychloroquine			S	Unknown			Concordia
	Doxycycline			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2016	12790398	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS		3 YR	Male	AUS

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteomyelitis Bacterial; Q Fever	Hydroxychloroquine			S	Unknown			Concordia
	Doxycycline			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	11774177	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015377860		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Depression; Fatigue; Herpes Simplex; Nasopharyngitis; Oropharyngeal Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pharyngitis; Renal Failure; Rhinalgia; Rhinitis; Sinusitis; Skin Lesion; Treatment Failure	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Plaquenil			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	11915826	EXPEDITED (15-DAY)		HO	DE-ROCHE-1694328		66 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ulcer; Gastroenteritis Salmonella	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexat			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Dicofenac	C	Unknown	As Required		Not Reported
	Pantoprazol	C				Not Reported
	Ramipril	C				Not Reported
	Quensyl	C				Not Reported
	Amitriptilina	C				Not Reported
	Folinic Acid	C				Not Reported
	Calcium D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12790993	NON-EXPEDITED			US-PFIZER INC-2016450950		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ibuprofen			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Sumatriptan Succinate			S				Pfizer
	Lasix			S				Not Reported
	Trimethoprim			S				Not Reported
	Cephalexin			S				Not Reported
	Probenecid			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cilastatin/Imipen			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Aztreonam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12796456	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20160928445		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Tramadol Hydochloride/Apap			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Ketotifen Fumarate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12796762	EXPEDITED (15-DAY)		DE, OT	IL-FRESENIUS KABI-FK201607197		27 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Interstitial Lung Disease; Pneumonia	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methotrexate (Manufacturer Unknown)			S				Fresenius Medical Care
	Cyclophosphamide (Manufacturer Unknown)			S	Unknown			Not Reported
	Cyclophosphamide (Manufacturer Unknown)			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prostaglandins			S				Not Reported
	Prostaglandins			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2016	12796802	DIRECT	Y	OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Hydroxychloroquine 200 Mg			S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12663948	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016386433		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Gastric Disorder	Methotrexate Sodium			S		Unk Unk, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported

	Cortisone	S	Unk	Not Reported
	Plaquenil /00072603/	S	Unk	Not Reported
	Plaquenil /00072603/	S	200 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12676577	NON-EXPEDITED			US-PFIZER INC-2016396618		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dry Skin; Psoriasis; Rash; Skin Burning Sensation	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, Unk		Pfizer
	Plaquenil			S		2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12798913	DIRECT	Y				43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Anxiety; Back Pain; Connective Tissue Disorder; Contusion; Hot Flush; Muscle Tone Disorder; Muscular Weakness; Neck Pain	Leflunomide			S	Oral			Sanofi
	Plaquenil			S		Filled At Different Pharmacy		Unknown
	Diclofenac			C				Not Reported
	Lexapro			C				Not Reported
	Norco			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2016	12799636	EXPEDITED (15-DAY)		OT	CA-SA-2016SA178382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Disease Progression; Vomiting	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2016	12800965	EXPEDITED (15-DAY)		LT	RU-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004874		42 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Lip Oedema	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2016	12805622	DIRECT		LT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anorectal Discomfort; Burning Sensation; Drug Eruption; Muscle Twitching; Nail Disorder; Stevens-Johnson Syndrome; Urine Odour Abnormal; Urticaria	Hydroxycholoroq-Uine			S	Oral	Other Daily Oral		Prasco
	Alendronate			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Diazepam			C				Not Reported
	Ezetimibe			C				Not Reported
	Omega-3 Acid Ethyl Esters			C				Not Reported
	Pregabalin			C				Not Reported
	Tramadol			C				Not Reported
	Lactulose			C				Not Reported
	Lactobacillus			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Melatonin			C				Not Reported
	Cinnamon Bark			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	11894179	EXPEDITED (15-DAY)		OT	IT-STRIDES ARCOLAB LIMITED-2016SP000028			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunosuppression; Mycobacterial Infection; Off Label Use; Osteoporosis; Spinal Fracture	Mycophenolate Mofetil			S		Unk		Strides
	Prednisolone			S		Low Dose		Not Reported
	Azathioprine			S		Unk		Not Reported

		Hydroxychloroquine			S		Unk			Not Reported
		Cyclophosphamide			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12800970	EXPEDITED (15-DAY)		HO	LT-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004911		52 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Body Temperature Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Enzyme Increased; Inflammatory Marker Increased; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12801375	EXPEDITED (15-DAY)		DS	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004932		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Muscular Weakness	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12801379	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004933		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anosmia; Anosmia; Drug Ineffective; Gait Inability; Pain In Extremity; Peripheral Swelling; Respiratory Tract Infection	Plaquenil	S	Unknown	Concordia
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12802488	EXPEDITED (15-DAY)		DS, OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004879			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Motor Dysfunction; Systemic Lupus Erythematosus; Xerophthalmia	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12804763	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016133604		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Cranial Nerve Injury; Drug Hypersensitivity; Herpes Zoster; Nodule; Pain In Extremity; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			C		Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12804875	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004940		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nausea; Visual Impairment	Plaquenil	S	Unknown			Concordia
	Humira	S	Subcutaneous	40mg/0.8ml		Not Reported
	Methotrexate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2016	12806289	DIRECT		OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Product Quality Issue; Product Substitution Issue	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Zydus Pharm
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	10490401	EXPEDITED (15-DAY)		HO	TH-PFIZER INC-2014269431		64 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Atenolol			S	Oral	Unk		Pfizer
	Metformin Hcl			S	Oral	Unk		Pfizer
	Lipitor			S	Oral	Unk		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Norvasc			S	Oral	Unk		Pfizer
	Dalacin [Clindamycin Phosphate]			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Tramadol Hcl			S	Oral	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported

	Diamicron	S	Oral	Unk		Not Reported
	Methylcobal	S	Oral	Unk		Not Reported
	Vitamin D2	S	Oral	Per Week		Not Reported
	Ticagrelor	S	Oral	90 Mg, 2x/Day		Not Reported
	Controloc	C	Oral	Unk		Not Reported
	Folic Acid	C	Oral	Unk		Not Reported
	Olmetec	C	Oral	Unk		Not Reported
	Pletaal	C	Oral	Unk		Not Reported
	Diacerein	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12578023	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016026738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Cimzia			S		200 Mg, Ev 2 Weeks(Qow)		Ucb
	Methotrexate Sodium			S		25 Mg, Weekly (Qw)		Not Reported
	Folic Acid			S		Unk, Weekly (Qw)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Humira			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, Ev 4 Weeks		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly (Qw)		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		2 Df, Ev 2 Days (Qod) (Wean The Dose)		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12804934	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		82 YR	Female	CAN

PHARMA-TREX2016-1860

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Depression; Fatigue; Impaired Healing; Infection; Nasal Discomfort; Nasopharyngitis; Oropharyngeal Pain; Renal Failure; Rhinitis; Skin Lesion; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12804982	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037859		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Cimzia			S		Unk		Ucb
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Infliximab			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Orencia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12805340	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004936			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Nausea; Product Dose Omission; Rheumatoid Arthritis; Stomatitis; Therapy Interrupted; Tongue Ulceration	Plaquenil			S	Unknown			Concordia
	Humira 40mg/0.8 Ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8 Ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12805341	EXPEDITED (15-DAY)		OT	PR-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004952		57 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Blood Triglycerides Abnormal; Cataract; Cataract; Diplopia; Eye Disorder; Inflammation; Ophthalmoplegia; Retinal Detachment; Tooth Extraction	Plaquenil			S	Oral	1 Am And 1 Pm		Concordia
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cymbalta			C	Oral			Not Reported
	Protonix			C	Oral			Not Reported
	Methotrexate Tablet			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Neurontin			C	Oral			Not Reported
	Cataflam			C	Oral			Not Reported
	Cataflam			C				Not Reported
	Caltrate			C				Not Reported
	Vitamin D Nos			C	Oral			Not Reported
	Norvasc			C				Not Reported
	Atorvastatin			C	Oral			Not Reported
	Tramadol			C	Oral	37.5 / 325 Mg		Not Reported

	Benzonatate			C	Oral					Not Reported
	Reclaf			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12805388	EXPEDITED (15-DAY)		OT	US-ACCORD-044412		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nodule	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12805665	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP012421			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Apo Folic Acid Tab 5mg			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Pantoprazole			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Aleve			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12808327	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037630		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Cimzia			S		Solution Subcutaneous		Ucb
	Arava			S				Not Reported
	Actemra			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12809269	NON-EXPEDITED			US-AMGEN-USASP2016130660		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12809291	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016037637		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Cimzia			S		Solution Subcutaneous		Ucb
	Celebrex			S		Unk		Not Reported
	Enbrel			S		Solution Subcutaneous		Not Reported
	Humira			S		Solution Subcutaneous		Not Reported
	Imuran			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Neoral			S				Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12809301	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037862		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Cimzia			S	Subcutaneous	Solution Subcutaneous		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2016	12809310	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037651		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Cimzia			S		Unk		Ucb
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12673211	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1392		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Gastric Disorder	Methotrexate (Trade Name Unknown)			S	Unknown	Weekly		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

		Cortisone			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12811201	NON-EXPEDITED			GXBR2016US000450		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Unk		Novartis
	Celecoxib			S	Unknown	200 Mg, Qd		Not Reported
	Celecoxib			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	6 Df, Qw		Not Reported
	Remicade			S	Intravenous drip	Unk Df, Unk		Not Reported
	Kenalog//Triamcinolone Acetonide			S	Unknown	Unk Df, Unk		Not Reported
	Folic Acid			C		Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12811377	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037702		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Diverticulum; Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12812679	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037671		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Unevaluable Event	Cimzia			S		Unk		Ucb
	Hydroxychloroquine			S		400 Mg, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Mg, Once Daily (Qd)		Not Reported
	Hydroxyzine			C		Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12812837	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016037856		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Cimzia			S		Solution Subcutaneous		Ucb
	Arava			S		Unk		Not Reported
	Enbrel			S		Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Procytox			S		Unk		Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Simponi			S		Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12813644	NON-EXPEDITED			US-SA-2016SA013254		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Diarrhoea	Arava			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12813650	NON-EXPEDITED			US-SA-2016SA068034		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Disorder	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12813654	NON-EXPEDITED			US-SA-2016SA073884			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Madarosis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12813656	NON-EXPEDITED			US-SA-2016SA080682			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Madarosis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12813666	NON-EXPEDITED			US-SA-2016SA100954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gastrointestinal Disorder	Leflunomide		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12813687	NON-EXPEDITED			US-SA-2016SA137494			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12815300	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016037804		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Hepatic Enzyme Increased; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress	Cimzia			S		Unk, Subcutaneous		Ucb
	Enbrel			S		Unk, Solution Subcutaneous		Not Reported
	Humira			S		Unk, Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported
	Sulfasalazine			S		1 G, Unk		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Azathioprine Sodium			S		25 Mg, Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Imuran			C		25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12815693	EXPEDITED (15-DAY)		OT	HU-MYLANLABS-2016M1041785			Unknown	HUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolon /00049601/			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2016	12815872	EXPEDITED (15-DAY)		OT	PT-GLAXOSMITHKLINE-PT2016GSK145235			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Atrioventricular Block Complete; Dry Skin; Pneumonitis; Sepsis; Systemic Lupus Erythematosus; Thrombocytopenia	Prednisolone			S	Transplacental			Glaxosmithkline
	Hydroxychloroquine			S	Transplacental			Not Reported
	Dexamethasone			S	Transplacental			Glaxosmithkline
	Salbutamol			S	Transplacental			Glaxosmithkline
	Meropenem			S	Intravenous (not otherwise specified)			Glaxosmithkline
	Vancomycin			S	Intravenous (not otherwise specified)			Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12779735	NON-EXPEDITED			US-PFIZER INC-2016446626		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

Leflunomide	S	Unk	Not Reported
Humira	S	Unk	Not Reported
Orencia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12815847	EXPEDITED (15-DAY)		HO	DK-CONCORDIA PHARMACEUTICALS INC.-E2B_00007853		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Anembryonic Gestation; Benign Hydatidiform Mole; Exposure During Pregnancy; Vaginal Haemorrhage	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12815917	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201610-004972			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Retinal Injury; Retinal Scar; Swelling; Vision Blurred	Plaquenil			S				Concordia
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2016	12818729	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1232		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Drug Intolerance; Dysuria; Malaise; Myalgia;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Rheumatoid Arthritis	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12047949	EXPEDITED (15-DAY)		HO	FR-009507513-1602FRA002749			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myalgia; Paresis	Ezetrol			S	Oral	Unknown		Merck
	Plaquenil			S	Oral	Unknown, Duration: 1 Year.		Not Reported
	Bisoprolol			S	Oral	2.5 Mg, Qd		Not Reported
	Seresta			C	Oral	3 Df (1 Df, 10 Mg, Tid)		Not Reported
	Lormetazepam			C	Oral	2 Mg, Qd		Not Reported
	Levothyrox			C	Oral	100 Microgram, Qd		Not Reported
	Dafalgan			C	Oral	4 Df (1 Df, 4 Times Daily)		Not Reported
	Lansoprazole			C	Oral	15 Mg, Qd		Not Reported
	Mirtazapine			C	Oral	15 Mg, Qd		Merck
	Lyrica			C	Oral	75 Mg, 2 Capsules Daily		Not Reported
	Oxycontin			C	Oral	10 Mg, 2 Tablets Daily		Not Reported
	Oxynorm			C	Oral	On Request Until 4 Tablets Daily		Not Reported
	Candesartan			C	Oral	8 Mg, Qd		Not Reported
	Calciparine			C	Subcutaneous	2 Bag Daily		Not Reported
	Cetirizine Hydrochloride			C	Oral	10 Mg, Qd		Not Reported
	Movicol			C	Oral	2 Df, Unk		Not Reported
	Calcidose Vitamine D			C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12108874	EXPEDITED (15-DAY)			TR-SA-2016SA032339			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral	Start Date:7 Months Ago		Not Reported
	Deltacortil			S	Oral	Dose: 2 In Evening 1 In Morning. Strength: 5mg Start Date:7 Month Ago		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12582199	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-01		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Menorrhagia; Rheumatoid Arthritis	Folic Acid			S	Oral			Hikma
	Hydroxychloroquine			S	Oral			Hikma
	Methotrexate			S	Oral			Roxane
	Prednisone			S	Oral			Roxane
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Iron			C	Unknown			Not Reported
	Naprosyn			C	Oral			Not Reported
	Vitamin D2			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12821288	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005011			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12821739	EXPEDITED (15-DAY)		OT	US-ROCHE-1838866		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Ivig			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12822996	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-125739		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Pantoprazole			S	Unknown	Unk		Sun
	Sulfasalazine			S	Oral	500 Mg, Qd		Sun
	Sulfasalazine			S	Oral	1 G, Bid		Sun
	Methotrexate			S	Unknown	20 Mg, 1/Week		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Prinivil			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Voltaren Sr			S	Oral	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Mg, Bid		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2016	12826563	EXPEDITED (15-DAY)		OT	IE-PFIZER INC-2016469011		62 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metastatic Renal Cell Carcinoma	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2016	12831629	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201610-004982		60 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Weight Decreased	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava 20 Milligram Film Coated Tablet			S	Oral			Not Reported
	Melox Plus			S	Oral			Not Reported
	Azulfidine			C				Not Reported
	Rantudil			C				Not Reported
	Prednisone			C				Not Reported
	Pregabalin			C				Not Reported
	Omeprazole			C				Not Reported
	Dotbal			C				Not Reported
	Valsartan			C	Oral			Not Reported
	Valsartan			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	11696522	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015369706		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Pneumocystis Jirovecii	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer

Pneumonia	Methotrexate Sodium	S	Parenteral	Weekly Injections	Unknown
	Sulfasalazine	S	Oral	1000 Mg, 1x/Day	Pfizer
	Plaquenil	S		200 Mg, Daily	Not Reported
	Cortisone	S		Unk, Massive Doses	Not Reported
	Arava	C	Oral	20 Mg, 1x/Day	Not Reported
	Tylenol	C		Unk	Not Reported
	Folic Acid	C	Oral	1 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12790039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016230639		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Anaemia; Arthralgia; Arthropathy; Condition Aggravated; Condition Aggravated; Diarrhoea; Drug Ineffective; Dry Mouth; Fall; Fatigue; Haematuria; Hand Deformity; Hypoaesthesia; Joint Range Of Motion Decreased; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Osteoarthritis; Pain In Extremity; Paraesthesia; Peripheral Swelling; Pleural Effusion; Pneumonia; Rheumatoid Arthritis; Sinusitis; Sleep Disorder; Synovitis; Temperature Intolerance; Tenderness; Urinary Tract Infection; Viith Nerve Injury; Weight Increased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S		2.5 Mg, Qwk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Atenolol			C		25 Mg, Qd		Not Reported
	Irbesartan			C		Unk		Not Reported
	Nitroglycerin			C		0.4 Mg/Spray Solution, Asdirected By Physician		Not Reported
	Loratadine			C		10 Mg, Qd		Not Reported
	Lipitor			C		40 Mg, Qd		Not Reported
	Imovane			C		Unk		Not Reported
	Plavix			C		75 Mg, Qd		Not Reported
	Cipralex			C		Unk		Not Reported
	Vesicare			C		5 Mg, As Necessary		Not Reported
	Myrbetriq			C		Unk, As Needed		Not Reported
	Omnaris			C		50 Mug, Qd		Not Reported

Aspirin /00002701/	C	81 Mg, Qd	Not Reported
Cyanocobalamine	C	Unk, Twice A Month	Not Reported
Irbesartan/Hydrochlorothiazide	C	300-12.5 Mg. Once A Day	Not Reported
Docusate Sodium	C	100 Mg, As Needed Twice A Day	Not Reported
Escitalopram Oxalate	C	10 Mg, Qd	Not Reported
Effexor	C	75 Mg, Qd With Food	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12818219	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037642		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Haemoglobin Decreased; Hepatic Steatosis; Osteoporosis; Pyrexia; Rash; Rheumatoid Arthritis	Cimzia			S		Unk		Ucb
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Actonel			C				Not Reported
	Arthrotec			C				Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12832579	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-004995		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Abnormal; Hypotension	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Venlafaxine			S	Oral			Not Reported
	Flecaine			S	Oral			Not Reported

	Flecaine			S	Oral					Not Reported
	Atacand			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12832625	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005090			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Intolerance; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Venlafaxine			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12834724	NON-EXPEDITED			US-PFIZER INC-2016470133		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Tetracaine			S		Unk		Not Reported
	Cellcept			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Nabumetone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Sulfamethoxazole			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12265993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016207026		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthralgia; Asthenia; Impaired Work Ability; Joint Range Of Motion Decreased; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Musculoskeletal Pain; Nasopharyngitis; Synovitis	Salazopyrin	S	Oral	500 Mg, 4x/Day		Pfizer
	Plaquenil /00072603/	S		400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12499590	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016310332		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Drug Ineffective; Drug Level Changed; Fall; Muscle Spasms; Myocardial Infarction; Neck Pain	Methotrexate Sodium			S		15 Mg, Weekly (2.5mg, Now Taking 6 Tabs Weekly)		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly [For 8-9 Years]		Pfizer
	Methotrexate Sodium			S		8 Df, Unk (8 Tabs)		Pfizer
	Methotrexate Sodium			S		4 Df, Weekly (4 Tabs Weekly)		Pfizer
	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		5 Mg, Daily (1-3 Tabs)		Not Reported
	Prednisone			C		2.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12835255	EXPEDITED (15-DAY)		HO	AU-ROCHE-1839606			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Reaction	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported

With Eosinophilia And Systemic Symptoms; Erythema Multiforme; Linear Iga Disease; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Diazepam	S	Unknown	Not Reported
	Clindamycin	S	Unknown	Not Reported
	Daptomycin	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Lincomycin	S	Unknown	Not Reported
	Meropenem	S	Unknown	Not Reported
	Metronidazole	S	Unknown	Not Reported
	Pentamidine	S	Unknown	Not Reported
	Telaprevir	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Amphetamine	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Diltiazem	S	Unknown	Not Reported
	Ferrous Sulphate	S	Unknown	Not Reported
	Frusemide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Loratadine	S	Unknown	Not Reported
	Nomegestrol	S	Unknown	Not Reported
	Penicillamine	S	Unknown	Not Reported
	Pholcodine	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Quetiapine	S	Unknown	Not Reported
	Sodium Valproate	S	Unknown	Not Reported
	Venlafaxine	S	Unknown	Not Reported
	Phenytoin	S	Unknown	Not Reported
	Carbamazepine	S	Unknown	Not Reported
	Lamotrigine	S	Unknown	Not Reported

	Sulphasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12835943	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016166144		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Therapeutic Product Ineffective	Sulfasalazine			S		500 Mg, Daily		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Plaquenil			S		200 Mg, Daily		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Prednisone			S				Not Reported
	Synthroid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12784817	EXPEDITED (15-DAY)		HO	IN-IPCA LABORATORIES LIMITED-IPC201609-000817		46 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia	Hydroxychloroquine Sulfate			S	Oral			Ipca
	Metformin Hydrochloride			S	Oral			Ipca
	Glyree			S	Oral			Not Reported
	Glyree			S	Oral			Not Reported
	Glyree			S	Oral			Not Reported
	Sompraz-D			C	Oral			Not Reported
	Sompraz-D			C				Not Reported
	Dexorange			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12790390	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004877		2 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteomyelitis Bacterial; Q Fever	Hydroxychloroquine			S	Unknown			Concordia
	Doxycycline			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Prednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Hydrocortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12817683	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037808		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Drug Ineffective; Feeling Jittery; Macrocytosis; Neck Pain; Night Sweats; Pustular Psoriasis; Synovitis; Tachycardia	Cimzia			S				Ucb
	Plaquenil			S		Unk		Not Reported
	Asa			S	Oral	81 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Calcium			C	Oral	500 Mg, Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Elavil			C		10 Mg, Unk		Not Reported
	Ergocalciferol			C	Oral	Unk		Not Reported
	Iron W/Minerals Nos/Vitamins Nos			C	Oral	Unk, Once Daily (Qd)		Not Reported
	Leflunomide			C		20 Mg, Once Daily (Qd)		Not Reported

Leflunomide	C		Unk		Not Reported
Leucovorin Calcium	C	Oral	5 Mg, Unk		Not Reported
Lorazepam	C	Oral	0.5 Mg, Unk		Not Reported
Methotrexate	C		25 Mg, Once Daily (Qd)		Not Reported
Pantoprazole	C	Oral	Unk		Not Reported
Prednisone	C		10 Mg, Once Daily (Qd)		Not Reported
Prednisone	C	Oral	5 Mg, Unk		Not Reported
Prednisone	C		10 Mg, Once Daily (Qd)		Not Reported
Sulfasalazine	C	Oral	500 Mg, Unk		Not Reported
Valtrex	C	Oral	500 Mg, Once Daily (Qd)		Not Reported
Vitamins Nos	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2016	12818364	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005013		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Disease Progression; Joint Swelling; Vomiting	Plaquenil			S	Unknown			Concordia
	Arava			S				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12331216	EXPEDITED (15-DAY)		OT	CA-SA-2016SA086798		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Burning Sensation; Condition Aggravated; Diarrhoea; Fatigue; Limb Mass; Malaise; Peripheral Embolism; Peripheral Swelling; Peripheral Swelling; Sciatica; Urinary	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

Tract Infection	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12624948	NON-EXPEDITED			US-PFIZER INC-2016372747			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12820910	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1888		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Pneumocystis Jirovecii Pneumonia	Methotrexate (Trade Name Unknown)			S	Oral	2.5 Mg, 6 Tablets		Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cortisone			S	Unknown	Massive Doses		Not Reported
	Arava			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2016	12842359	EXPEDITED (15-DAY)		HO, OT	IE-ORION CORPORATION ORION PHARMA-TREX2016-1960		62 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Flank Pain; Malaise; Metastases	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

To Liver; Metastatic Renal Cell Carcinoma; Night Sweats; Pulmonary Mass; Pyrexia; Retroperitoneal Neoplasm Metastatic; Weight Decreased	Plaquenil	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12846847	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007863		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Productive Cough; Temporomandibular Joint Syndrome	Plaquenil			S	Oral			Concordia
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xylocaine			C				Not Reported
	Methotrexate			C				Not Reported
	Tylenol Arthritis			C				Not Reported
	Folic Acid			C				Not Reported
	Triamcinolone Acetate			C				Not Reported
	Voltaren			C				Not Reported
	Rabeprazole			C				Not Reported
	Candesartan Cilexetil			C				Not Reported
	Plavix			C				Not Reported
	Nitro			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Salbutamol Sulfate			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Vitamin B12			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12846849	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1982		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Methotrexate (Trade Name			S	Unknown			Not Reported

Ineffective; Pain In Extremity	Unknown)					
	Methotrexate (Trade Name Unknown)		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Synthroid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12847053	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00007865		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myalgia; Paresis	Plaquenil Tablet			S	Oral			Concordia
	Ezetrol			S	Oral			Not Reported
	Seresta			C				Not Reported
	Bisoprolol			C				Not Reported
	Levothyrox			C				Not Reported
	Daflagan			C				Not Reported
	Mirtazapine			C				Not Reported
	Lansoprazole			C				Not Reported
	Lormetazepam			C				Not Reported
	Lyrica			C				Not Reported
	Oxycontin			C				Not Reported
	Oxynorm			C				Not Reported
	Candesartan Cilexetil			C				Not Reported
	Calciparine			C				Not Reported
	Cetrizine			C				Not Reported
	Calcidose Vitamine D			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12849163	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2016DEP012511		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain	Diclofenac Potassium			S		Unk		Depomed
	Amitriptyline			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Naprosyn /00256201/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2016	12851798	DIRECT		DS, HO, LT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Dyspnoea; Fatigue; Gait Disturbance; Rash; Rash; Rash; Rash; Somnolence	Hydroxychloroquine, Plaquenil Mylan			S	Oral	Quantity:2 Tablet(S);		Mylan
	Alprazolam			C				Not Reported
	Amitriptyline			C				Not Reported
	Desonide			C				Not Reported
	Dulera Inhalant			C				Not Reported
	Fluticasone Prop Nasal Spray			C				Not Reported
	Furosemide			C				Not Reported
	Levothyroxine			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol			C				Not Reported
	Pravastatin			C				Not Reported
	Sertraline			C				Not Reported
	Allegra			C				Not Reported
	Centrum Silver Women 50+			C				Not Reported
	Calcium Plus Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	8330029	EXPEDITED (15-DAY)		HO	CA-UCBSA-048187		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Hepatic Enzyme Increased; Peripheral Swelling; Pneumonia; Viral Infection	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Ucb
	Certolizumab Pegol Ra			S		400 Mg, Ev 4 Weeks		Ucb
	Plaquenil			S	Oral	2008 Mg, 2x/Day (Bid)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Ferrous Gluconate			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Methotrexate			C	Oral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate			C		15 Mg, Weekly (Qw)		Not Reported
	Naprosen			C	Oral	500 Mg, Twice Daily As Needed		Not Reported
	Prednisone			C		15 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12705526	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0972		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Slow Increase In Dose		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Plaquenil	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Prednisone	S	Oral	Tapering Down		Not Reported
	Prednisone	S	Unknown	Dose Increased		Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12737876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016426082		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Pain In Extremity	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Imuran /00001501/			S		50 Mg, 3x/Day		Not Reported
	Leflunomide			S		20 Mg, Daily		Not Reported
	Plaquenil /00072603/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12852123	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2016DEP012508		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Diclofenac Potassium			S		Unk		Depomed
	Apo-Amitriptyline			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

	Naprosyn	S	Unk		Not Reported
	Prednisone	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12852770	EXPEDITED (15-DAY)		LT, OT	CA-ROCHE-1695185		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Infection; Rheumatoid Arthritis; Sepsis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral	4 Pills		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12854274	EXPEDITED (15-DAY)		OT	SG-MYLANLABS-2016M1044412			Unknown	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Separation Of Placenta	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Immunoglobulin (Ivig)			S	Intravenous (not otherwise specified)	Monthly		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12854340	EXPEDITED (15-DAY)		DE, OT	SG-MYLANLABS-2016M1044430			Unknown	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Hydroxychloroquine			S	Transplacental			Not Reported

Pregnancy; Stillbirth	Prednisolone		S	Transplacental	Not Reported
	Acetylsalicylic Acid		S		Not Reported
	Immunoglobulin (Ivig)		S		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12855280	EXPEDITED (15-DAY)		HO	PHHY2016CA141518			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Aspirin /00346701/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2016	12856437	DIRECT	Y	OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Diarrhoea	Hydroxychloroquine 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	11802478	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415846			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Diarrhoea; Hepatic	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown

Function Abnormal; Hepatotoxicity; Renal Impairment; Therapeutic Product Effect Delayed; Tooth Loss	Sulfasalazine	S	Unk	Pfizer
	Naproxen	S	Unk, As Needed	Not Reported
	Arava	S	20 Mg, Daily	Not Reported
	Plaquenil	S	200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12583074	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015378069		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Chest Discomfort; Condition Aggravated; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Gastrooesophageal Reflux Disease; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Oral Pain; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Slow Increase In Dose		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		400 Mg, Daily		Not Reported
	Arava			S		20 Mg, Daily		Not Reported
	Arava			S		20 Mg, Alternate Day		Not Reported
	Humira			S		40 Mg, Every Other Week		Not Reported
	Prednisone			S	Oral	Tapering Down		Not Reported
	Prednisone			S		Md Increased Her Prednisone		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12842034	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005092		58 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastric Ulcer; Therapeutic Response Decreased	Plaquenil		S	Unknown		Concordia
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12857000	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2016M1043615			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Blood Lactic Acid Increased; Blood Potassium Decreased; Bradycardia; Cinchonism; Confusional State; Cough; Decreased Appetite; Diarrhoea; Disorientation; Long Qt Syndrome; Speech Disorder; Torsade De Pointes; Ventricular Tachycardia; Vomiting	Quinine			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12859104	EXPEDITED (15-DAY)		HO	LT-IPCA LABORATORIES LIMITED-IPC201610-000850		52 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine Sulfate			S				Ipca
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12859133	EXPEDITED (15-DAY)		HO	US-TEVA-702869USA		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Quinine Sulfate			S	Unknown			Teva
	Amiodarone			S	Unknown			Teva

	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2016	12859168	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA186940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	11177546	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015189191		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Mycobacterium Tuberculosis Complex Test Positive; Nausea; Treatment Failure; Vomiting	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Sulfasalazine			S		1 G, Daily		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Arava			S		Unk		Not Reported
	Naprosyn			C		500 Mg, 1x/Day		Not Reported
	Metformin			C		500 Mg, 1x/Day		Not Reported
	Ramipril			C		5 Mg, 1x/Day		Not Reported
	Clonazepam			C		2 Mg, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	11976322	EXPEDITED (15-DAY)		OT	CA-SA-2015SA188793		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Arthralgia; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Headache; Hypertension; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Malaise; Myalgia; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Viral Infection; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Orencia	C				Not Reported
	Xeljanz	C	Oral			Not Reported
	Methotrexate	C		Up To 20 Mg Weekly		Not Reported
	Enbrel	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12861678	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007871		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Burning Sensation; Condition Aggravated; Diarrhoea; Fatigue; Limb Mass; Malaise; Peripheral Embolism; Peripheral Swelling; Peripheral Swelling; Sciatica; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12861695	EXPEDITED (15-DAY)		HO, OT	CA-PAR PHARMACEUTICAL COMPANIES-2016SCPR015996		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Infusion	Adrenalin			S	Unknown	Unk Unk, Unknown		Par
	Hydroxychloroquine			S	Unknown	Unk Unk, Unknown		Not Reported

Related Reaction; Off Label Use; Pharyngeal Oedema; Poor Venous Access; Vasculitis	Prednisone	S	Unknown	Unk Unk, Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	500 Mg, Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	500 Mg, Unknown		Not Reported
	Fentanyl	C	Unknown	Unk Unk, Unknown		Not Reported
	Ivig	C	Unknown	Unk Unk, Unknown		Not Reported
	Losartan	C	Unknown	Unk Unk, Unknown		Not Reported
	Mirtazapine	C	Unknown	Unk Unk, Unknown		Not Reported
	Progesterone	C	Unknown	Unk Unk, Unknown		Not Reported
	Rabeprazole	C	Unknown	Unk Unk, Unknown		Not Reported
	Sertraline	C	Unknown	150 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12861697	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005249		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12861716	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005250			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Cough; Dry Skin; Psoriasis	Hydroxychloroquine			S				Concordia
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2016	12864073	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005266		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Headache; Pyrexia	Plaquenil			S	Oral	Alternate Dose Of 1 Tablet Daily And 2 Tablets Daily		Concordia
	Plaquenil			S				Concordia
	Predonine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12864267	NON-EXPEDITED			US-TEVA-609393USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12864998	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005270		64 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cartilage Injury	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Gelicart			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12865012	EXPEDITED (15-DAY)		OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005248		62 YR	Male	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Metastatic Renal Cell Carcinoma	Plaquenil	S	Unknown		Concordia
	Methotrexate	S	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12865023	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00007869		47 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12865980	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK153023		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S				Glaxosmithkline
	Diclofenac Sodium			S				Glaxosmithkline
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Arthrotec			S				Glaxosmithkline
	Celebrex			S				Not Reported
	Apo-Amitriptyline			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S				Not Reported
	Naprosyn			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	11143070	EXPEDITED (15-DAY)		HO	FR-ROCHE-1161190		56 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Limb; Cough; Device Related Infection; Diverticulum Intestinal; Drug Hypersensitivity; Drug Reaction With	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Eosinophilia And Systemic Symptoms; Fatigue; Headache; Pollakiuria; Varicella	Plaquenil		S	Unknown		Not Reported
	Cortancyl		C			Not Reported
	Roactemra		C			Not Reported
	Infliximab		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12868676	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2016-04745		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Toxicity To Various Agents	Quinine			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12869057	NON-EXPEDITED			US-PFIZER INC-2016489428		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Doxycycline Hyclate			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Azulfidine			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12869186	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported

	Actemra			S	Unknown					Not Reported
	Gold Injections			S	Unknown					Not Reported
	Methotrexate			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12871018	EXPEDITED (15-DAY)		OT	CA-SA-2015SA199346			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Diarrhoea; Hepatotoxicity	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12872040	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00007868		10 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Maculo-Papular	Plaquenil			S	Oral			Concordia
	Protopic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12872047	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005215		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Psoriasis; Pyrexia	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12838494	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005091		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Leflunomide Film Coated Tablet			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12875546	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-012510		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrasystoles; Long Qt Syndrome; Sinus Bradycardia; Torsade De Pointes	Amiodarone			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Not Reported
	Quinine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2016	12876346	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007877		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Pneumonia	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			C				Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	11471843	EXPEDITED (15-DAY)		OT	CA-SA-2015SA132021		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Joint Swelling; Knee Arthroplasty; Mycobacterium Tuberculosis Complex Test Positive; Nausea; Pain; Treatment Failure; Vomiting	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Naprosyn			C				Not Reported
	Metformin			C				Not Reported
	Ramipril			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12837295	NON-EXPEDITED			US-AMGEN-USASL2016137155		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Incorrect Dose Administered; Injection Site Extravasation; Nausea; Unevaluable Event	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12852849	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2016130496		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Fibromyalgia; Pruritus; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Xeljanz			S	Unknown	11 Mg, Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879276	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005357		84 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swollen Tongue; Urticarial Vasculitis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Acetylsalicylzuur			C				Not Reported
	Lanoxin			C				Not Reported
	Prednisolon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12879708	EXPEDITED (15-DAY)		HO	GB-ORION CORPORATION ORION PHARMA-TREX2016-2059		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Bleeding; Haematochezia; Platelet Count Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Eliquis			S	Oral			Not Reported
	Etoricoxib			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12883684	EXPEDITED (15-DAY)		DE, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005349		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Headache; Muscle Fatigue; Pruritus; Rash; Red Blood Cell Count Decreased; Surgery; Tinnitus; Visual	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Irbesartan			C				Not Reported
	Previscan (Fluindione)			C				Not Reported

Impairment; White Blood Cell Count Decreased	Lasilix Retard			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	8055712	NON-EXPEDITED		OT	CA-PFIZER INC-2011150031		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Gait Disturbance; Infection; Muscular Weakness; Pneumonia	Enbrel			S		In The Evening On Wednesday		Pfizer
	Methotrexate Sodium			S		In The Evening On Wednesday		Unknown
	Prednisone			S		5 Mg		Pfizer
	Celebrex			S		Unk		Pfizer
	Naproxen Sodium			S		Unk		Pfizer
	Arava			S	Parenteral	Unk		Not Reported
	Remicade			S	Parenteral	Infusions		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S	Parenteral	Unk		Not Reported
	Gold			S		Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12869152	NON-EXPEDITED			US-PFIZER INC-2016492108		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Bleph 10			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12884443	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007878		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Headache; Hypertension; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Malaise; Myalgia; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Viral Infection; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Orencia			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12884446	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005367		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myalgia; Rash Papular	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Atarax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12884465	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005370			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Diarrhoea; Hepatotoxicity	Plaquenil			S	Unknown			Concordia

	Arava				S	Unknown				Not Reported
	Sulfasalazine				S	Unknown				Not Reported
	Methotrexate				S	Subcutaneous				Not Reported
	Methotrexate				S	Oral				Not Reported
	Naproxen				C					Not Reported
	Xeljanz				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	12885164	EXPEDITED (15-DAY)		DE	CA-SA-2016SA135604			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Ineffective; Drug Intolerance	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Amlodipine			C				Not Reported
	Cymbalta			C				Not Reported
	Irbesartan			C				Not Reported
	Baclofen			C				Not Reported
	Dexilant			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12779647	NON-EXPEDITED			US-PFIZER INC-2016443512			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Desvenlafaxine			S		Unk		Pfizer
	Fentanyl Citrate			S		Unk		Unknown
	Ibuprofen			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Pregabalin			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Anakinra			S		Unk		Not Reported

	Arava	S	Unk	Not Reported
	Azathioprine	S	Unk	Not Reported
	Duloxetine	S	Unk	Not Reported
	Etodolac	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Levaquin	S	Unk	Not Reported
	Milnacipran	S	Unk	Not Reported
	Pramipexole	S	Unk	Not Reported
	Silodosin	S	Unk	Not Reported
	Tapentadol	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12797100	NON-EXPEDITED			US-PFIZER INC-2016450193		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Urine Calcium	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Unknown
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported
	Cymbalta			C		60 Mg, 2x/Day		Not Reported
	Fentanyl			C				Not Reported
	Oxycodone			C		30 Mg, Unk, (One Or Two Every 4-6 Hours) (Basically She Took Two Every 4 Hours)		Not Reported
	Promethazine			C		25 Mg, As Needed, (Takes One Every 6 Hours As Needed. She Did Not Take It Every Day)		Not Reported
	Meloxicam			C		15 Mg, 1x/Day		Not Reported
	Cyclobenzaprine			C		10 Mg, As Needed, (Once Three Times A Day)		Not Reported

	Cyclobenzaprine	C				Not Reported
	Zolpidem	C				Not Reported
	Ondansetron	C		8 Mg, As Needed, (One Every 4-6 Hours)		Not Reported
	Metoprolol Tartrate	C		25 Mg, 2x/Day		Not Reported
	Vitamin D3	C		1000 Mg, Unk		Not Reported
	Calcium	C		1500 Mg, 3x/Day		Not Reported
	Vitamin B12	C	Sublingual			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12840202	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016463815			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12889932	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-202929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S	Unknown	Unk		Bayer
	Diclofenac			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12889994	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-202952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S	Unknown	Unk		Bayer
	Diclofenac			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2016	12891007	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2016-026356			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nodular Vasculitis; Product Use Issue; Rebound Effect	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Ethambutol Hydrochloride			C	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported
	Pyrazinamide			C	Unknown			Not Reported
	Rifampicin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	11756020	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2015391475		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Urinary Tract Infection	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12432840	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-043511			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Off Label Use; Rheumatoid Arthritis	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Xeljanz			S	Oral	11 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Unknown	100 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	700 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Coumadine			C	Unknown	3 Mg, Qd		Not Reported
	Sotalol			C	Unknown	80 Mg, Tid		Not Reported
	Tylenol /00020001/			C	Unknown	Unk, Prn		Not Reported
	Folic Acid			C	Unknown	1 Mg, Qwk		Not Reported
	Prednisone			C	Unknown	10 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12891534	EXPEDITED (15-DAY)		OT	CA-AMGEN-USACT2011035069		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Gait Disturbance; Infection; Muscular Weakness; Pneumonia	Enbrel			S	Unknown	In The Evening On Wednesday		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Remicade			S	Parenteral	Infusions		Not Reported
	Humira			S	Parenteral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	In The Evening On Wednesday		Not Reported
	Gold			S	Unknown	Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12892037	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007893		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Joint Swelling; Knee Arthroplasty; Mycobacterium Tuberculosis Complex Test Positive; Nausea; Pain; Treatment Failure; Vomiting	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Naprosyn			C				Not Reported
	Metformin			C				Not Reported
	Ramipril			C				Not Reported
	Clonazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12892355	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00007885		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Decreased; Blood Immunoglobulin A Increased; Dry Eye; Glare; Off Label Use; Visual Field Defect	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12892496	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005430		304 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hydroxychloroquine			S	Oral			Concordia
	L-Thyroxine			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12893193	EXPEDITED (15-DAY)		OT	PHHY2016IT144793		32 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Acetylsalicylic Acid			S	Unknown	100 Mg, Qd		Not Reported
	Betamethasone			S	Oral	4 Mg, Qd		Not Reported
	Immunoglobulin G Human			S	Intravenous (not otherwise specified)	1 G/Kg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894035	NON-EXPEDITED			US-PFIZER INC-2016502311		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Talwin			S				Pfizer
	Effexor Xr			S				Pfizer
	Lipitor			S				Pfizer
	Paxil			S				Not Reported
	Lescol			S				Not Reported
	Zocor			S				Not Reported
	Zetia			S				Not Reported
	Humira			S				Not Reported
	Plaquenil			S				Not Reported
	Victoza			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894330	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-202935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S	Unknown	Unk		Bayer
	Aspirin			S	Unknown	Unk		Bayer
	Aspirin			S	Unknown	Unk		Bayer
	Aspirin			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Humira	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894664	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016070185		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Inability; Swelling	Methotrexate Sodium	S	Unknown	Injections Weekly		Unknown
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Over 15 Mg		Not Reported
	Prednisone	S	Unknown	1 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2016	12894714	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016505576		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12895655	EXPEDITED (15-DAY)		OT	PHHY2016IT148340			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Acetylsalicylic Acid			S	Transplacental	Maternal Dose Is 100 Mg Qd		Not Reported
	Immunoglobulin G Human			S	Transplacental	Maternal Dose Is 1g/Kg		Not Reported
	Betamethasone			S	Transplacental	Maternal Dose Is 4 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12896275	NON-EXPEDITED		HO	US-AMGEN-USASP2016150094		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Viral; Myalgia; Myositis	Enbrel			S	Unknown	50 Mg, Once A Week		Amgen
	Enbrel			S				Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2016	12896511	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-13226			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Condition Aggravated; Decreased Appetite; Diarrhoea; Dysarthria; Electrocardiogram Qt Prolonged; Malaise; Mental Status Changes; Nausea; Sepsis; Torsade De Pointes; Toxicity To Various Agents; Ventricular Hypertrophy; Vomiting	Amiodarone			S				Aurobindo
	Quinine			S				Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12832630	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005089		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Dilatation Atrial	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	Every Other Week		Not Reported
	Certolizumab Pegol			S				Not Reported
	Bromazepam			C				Not Reported

	Bromazepam				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12855694	EXPEDITED (15-DAY)		HO, OT	MY-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005212		50 YR	Male	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Therapeutic Response Unexpected; Tinnitus	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12898916	EXPEDITED (15-DAY)		HO	GB-ORION CORPORATION ORION PHARMA-TREX2016-2124		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Pancytopenia	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Eliquis			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12899053	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005470			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Sensation In Eye; Anaphylactic Reaction; Drug Eruption; Stevens-Johnson Syndrome	Plaquenil			S	Oral			Concordia
	Benambax			S	Unknown			Not Reported
	Baktar			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2016	12900243	EXPEDITED (15-DAY)		OT	CA-ACTELION-A-US2016-144788		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Anxiety; Cardiac Flutter; Dyspnoea; Hepatic Enzyme Increased	Tracleer			S	Oral	1 Df, Bid		Actelion
	Hydroxychloroquine			S	Unknown			Not Reported
	Vitamin D2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12643170	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-121750		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Oxycodone/Acetaminophen			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12731979	NON-EXPEDITED			US-PFIZER INC-2016427266		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Xeljanz Xr			S		11 Mg		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12769938	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS			Female	USA

						INC.-GSH201609-004761			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Plaquenil			S				Concordia
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C		15mg Weekly		Not Reported
	Methotrexate			C				Not Reported
	Prednisone 5 Mg			C		1 To 3 Tablets Daily		Not Reported
	Prednisone 5 Mg			C				Not Reported
	Xeljanz			C				Not Reported
	Lipitor			C				Not Reported
	Folic Acid			C				Not Reported
	Cozaar			C				Not Reported
	Symbicort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12831640	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005065			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Haemophagocytic Lymphohistiocytosis; Myalgia; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown	1mg/Kg/Day With Gradual Decrease		Not Reported
	Prednisone			S	Unknown			Not Reported
	Aspirin			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12891215	EXPEDITED (15-DAY)		OT	PHHY2016CA148264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin	S	Unknown		Novartis
	Methotrexate Sodium	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Cellcept	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12901770	NON-EXPEDITED			US-AMGEN-USASP2016149827		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2016	12903148	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2016502314		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Pancytopenia	Methotrexate Sodium			S	Oral	17.5 Mg, Unk		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Not Reported
	Eliquis			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2016	12905309	EXPEDITED (15-DAY)		HO	CA-ROCHE-1849453		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial	Mycophenolate Mofetil			S	Unknown			Not Reported

Lung Disease; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Abatacept		S	Unknown	Not Reported
	Anakinra		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Celebrex		C		Not Reported
	Humira		C	Subcutaneous	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2016	12905526	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2163		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate			S	Unknown	Intra-Arterial		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12909635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1564010		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12909908	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005541		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Plaquenil Tablet			S	Oral			Concordia
	Salazopyrine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12913794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Plaquenil /00072602/			S	Unknown	Unk				Not Reported
	Sulfasalazine			S	Unknown	1 G, Cyclic				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2016	12913948	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091495		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Surgery; Joint Swelling; Knee Arthroplasty; Pain; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Clindamycin			C	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2016	12859952	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005247		33 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Kidney Abnormal; Condition Aggravated; Drug Ineffective; Lupus Nephritis; Proteinuria; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Methylprednisolone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12838078	NON-EXPEDITED		OT	ES-AMGEN-USASP2016138041		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Mycobacterium Avium Complex Infection; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12856019	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005219		28 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; C-Reactive Protein Increased; Diabetes Mellitus; Drug Ineffective; Herpes Zoster Disseminated; Hypoalbuminaemia; Leukocytosis; Lumbar Vertebral Fracture; Myopathy; Oropharyngeal Pain; Pyrexia; Rash; Rebound Effect; Red Blood Cell Sedimentation Rate Increased; Serum Ferritin Increased; Splenomegaly; Still'S Disease; Therapeutic Response Decreased; Thrombocytosis; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915814	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005548		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypersensitivity	Hydroxychloroquine			S				Concordia
	Elavil			S				Not Reported
	Ms Contin			S				Not Reported
	Codeine			S				Not Reported
	Imitrex			S				Not Reported
	Talwin			S				Not Reported
	Toradol			S				Not Reported
	Ultram			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12915879	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2016154267		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral	Enbrel			S	Subcutaneous	50 Mg, Once A Week		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Diclofenac			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Elmiron			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Flector [Diclofenac Sodium]			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Nucynta			C		Unk		Not Reported
	Prempro			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12916321	EXPEDITED (15-DAY)		DS	CA-ROCHE-1850352		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12916454	EXPEDITED (15-DAY)		HO	GB-ACCORD-045312		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Pancytopenia	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Eliquis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12916513	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Plaquenil			S	Unknown			Concordia
	Etanercept			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12917098	EXPEDITED (15-DAY)		HO	DE-ROCHE-1804144			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simvastatin			C				Not Reported
	Prednisolone			C				Not Reported
	Lodotra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12920125	EXPEDITED (15-DAY)		DE	NL-PFIZER INC-2016512236		74 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Doxycycline Hyclate			S		200 Mg, Daily		Pfizer
	Hydroxychloroquine			S		600 Mg, Daily		Not Reported
	Prednisone			C		5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12920937	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-16K-163-1767997-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
End Stage Renal Disease; Ophthalmic Herpes Zoster; Red Blood Cell Count Decreased; Renal Disorder; White Blood Cell Count Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12921218	EXPEDITED (15-DAY)		HO	PHHY2016GB148234		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Pancytopenia	Methotrexate			S	Oral	17.5 Mg, Unk		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Not Reported
	Eliquis			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	9748218	NON-EXPEDITED			US-PFIZER INC-2013354281		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Isoptin Sr			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Monopril			S		Unk		Not Reported
	Vasotec			S		Unk		Not Reported
	Toprol Xl			S		Unk		Not Reported
	Avalide			S		Unk		Not Reported

	Codeine	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Cimzia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	11911090	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015412210		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Discharge; Fatigue; Headache; Nasopharyngitis; Nausea; Oropharyngeal Pain; Rhinorrhoea; Sinus Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	6 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	2 G, Unk		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12197652	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1727368		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Inflammation; Nausea; Osteoarthritis; Osteopenia;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported

Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate Sodium	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Omega 3 Fatty Acids	C	Unknown			Not Reported
	Diphenoxylate	C	Unknown	2.5/0.025 Mg Daily		Not Reported
	Actonel	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Aclasta	C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	5mg/B.I.D		Not Reported
	Ferrous Gluconate	C	Unknown			Not Reported
	Nasonex	C	Unknown	2 Sprays Intranasal		Not Reported
	Lomotil (Canada)	C	Unknown	3-4 Times/Day.		Not Reported
	Lomotil (Canada)	C	Unknown	1 Dosage Form		Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Loperamide Hydrochloride	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Tylenol	C	Oral			Not Reported
	Tylenol	C	Oral			Not Reported
	Trazodone Hydrochloride	C	Oral			Not Reported
	Perphenazine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12842999	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1984		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Pantoloc			S	Unknown			Not Reported

Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Sulfasalazine			S	Oral				Not Reported
	Folic Acid			S	Unknown				Not Reported
	Co Atenolol			S	Unknown				Not Reported
	Naprosyn			S	Oral				Not Reported
	Palafer Cf			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12852663	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2000		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematocrit Decreased; Haemoglobin Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Atenolol			S	Unknown	Strength: 25 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12918895	EXPEDITED (15-DAY)		DE	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005540		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxychloroquine			S	Oral			Concordia
	Hydroxyzine			S	Oral			Not Reported

	Acetaminophen Butalbital Caffeine			S	Oral					Not Reported
	Meloxicam			S	Oral					Not Reported
	Cetirizine			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12918898	EXPEDITED (15-DAY)		DE	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005546		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Hydroxychloroquine			S	Oral			Concordia
	Amitriptyline			S	Oral			Not Reported
	Cyclobenzaprine			S	Oral			Not Reported
	Acetaminophen Diphenhydramine			S	Oral			Not Reported
	Tramadol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12918998	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Intolerance; Fatigue; Impaired Work Ability; Pain; Rheumatoid Arthritis; Sleep Disorder	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12921832	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Nausea;	Arava			S	Unknown			Not Reported

Vomiting	Plaquenil	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Clonazepam	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12921883	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201418		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Gastric Disorder; Nausea; Vomiting	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Multivitamine Axium Multi Extra			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Omega-3			C	Unknown			Not Reported
	Osto-D2			C	Unknown			Not Reported
	Oxybutynin			C	Unknown			Not Reported
	Quinapril			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Slow-K			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Acebutolol			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Calcium Citrate			C	Unknown			Not Reported

	Cipralex			C	Unknown				Not Reported
	Fenofibrate			C	Unknown				Not Reported
	Hydrochlorothiazide			C	Unknown				Not Reported
	Hydromorphone			C	Unknown				Not Reported
	Lorazepam			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12923851	EXPEDITED (15-DAY)		HO	PHHY2016US151926		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Adalimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12924694	EXPEDITED (15-DAY)		OT	CA-SA-2015SA048709		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Foot Deformity; Gait Disturbance; Gastric Disorder	Leflunomide			S	Unknown	Dose: 10		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12926797	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2016M1048106			Unknown	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine			S	Unknown	200 Mg/Day		Not Reported

Prednisolone	C	Oral	4 Mg/Day			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2016	12926889	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005629			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Ear Lobe Infection; Erythema; Localised Oedema; Purulent Discharge; Rash Papular; Rash Pruritic; Skin Exfoliation; Skin Ulcer; Stomatitis	Plaquenil			S	Unknown			Concordia
	Humira 40mg/ 0.8m			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	11540085	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015317232		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Celebrex			S		Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072603/			S		400 Mg, 1x/Day		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Naprosyn /00256201/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	11926787	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2016016529		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Rigidity;	Salazopyrine			S	Oral	1 G, 3x/Day (1 G,Morning,		Pfizer

Adrenal Insufficiency; Erysipelas; General Physical Health Deterioration; Livedo Reticularis; Oral Fungal Infection; Pancytopenia; Pneumonia; Pulmonary Sepsis; Purpura; Shock; Vomiting				Midday, Evening)	
	Imeth	S	Oral	10 Mg, Weekly	Pfizer
	Plaquenil /00072602/	S	Oral	200 Mg, 2x/Day (200 Mg,Morning, Evening)	Not Reported
	Risedronate Eg	S	Oral	35 Mg, Weekly	Not Reported
	Caltrate Vitamine D3	S	Oral	1 Df (600 Mg/400 Iu) Morning, Evening	Not Reported
	Doliprane	S	Oral	1 G, 3x/Day (1 G,Morning. Midday, Evening)	Not Reported
	Oxycontin Lp	S	Oral	10 Mg, 2x/Day (1 Dosage Form, Morning, Evening)	Not Reported
	Oxynorm	S	Unknown	5 Mg, 3x/Day	Not Reported
	Lorazepam Mylan	S	Oral	2.5 Mg, Daily	Not Reported
	Amlodipine Eg	S	Oral	10 Mg, Daily	Not Reported
	Lansoprazole Eg	S	Oral	15 Mg, Daily	Not Reported
	Amoxicilline/Acide Clavulanique Eg	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12325471	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748857		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra			S	Intravenous (not otherwise specified)	Most Recent Infusion On 08/Apr/2016		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12860433	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2016AP012999		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Condition Aggravated; Long Qt Syndrome; Torsade De Pointes; Toxicity To Various Agents; Ventricular Tachycardia	Amiodarone Hcl Injection			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Quinine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12892361	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005395		78 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Pancytopenia	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Eliquis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12923800	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005660		60 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonitis; Small Cell Lung Cancer	Hydroxychloroquine			S	Oral			Concordia
	Lansox			C				Not Reported
	Medrol			C				Not Reported
	Dibase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12924232	EXPEDITED (15-DAY)		OT	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-		51 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthosis; Biopsy Skin Abnormal; Eczema; Erythema; Erythema Multiforme; Hyperkeratosis; Papule; Rash Maculo-Papular; Rash Pruritic; Rash Pustular; Skin Lesion; Skin Oedema; Skin Plaque	Hydroxychloroquine			S				Concordia
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12924588	EXPEDITED (15-DAY)		DE, HO	PHHY2016US151924		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown	Every 6 Weeks 2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12925873	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201413		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Sleep Disorder	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Ergocalciferol			C	Unknown					Not Reported
	Naprosyn			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12925931	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201400		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Intolerance; Hypersensitivity; Infection; International Normalised Ratio Fluctuation	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Flagyl			S	Unknown			Not Reported
	Humira			S	Unknown	Subcutaneous Solution		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12926352	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201369		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome;	Leflunomide			S	Unknown	Therapy Duration:3.0		Not Reported

Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder					Month(S)	
	Methotrexate	S	Unknown		Therapy Duration:10.0 Year(S)	Not Reported
	Naproxen	S	Unknown			Not Reported
	Plaquenil	S	Unknown		Therapy Duration:17.0 Year(S)	Not Reported
	Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2016	12927809	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1851583		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported
	Methylprednisolone Sodium			C	Intravenous (not			Not Reported

	Succinate					otherwise specified)				

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12854030	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2016474377		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Drug Intolerance; Pain In Extremity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12898979	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Nausea; Oral Pain; Rheumatoid Arthritis; Stomatitis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12927918	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005634			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Dysstasia; Gait Disturbance; Pain In	Plaquenil			S				Concordia
	Leflunomide			S				Not Reported
	Leflunomide			S				Not Reported

Extremity; Pain In Extremity; Peripheral Swelling	Prednisone			S						Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12929594	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016516713		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12930186	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201441		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Drug Ineffective; Dysgeusia; Dyspepsia; Epistaxis; Headache; Sinus Congestion; Sinusitis; Urinary Tract Infection	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12930415	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201220		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling;	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Retinal Toxicity; Swelling	Humira		S	Unknown	Solution		Not Reported
	Methotrexate Sodium		S	Unknown			Not Reported
	Tramadol Hydrochloride		C	Oral			Not Reported
	Xeljanz		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12930457	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201222		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Swelling	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12930867	NON-EXPEDITED			US-ANTARES PHARMA, INC.-2016-LIT-ME-0312		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Nodule	Methotrexate			S				Not Reported
	Hydroxychloroquinum			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931117	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201535		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Drug	Leflunomide			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Dyspepsia; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Abatacept	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Form: Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Salicylates	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931681	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005687		76 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Duodenitis; Hypertension	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Meticorten			S	Oral			Not Reported
	Biconcor			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931685	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Rheumatoid Arthritis	Plaquenil			S				Concordia
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931689	EXPEDITED (15-DAY)		HO, OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005696		56 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection; Visual Acuity Reduced	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Azathioprine			C				Not Reported
	Chloroquine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2016	12931728	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005661		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Minocycline			S	Oral			Not Reported
	Minocycline			S	Oral			Not Reported
	Oxycontin			S	Oral			Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	11399544	EXPEDITED (15-DAY)		OT	CA-SA-2015SA080697		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm	Plaquenil	S	Oral		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Orencia	S	Unknown	Did This Infusion Twice.	Not Reported
	Rituxan	S	Unknown	Dosage Form_Solution Intravenous	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12531054	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015249874		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Interstitial Lung Disease	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Xeljanz			S		Unk		Pfizer
	Plaquenil /00072602/			S		400 Mg		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12709748	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1552		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Methotrexate (Trade Name Unknown)			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Minocycline			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Azathioprine			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Amoxil			C	Unknown				Not Reported
	Gold			C	Unknown				Not Reported
	Clavulin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12906139	EXPEDITED (15-DAY)		DE	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005509			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12931927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16P-028-1767654-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete	Amitriptyline	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Naproxen	C			Not Reported
	Pantoprazole	C			Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12931983	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0486		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Headache; Lacrimation Disorder; Nasopharyngitis; Nausea; Oropharyngeal Pain; Sinus Pain; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12933089	EXPEDITED (15-DAY)		HO, OT	FR-MUNDIPHARMA DS AND PHARMACOVIGILANCE -GBR-2016-0		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema; Streptococcal Bacteraemia	Oxycontin Lp			S	Oral	10 Mg, Bid		Purdue
	Oxycontin Lp			S		Unk		Purdue
	Minocycline			S	Oral	100 Mg, Bid		Not Reported

	Plaquenil /00072602/			S	Oral	200 Mg, Tid			Not Reported
	Plaquenil /00072602/			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12933755	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201472		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown	Duration 3 Years		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form Solution Subcutaneous And Duration 8 Months		Not Reported
	Humira			S	Subcutaneous	Dosage Form Solution Subcutaneous And Duration 1 Year		Not Reported
	Hydroxychloroquine			S	Unknown	Duration 2 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Duration 312 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form Solution Intravenous		Not Reported
	Orencia			S	Unknown	Dosage Form Powder For Solution For Intravenous. Duration 11 Months		Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex			C	Unknown			Not Reported

	Lyrica			C	Unknown				Not Reported
	Plaquenil			C	Unknown				Not Reported
	Premarin			C	Unknown				Not Reported
	Tenormin			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12933856	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201433		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Diverticulum; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12933985	EXPEDITED (15-DAY)		OT	US-SA-2016SA205285			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Dysstasia; Gait Disturbance; Pain In Extremity; Pain In Extremity; Peripheral Swelling	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			C		Frequency: 4 Pills Once A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12934260	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Placenta Praevia; Product Use Issue	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Pentoxifylline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12154825	EXPEDITED (15-DAY)		OT	CA-SA-2016SA033680		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Non-Hodgkin'S Lymphoma; Unevaluable Event	Arava			S	Unknown	Dose-20		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Amoxil	C	Unknown		Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12933763	EXPEDITED (15-DAY)		OT	CA-SA-2015SA083741		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Drug Ineffective; Dysgeusia; Dyspepsia; Epistaxis; Headache; Sinus Congestion; Sinusitis; Synovitis; Urinary Tract Infection	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Mg For 28 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg Taken For 28 Months Had Active Synovitis		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg Taken For 28 Months Had Active Synovitis		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	90 Mg Sc Q 2 Weeks Had Sinus Congestion And Unbearable Headache		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12935505	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005719		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Foot Deformity; Gait	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

Disturbance; Gastric Disorder	Methotrexate Sodium		S	Unknown		Not Reported
	Naproxen		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12936401	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2264		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12937968	EXPEDITED (15-DAY)		OT	PHHY2016CA155549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Novartis
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12939640	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA155558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Novartis
	Diclofenac			S				Novartis
	Diclofenac			S				Novartis
	Diclofenac			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported

	Motrin	S	Unknown	Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Tramadol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12941682	NON-EXPEDITED			GXBR2016US001737			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk Df, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12941776	NON-EXPEDITED			GXBR2016US000749		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Headache; Malaise; Nausea; Pollakiuria; Urine Output Decreased; Vomiting	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Bid		Novartis
	Gabapentin			C	Unknown	Unk Df, Unk		Not Reported
	Amlodipine			C	Unknown	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12942134	NON-EXPEDITED			GXBR2016US001903			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Throat Irritation	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Unk		Novartis

Tizanidine	C	Unknown	2 Mg, Unk		Not Reported
Vit D	C	Unknown	50000 U, Unk		Not Reported
Naproxen	C	Unknown	550 Mg, Unk		Not Reported
Dulera	C	Respiratory (inhalation)	Unk Df, Unk		Not Reported
Rizatriptan	C		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12942167	NON-EXPEDITED			GXBR2016US002280		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Dry Eye; Oral Pain; Pain In Extremity; Rheumatoid Arthritis	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12942229	NON-EXPEDITED			GXBR2016US002201			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Eye; Inflammation; Pruritus; Vision Blurred; Visual Impairment	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12780871	NON-EXPEDITED			US-PFIZER INC-2016446836		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Daily		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Enbrel			C		50 Mg, Weekly		Not Reported

Plaquenil /00072602/	C	Oral	200 Mg, Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12939483	NON-EXPEDITED			US-AMGEN-USASP2016158464		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Weight Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12939768	EXPEDITED (15-DAY)		OT	PHHY2016CA155563		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Diclofenac			S	Unknown			Novartis
	Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12939770	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA155561		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12941347	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA155560		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Decreased Appetite; Dizziness; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Novartis
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12941538	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2016DEP012751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Diclofenac Potassium			S		Unk		Depomed
	Amitriptyline			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Naprosyn /00256201/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Xeljanz			S	Oral	10 Mg, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12941567	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2016DEP012756		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Movement Disorder; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased	Diclofenac Potassium			S		Unk		Depomed
	Amitriptyline			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Naprosyn /00256201/			S		Unk		Not Reported

Plaquenil /00072602/	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Xeljanz	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12941709	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005795		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Intolerance; Hypersensitivity; Infection; International Normalised Ratio Fluctuation	Plaquenil Tablet			S	Unknown			Concordia
	Erythromycin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Flagyl			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12941886	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Sleep Disorder	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12942626	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2016DEP012757		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Diclofenac Potassium			S	Unknown	Unk		Depomed
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Elavil			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12944164	NON-EXPEDITED			GXBR2016US002602			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk Df, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12944225	NON-EXPEDITED			GXBR2016US003058			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Dry Eye	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12944354	EXPEDITED (15-DAY)		OT	PHHY2016CA155564		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Movement Disorder; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased	Diclofenac			S	Unknown			Novartis
	Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12946312	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-E2B_00007908		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Erythema; Lymphadenopathy; Myalgia; Oedema; Pain; Pruritus; Pustular Psoriasis; Pyrexia; Rash Pustular	Plaquenil Tablet	S	Oral		Concordia
	Prednisolone	C			Not Reported
	Prograf	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12946320	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005741			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Nausea; Vomiting	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Clonazepam			C				Not Reported
	Metformin			C				Not Reported
	Naprosyn			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12946323	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005764			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Hydroxychloroquine			S	Unknown			Concordia
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2016	12946333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853943		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Arava			S	Unknown				Not Reported
	Azathioprine			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Parenteral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12898729	EXPEDITED (15-DAY)		HO	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005437		36 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Tenderness; Condition Aggravated; Gastrointestinal Sounds Abnormal; Gastrointestinal Wall Thickening; Haematochezia; Lupus Vasculitis; Neutropenia; Rash; Therapeutic Response Decreased; Vasculitis Gastrointestinal	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Not Reported
	Lenograstim			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12944868	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		43 YR	Female	CAN

INC.-GSH201611-005806

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Swelling	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12945867	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005811		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Diverticulum; Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12945873	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005686			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Plaquenil			S				Concordia

Gluten Sensitivity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12946019	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0767		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Interstitial Lung Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12946702	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005733		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Gastric Disorder; Nausea; Vomiting	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Multivitamine Axium Multi Extra			C				Not Reported
	Nexium			C				Not Reported
	Omega-3			C				Not Reported
	Osto-D2			C				Not Reported
	Oxybutynin			C				Not Reported
	Quinapril			C				Not Reported
	Salbutamol			C				Not Reported
	Slow K			C				Not Reported
	Tylenol			C				Not Reported
	Acebutolol			C				Not Reported

	Aspirin			C						Not Reported
	Calcium Citrate			C						Not Reported
	Cipralex			C						Not Reported
	Fenofibrate			C						Not Reported
	Hydrochlorothiazide			C						Not Reported
	Hydromorphone			C						Not Reported
	Lorazepam			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2016	12946943	NON-EXPEDITED			US-PFIZER INC-2016532566		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Weight Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12109940	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016103770		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Deformity; Pain; Pneumonia; Swelling	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12916065	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016041574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Pain; Rheumatoid Arthritis;	Cimzia			S		Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

Sleep Disorder	Methotrexate	C	Unk		Not Reported
	Meloxicam	C	Unk		Not Reported
	Sulfasalazine	C	Unk		Not Reported
	Tofacitinib Citrate	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948203	NON-EXPEDITED			US-ZYDUS-009201		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine			S	Oral			Zydus Pharm
	Iron			C				Not Reported
	Metoprolol			C				Not Reported
	Furosemide			C				Not Reported
	Simvastatin			C				Not Reported
	Potassium			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Ergocalciferol			C				Not Reported
	Duloxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948211	NON-EXPEDITED			US-ZYDUS-012757		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Oral			Zydus Pharm
	Prednisone			C				Not Reported
	Sulindac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948223	NON-EXPEDITED			US-ZYDUS-009824		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Lymphadenopathy; Nausea	Hydroxychloroquine			S	Oral			Zydus Pharm
	Prednisone/Prednisone Acetate			C				Not Reported

		Amlodipine/Benazepril Hydrochloride			C					Not Reported
		Montelukast			C					Not Reported
		Doxazosin			C					Not Reported
		Fluticasone Propionate/Salmeterol Xinafoate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948227	NON-EXPEDITED			US-ZYDUS-009891		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Confusional State; Headache; Nausea	Hydroxychloroquine			S	Oral			Zydus Pharm
	Buspirone			S				Not Reported
	Escitalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948261	NON-EXPEDITED			US-ZYDUS-010045			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948262	NON-EXPEDITED			US-ZYDUS-010434		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Nausea	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948268	NON-EXPEDITED			US-ZYDUS-010591		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Papular	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948269	NON-EXPEDITED			US-ZYDUS-010189			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dyspepsia; Dysphagia; Nausea	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948271	NON-EXPEDITED			US-ZYDUS-010984			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948274	EXPEDITED (15-DAY)			US-ZYDUS-011104			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948276	NON-EXPEDITED			US-ZYDUS-011321		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Hydroxychloroquine			S	Oral			Zydus Pharm
	Estradiol			C	Transdermal			Not Reported
	Progesterone			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948280	NON-EXPEDITED			US-ZYDUS-011645		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Nausea	Hydroxychloroquine			S	Oral			Zydus Pharm
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948281	NON-EXPEDITED			US-ZYDUS-012097		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Glucose Decreased; Dizziness; Dyspepsia; Hyperhidrosis	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948860	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005798		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Drug Ineffective; Dysgeusia; Dyspepsia; Epistaxis; Headache; Sinus Congestion; Sinusitis; Synovitis; Urinary Tract Infection	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948865	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005828		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Swelling	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12948985	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005827		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm	Plaquenil			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2016	12949315	NON-EXPEDITED			US-PFIZER INC-2016532896		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Accupril			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12845242	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016460182		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diverticulitis; Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Injection Site Reaction; Liver Function Test Increased; Rash; Urticaria	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Plaquenil /00072603/			S		200 Mg, 2x/Day		Not Reported
	Leflunomide			S		20 Mg, Daily		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2016	12957814	EXPEDITED (15-DAY)		OT	CA-CANTON LABORATORIES, LLC-1059775		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Naprosyn			S	Unknown			Canton Laboratories
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate Sodium		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2016	11906019	EXPEDITED (15-DAY)		OT	CA-ROCHE-1691198			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2016	12130435	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717266		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2016	12958192	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005880			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Rheumatoid Arthritis; Sleep Disorder	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	11324269	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015249939		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Diarrhoea; Hypoaesthesia; Pain; Post Procedural Complication; Swelling; Therapeutic Product Effect Incomplete; Thrombosis	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12889529	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013268		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contusion; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nodule; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Variable; Urinary Tract Infection	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd		Apotex
	Apo-Sulfasalazie	S	Unknown	500 Mg, Bid		Not Reported
	Ratio-Methotrexate	S	Oral	10 Mg, Q.Wk.		Not Reported
	Ratio-Methotrexate	S	Oral	15 Mg, Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Actemra	C	Unknown			Not Reported
	Cimzia	C	Unknown			Not Reported
	Cortisone	C	Unknown			Not Reported
	Enbrel	C	Unknown			Not Reported
	Humira	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Orencia	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Simponi	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12932241	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007903		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Non-Hodgkin'S Lymphoma; Unevaluable Event	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Sulfasazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Xeljanz	S	Unknown			Not Reported
	Amoxil	C				Not Reported
	Clavulin	C				Not Reported
	Gold	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12958774	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005899		49 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2016	12960749	EXPEDITED (15-DAY)		OT	CA-SA-2016SA211173		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis	Arava			S	Oral	Dose: 20		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	11748418	NON-EXPEDITED			US-PFIZER INC-2015226620		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Detrol			S		Unk		Pfizer
	Robaxin			S		Unk		Not Reported

	Plaquenil	S	Unk	Not Reported
	Baclofen	S	Unk	Not Reported
	Flexeril	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Soma	S	Unk	Not Reported
	Cipro	S	Unk	Not Reported
	Synthroid	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12890128	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013297		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Sulfasalazie			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12927702	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-E2B_00007901		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram Qt Prolonged; Electrocardiogram U-	Hydroxychloroquine			S	Unknown			Concordia
	Oxycodone/Paracetamol			S	Unknown			Not Reported

Wave Abnormality; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963186	EXPEDITED (15-DAY)		OT	GR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005908		63 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Pustular Psoriasis; Rash Pustular	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963386	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005935		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12963742	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		70 YR	Female	CAN

						PHARMA-TREX2016-2357				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Deformity; Pain; Pneumonia; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2016	12966526	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005896		46 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anosmia; Deafness Transitory; Swelling	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12961916	EXPEDITED (15-DAY)		OT	PHHY2016CA159381		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count Decreased	Voltaren			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Novartis
	Sulfasalazine			S	Unknown	2 Df, Qd		Not Reported
	Arava			S	Unknown	20.0 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12968891	NON-EXPEDITED			US-APOTEX-2016AP010646			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Mycophenolate Mofetil			S	Oral	1500 Mg, Q.Am		Apotex
	Mycophenolate Mofetil			S	Oral	1000 Mg, Q.H.S.		Apotex
	Omeprazole			S	Unknown	20 Mg, Daily		Apotex
	Losartan Potassium Film-Coated Tablets			S	Unknown	100 Mg, Daily		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Calcium Vit D			S	Unknown	1 Df, Bid		Not Reported
	Ferrous Sulphate /00023503/			S	Unknown	325 Mg, Daily		Not Reported
	Micronor			S	Unknown	0.35 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12969378	NON-EXPEDITED			US-PFIZER INC-2016542309			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12970203	NON-EXPEDITED			US-PFIZER INC-2016538028		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2016	12970518	EXPEDITED (15-DAY)		OT	CA-CANTON LABORATORIES, LLC-1060020		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Diarrhoea; Dizziness; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Synovitis; Vomiting	Naprosyn	S	Unknown	Canton Laboratories
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Methotrexate (Methotrexate Sodium)	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2016	12972628	EXPEDITED (15-DAY)		DE	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005932		43 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Dyspnoea; Malaise; Toxicity To Various Agents	Plaquenil			S	Unknown			Concordia
	Diazepam			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Dilantin			C				Not Reported
	Lamotrigine			C				Not Reported
	Mirtazapine			C				Not Reported
	Propranolol			C				Not Reported
	Cannabis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12888024	NON-EXPEDITED			US-AMGEN-USASP2016145981		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Photosensitivity Reaction	Enbrel		S	Unknown	Unk		Amgen
	Leflunomide		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Azulfidine		S	Unknown	Unk		Not Reported
	Doxycycline		S	Unknown	Unk		Not Reported
	Prednisone		S	Unknown	Unk		Not Reported
	Xeljanz		C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974127	EXPEDITED (15-DAY)		OT	CA-ROCHE-1858727		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Imuran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974276	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016163527		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

	Cimzia	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Actemra	C	Unknown	Unk		Not Reported
	Arava	C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974513	EXPEDITED (15-DAY)		DS	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005981		99 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dizziness	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1858809		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974534	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005979			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2016	12974552	EXPEDITED (15-DAY)		OT	CA-ROCHE-1859524		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12935942	EXPEDITED (15-DAY)		DE, HO	US-HORIZON-PRE-0328-2016		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated	Prednisone			S				Not Reported
	Infliximab			S				Not Reported
	Methothrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977301	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Intestinal Perforation; Liver	Plaquenil 200 Mg			S				Concordia
	Arava			S				Not Reported

Function Test Increased; Rash; Urticaria	Sulfasalazine			C						Not Reported
	Methotrexate			C						Not Reported
	Humira			C						Not Reported
	Actemra			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977303	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-006018			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Intolerance; Limb Discomfort; Pain In Extremity	Plaquenil			S				Concordia
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977528	EXPEDITED (15-DAY)		OT	CL-ABBVIE-16K-034-1787206-00		20 YR	Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Peripheral Swelling; Retinal Injury	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquinol			S	Unknown			Not Reported
	Azulfidine			C				Not Reported
	Prednisone			C				Not Reported
	Calcium Supplement			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12977964	EXPEDITED (15-DAY)		OT	PT-BAYER-2016-224641			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Cell Carcinoma	Naproxen Sodium (<=220 Mg)			S	Unknown	Unk		Bayer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported

		Methylprednisolone			S	Unknown	Unk				Not Reported
		Pantoprazole Sodium			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12979103	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2016GSK172560			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Benlysta			S				Glaxosmithkline
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12979524	EXPEDITED (15-DAY)		OT	TR-IPCA LABORATORIES LIMITED-IPC201611-000957		51 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Rash Maculo-Papular; Rash Pustular	Hydroxychloroquine Sulfate			S				Ipca
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12980215	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16P-028-1793118-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Synthroid			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12980422	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1050362			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	200mg Two Times A Day		Not Reported
	Azathioprine			S	Unknown	50mg Three Times A Day		Not Reported
	Prednisone			S	Unknown	40mg Daily		Not Reported
	Prednisone			S	Unknown	100mg Daily		Not Reported
	Glyceryl Trinitrate			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide			S	Other			Not Reported
	Furosemide			S	Oral	80mg Daily		Not Reported
	Carvedilol			S	Oral	12.5mg Twice A Day		Not Reported
	Hydralazine			S	Oral	25mg Three Times A Day		Not Reported
	Isosorbide Mononitrate			S	Oral			Mylan
	Isosorbide Dinitrate			S	Unknown	60mg Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2016	12980578	EXPEDITED (15-DAY)		OT	CA-SA-2016SA150731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diverticulitis; Drug Ineffective; Fatigue; Malaise; Nausea; Poor Quality Sleep	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	8104519	EXPEDITED (15-DAY)		OT	CA-UCBSA-039141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Previously On 400 Mg		Ucb
	Cimzia			S		Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12131566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016121617		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Red Blood Cell Sedimentation Rate Increased	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Methotrexate Sodium			C	Oral	20 Mg, Weekly		Not Reported
	Naproxen			C		500 Mg, As Needed		Not Reported
	Hydromorph			C		2 Mg, As Needed		Not Reported
	Hydromorph Contin			C		9 Mg, 2x/Day		Not Reported
	Alendronate			C		70 Mg, Weekly		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported
	Citalopram			C		20 Mg, 1x/Day		Not Reported
	Pregabalin			C		150 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12286600	EXPEDITED (15-DAY)		OT	ALCN2016CA002620		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Novartis
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12602484	NON-EXPEDITED		OT	US-PFIZER INC-3190842		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Eye Disorder; Nail Dystrophy; Nausea	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		10 Mg, 1x/Day		Pfizer
	Arava			S	Oral	10 Mg, 1x/Day		Not Reported
	Myochrysine			S	Oral	Unk		Not Reported
	Orencia			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous drip	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	10 Mg, 1x/Day		Not Reported
	Ridaura			S	Oral	10 Mg, 1x/Day		Not Reported
	Estrace			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Plavix			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12953440	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2016159984		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Haemoglobin Abnormal; Injection Site Pain; Paralysis; Product Dose Omission; Unevaluable Event	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12968839	EXPEDITED (15-DAY)		HO	CA-SA-2016SA188250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Intestinal Perforation; Liver Function Test Increased; Rash; Urticaria	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Actemra			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12980510	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015395677		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Intervertebral Disc Compression; Intervertebral Disc Protrusion; Pain; Rheumatoid Arthritis	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2016	12981852	EXPEDITED (15-DAY)		OT	PT-TAKEDA-2016TEU005885			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Cell Carcinoma	Pantoprazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Takeda
	Naproxen			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12919169	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2221		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gait Disturbance; Pneumonitis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12985312	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-006051		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Infection	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Locapred			S	Cutaneous			Not Reported
	Locapred			S	Cutaneous			Not Reported

		Lexomil			C					Not Reported
		Folic Acid			C					Not Reported
		Uvedose			C					Not Reported
		Artelac [Hypromellose]			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12985318	EXPEDITED (15-DAY)		OT	CA-ROCHE-1859492		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C				Not Reported
	Elavil (Canada)			C	Unknown			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Imitrex			C				Not Reported
	Lyrica			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Premarin			C				Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12985551	EXPEDITED (15-DAY)		OT	CA-ROCHE-1860184		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12988541	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2016-030175			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Acute Myocardial Infarction; Angina Unstable; Musculoskeletal Stiffness; Polyarthritis	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Bausch And Lomb
	Methotrexate			S	Unknown			Bausch And Lomb

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2016	12990896	DIRECT		HO, LT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Stevens-Johnson Syndrome	Hydroxychloroqu- Ine			S	Oral			Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12990362	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK176424		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Voltaren (Diclofenac Sodium)	S	Unk	Glaxosmithkline
	Methotrexate	S	Unk	Glaxosmithkline
	Enbrel	S	Unk	Not Reported
	Cortisone	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Humira	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12990715	EXPEDITED (15-DAY)		OT	CA-SA-2016SA214308		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported

	Imuran			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2016	12992121	EXPEDITED (15-DAY)		OT	CA-BAXTER-2016BAX060295		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	11688514	EXPEDITED (15-DAY)		OT	GB-TEVA-604694ACC		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12705489	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1494		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12913953	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013716		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Apo-Lisinopril			S	Unknown			Apotex
	Pantoprazole			S	Unknown			Apotex
	Apo-Sulfasalazie			S	Oral	1 G, Bid		Not Reported
	Synthroid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.I.W		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Unk		Not Reported
	Voltaren /00372301/			S	Oral	75 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12992565	EXPEDITED (15-DAY)		OT	CA-ROCHE-1861345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2016	12993413	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-006117		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Minocycline			S	Oral			Not Reported
	Minocycline			S	Oral			Not Reported
	Oxycontin			S	Oral			Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2016	12996737	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Fatigue Syndrome; Drug Intolerance; Fatigue; Haemorrhage; Headache; Influenza; Joint Swelling; Malaise; Migraine; Nausea; Pain; Peripheral Swelling; Rash; Vision Blurred	Plaquenil			S				Concordia
	Xanax			C	Oral			Not Reported
	Flovent Hfa			C		Inhale 1 Puff Into The Lungs 2 Times Daily		Not Reported
	Qvar			C		Inhale 2 Puffs Into The Lungs 2 Times Daily		Not Reported
	Coumadin			C				Not Reported
	Levothyroxine			C	Oral			Not Reported
	Fosamax			C	Oral			Not Reported
	Norco			C	Oral			Not Reported
	Prinivil Zestril			C	Oral			Not Reported
	Lipitor			C	Oral	One Tablet By Mouth Every Night At Bedtime		Not Reported
	Toprol-Xl			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Cranberry Vitamin C Vitamin E			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Parafon Forte			C	Oral	Nightly		Not Reported
	Migralief Supplement			C				Not Reported
	Lutein			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Collagen			C	Oral			Not Reported
	Glucosamine Hcl			C	Oral			Not Reported
	Vitamin D Nos			C	Oral			Not Reported
	Protonix			C	Oral			Not Reported

	Coq-10			C	Oral	Not Reported
	Vitamin B12			C	Oral	Not Reported
	Colace			C	Oral	Not Reported
	Ginger Root			C	Oral	Not Reported
	Folvite			C	Oral	Not Reported
	Vitamin C			C	Oral	Not Reported
	Tessalon			C	Oral	Not Reported
	Multi-Vitamin			C		Not Reported
	Arava			C		Not Reported
	Remicade			C		Not Reported
	Prednisone			C		Not Reported
	Prolia			C		Not Reported
	Sulfasalazine			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12958768	EXPEDITED (15-DAY)		LT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005903		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Lupus Myocarditis	Hydralazine			S	Unknown			Not Reported
	Hydralazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Concordia
	Isosorbide Mononitrate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Furosemide			S	Intravenous drip			Not Reported
	Furosemide			S	Unknown			Not Reported
	Carvedilol			S	Oral			Not Reported
	Carvedilol			S	Oral			Not Reported
	Isosorbide Dinitrate			S	Unknown			Not Reported

		Nitroglycerine			S	Intravenous (not otherwise specified)				Not Reported
		Methylprednisolone			S	Unknown				Not Reported
		Methylprednisolone			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12997375	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diverticulitis; Drug Ineffective; Fatigue; Malaise; Nausea; Poor Quality Sleep	Plaquenil			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12997378	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006181		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrogram Abnormal; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Rotator Cuff Syndrome; Shoulder Arthroplasty; Synovial Disorder; Treatment	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			C				Not Reported

Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12997388	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapy Non-Responder	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Rituxan			C				Not Reported
	Morphine			C				Not Reported
	Florinal			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12998175	NON-EXPEDITED			US-PFIZER INC-2016554604		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12998870	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA220232		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Arava			S	Unknown			Not Reported

Arthralgia; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Plaquenil	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Methotrexate	C	Unknown	7-2009(Month Unknown)		Not Reported
	Duloxetine	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported
	Vitamin D2	C	Unknown			Not Reported
	Humira	C	Unknown			Not Reported
	Orencia	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2016	12999233	EXPEDITED (15-DAY)		DE	AU-PURDUE PHARMA-GBR-2016-0041998		43 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Dyspnoea; Malaise; Toxicity To Various Agents	Oxycodone Hydrochloride			S	Unknown	Unk		Purdue
	Diazepam			S	Unknown	Unk		Not Reported
	Methadone			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Dilantin /00017401/			C				Not Reported
	Lamotrigine			C				Not Reported
	Mirtazapine			C				Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	11788121	EXPEDITED (15-DAY)		HO	CA-ROCHE-1667828			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis;	Cellcept			S	Unknown			Not Reported

Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Eye Laser Surgery; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Acuity Reduced; Visual Impairment; Weight Decreased	Belimumab	S	Unknown	Not Reported
	Belimumab	S	Unknown	Not Reported
	Belimumab	S	Intravenous (not otherwise specified)	Not Reported
	Belimumab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Gravol	C	Unknown	Not Reported
	Neurontin (Canada)	C	Oral	Not Reported
	Neurontin (Canada)	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	12891415	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL		17 YR	Female	USA

						INDUSTRIES LTD-2016US-126648			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Pleural Effusion; Pneumonia	Prednisone			S	Unknown	60 Mg, Daily		Mutual
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amlodipine			S	Unknown	Unk		Sun
	Colecalciferol			S	Unknown	Unk		Not Reported
	Co-Trimoxazole			S	Unknown	Unk		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Ranitidine			S	Unknown	Unk		Ranbaxy
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg/M2, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	12972678	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005948			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	12996761	NON-EXPEDITED			US-AMGEN-USASL2016167396			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Pain; Upper-Airway Cough Syndrome	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000606	EXPEDITED (15-DAY)		HO	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006203		81 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Hypoglycaemia	Plaquenil 200 Mg			S	Oral			Concordia
	Tazobac			S	Intravenous drip			Not Reported
	Arixtra			C				Not Reported
	Aspirin Cardio			C				Not Reported
	Atorvastatin			C				Not Reported
	Metoprolol			C				Not Reported
	Torasemid			C				Not Reported
	Doxycycline			C				Not Reported
	Escitalopram			C				Not Reported
	Nexium			C				Not Reported
	Hydrocortisone			C				Not Reported
	Keppra			C				Not Reported
	Seretide			C				Not Reported
	Morphine			C				Not Reported
	Florinef			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000608	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006209		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednlsone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13000949	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016169307		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Cardiac Disorder; Condition Aggravated; Diarrhoea; Headache; Hypercholesterolaemia; Impaired Work Ability; Latent Tuberculosis; Pain; Psoriatic Arthropathy; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Inflectra			S	Intravenous (not otherwise specified)	716.25 Mg/Kg, Unk (Then Every 6 Weeks For 12 Months)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Crestor			C	Oral	Unk		Not Reported
	Ezetrol			C	Oral	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Plavix			C	Oral	Unk		Not Reported
	Nitro			C	Transdermal	Unk		Not Reported
	Niaspan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13001014	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006212		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia

Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine	S	Unknown		Concordia
	Hydroxychloroquine	S			Concordia
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Imuran	C			Not Reported
	Vitamin D Nos	C			Not Reported
	Arthrotec	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13001095	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006242		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

	Duloxetine			C						Not Reported
	Folic Acid			C						Not Reported
	Calcium			C						Not Reported
	Vitamin D Nos			C						Not Reported
	Humira			C						Not Reported
	Orencia			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2016	13001286	NON-EXPEDITED			US-PFIZER INC-2016563103		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Levothyroxine Sodium			S	Unknown	Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	12967983	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005910		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Antinuclear Antibody Increased; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Drug-Induced Liver Injury; Hepatic Steatosis; Hyperhidrosis; Porphyrins Urine Increased; Pyrexia	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	13004689	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Intervertebral Disc Protrusion; Mobility Decreased; Neck Pain; Pain; Rheumatoid Arthritis	Plaquenil	S	Unknown	Unknown		Concordia
	Methotrexate	C				Not Reported
	Cortisone	C				Not Reported
	Orencia	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	13005036	NON-EXPEDITED			US-PFIZER INC-2016556786		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Percocet			S		Unk		Not Reported
	Tylenol W/Codeine No. 3			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2016	13006214	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK173070		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count Decreased	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S		2 Df, Qd		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Plaquenil			S		2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	12984483	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015058709		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Increased; Clostridium Difficile Infection; Diarrhoea; Eye Disorder; Fatigue; Gastrointestinal Disorder; Malaise; Osteomyelitis; Pleurisy; Pneumonia; Postoperative Wound Infection; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium	S	Oral	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Actemra	S		250 Mg, Unk	Not Reported
	Arava	S		20 Mg, Unk	Not Reported
	Gold	S		Unk	Not Reported
	Plaquenil	S		400 Mg, Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	12995230	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2016CA164226			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Methotrexate Sodium Injection			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported

	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	12996048	EXPEDITED (15-DAY)		HO, LT	PHHY2016CA164223			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Novartis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Remicade		S			Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S			Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Sulfasalazine		S			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
08-Dec-2016	13002103	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2016CA164857			Male	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Not Reported		
	Ilaris			S				Not Reported		
	Methotrexate Sodium Injection			S	Unknown			Not Reported		
	Methotrexate Sodium Injection			S				Not Reported		
	Leflunomide			S	Unknown			Novartis		
	Leflunomide			S				Novartis		
	Actemra			S	Unknown			Not Reported		
	Actemra			S				Not Reported		
	Anakinra			S	Unknown			Not Reported		
	Anakinra			S				Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Enbrel			S				Not Reported		
	Gold			S	Unknown			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Humira			S				Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported		
	Hydroxychloroquine Sulfate			S				Not Reported		
	Orencia			S	Intravenous (not otherwise specified)			Not Reported		
	Orencia			S				Not Reported		
	Plaquenil			S	Unknown			Not Reported		

	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13008292	NON-EXPEDITED			US-AMGEN-USASP2016171991		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Drug Ineffective; Foot Fracture; Intervertebral Disc Disorder; Joint Swelling; Muscular Weakness; Musculoskeletal Stiffness; Osteoarthritis; Pain; Psoriasis; Rash; Rash Pruritic	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	400 Mg, Q2wk		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Aspirin			C	Oral	81 Mg, Qd		Not Reported
	Nexium			C	Oral	20 Mg, Qd		Not Reported
	Felodipine			C	Oral	5 Mg, Qd		Not Reported
	Xopenex Hfa			C		2 Df, Q6h		Not Reported
	Spironolactone			C	Oral	50 Mg, Qd		Not Reported
	Metformin			C	Oral	500 Mg, Bid		Not Reported
	Toujeo			C	Subcutaneous	Unk		Not Reported
	Carvedilol			C	Oral	125 Mg, Bid		Not Reported
	Crestor			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13008880	EXPEDITED (15-DAY)			CA-WARNER CHILCOTT, LLC-1060557		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Condition Aggravated; Hypoacusis; Rheumatoid Arthritis	Actonel			S	Oral			Warner Chilcott
	Hydroxychloroquine			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Folic Acid			S				Not Reported
	Caltrate Plus			S				Not Reported
	Centrum			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2016	13009582	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006296			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Blister; Confusional State; Depression; Dizziness; Feeling Cold; Feeling Cold; Head Discomfort; Headache; Impaired Work Ability; Muscle Tightness; Myalgia; Nausea; Restlessness; Sleep Disorder; Spinal Pain; Suicidal Ideation	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	11611346	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA018887		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased;	Arava			S	Unknown	Form Strength: 20 Mg		Not Reported

Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Fatigue; Malaise; Osteomyelitis; Pleurisy; Pneumonia; Red Blood Cell Sedimentation Rate Increased	Plaquenil	S	Unknown			Not Reported
	Methotrexate Sodium	S	Oral	10 Mg		Not Reported
	Methotrexate Sodium	S	Oral	15 Mg		Not Reported
	Actemra	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	12876610	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016469170		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Naproxen			S	Oral	500 Mg, Unk		Not Reported
	Plaquenil /00072603/			S	Oral	200 Mg, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	12907284	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-02		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated	Methotrexate			S	Oral			Roxane
	Plaquenil			S	Oral			Hikma
	Adalimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	12907309	EXPEDITED (15-DAY)		DE, HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-02		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis	Methotrexate			S	Oral			Roxane

Disseminated; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Prednisone		S	Oral	Roxane
	Prednisone		S	Oral	Roxane
	Plaquenil		S	Oral	Not Reported
	Infliximab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2016	13011526	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006302			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2016	13015004	EXPEDITED (15-DAY)		CA	DE-STRIDES ARCOLAB LIMITED-2016SP019068			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brachycephaly; Camptodactyly Congenital; Coloboma; Congenital Cardiovascular Anomaly; Dysmorphism; External Auditory Canal Atresia; Foetal Exposure During Pregnancy; Hypertelorism Of Orbit; Microtia; Oesophageal Atresia; Olfactory Nerve Agenesis; Retrognathia	Mycophenolate Mofetil			S	Transplacental	Maternal Dose: 0.75g Per Day		Strides
	Prednisolone			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Enalapril			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Not Reported
	Alendronic Acid			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2016	13015029	EXPEDITED (15-DAY)		OT	DE-STRIDES ARCOLAB LIMITED-2016SP019561			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced; Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil		S	0.75 G Per Day	Strides
	Prednisolone		S	Unk	Not Reported
	Azathioprine		S	Unk	Not Reported
	Enalapril		S	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unk	Not Reported
	Alendronic Acid		S	Unk	Not Reported
	Acetylsalicylic Acid		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2016	13015453	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865660		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Unknown	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2016	13015462	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865091		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	11399350	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015000207		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infusion Related Reaction; Pneumonia; Sarcoidosis	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S				Pfizer
	Plaquenil /00072603/			S				Not Reported
	Arava			S				Not Reported
	Rituxan			S				Not Reported
	Celebrex			C		2 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12968814	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2016537159			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Cell Carcinoma	Methylprednisolone			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Pantoprazole			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported

	Colchicine			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	12980565	EXPEDITED (15-DAY)		OT	CA-SA-2016SA214321		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage; Pharyngeal Swelling; Rash; Swollen Tongue	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13015548	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007934		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Fatigue; Malaise; Osteomyelitis; Pleurisy; Pneumonia; Red Blood Cell Sedimentation Rate Increased	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13016851	EXPEDITED (15-DAY)		CA, HO	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201612-		3 DAY	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemangioma Congenital; Maternal Exposure During Breast Feeding; Neonatal Gastrointestinal Disorder	Plaquenil			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020198	EXPEDITED (15-DAY)		OT	CA-SA-2016SA222169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Toxicity; Drug Ineffective	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported
	Mavik			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2016	13020877	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006338		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Left Ventricular Dysfunction; Ventricular Extrasystoles; Ventricular Extrasystoles	Plaquenil			S	Oral			Concordia
	Cortancyl			C				Not Reported
	Sintrom			C				Not Reported
	Kardegic			C				Not Reported
	Inexium			C				Not Reported
	Perindopril			C				Not Reported

	Bisoce			C						Not Reported
	Metformin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	12939822	EXPEDITED (15-DAY)		LT	PHHY2016US153012		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Lupus Myocarditis	Hydralazine			S	Unknown	Unk		Novartis
	Hydralazine			S	Unknown	25 Mg, Tid		Novartis
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Azathioprine			S	Unknown	50 Mg, Tid		Not Reported
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	100 Mg, Qd		Not Reported
	Furosemide			S	Intravenous drip	80 Mg, Qd		Not Reported
	Furosemide			S	Unknown	80 Mg, Qd		Not Reported
	Carvedilol			S	Oral	Unk		Not Reported
	Carvedilol			S	Oral	12.5 Mg, Tid		Not Reported
	Isosorbide Dinitrate			S	Unknown	60 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	250 Mg, Q6h		Not Reported
	Methylprednisolone			S				Not Reported
	Nitroglycerine			S	Intravenous (not otherwise specified)	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	12988435	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016523406		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Faeces Discoloured; Muscle Spasms; Renal Impairment	Sulfasalazine			S	Oral	2 G, Daily		Pfizer
	Plaquenil /00072602/			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13024913	EXPEDITED (15-DAY)		HO	CN-ASTRAZENECA-2016SF31559			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Ear Pain; Haemoglobin Decreased; Mouth Ulceration; Platelet Count Decreased; Pyrexia; Rash; White Blood Cell Count Decreased	Esomeprazole Magnesium			S	Oral			Astrazeneca
	Esomeprazole Magnesium			S	Oral			Astrazeneca
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	7.5 Mg Every Friday		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Prednisone Acetate			C	Oral			Not Reported
	Prednisone Acetate			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral	5 Mg Every Saturday		Not Reported
	Potassium Citrate			C	Oral	1 Pouch Two Times A Day		Not Reported
	Potassium Citrate			C	Oral	2 G Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	12870238	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2016489403		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Toxicity To Various Agents	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Arava			S		20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	12888218	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2089		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Work Ability; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	12901866	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2156		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Grip Strength Decreased; Nausea	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Quinapril			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13009274	EXPEDITED (15-DAY)		OT	TH-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006275		36 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Optical Coherence Tomography Abnormal; Retinal Depigmentation; Retinopathy; Visual Field Defect	Hydroxychloroquine		S	Unknown	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13026775	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-02		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13028954	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Toxicity; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Lansoprazole			C				Not Reported
	Bisoprolol			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin B12			C				Not Reported
	Mavik			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2016	13028983	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Faeces Discoloured; Muscle	Plaquenil			S	Unknown			Concordia

Spasms; Renal Impairment	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	12997236	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006133		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage; Pharyngeal Swelling; Rash; Swollen Tongue	Plaquenil			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13008545	EXPEDITED (15-DAY)		OT	TH-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006277		39 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optical Coherence Tomography Abnormal; Retinal Depigmentation; Retinopathy; Visual Field Defect	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13029429	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006399		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Nausea; Vomiting	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13029704	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006396		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13029741	EXPEDITED (15-DAY)		OT	CA-ROCHE-1867962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported

		Methotrexate			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13029870	EXPEDITED (15-DAY)		DS	CA-ROCHE-1865582		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13030461	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2016CA1081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash;	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Hydroxychloroquine	S			Not Reported
	Leflunomide	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13031182	EXPEDITED (15-DAY)		HO	CA-CELLTRION HEALTHCARE HUNGARY KFT-2016CA013356			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Body Height Below Normal; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction; Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg		Celltrion
	Methotrexate Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Unknown	250 Mg		Not Reported
	Naproxen			S				Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Dipotassium Phosphate							
	Prednisone			S				Not Reported
	Tocilizumab			S		280 Mg		Not Reported
	Abatacept			S		250 Mg		Not Reported
	Adalimumab			S				Not Reported
	Anakinra			S				Not Reported
	Etanercept			S		12.5 Mg		Not Reported
	Etanercept			S		25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Immune Globulin Nos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13031762	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2016-006096			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2016	13031790	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2016-005312			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone Tablets			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	11340703	NON-EXPEDITED			US-PFIZER INC-2015256963			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Lincomycin Hcl			S		Unk		Pfizer
	Doxycycline Calcium			S		Unk		Pfizer
	Glucotrol			S		Unk		Pfizer
	Indomethacin			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Bextra			S		Unk		Not Reported

	Cephalexin	S	Unk	Not Reported
	Pb-Hyoscy-Atropine-Scopolamine	S	Unk	Not Reported
	Phenobarbital	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Plavix	S	Unk	Not Reported
	Provigil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12259824	EXPEDITED (15-DAY)			TR-SA-2016SA068121		39 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Arava			S	Oral	Fetal/Neonatal Exposure: 1-2		Not Reported
	Prednol (Methylprednisolone)			S	Oral	Fetal/Neonatal Exposure: 1-2		Not Reported
	Plaquenil			S	Oral	Fetal/Neonatal Exposure: 1-2		Not Reported
	Salazopyrine Enteric-Coated			S	Oral	Fetal/Neonatal Exposure: 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12893605	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2016-2073		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Toxicity To Various Agents	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12977649	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007922		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Cough; Dysphonia; Fatigue; Herpes Zoster; Limb Discomfort; Lower Respiratory Tract Infection; Lyme Disease; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Plantar Fasciitis; Rheumatoid Arthritis; Sciatica; Sputum Discoloured; Tendon Injury; Tendon Pain	Plaquenil			S	Unknown			Concordia
	Methotrexate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Tens Therapy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12990145	NON-EXPEDITED			US-AMGEN-USASL2016156120		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Bone Pain; Condition Aggravated; Cushingoid; Drug Ineffective; Headache; Injection Site Extravasation; Injection Site Pain; Injection Site Urticaria; Memory Impairment; Nausea; Pain In Extremity; Rash; Rash Erythematous; Rash Pruritic; Weight Increased; Wrong Technique In Product Usage Process	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	12993401	EXPEDITED (15-DAY)		OT	IR-CONCORDIA PHARMACEUTICALS INC.-GSH201611-006114		14 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Double Stranded Dna Antibody Positive; Drug Ineffective; Drug Resistance; Lupus Nephritis; Proteinuria; Red Blood Cell Sedimentation Rate Increased; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Dapsone			C	Unknown			Not Reported
	Immune Globulin Nos			C	Intravenous (not otherwise specified)	1 G/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13005142	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006272		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Depigmentation; Retinal Toxicity; Toxicity To Various Agents; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13033499	EXPEDITED (15-DAY)		OT	SG-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006419		75 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13034128	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC.-2016-002693		70 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Texture Abnormal	Rheumatrex Tablets 2.5 Mg			S	Unknown			Not Reported
	Prednisone Tablets			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13035556	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1805248-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown	Every Tuesday		Not Reported
Sulfasalazine	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Celebrex	S	Oral			Not Reported
Orencia	S	Unknown			Not Reported
Gabapentin	C				Not Reported
Gabapentin	C				Not Reported
Gabapentin	C				Not Reported
Atorvastatin	C				Not Reported
Altace	C				Not Reported
Estrogens Conjugated	C				Not Reported
Hydrochlorothiazide	C				Not Reported
Hydromorphone Hcl	C				Not Reported
Prednisone	C				Not Reported
Prednisone	C				Not Reported
Prednisone	C				Not Reported
Taro-Mupirocin 2%	C				Not Reported
Tramadol Hcl	C				Not Reported
Tramacet	C				Not Reported
Celexa	C				Not Reported
Cipralex	C				Not Reported
Cymbalta	C				Not Reported
Estrace	C				Not Reported
Nucynta	C				Not Reported
Shark Liver Oil	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2016	13036530	EXPEDITED (15-DAY)		OT	CA-SA-2016SA216531		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Neutrophil Count	Hydroxychloroquine			S	Unknown	400 Mg Die		Not Reported

Decreased; Pain; Pruritus; Therapeutic Response Decreased	Leflunomide	S	Unknown			Not Reported
	Methotrexate	C	Oral	Dose And Frequency:Unknown Up To 25mg/Week Route: Po Injection		Not Reported
	Salazopyrin	C				Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	12266316	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016045430		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Increased; Drug Ineffective; Impaired Healing; Joint Range Of Motion Decreased; Joint Swelling; Lichen Planus; Musculoskeletal Pain; Rosacea; Shoulder Operation; Spinal Stenosis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Salazopyrin			S	Oral	500 Mg, Qid (Four Times Per Day)		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13038473	EXPEDITED (15-DAY)		DE, HO, OT	US-ROCHE-1867244			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Death; Infection; Nausea; Pancreatitis; Respiratory Disorder; Transaminases Increased; Treatment Failure; Vomiting	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Rituximab			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)	Not Reported
	Tumor Necrosis Factor-Tnf (Unk Ingredients)	S	Unknown	Not Reported
	Cyclophosphamide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Penicillamine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13039642	EXPEDITED (15-DAY)		DE, HO	US-HORIZON-PRE-0374-2016		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13040298	EXPEDITED (15-DAY)		HO	PHHY2016FR173133		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Novartis
	Salazopyrine			S	Oral	Unk		Not Reported
	Opdivo			S	Intravenous (not otherwise specified)	1 Df, Biw		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2016	13043215	EXPEDITED (15-DAY)		HO, LT	PHHY2016US169034		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bacteraemia; Pneumonia Cryptococcal	Hydroxychloroquine	S	Unknown		Novartis
	Hydroxychloroquine	S			Novartis
	Prednisone	S	Unknown		Not Reported
	Prednisone	S			Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	12767720	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076965		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Fibromyalgia; Foot Operation; Hand Deformity; Malaise; Myalgia; Staphylococcal Infection	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	12837587	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005064		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cinchonism; Long Qt Syndrome; Torsade De Pointes; Ventricular Tachycardia	Hydroxychloroquine			S				Concordia
	Quinine Sulfate			S				Not Reported
	Tonic Water			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	12947827	EXPEDITED (15-DAY)		OT	CA-SA-2016SA204338			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Hypersensitivity; Drug Ineffective; Petechiae	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

Arava	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	13044946	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006477		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Ineffective; Dyspnoea Exertional; Off Label Use; Pulmonary Function Test Abnormal; Shrinking Lung Syndrome; Total Lung Capacity Decreased; Vital Capacity Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2016	13045209	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2016178653		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthma; Back Pain; Bone Lesion Excision; Bronchitis; Bursa Removal; Carpal Tunnel Decompression; Diabetes Mellitus; Diarrhoea; Dry Mouth; Folliculitis; Gastrooesophageal Reflux Disease; Intervertebral Disc Degeneration; Intervertebral Disc Protrusion; Mitral Valve Prolapse; Peripheral Nerve Decompression; Postoperative Wound Infection; Restless Legs	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Unknown	20 Mg, Qhs		Not Reported
	Xeljanz Xr			S				Not Reported
	Methotrexate			S	Unknown	1.00 Cc, Qwk		Not Reported
	Methotrexate			S				Not Reported
	Folic Acid			S	Unknown	1 Mg, Qd (Once In A.M)		Not Reported
	Folic Acid			S				Not Reported
	Plaquenil			S	Unknown	200 Mg, 2 Tablets Daily (Pm)		Not Reported
	Plaquenil			S				Not Reported
	Tramadol Hcl			S	Unknown	Unk, Q4hs If Needed		Not Reported
	Tramadol Hcl			S				Not Reported

Syndrome; Toe Operation	Cyclobenzaprine Hcl	S	Unknown	5 Mg, Qhs (If Needed)	Not Reported
	Cyclobenzaprine Hcl	S	Unknown	1/2 Tab During Day As Needed	Not Reported
	Cyclobenzaprine Hcl	S			Not Reported
	Albuterol	C		Unk, 2 Puffs As Necessary	Not Reported
	Atorvastatin	C		80 Mg, Qhs	Not Reported
	Calcium	C		1200 Mg, Qd	Not Reported
	Vitamin D3	C		5000 Unit, Qd (At Breakfast)	Not Reported
	Claritin	C		10 Mg, Morning	Not Reported
	Tylenol	C		Unk Unk, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	12268251	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016045635		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Infection; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Gabapentin			C	Oral	400 Mg, Qid		Not Reported
	Ibuprofen			C		100 Mg, Bid		Not Reported
	Rosuvastatin			C		10 Mg, Qd		Not Reported
	Amitriptyline			C		150 Mg, Qd		Not Reported
	Vitamin D2			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	12757338	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004608		56 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Plaquenil			S	Oral			Concordia
	Reumaflex [Methotrexate Sodium]			C				Not Reported
	Dibase			C				Not Reported
	Folina [Folic Acid]			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13004773	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-E2B_00007929		75 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema Multiforme; Rash	Plaquenil			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Bepricor			C				Not Reported
	Eliquis			C				Not Reported
	Teprenone			C				Not Reported
	Digosin			C				Not Reported
	Onealfa			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13049746	EXPEDITED (15-DAY)		OT	CA-SA-2016SA230105		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Quinapril			C				Not Reported
	Rosuvastatin			C				Not Reported

	Hydrochlorothiazide	C				Not Reported
	Oxycodone	C				Not Reported
	Methotrexate Sodium	C	Oral			Not Reported
	Enbrel	C	Subcutaneous			Not Reported
	Sulfasalazine	C	Oral			Not Reported
	Leucovorin	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13049857	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2645		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pneumonitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13049871	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016179411		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Mobility Decreased; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13050514	EXPEDITED (15-DAY)		HO	DK-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006478		36 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer Female; Mastectomy	Plaquenil 200 Mg Tablet	S	Oral		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2016	13050520	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006464		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Neutrophil Count Decreased; Pain; Pruritus; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Salazopyrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	11183455	EXPEDITED (15-DAY)		OT	CA-ROCHE-1591481		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Rituximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8 Mg/Kg Therapy Duration: 5 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 4 Months		Not Reported
	Plaquenil			S	Unknown	400 Die		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Cortisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13053323	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016180081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Drug Ineffective; Glaucoma; Hypersensitivity; Hypoaesthesia; Joint Swelling; Rash; Tuberculosis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13054062	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dispensing Error; Wrong Product Administered	Hydroxyzine Hcl			S		Liquid Dosage Form		Not Reported
	Hydroxyurea			S		Liquid Dosage Form		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2016	13054160	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bile Duct Stenosis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Elavil /00002202/			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

	Methotrexate				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	12313024	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016052730		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Neck Injury; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		10 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	12916531	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Impaired Work Ability; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Naproxen			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	12958454	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delirium; Drug Hypersensitivity; Drug Ineffective; Petechiae	Plaquenil			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13057534	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-107955		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Opdivo			S	Intravenous drip	1 Df, Q2wk		Bristol Myers Squibb
	Salazopyrine			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Voltarene /00372302/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13057895	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015724		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13057973	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006523		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Quinapril			C				Not Reported

Rosuvastatin	C			Not Reported
Hydrochlorothiazide	C			Not Reported
Oxycodone	C			Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Enbrel	C	Subcutaneous		Not Reported
Sulfasalazine	C	Oral		Not Reported
Leucovorin	C			Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13058616	EXPEDITED (15-DAY)		HO	CA-APOTEX-2016AP015713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13058989	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015770		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Crystal Urine Present; Fungal Skin Infection; Gastrointestinal Bacterial Infection; Gastrointestinal Candidiasis; Hepatotoxicity; Hypertension; Renal Disorder; Retinal Disorder	Apo-Leflunomide			S	Unknown			Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Curcuma Zanthorrhiza			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13059013	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE			Unknown	CAN

HUNGARY KFT-
2016CA013954

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Unk		Celltrion
	Enbrel			S		50 Mg, Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Sulfasalazine Gf			S				Not Reported
	Actemra			S		640 Mg, Qwk		Not Reported
	Arava			S				Not Reported
	Ciclosporin			S				Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Imuran /00001501/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13059178	EXPEDITED (15-DAY)		HO, OT	CA-HIKMA PHARMACEUTICALS CO. LTD-2015CA012469			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Human Antichimeric Antibody Positive; Juvenile	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg, 1 Every 1 Week		Celltrion
	Infliximab Hospira			S		5 Mg/Dose, Unk		Celltrion
	Enbrel			S	Subcutaneous	12.5 Mg, Once Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Weekly		Not Reported
	Sulfasalazine			S	Oral	250 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Daily		Not Reported

Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	5 Mg/Kg, Daily	Not Reported
	Naproxen	S		Unk	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Immunoglobulin /00025201/	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Immunoglobulin /00025201/	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Daily	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
	Triamcinolone Hexacetonide	S		Unk	Not Reported
	Immunoglobulin (Ivig)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulin (Ivig)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S		250 Mg, Monthly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13059589	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015779		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Sulfasalazie			S	Unknown			Not Reported

Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra		S	Unknown			Not Reported
	Enbrel		S	Unknown			Not Reported
	Lyrica		S	Unknown			Not Reported
	Methotrexate		S	Unknown	25 Mg, Unk		Not Reported
	Orencia		S	Unknown			Not Reported
	Plaquenil /00072602/		S	Unknown			Not Reported
	Mirtazapine		C	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2016	13060287	EXPEDITED (15-DAY)		OT	CA-SA-2016SA231681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypoaesthesia; Unevaluable Event	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2016	13060593	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016180812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	10257908	NON-EXPEDITED			US-PFIZER INC-2014170977		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Food Allergy; Milk Allergy; Mite Allergy; Mycotic Allergy; Rubber Sensitivity	Dilantin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Septra			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Meperidine Hcl			S		Unk		Unknown
	Cephalexin Monohydrate			S		Unk		Not Reported
	Darvon			S		Unk		Not Reported
	Imipramine Hcl			S		Unk		Not Reported
	Oxybutynin Chloride			S		Unk		Not Reported
	Invokana			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Sitagliptin			S		Unk		Not Reported
	Amantadine			S		Unk		Not Reported
	Tegretol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	12779913	NON-EXPEDITED			US-PFIZER INC-2016447254		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Cimzia			C		Unk		Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	12783694	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1796		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Anaemia; Arthropathy; Diarrhoea; Drug Ineffective; Dry Mouth; Fall; Fatigue; Haematuria; Hand Deformity; Hypoaesthesia; Ill-Defined Disorder; Nasopharyngitis; Osteoarthritis; Paraesthesia; Peripheral Swelling; Pleural Effusion; Pneumonia; Rheumatoid Arthritis; Sinusitis; Sleep Disorder; Synovitis; Temperature Intolerance; Urinary Tract Infection; Viith Nerve Injury; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Atenolol			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported
	Cipralex			C	Unknown			Not Reported
	Vesicare			C	Unknown			Not Reported
	Myrbetriq			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Cyanocobalamine			C	Unknown			Not Reported
	Irbesartan-Hydrochlorothiazide			C	Unknown			Not Reported
	Docusate Sodium			C	Unknown			Not Reported

	Escitalopram Oxalate	C	Unknown	Not Reported
	Effexor	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	12965873	EXPEDITED (15-DAY)		OT	ALCN2016CA007711		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count Decreased	Voltaren			S	Unknown			Novartis
	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13063053	EXPEDITED (15-DAY)		OT	CA-ROCHE-1871521		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13063963	NON-EXPEDITED			US-PFIZER INC-2016590869		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Trimethoprim			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13063985	NON-EXPEDITED			US-PFIZER INC-2016599196		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2016	13065618	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-109285		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown	1 Df, Qwk (25 Millicuries)		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

			Ibuprofen	C	Unknown				Not Reported
			Morphine	C	Unknown				Not Reported
			Sulfonamide	C	Unknown				Not Reported
			Pertussis Vaccine	C	Unknown				Not Reported
			Prednisone	C	Unknown	20 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	13067999	EXPEDITED (15-DAY)		HO	AR-ROCHE-1870231			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Disorder; Cardiac Disorder; Dyspepsia; Fatigue; Herpes Zoster; Neoplasm; Nodule; Off Label Use; Oral Disorder; Pneumonia; Pneumonitis; Pruritus; Renal Failure; Transaminases Increased; Urinary Tract Infection	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2016	13069156	NON-EXPEDITED			US-PFIZER INC-2016588470		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13043937	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006421		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bacteraemia; Cryptococcal Fungaemia; Dyspnoea; Lung Infiltration; Lung Opacity; Metabolic Acidosis; Pneumonia Cryptococcal; Productive Cough; Pulmonary Mass; Pyrexia; Tachycardia; Tachypnoea	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13070791	NON-EXPEDITED			US-AMGEN-USASL2016182058		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Activity; Drug Ineffective; Haemoglobin Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cataflam			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13070813	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007955		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diabetes Mellitus; Joint Swelling; Lower Respiratory Tract Infection; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2016	13074092	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

INC.-GSH201612-006544

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Hypoaesthesia; Unevaluable Event	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	12844852	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20161008783		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated	Infliximab, Recombinant			S	Intravenous (not otherwise specified)	Weeks 2		Not Reported
	Prednisone			S	Unknown	Start Date Was Before 2005		Not Reported
	Methotrexate			S	Unknown	Start Date Before 2005		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Amphotericin B			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Between 2005 To 2006		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13074192	EXPEDITED (15-DAY)		OT	GR-ROCHE-1873300			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Prostate Cancer	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

		Mycophenolate Mofetil			S	Unknown					Not Reported
		Mycophenolate Mofetil			S						Not Reported
		Prednisolone			S	Unknown					Not Reported
		Prednisolone			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13074480	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2016-2783		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hepatic Enzyme Increased; Pyrexia; Streptobacillus Test Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulphasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13075096	EXPEDITED (15-DAY)		OT	US-ZYDUS-013002		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Maculopathy; Renal Impairment; Retinal Degeneration; Retinal Depigmentation; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13076221	EXPEDITED (15-DAY)		OT	CA-SA-2016SA235900		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Rituxan		S	Unknown		Not Reported
	Sulfasalazine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2016	13077006	EXPEDITED (15-DAY)		OT	CA-SA-2016SA237184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2016	12475855	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016077323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hip Arthroplasty; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2017	12930172	EXPEDITED (15-DAY)		OT	US-ABBVIE-16K-163-1770906-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Fibrillation; Drug Ineffective; Peripheral Swelling; Rheumatoid Arthritis; Sleep Apnoea Syndrome; Vertigo	Humira 40mg/0.8ml	S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml	S				Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	11 Mg One Tablet Every Day		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Oral	17.5 Mg Every Week		Not Reported
	Methotrexate	S	Unknown	2.5 Mg, Every Week		Not Reported
	Coumadin	C		3 Mg Every Day		Not Reported
	Sotalol	C		80 Mg, One Half Tablet Thrice A Day		Not Reported
	Prednisone	C		10 Mg, As Necessary		Not Reported
	Folic Acid	C		1 Mg, Every Week		Not Reported
	Tylenol	C		As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2017	13020884	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Disturbance; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tooth Infection	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Simponi			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Meloxicam			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2017	13077914	EXPEDITED (15-DAY)		DE	GR-ROCHE-1873299			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm Malignant	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2017	13078191	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2016183861		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2017	13079138	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006574		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Every Other Week		Not Reported
	Methotrexate			S	Oral			Not Reported

Decreased	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	11872379	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015377610		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Constipation; Dyspepsia; Emotional Disorder; Herpes Zoster; Multiple Sclerosis; Musculoskeletal Stiffness; Nausea; Pain; Porphyria Acute; Product Dose Omission	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Arava			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13074333	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0512		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13079446	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13079468	EXPEDITED (15-DAY)		HO	GB-ABBVIE-17K-167-1827230-00		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Aspirin			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Colecalciferol			C				Not Reported
	Ferrous Fumarate			C				Not Reported
	Folic Acid			C				Not Reported
	Gliclazide			C				Not Reported
	Metformin			C				Not Reported
	Ramipril			C				Not Reported
	Sitagliptin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13079523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1874033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased;	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported

Thyroid Disorder	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13080045	NON-EXPEDITED			US-AMGEN-USASP2016185222			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Advair			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Astelin			S	Unknown			Not Reported
	Azelastine			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Boniva			S	Unknown	Unk		Not Reported
	Chlorthalidone			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Ferrous Sulfate			S	Unknown	Unk		Not Reported
	Flonase			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Klor-Con			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Salicylates			S	Unknown	Unk		Not Reported
	Sulfa			S	Unknown	Unk		Not Reported
	Tiotropium			S	Unknown	Unk		Not Reported
	Xolair			S	Unknown	Unk		Not Reported

	Omnaris	C	Unk		Not Reported
	Methotrexate	C	Unk		Not Reported
	Vitamin D2	C	Unk		Not Reported
	Folic Acid	C	Unk		Not Reported
	Serevent	C	Unk		Not Reported
	Pramipexole	C	Unk		Not Reported
	Doxepin	C	Unk		Not Reported
	Zyflo	C	Unk		Not Reported
	Latanoprost	C	Unk		Not Reported
	Gabapentin	C	Unk		Not Reported
	Flovent	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13080969	EXPEDITED (15-DAY)		OT	CA-SA-2016SA001593			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13081859	NON-EXPEDITED			US-PFIZER INC-2016601466		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2017	13084598	DIRECT	Y	OT			29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pruritus; Rash; Vomiting	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	12539294	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016025660		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk 8 Tablets		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Oral	600 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C		Unk Unk, As Necessary		Not Reported
	Folic Acid			C		1.0 Df, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13057835	NON-EXPEDITED			US-AMGEN-USASP2016180585		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13057984	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006522		41 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Biopsy Heart Abnormal; Cardiac Failure Acute; Cardiotoxicity	Hydroxychloroquine	S	Unknown		Not Reported
	Mycophenolate	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Tacrolimus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13065791	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016296980		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13085169	EXPEDITED (15-DAY)		CA	DE-BAYER-2016-240760			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brachycephaly; Camptodactyly Congenital; Coloboma; Craniofacial Deformity; Exposure During Pregnancy; External Auditory Canal Atresia; Hypertelorism Of Orbit; Microtia; Oesophageal Atresia; Olfactory Nerve Agenesis; Retrognathia; Right Aortic Arch	Acetylsalicylic Acid			S		Unk		Bayer
	Mycophenolate Mofetil			S		0.75 Unk, Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13085292	EXPEDITED (15-DAY)		OT	CA-SA-2016SA238080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Hip Arthroplasty; Rash; Retinal Deposits	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13085875	EXPEDITED (15-DAY)		HO	CA-TEVA-725357USA		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Condition Aggravated; Pyrexia; Synovitis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13086098	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017002948		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2017	13088033	DIRECT	Y	RI				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Product Substitution Issue	Hydroxychloroquin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	10563681	NON-EXPEDITED			US-PFIZER INC-2014302866		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Oxycodone			S		Unk		Pfizer
	Metoclopramide Hcl			S		Unk		Pfizer
	Tramadol Hcl			S		Unk		Pfizer
	Lovenox			S		Unk		Not Reported
	Torsemide			S		Unk		Not Reported
	Lasix			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Dilaudid Cough Syrup			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Quinidine			S		Unk		Not Reported
	Magnesium Sulfate			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Fenoprofen Calcium			S		Unk		Not Reported
	Nifedipine			S		Unk		Not Reported
	Phentolamine			S		Unk		Not Reported
	Pravastatin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13087078	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0453		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Constipation; Crying;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Dyspepsia; Emotional Disorder; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Porphyria Acute	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Plaquenil		S	Oral		Not Reported
	Arava		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13090169	EXPEDITED (15-DAY)		HO	CA-FRESENIUS KABI-FK201700118		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hepatic Enzyme Increased; Pyrexia; Synovitis	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Sulphasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2017	13090688	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000004		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysaesthesia; Hypoaesthesia; Neuropathy Peripheral	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	11812850	EXPEDITED (15-DAY)		OT	CA-ROCHE-1377756		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Cataract; Drug Ineffective; Epistaxis; Granulomatosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Last Dose Of Rituximab: 04/Jun/2014		Not Reported

With Polyangiitis; Haemoptysis; Heart Rate Decreased; Infusion Related Reaction; Injection Site Extravasation; Injection Site Pain; Pain; Sciatica; Sinusitis; Somnolence; Spinal Disorder; Vein Disorder; Weight Decreased; Weight Increased; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Oracort (Canada)	S	Unknown	Not Reported
	Oracort (Canada)	S	Unknown	Not Reported
	Benadryl (Canada)	S	Oral	Not Reported
	Benadryl (Canada)	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Tylenol	C	Oral	Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	Not Reported
	Premarin	C		Not Reported
	Rabeprazole	C		Not Reported
	Synthroid	C		Not Reported
	Lyrica	C		Not Reported
	Warfarin	C		Not Reported
	Pramipexole	C		Not Reported
	Vitamin K	C		Not Reported
	Vitamin B12	C		Not Reported
	Vitamin B6	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Domperidone	C		Not Reported
	Paxil (Canada)	C		Not Reported
	Oxyneo	C		Not Reported
	Methotrexate	C		Not Reported
	Clonazepam	C		Not Reported
	Apo-Risedronate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	12108355	EXPEDITED (15-DAY)		OT	CA-ROCHE-1617835		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Actemra	S	Unknown	Last Dose Was Received On 09/Jul (Year Unspecified)	Not Reported
	Leflunomide	S	Unknown	Contraindicated - Severe Hepatic Steatosis And Transaminases	Not Reported
	Hydroxychloroquine	S	Unknown	No Efficacy	Not Reported
	Methotrexate	S	Unknown	Contraindicated - Severe Hepatic Steatosis And Transaminases Severe Side Effects Including Diarrhea,	Not Reported
	Enbrel	S	Subcutaneous	Lack Of Efficacy	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	No Efficacy, Failed	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13024481	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016525864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rash; Seizure	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Plaquenil			S		400 Mg, Unk		Not Reported
	Arava			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13089430	NON-EXPEDITED			US-PFIZER INC-2016602672		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enalaprilat			S		Unk		Unknown
	Erythromycin			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer

Abatacept	S	Unk	Not Reported
Tylenol	S	Unk	Not Reported
Advair	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Astelin	S	Unk	Not Reported
Azelastine	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Boniva	S	Unk	Not Reported
Chlorthalidone	S	Unk	Not Reported
Enbrel	S	Unk	Not Reported
Ferrous Sulfate	S	Unk	Not Reported
Flonase	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported
Ibandronate	S	Unk	Not Reported
Klor-Con	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Losartan	S	Unk	Not Reported
Omalizumab	S	Unk	Not Reported
Orencia	S	Unk	Not Reported
Tiotropium	S	Unk	Not Reported
Xolair	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13091006	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP016262		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Apo Folic Acid			S	Unknown	1 Df, B.I.Wk.		Not Reported
	Apo-Gabapentin			S	Unknown			Apotex
	Apo Prednisone Tab 5mg			S	Unknown	5 Mg, Qd		Apotex

	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Nexium /01479302/	S	Unknown	40 Mg, Qd		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13091577	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875078		50 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13092269	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017003974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain; Peripheral Swelling; Stevens-Johnson Syndrome	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13092270	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017003981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Neuropathy Peripheral; Osteoarthritis; Rheumatoid Arthritis	Sulfasalazine			S	Unknown			Pfizer
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, 2x/Day		Not Reported
	Actonel			C		135 Mg, Weekly		Not Reported
	Advair			C				Not Reported
	Amlodipine			C		5 Mg, Daily		Not Reported
	Ascorbic Acid			C		1000 Mg, Daily		Not Reported
	Aspirin /00002701/			C		81 Mg, Daily		Not Reported
	Calcium			C		500 Mg, 2x/Day		Not Reported
	Citalopram			C		30 Mg, Daily		Not Reported
	Ascorbic Acid, Copper Sulfate, Cyanocobalamin, Ferrous Gluconate, Foli			C				Not Reported
	Enbrel			C				Not Reported
	Ergocalciferol			C		3000 Df, Daily		Not Reported
	Ferrous Gluconate			C		300 Mg, Daily		Not Reported
	Folic Acid			C		Unk, Daily		Not Reported
	Hydrochlorothiazide			C		25 Mg, Daily		Not Reported
	Olmesartan Medoxomil			C		40 Mg, Daily		Not Reported
	Oxybutynin			C		2.5 Mg, Daily		Not Reported
	Prednisone			C		9 Mg, Daily		Not Reported
	Rabeprazole			C		20 Mg, Daily		Not Reported
	Senna Alexandrina			C				Not Reported
	Vitamin B12 /00056201/			C	Sublingual	1500 Mg, Daily		Not Reported
	Tiotropium Bromide			C				Not Reported
	Tylenol /00020001/			C		Unk Unk, 4x/Day		Not Reported

Zinc Gluconate	C	25 Mg, Daily	Not Reported
Zopiclone	C	7.5 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2017	13094326	NON-EXPEDITED			US-PFIZER INC-2017004353		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Cleocin			S		Unk		Pfizer
	Avelox			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Ofloxacin			S		Unk		Not Reported
	Vimovo			S		Unk		Not Reported
	Cortisporin-Tc			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2017	13095119	EXPEDITED (15-DAY)		OT	PT-GRANULES INDIA LIMITED-1061691		48 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Decreased Appetite; Hyperbilirubinaemia; Nausea; Systemic Lupus Erythematosus	Naproxen Sodium			S				Granules India
	Deflazacort			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	12582026	NON-EXPEDITED			US-AMGEN-USASP2016093632		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	12968028	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2016163631		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blindness; Drug Ineffective; Drug Intolerance; Headache; Infection; Insomnia; Mobility Decreased; Muscle Spasms; Myalgia; Oedema; Osteoarthritis; Pain; Paraesthesia; Rheumatoid Arthritis; Scleroderma; Sjogren'S Syndrome; Snoring	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mtx			S	Oral	2.5 Mg, Qwk Take 8 Tablet Every Week		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Atenolol			C	Oral	50 Mg, Qd		Not Reported
	Diazepam			C	Oral	5 Mg, Tid		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Lyrica			C	Oral	75 Mg, Bid		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported
	Tizanidine			C	Oral	4 Mg, Tid		Not Reported
	Tramadol			C	Oral	50 Mg, Q6h As Needed		Not Reported
	Tramadol			C	Unknown	50 Mg, Qid		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13095655	EXPEDITED (15-DAY)		HO, OT	FR-ROCHE-1875545		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Off Label Use; Peritonitis; Product Use In Unapproved Indication	Roactemra			S	Subcutaneous			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cortancyl			C	Oral			Not Reported
	Speciafoldine			C	Unknown	2 Tablets On Saturdays And Sundays		Not Reported
	Xanax			C	Unknown			Not Reported
	Effexor			C	Unknown			Not Reported
	Inexium			C	Unknown			Not Reported
	Levothyrox			C	Unknown			Not Reported
	Hyzaar			C	Unknown	50/12.5 Mg		Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13095808	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000008		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Cardiac Disorder; Dyspnoea; Heart Rate Increased	Plaquenil			S	Oral			Concordia
	Rituximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13095813	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13098319	EXPEDITED (15-DAY)		HO	FR-MEDAC PHARMA, INC.-1061808		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Peritonitis; Product Use Issue	Metoject			S	Subcutaneous			Medac
	Roactemra			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Xanax			C				Not Reported
	Effexor Xr			C				Not Reported
	Esomeprazole Magnesium			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Hyzaar			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13099202	EXPEDITED (15-DAY)		OT	PHHY2016US181713		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Enterobacter Infection	Prednisone			S	Unknown	15 Mg, Qd		Novartis
	Methotrexate			S	Unknown	12 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	11512153	EXPEDITED (15-DAY)		OT	CA-ROCHE-1633524		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; C-Reactive Protein Increased; Drug Dependence; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Liver Disorder; Lung Disorder; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Cortisone	S	Oral	Not Reported
	Desoximetasone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	12367962	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016057834		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Gastric Disorder; Interstitial Lung Disease; Lung Disorder; Pneumonitis; Polyarthritis; Rheumatoid Arthritis; Treatment Failure; Unevaluable Event	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Not Reported
	Plaquenil			S	Unknown	200 Mg, Daily		Not Reported
	Sulfasalazine			S	Unknown	1 G, Three Times Daily		Not Reported
	Folic Acid			C		5 Mg, Cyclical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	12441073	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016068795		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Surgery; Joint Swelling; Knee Arthroplasty; Pain; Therapeutic Response Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Gold			S	Unknown	Unk		Not Reported

	Celebrex			C	Oral	Unk			Not Reported
	Clindamycin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13099669	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017002516		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Enbrel			S	Unknown	Unk		Amgen
	Cortisone			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13099777	EXPEDITED (15-DAY)		OT	CA-ROCHE-1595142		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Rituxan			S	Intravenous (not otherwise specified)	Cyclical, Therapy Duration: 8 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Went Up To 25 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown			Not Reported
	Orencia	S	Unknown	Did Not Work Therapy Duration: 3 Years		Not Reported
	Plaquenil	S	Unknown	Therapy Duration: 3 Years		Not Reported
	Actonel	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13100433	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017002406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Weekly		Amgen
	Sulfasalazine			S	Oral	1 G, Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Prednisone			C	Oral	5 Mg, Unk		Not Reported
	Prednisone			C		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13102640	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1001713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Mylan
	Leflunomide			S		20 Mg, Q2d		Mylan
	Folic Acid			C				Mylan
	Prednisone			C				Mylan
	Tylenol /00020001/			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13102667	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1001716			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Treatment Failure	Methotrexate			S				Not Reported
	Actemra			S				Mylan
	Arava			S				Mylan
	Cellcept /01275102/			S				Mylan
	Enbrel			S				Mylan
	Gold			S				Mylan
	Humira			S				Mylan
	Lyrica			S	Oral			Mylan
	Orencia			S				Mylan
	Plaquenil /00072602/			S				Mylan
	Remicade			S				Mylan
	Rituxan			S				Mylan
	Simponi			S				Mylan
	Sulfasalazine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	13102687	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1001726			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis; Liver Disorder	Methotrexate			S				Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Mylan
	Leflunomide			S	Oral	20 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13073791	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016597963		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Gait Inability; Spinal Osteoarthritis	Methotrexate Sodium			S		Unk, Weekly		Unknown
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, 1x/Day		Not Reported
	Allopurinol			C	Oral	300 Mg, 1x/Day		Not Reported
	Colchicine			C		0.6 Mg, 2x/Day		Not Reported

	Temisartan	C		40 Mg, 1x/Day	Not Reported
	Asa	C		81 Mg, 1x/Day	Not Reported
	Furosemide	C		40 Mg, 2x/Day (2 Tablets (Am And One Tablet At Noon)	Not Reported
	Kcl	C	Oral	32 Mg, 1x/Day	Not Reported
	Esmep	C	Oral	Unk Unk, 1x/Day	Not Reported
	Magnesium	C	Oral	100 Mg, Unk	Not Reported
	Furosemide	C	Oral	160 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13104179	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Deposits	Plaquenil			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Gold			C				Not Reported
	Rituxan			C				Not Reported
	Certolizumab Pegol			C				Not Reported
	Humira			C				Not Reported
	Enbrel			C				Not Reported
	Motrin			C				Not Reported
	Xeljanz			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13105145	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017010160		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cortisone			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

		Plaquenil			S	Unknown	Unk			Not Reported
		Voltaren			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2017	13106710	EXPEDITED (15-DAY)		DE, OT	US-ABBVIE-17P-163-1836427-00		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Respiratory Arrest; Rhabdomyolysis; Serotonin Syndrome	Levothyroxine			S	Oral			Not Reported
	Tranylcypromine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported
	Sertraline			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	12972001	EXPEDITED (15-DAY)		DS	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005888		52 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Blindness; Ocular Toxicity; Retinal Injury; Visual Impairment	Plaquenil Tablet			S				Concordia
	Plaquenil Tablet			S				Concordia
	Mercaptopurine			C				Not Reported
	Zantac			C				Not Reported
	Singulair			C				Not Reported
	Periactin			C				Not Reported
	Omeprazole			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13107435	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS		55 YR	Female	FRA

						INC.-GSH201701-000051			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Peritonitis	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Roactemra			S	Subcutaneous			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Speciafoldine			C				Not Reported
	Effexor Lp			C				Not Reported
	Levothyrox			C				Not Reported
	Hyzaar			C				Not Reported
	Cortancyl			C				Not Reported
	Xanax			C				Not Reported
	Inexium			C				Not Reported
	Paracetamol			C				Not Reported
	Debridat			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13107603	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Hip Arthroplasty; Rash; Retinal Deposits	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13107657	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000027			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angioedema	Plaquenil			S	Unknown				Concordia
	Arava			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2017	13109188	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105848			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	12807341	EXPEDITED (15-DAY)		OT	CA-SA-2016SA068804		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Arthralgia; Arthritis; Cardiac Failure Congestive; Drug Ineffective; Dyspnoea; Eye Disorder; Joint Swelling; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Toxicity;	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown	20mg/D M-W-F, 10mg/D 4x/Wk		Not Reported
	Arava			S	Unknown	20mg/D M-W-F, 10mg/D 4x/Wk		Not Reported
	Arava			S	Unknown	20mg/D M-W-F, 10mg/D 4x/Wk		Not Reported
	Arava			S	Unknown	20mg/D M-W-F, 10mg/D 4x/Wk		Not Reported

Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vascular Graft	Sulfasalazine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Omega 3		C			Not Reported
	Vitamin B12		C			Not Reported
	Endocet		C		5 + 325mg Tablet	Not Reported
	Indomethacin		C			Not Reported
	Pennsaid		C			Not Reported
	Oxycocet		C		2 Tabs 4-5 X/Week	Not Reported
	Asa		C			Not Reported
	Naprelan		C		1000mg 1-2x/Mth	Not Reported
	Metoprolol		C			Not Reported
	Folic Acid		C		5mg 3x/Wk	Not Reported
	Bisoprolol		C			Not Reported
	Lax-A-Day		C			Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13107464	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000023		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Every Other Week		Not Reported
	Sitagliptin			C				Not Reported
	Gliclazide			C				Not Reported
	Aspirin			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Colecalciferol			C				Not Reported
	Ferrous Fumarate			C				Not Reported
	Folic Acid			C				Not Reported
	Metformin			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13111910	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-131191		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Bacterial Infection	Prednisone			S	Unknown	Unk		Mutual
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13111996	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001277		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Cimzia			S		Unk		Ucb
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Estradiol			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Valsartan			C		Unk		Not Reported
	Xalatan			C		Unk		Not Reported
	Dorzolamide Hcl And Timolol Maleate			C		Unk		Not Reported

	Baclofen			C		Unk				Not Reported
	Levaquin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13112074	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000127		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Oedema Peripheral; Urticaria	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13112137	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000130		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Baraclude			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13112331	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2013031232		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Abnormal; Hepatotoxicity; Interstitial Lung Disease; Treatment	Enbrel			S	Subcutaneous	25 Mg, Bid Weekly		Amgen
	Orencia			S	Unknown	1000 Mg, Unk (For 94 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qwk		Not Reported

Failure	Hydroxychloroquine	S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13112439	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878400		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Injection		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Ativan			C				Not Reported
	Benadryl (Canada)			C				Not Reported
	Codeine			C				Not Reported
	Cortisone			C				Not Reported
	Dilaudid			C	Unknown			Not Reported
	Enablex			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog (Canada)			C	Unknown	Suspension For Injection		Not Reported
	Kineret			C	Unknown			Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported

	Norflex			C					Not Reported
	Omnaris			C					Not Reported
	Oxyneo			C	Unknown				Not Reported
	Pantoloc			C	Unknown				Not Reported
	Restasis			C					Not Reported
	Rituxan			C	Unknown				Not Reported
	Synthroid			C					Not Reported
	Trimethoprim			C	Unknown				Not Reported
	Urispas			C	Unknown				Not Reported
	Vagifem			C	Unknown				Not Reported
	Dexamethasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13113124	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0141		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13113802	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006073		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea;	Arava			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Synovitis	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Salazopyrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13113848	EXPEDITED (15-DAY)		OT	CA-SA-2016SA051029			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Form:Subcutaneous Solution Frequency:1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	Form:Solution Subcutaneous		Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2017	13114935	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170105867			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Retinitis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Sulfasalazine			S	Oral	Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2017	13115818	EXPEDITED (15-DAY)		DE	US-ALVOGEN-2017-ALVOGEN-091012		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Lisinopril			S	Oral			Not Reported
	Tranylcypromine			S	Oral			Not Reported
	Olanzapine			S	Oral			Not Reported
	Sertraline			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Buspirone			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	12275677	EXPEDITED (15-DAY)		HO	CA-ROCHE-1741799		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bronchitis; Cystitis; Diarrhoea; Dizziness; Nausea; Pneumonia; Urinary Tract Infection	Esbriet			S	Unknown			Not Reported
	Esbriet			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	For 6 Months		Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13079161	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000001		53 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Visual Field Defect	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13099549	EXPEDITED (15-DAY)		DE, LT, OT	IN-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000014		13 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Biopsy Bone Marrow Abnormal; Erythema; Hepatosplenomegaly; Hilar Lymphadenopathy; Histoplasmosis Disseminated; Lymphadenopathy; Productive Cough; Pulmonary Alveolar Haemorrhage; Pulmonary Hypertension; Pyrexia; Rash Maculo-Papular; Septic Shock	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13116244	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP005509		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Myoclonus; Respiratory	Olanzapine			S	Oral			Apotex

Arrest; Rhabdomyolysis; Serotonin Syndrome; Unresponsive To Stimuli	Lisinopril		S	Oral	Apotex
	Sertraline Hydrochloride		S	Oral	Apotex
	Amlodipine Besylate		S	Oral	Apotex
	Buspiprone Hydrochloride Tablets Usp		S	Oral	Apotex
	Tranylcypromine		S	Oral	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Levothyroxine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13116927	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878962		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13118633	EXPEDITED (15-DAY)		DE, HO	US-LEHIGH_VALLEY-USA-POI0580201700067		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Blood Potassium Increased; Blood Pressure Systolic Increased; Body Temperature Decreased; Bundle Branch Block; Completed Suicide; Extensor Plantar	Levolet (Levothyroxine)			S				Lehigh Valley Tech
	Tranylcypromine			S				Not Reported
	Olanzapine			S				Not Reported
	Lisinopril			S				Not Reported
	Sertraline			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Amlodipine			S				Not Reported

Response; Gastrointestinal Sounds Abnormal; Hyperthermia; Intentional Overdose; Muscle Twitching; Myoclonus; Respiratory Arrest; Rhabdomyolysis; Serotonin Syndrome	Buspirone			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13118865	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1835812-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Amlodipine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13119166	EXPEDITED (15-DAY)		OT	CA-CANTON LABORATORIES, LLC-1062053			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Naprosyn			S	Oral			Canton Laboratories
	Rituximab			S				Not Reported
	Kineret			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Vioxx (Rofecoxib)	S	Unknown		Not Reported
	Leflunomide	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2017	13119346	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1431760-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13028484	NON-EXPEDITED			US-PFIZER INC-2016577872		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Diarrhoea; Dyspepsia; Eructation; Flatulence; Gastrooesophageal Reflux Disease; Malaise; Nervousness; Vomiting	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Pravastatin			C		20 Mg, 1x/Day		Not Reported
	Lisinopril			C		10 Mg, 1x/Day		Not Reported
	B6			C		100 Mg, Unk		Not Reported
	B6			C		100 Mg, Unk		Not Reported
	D3			C		1000 Iu, Unk		Not Reported
	Omeprazole			C		20 Mg, 1x/Day (In		Not Reported

						Morning)			
	Docusate Sodium			C		100 Mg, 2x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13103011	EXPEDITED (15-DAY)			CA-PFIZER INC-2017004243		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Joint Swelling	Atorvastatin Calcium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Hydroxychloroquine /00072603/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Triazide (Trichlormethiazide)			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13119763	EXPEDITED (15-DAY)		HO, OT	US-RANBAXY-2014US-83831		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Substance-Induced Psychotic Disorder	Ciprofloxacin			S	Unknown	750 Mg, Bid		Sun
	Hydroxychloroquine			S	Unknown	300 Mg, Daily		Not Reported
	Rifampin			S	Unknown	600 Mg, Daily		Not Reported
	Doxycycline			C	Unknown	100 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120092	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000380		1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Plaquenil 200 Mg			S	Transplacental			Concordia

Pregnancy; Leukopenia; Lymphopenia; Neutropenia	Cortancyl			S	Transplacental	Not Reported
	Kardegic			S	Transplacental	Not Reported
	Imurel			S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13120332	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1777388-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Therapeutic Response Decreased; Therapeutic Response Decreased; Therapeutic Response Decreased; Therapeutic Response Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Coversyl			C				Not Reported
	Vitamin D2			C				Not Reported
	Leucovorin			C				Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13121002	EXPEDITED (15-DAY)		OT	CA-SA-2017SA005977		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Arava			S	Unknown	Not Reported
	Humira			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13121232	EXPEDITED (15-DAY)		HO	CA-SA-2017SA006177		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Pneumonitis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13121306	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006034		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not	Every 4 Week.		Not Reported

Arthritis; Therapeutic Response Decreased			otherwise specified)			
	Methotrexate Sodium	S	Oral	Qwk.		Not Reported
	Methotrexate Sodium	S	Oral	Qweek.		Not Reported
	Methotrexate Sodium	S	Oral	Qwk.		Not Reported
	Leucovorin	C	Unknown			Not Reported
	Vitamin D2	C	Unknown			Not Reported
	Coversyl	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13121927	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201701004214		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Constipation; Dactylitis; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Psoriasis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect Incomplete	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Amitriptyline			S	Unknown	Unk, Unknown		Not Reported
	Lyrica			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unknown		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Clonazepam			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Ergocalciferol			C				Not Reported
	Tylenol /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2017	13122723	EXPEDITED (15-DAY)		OT	CA-SA-2016SA088980		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13095812	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000020		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Mass; Breast Pain; Granuloma; Histoplasmosis; Lymph Node Palpable; Mastitis	Hydroxychloroquine			S	Unknown			Concordia
	Methylprednisolone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Enalapril			C				Not Reported
	Metoprolol			C				Not Reported
	Calcium Carbonate			C				Not Reported

		Ergocalciferol			C					Not Reported
		Aspirin			C					Not Reported
		Venlafaxine			C					Not Reported
		Omeprazole			C					Not Reported
		Ipratropium			C	Nasal				Not Reported
		Colchicine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13123938	EXPEDITED (15-DAY)		OT	CA-ROCHE-1783077		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown	More Than 3 Month		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13123980	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880397		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124063	EXPEDITED (15-DAY)		OT	CA-CONCORDIA		59 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124274	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000418		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arthrotec			S	Oral			Not Reported
	Tylenol			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124323	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1431033-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Ineffective; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Humira 40mg/0.8ml	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124372	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000466		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Pneumonitis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13124600	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000468		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported

Congestion; Rhinorrhoea; Synovitis	Enbrel			S	Unknown				Not Reported
	Cimzia			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Salazopyrin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13126877	NON-EXPEDITED			US-ROCHE-1781486			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	14 Dyas, 28 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13128406	NON-EXPEDITED			GXBR2016US003449			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Malaise	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Unk		Novartis
	Pilocarpine			C	Unknown	Unk Df, Unk		Not Reported
	Diuretics			C	Unknown	Unk Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13128601	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1835469-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Ciclosporin			S	Unknown					Not Reported
	Cimzia			S	Subcutaneous					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported
	Imuran			S	Unknown					Not Reported
	Infliximab			S	Intravenous (not otherwise specified)					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2017	13128615	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1835553-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	11310654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1431751-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Lung Disorder	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Intravenous (not otherwise specified)					Not Reported
	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13017310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016570836		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Methotrexate Sodium			S	Oral	17.5-25 Mg		Pfizer
	Leflunomide			S		Lower Dose Than 20 Mg		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Plaquenil /00072603/			S		400 Mg, 1x/Day		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13055383	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA230918		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Daily Dose-Lower Dose Than 20 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Daily Dose-17.5-25 Mg		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13107816	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-TREX2017-0126		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Joint Stiffness; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Unknown				Not Reported
	Atorvastatin Calcium			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Lyrica			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Triazide (Trichlormethiazide)			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13128737	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000475		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13128853	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000494		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			C				Not Reported

		Atasol (Acetaminophen)			C						Not Reported
		Acetaminophen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13128904	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000493		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Leucovorin			C				Not Reported
	Vitamin D2			C				Not Reported
	Coversyl			C				Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13128968	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007994			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13128997	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000498		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown	50 Milligram(S); Weekly		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown	2.5 Milligram(S);Weekly		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Atenolol			C				Not Reported
	Irbesartan			C				Not Reported
	Nitroglycerin			C				Not Reported
	Loratadine			C				Not Reported
	Lipitor			C				Not Reported
	Imovane			C				Not Reported
	Plavix			C				Not Reported
	Cipralex			C				Not Reported
	Vesicare			C				Not Reported
	Myrbetriq			C				Not Reported
	Omnaris			C				Not Reported
	Aspirin			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Hydrochlorothiazide Irbesartan			C				Not Reported
	Docusate Sodium			C				Not Reported

		Escitalopram Oxalate			C					Not Reported
		Effexor			C					Not Reported
		Clopidogrel Bisulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13129031	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000289		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13129393	EXPEDITED (15-DAY)		OT	CA-ROCHE-1775934		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis	Actemra			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13129487	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000413			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Plaquenil			S	Unknown			Concordia

Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Xeljanz		C		Not Reported
	Hydroxychloroquine Sulfate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13129650	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000514		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Dorzolamide Hydrochloride Timolol Maleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13129905	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000492		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; Vomiting; X-Ray Abnormal	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2017	13131559	EXPEDITED (15-DAY)		OT	CA-SA-2017SA008740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Seizure	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	12235467	EXPEDITED (15-DAY)		DS	CA-BAXTER-2016BAX016534		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme	Metronidazole 5mg/Ml Injection			S	Unknown			Baxter
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported

Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Celebrex		S	Oral	Not Reported
	Demerol		S	Unknown	Not Reported
	Erythromycin		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Levofloxacin		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Norfloxacin		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	12831625	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005046		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Arthralgia; Arthritis; Cardiac Failure Congestive; Drug Ineffective; Dyspnoea; Eye Disorder; Joint Swelling; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vascular Graft	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Vitamin B12			C				Not Reported
	Endocet			C				Not Reported
	Indomethacin			C				Not Reported
	Pennsaid			C				Not Reported
	Oxycocet			C				Not Reported
	Asa			C				Not Reported
	Naprelan			C				Not Reported
	Metoprolol			C				Not Reported

	Folic Acid			C						Not Reported
	Bisoprolol			C						Not Reported
	Lax A Day			C						Not Reported
	Prednisone			C						Not Reported
	Omega 3			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13132922	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Enbrel			S	Unknown			Not Reported
	Sulfasalazin			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13132963	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000410			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blister; Drug Ineffective; Drug Ineffective; Malaise; Pain; Weight Decreased	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13133030	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000573		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased; Therapy Non-Responder	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2017	13135476	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1002604			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lyme Disease; Skin Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2017	13136438	EXPEDITED (15-DAY)		HO	US-ABBVIE-17K-163-1838584-00		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Eruption; Drug Ineffective; Fatigue; Femur Fracture; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2017	13136523	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000384		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fistula; Rash; Systemic Lupus Erythematosus	Plaquenil			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Cymbalta			C				Not Reported
	Gabapentin			C				Not Reported
	Albuterol			C				Not Reported
	Simvastin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	12269147	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201604001774		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Feeling Hot; Gait Inability; Immunisation Reaction; Loss Of Personal Independence In Daily Activities; Ocular Vascular Disorder; Off Label Use; Ophthalmic Vein Thrombosis; Pain; Pain In Extremity; Pyrexia; Therapeutic Response Decreased; Thrombosis; Vaccination Complication	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly (1/W)		Not Reported
	Zostavax			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			C	Oral	20 Mg, Weekly (1/W)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	12310120	EXPEDITED (15-DAY)			DE-SA-2016SA075499			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy	Arava			S	Oral				Not Reported
	Quensyl			S	Oral				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	L-Thyroxin			S	Oral				Not Reported
	Folic Acid			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13029262	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2581		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Methotrexate (Trade Name Unknown)			S	Oral	17.5-25 Mg		Not Reported
	Leflunomide			S	Unknown	Lower Dose Than 20 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13125511	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170113383		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia;	Ultram Er			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Rubramin Pc			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S	Unknown			Not Reported

Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Joint Swelling; Mental Impairment; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Visual Impairment; Vomiting; Wheezing	Arava	S	Unknown	Not Reported
	Ampicillin	S	Unknown	Not Reported
	Zyrtec	S	Unknown	Not Reported
	Isordil	S	Unknown	Not Reported
	Erythromycin	S	Unknown	Not Reported
	Iron	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Geodon	S	Unknown	Not Reported
	Antivert	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Colchicine	S	Unknown	Not Reported
	Compazine	S	Unknown	Not Reported
	Cyclosporin	S	Unknown	Not Reported
	Diamox	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Dyazide	S	Unknown	Not Reported
	Hepatitis B Vaccine	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Lasix	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Potassium	S	Unknown	Not Reported
	Sudafed	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Trileptal	S	Unknown	Not Reported
	Zenpep	S	Unknown	Not Reported

Nasocort	C	Unknown	Not Reported
Vicodin	C	Unknown	Not Reported
Tamiflu	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Zoloft	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Advair	C	Unknown	Not Reported
Lamictal	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prevacid	C	Unknown	Not Reported
Refresh	C	Unknown	Not Reported
Flexeril	C	Unknown	Not Reported
Vitamin D2	C	Unknown	Not Reported
Piperacillin Sodium	C	Unknown	Not Reported
Tazobactam Sodium	C	Unknown	Not Reported
Phenergan	C	Unknown	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unknown	Not Reported
Isopto Tears	C	Unknown	Not Reported
Lamictal	C	Unknown	Not Reported
Diamode	C	Unknown	Not Reported
Mobic	C	Unknown	Not Reported
Bactroban	C	Unknown	Not Reported
Nexium	C	Unknown	Not Reported
Protopic	C	Unknown	Not Reported
Zanaflex	C		Not Reported
Retin A	C	Unknown	Not Reported
Influenza Vaccine	C	Unknown	Not Reported

	Pneumococcal Vaccine			C	Unknown	Not Reported
	Calcium Carbonate			C	Unknown	Not Reported
	Colecalciferol			C	Unknown	Not Reported
	Norco			C	Unknown	Not Reported
	Hydrocortisone			C	Unknown	Not Reported
	Zinc			C	Unknown	Not Reported
	Zaditor			C	Unknown	Not Reported
	Zantac			C	Unknown	Not Reported
	Celexa			C	Unknown	Not Reported
	Rubramin			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2017	13137099	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882158		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown	Cyclical		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13085176	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016597614		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Pain	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Hydroxychloroquine			S		300 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13130694	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016008299		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		1 Ml, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Arava			S		10 Mg, 1x/Day		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13143914	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2017029049		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Sertraline Hcl			S	Oral	Unk		Pfizer
	Amlodipine Besilate			S	Oral	Unk		Pfizer
	Levothyroxine Sodium			S	Oral	Unk		Pfizer
	Tranylcypromine			S	Oral	Unk		Not Reported
	Olanzapine			S	Oral	Unk		Not Reported
	Lisinopril			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

	Buspirone			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13145355	EXPEDITED (15-DAY)		OT	PHHY2017KR006508		63 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Drug Ineffective	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13146199	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1777413-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Tofacitinib Citrate			C				Not Reported
	Folic Acid			C				Not Reported
	Abatacept			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13146342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004387		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Not Reported
	Naprosyn /00256201/			S	Unknown	500 Mg, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13146448	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004121		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13146451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004226		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Drug	Orencia			S	Intravenous (not	750 Mg, Qmo		Bristol Myers Squibb

Ineffective; Hepatic Enzyme Increased; Lymphadenopathy			otherwise specified)			
	Arava	S	Unknown	20 Mg, Unk		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qcycle		Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown	2 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13146998	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004339		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Paraesthesia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13149180	NON-EXPEDITED			US-OTSUKA-2016_005789		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis	Pletal			S	Unknown	Unk		Otsuka
	Ambrisentan			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Diovan			S	Unknown	Unk		Not Reported
	Lovastatin			S	Unknown	Unk		Not Reported

	Levothyroxine			S	Unknown	Unk				Not Reported
	Plaquenil			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	13151159	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	20 Mg, Qd		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	11627742	EXPEDITED (15-DAY)		OT	CA-ROCHE-1644412		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Joint Stiffness; Lower Respiratory Tract Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	12970649	EXPEDITED (15-DAY)		OT	US-CANTON LABORATORIES, LLC-1060024		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Naprosyn			S	Unknown			Canton Laboratories
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate (Methotrexate Sodium)			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Ramipril			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lantus			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Indapamide			C	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13087449	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2820		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13107069	EXPEDITED (15-DAY)		DE, HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000126		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Blood Pressure Increased; Bundle Branch Block; Completed Suicide; Depressed Level Of Consciousness; Extensor Plantar Response; Gastrointestinal Sounds Abnormal; Heart Rate Increased; Hyperthermia; Muscle Twitching; Myoclonus; Respiratory Arrest; Rhabdomyolysis; Serotonin Syndrome; Toxicity To Various Agents; Unresponsive To Stimuli	Tranylcypromine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Olanzapine			S	Oral	Once		Not Reported
	Sertraline			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Buspirone Hydrochloride			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13107442	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000152		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Hyperpigmentation	Plaquenil			S	Unknown			Concordia
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13117086	EXPEDITED (15-DAY)		DE, HO	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00007976		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Cardiogenic Shock; Cardiomyopathy; Dyspnoea; Ejection Fraction Decreased; Fibrosis; Hypotension; Left Ventricular End-Diastolic Pressure Increased; Left Ventricular End-Diastolic Pressure Increased; Left Ventricular Hypertrophy; N-Terminal Prohormone Brain Natriuretic Peptide Increased; Peripheral Swelling; Renal Impairment	Hydroxychloroquine	S	Unknown		Concordia
	Sildenafil	C			Not Reported
	Iloprost	C			Not Reported
	Ramipril	C			Not Reported
	Carvedilol	C			Not Reported
	Torsemide	C			Not Reported
	Spironolactone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13152946	EXPEDITED (15-DAY)		OT	CA-ROCHE-1883579		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13153013	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000533		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Pruritus; Rash; Skin Exfoliation	Plaquenil			S	Oral			Concordia

	Plavix				S	Unknown				Not Reported
	Imuran				C					Not Reported
	Prednisone				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13153014	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000580			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colour Blindness	Hydroxychloroquine 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13153016	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000620			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Triazide (Trichlormethiazide)			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13156325	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2017DEP000237		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Diclofenac Potassium			S		Unk		Depomed
	Apo-Amitriptyline			S		Unk		Not Reported
	Arthrotec			S		Unk		Not Reported

	Celebrex	S		Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Lyrica	S		Unk		Not Reported
	Methotrexate	S		Unk		Not Reported
	Naprosyn /00256201/	S		Unk		Not Reported
	Prednisone	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2017	13156765	EXPEDITED (15-DAY)		HO	CA-ROCHE-1885009		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13076292	EXPEDITED (15-DAY)		HO, OT	TW-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-105608		45 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Fasciitis; Fasciotomy; Skin Graft	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Celecoxib			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	1 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	6 Tab, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Qd		Not Reported
	Prednisolone /00016202/			S	Unknown	0.5 Mg, Qd		Not Reported
	Sodium Chloride			S	Unknown	250 Ml, Qd		Not Reported
	Depyretin			C	Oral	1 Tab, Prn		Not Reported
	Celebrex			C	Unknown	200 Mg, Qd		Not Reported
	Plaquenil /00072602/			C	Oral	1 Tab, Qd		Not Reported
	Folacin /00024201/			C	Oral	5 Mg, Qd		Not Reported
	Ultracet			C	Oral	1 Tab, Qid		Not Reported
	Fucidin /00065701/			C	Oral	2 Tab, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13124402	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000385		71 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Skin Abnormal; Lyme Disease; Skin Lesion	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13132679	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000491		17 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Dermatitis; Hypertension; Obesity	Prednisolone			S				Concordia
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Doxycycline			S				Not Reported
	Nicotinamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13157180	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004934		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Surgery	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Endocervical	50 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Lovastatin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported

	Tramadol Hcl			C	Unknown					Not Reported
	Vitamin D /00107901/			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13159630	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2017M1003859			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus	Azathioprine			S	Transplacental	62.5 Mg, Qd		Not Reported
	Presinol			S	Transplacental	250 Mg, Tid		Mylan
	Quensyl			S	Transplacental	200 Mg, Qd		Mylan
	Prednisolon /00016201/			C	Transplacental	2 Mg, Qd		Mylan
	Colecalciferol			C	Transplacental	1000 Iu, Qd		Mylan
	Folic Acid			C	Transplacental	0.4 Mg, Qd		Mylan
	Calcium			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2017	13160071	EXPEDITED (15-DAY)		OT	PHHY2017CA012206		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Diclofenac Potassium			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2017	12601062	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1684651-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hand Deformity; Joint Arthroplasty; Knee Arthroplasty; Mobility Decreased; Pain; Swelling	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Leflunomide			S	Unknown	20mg/Day		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Percocet			C				Not Reported
	Ramipril			C				Not Reported
	Acetaminophen W/Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2017	13070545	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006542		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	17.5-25 Mg		Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13161958	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000583			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Seizure	Plaquenil	S	Oral		Concordia
	Leflunomide	S	Oral		Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	C			Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13162119	NON-EXPEDITED			US-PFIZER INC-2017036838			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Arthralgia; Back Pain; Constipation; Cough; Dizziness; Dry Eye; Dry Mouth; Dry Skin; Dyspepsia; Eye Pain; Flatulence; Head Titubation; Headache; Kyphosis; Laboratory Test Abnormal; Musculoskeletal Stiffness; Synovitis; Tremor; Weight Increased	Xeljanz			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13162213	NON-EXPEDITED			US-PFIZER INC-2017038997		69 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Metformin			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

	Lovenox	S	Unk		Not Reported
	Advair	S	Unk		Not Reported
	Dulera	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13164575	NON-EXPEDITED			US-AMGEN-USASP2017010133		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lacrimation Increased; Visual Field Defect; Visual Impairment	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2017	13165194	EXPEDITED (15-DAY)		HO	CA-ROCHE-1884327		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Plaquenil			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	11179339	EXPEDITED (15-DAY)		OT	CA-ROCHE-1590696		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Interaction; Drug Interaction; Hepatotoxicity; Joint Swelling; Joint Swelling; Nausea; Neoplasm Malignant; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Leflunomide			S	Oral	Therapy Duration: 9 Months		Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 13 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	12056183	NON-EXPEDITED			US-ABBVIE-15P-163-1470308-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Arthralgia; Drug Ineffective; Gastric Disorder; Gastrooesophageal Reflux Disease; Injection Site Pruritus; Injection Site	Humira			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Plaquenil			S	Unknown	For A Couple Weeks		Not Reported
	Plaquenil			S	Unknown			Not Reported

Rash; Joint Stiffness; Pain; Rash; Rash Pruritic	Enbrel			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	12298853	EXPEDITED (15-DAY)		OT	CA-ROCHE-1744560		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	12722977	EXPEDITED (15-DAY)		DS	CA-ROCHE-1826508			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral	Therapy Duration: 8.0 Year(S)		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Hydromorphone	C				Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	12915659	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1445951-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Unknown	Solution For Subcutaneous		Not Reported
	Rituxan			S	Unknown	Solution For Intravenous		Not Reported
	Orencia			S	Unknown	Powder For Solution Intravenous		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Lyrica			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13015683	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865158		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Arava			S	Unknown				Not Reported
	Celebrex			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Leflunomide			S	Oral				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13132233	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000518		38 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Decreased Appetite; Exposure During Pregnancy	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Fluimucil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13163107	EXPEDITED (15-DAY)		HO	PHHY2017CA013299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection;	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported

Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Arava			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13163109	EXPEDITED (15-DAY)		OT	PHHY2017CA013303		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Amitriptyline			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165736	EXPEDITED (15-DAY)		HO	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000643		30 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash	Plaquenil 200 Mg Tablet	S	Oral	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13165738	EXPEDITED (15-DAY)		CA	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000670			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Patent Ductus Arteriosus	Hydroxychloroquine			S	Transplacental			Concordia
	Azathioprine			S	Transplacental			Not Reported
	Presinol			S	Transplacental			Not Reported
	Prednisolone			C				Not Reported
	Colecalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166080	EXPEDITED (15-DAY)		OT	CA-ROCHE-1885000		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin Hydrobromide			C				Not Reported
	Desoximetasone			C	Intramuscular			Not Reported
	Dilaudid			C	Unknown			Not Reported

	Diphenhydramine Hydrochloride			C					Not Reported
	Furosemide			C	Unknown				Not Reported
	Loperamide			C	Unknown				Not Reported
	Norflex			C	Unknown				Not Reported
	Omnaris			C	Unknown				Not Reported
	Pantoprazole Sodium			C					Not Reported
	Synthroid			C					Not Reported
	Vagifem			C	Vaginal				Not Reported
	Cortisone			C	Oral				Not Reported
	Cortisone			C	Intramuscular				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166185	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886967		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13166736	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2017-28850		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Completed	Amlodipine			S	Oral			Aurobindo

Suicide; Hyperthermia; Muscle Twitching; Rhabdomyolysis; Unresponsive To Stimuli	Lisinopril			S	Oral				Aurobindo
	Sertraline			S	Oral				Aurobindo
	Olanzapine			S	Oral				Aurobindo
	Tranylcypromine			S	Oral				Not Reported
	Hydroxychloroquine			S	Oral				Not Reported
	Buspirone			S	Oral				Not Reported
	Levothyroxine			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13167482	NON-EXPEDITED			US-PFIZER INC-2017039459		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Docusate Sodium & Senna			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13169965	NON-EXPEDITED			US-ABBVIE-16K-163-1633946-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pain In Extremity; Tinnitus	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prevacid			C				Not Reported
	Prednisone			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Calcium			C				Not Reported
	Vitamin C			C				Not Reported

	Glucosamine Chondroitin	C	Not Reported
	Estrace	C	Not Reported
	Voltaren	C	Not Reported
	Vitamin D Nos	C	Not Reported
	Multivitamin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170134	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005847		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Condition Aggravated; Nodule; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Abatacept			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170423	NON-EXPEDITED			US-ABBVIE-16K-163-1786277-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Headache; Muscular Weakness; Rash; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170520	NON-EXPEDITED			US-ABBVIE-16K-163-1686592-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13170577	NON-EXPEDITED			US-ABBVIE-16K-163-1672035-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Menorrhagia; Rheumatoid Arthritis; Rheumatoid Nodule; Vitamin D Deficiency	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral	120 Quantity		Not Reported
	Hydroxychloroquine			S	Oral	60 Quantity		Not Reported
	Prednisone			C	Oral	3 Quantity		Not Reported
	Naprosyn			C	Oral	As Needed		Not Reported
	Vitamin D2			C	Oral			Not Reported
	Plaquenil			C				Not Reported
	Folic Acid			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13171486	NON-EXPEDITED			US-ABBVIE-16K-163-1786294-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Photosensitivity Reaction	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported

	Doxycycline			S	Unknown					Not Reported
	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13171822	NON-EXPEDITED			US-ABBVIE-16K-163-1708656-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Mucosal Inflammation	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13172130	NON-EXPEDITED			US-ABBVIE-16K-163-1720961-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blister; Drug Ineffective; Drug Ineffective; Malaise; Pain; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2017	13173637	NON-EXPEDITED			US-ABBVIE-16K-163-1739776-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective;	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported

Ineffective; Fatigue; Mobility Decreased; Pain; Weight Increased	Vitamin D Nos		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	11058249	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-023710		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Interstitial Lung Disease	Orencia			S	Unknown	1000 Mg, Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	17.5 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Bid		Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	11099092	EXPEDITED (15-DAY)		OT	CA-TEVA-560449USA		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Parkinson'S Disease; Therapeutic Product Effect Incomplete	Risedronic Acid			S	Oral	1 Dosage Forms Daily;		Teva
	Pregabalin			S	Oral	4 Dosage Forms Daily;		Teva
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Xeljanz			S		10 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	800 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	11692317	EXPEDITED (15-DAY)		DE, HO, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2015R1-105345		15 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Coma; Meningitis Cryptococcal; Septic Shock	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisone			S	Unknown	10 Mg, Daily		Mutual
	Azathioprine			S	Unknown	3 Mg/Kg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13169316	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13174531	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2017012969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Ear Infection; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

	Celebrex			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13175445	NON-EXPEDITED			US-PFIZER INC-2017038718		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Diclofenac Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2017	13176889	NON-EXPEDITED			US-PFIZER INC-2017039094		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Ketorolac Tromethamine			S		Unk		Pfizer
	Ketorolac Tromethamine			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Duexis			S		Unk		Not Reported
	Duexis			S				Not Reported
	Acetaminophen			S		Unk		Not Reported
	Acetaminophen			S				Not Reported
	Kenalog			S		Unk		Not Reported
	Kenalog			S				Not Reported
	Celestone			S		Unk		Not Reported
	Celestone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	12614575	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-061494			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Eye Disorder; Nail Dystrophy;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

Nausea	Methotrexate	S	Unknown	10 Mg, Qd		Not Reported
	Arava	S	Unknown	10 Mg, Qd		Not Reported
	Myochrysine	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Unknown	10 Mg, Qd		Not Reported
	Ridaura	S	Unknown	10 Mg, Qd		Not Reported
	Estrace	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Plavix	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	12960506	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC201611-000949			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	12962974	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13178684	EXPEDITED (15-DAY)		HO	US-ZYDUS-013618		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Condition Aggravated; Erythema; Macule; Malaise; Pain Of Skin; Paraesthesia; Pruritus; Pyrexia; Rash Pustular; Skin Exfoliation; Skin Plaque; Tachycardia; White Blood Cell Count Increased; Xerosis	Hydroxychloroquine			S	Oral			Zydus Pharm
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13178909	NON-EXPEDITED			US-PFIZER INC-2017038803		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13178923	NON-EXPEDITED			US-PFIZER INC-2017039244		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13178964	NON-EXPEDITED			US-PFIZER INC-2017043622		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Celebrex			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2017	13182160	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17P-028-1859897-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Pain; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	12692451	EXPEDITED (15-DAY)		HO	CA-ROCHE-1652998		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Drug Ineffective; Haematemesis; Hepatitis; Hepatotoxicity; Jaundice; Joint Swelling; Nausea; Platelet Count Increased; Rheumatoid Arthritis; Treatment Failure; Vitamin	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral	As Needed		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

D Decreased; Vomiting	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Vitamin C	C		Not Reported
	Cortisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Rosuvastatin	C		Not Reported
	Betahistamine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13036933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-105254		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Orencia			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	50 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qwk		Not Reported

Methotrexate	S	Unknown	7.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	7.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	5 Mg, Qwk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
Celebrex	S	Oral	200 Mg, Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Altace	C	Unknown	Unk	Not Reported
Estrogens Conjugated	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Taro-Mupirocin	C	Unknown	Unk	Not Reported
Tramadol Hcl	C	Unknown	Unk	Not Reported
Tramacet	C	Unknown	Unk	Not Reported
Celexa /00582602/	C	Unknown	Unk	Not Reported
Cipralex /01588501/	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown	Unk	Not Reported
Estrace	C	Unknown	Unk	Not Reported
Nucynta	C	Unknown	Unk	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13048892	EXPEDITED (15-DAY)		OT	US-ABBVIE-16K-163-1805110-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blindness; Discomfort; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Fatigue; Headache; Infection; Initial Insomnia; Malaise; Middle Insomnia; Mobility Decreased; Muscle Spasms; Musculoskeletal Pain; Myalgia; Oedema; Osteoarthritis; Pain; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Scleroderma; Sjogren'S Syndrome; Snoring	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Atenolol			C				Not Reported
	Folic Acid			C				Not Reported
	Tramadol			C				Not Reported
	Tramadol			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13077793	EXPEDITED (15-DAY)		OT	CA-ROCHE-1873007		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Hypersensitivity; Dyspnoea; Eosinophilic Bronchitis; Hypertension; Influenza; Respiratory Disorder	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	225 Mg, Biw		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Alvesco			C	Unknown			Not Reported
	Ventolin			C	Unknown			Not Reported

	Singulair			C	Unknown					Not Reported
	Aerius (Canada)			C	Unknown					Not Reported
	Pulmicort			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13182852	EXPEDITED (15-DAY)		OT	CA-SA-2017SA009590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Femur Fracture; Mobility Decreased; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183029	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13183127	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017041573		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Cirrhosis; Prothrombin Level Increased; Right Ventricular Failure	Salazopyrine			S	Oral	500 Mg, 4x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Plaquenil /00072603/			S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13184762	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2017DEP000292		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S		Unk		Depomed
	Desoximetasone			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2017	13185955	NON-EXPEDITED			US-AMGEN-USASP2017015295			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Injection Site Reaction	Enbrel			S	Unknown	Unk		Amgen
	Lodine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2017	13158940	EXPEDITED (15-DAY)		OT	GB-TEVA-732778ISR		71 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lyme Disease; Skin Infection	Hydroxychloroquine			S	Unknown			Teva
	Prednisolone			S	Unknown			Teva

	Tocilizumab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2017	13188683	DIRECT		DS, HO, LT, OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Nervous System Disorder	Plaquenil 200			S	Oral	Quantity:1 Tablet(S);		Unknown
	Insulin			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Metformin			C				Not Reported
	Norvasc			C				Not Reported
	Amlodipine			C				Not Reported
	Synthroid			C				Not Reported
	B12			C				Not Reported
	D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2017	13175575	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA011888		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Novartis
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13079647	EXPEDITED (15-DAY)		HO	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-130639		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Enzyme Increased	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Sun
	Prednisone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13180551	EXPEDITED (15-DAY)		OT	PHHY2017CA012933			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Neoral			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Novartis
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13180555	EXPEDITED (15-DAY)		OT	PHHY2017CA012940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Novartis
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13187220	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1850096-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13188393	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017019028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13190608	EXPEDITED (15-DAY)		HO, LT	DE-ABBVIE-17K-062-1861179-00		52 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Myocardial Infarction; Vascular Stent Thrombosis	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Quensyl	S	Unknown	Not Reported
	Kineret	C		Not Reported
	Remicade	C		Not Reported
	Orencia	C		Not Reported
	Orencia	C		Not Reported
	Simponi	C		Not Reported
	Mabthera	C		Not Reported
	Mabthera	C		Not Reported
	Roactemra	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2017	13190948	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017004519		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Ucb
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Mtx			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	11654904	EXPEDITED (15-DAY)		OT	CA-ROCHE-1648219		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage;	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 198 Days		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 156 Days		Not Reported
	Xeljanz			S	Oral			Not Reported

Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Methotrexate Sodium	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	12840381	EXPEDITED (15-DAY)		OT	CA-SA-2016SA186328		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Nausea; Pain; Pain In Extremity	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown	Strength: 1 Gm		Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported
	Celebrex			C	Oral			Not Reported
	Imuran			C	Unknown	Strength: 50 Mg		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	12872049	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005288		62 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Conjunctivitis; Erythema; Hypersensitivity; Pruritus; Urticaria	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	12974904	EXPEDITED (15-DAY)		DS	CA-ROCHE-1859498		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13162294	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000668		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; C-Reactive Protein Increased; Confusional State; Csf Glucose Increased; Csf Protein Increased; Csf Red Blood Cell Count Positive; Depressed Level Of Consciousness; Encephalopathy; Lumbar Puncture Abnormal; Meningitis Pneumococcal; Pyrexia; Rash Erythematous; Sepsis;	Plaquenil			S	Unknown			Concordia
	Cellcept			S	Unknown			Not Reported
	Coumadin			C				Not Reported

Streptococcal Infection; Streptococcus Test Positive

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13186012	EXPEDITED (15-DAY)		OT	PHHY2017CA017079		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13191668	EXPEDITED (15-DAY)		OT	CA-ROCHE-1821270		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 19 Years		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
			Xeljanz			C	Oral			Not Reported
			Lyrica			C	Oral			Not Reported
			Lyrica			C				Not Reported
			Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13195081	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2017	13195100	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008007		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; C-Reactive Protein Increased; Joint Swelling; Kidney Infection; Nephrolithiasis; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	11517657	EXPEDITED (15-DAY)		OT	CA-SA-2015SA139101		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Rituxan			S	Unknown	Form: Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Form- Solution		Not Reported
	Orencia			S	Subcutaneous	Form: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Form- Solution		Not Reported
	Imuran			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13160402	EXPEDITED (15-DAY)		OT	PHHY2017AU009443			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Graft Versus Host Disease; Disease Progression; Quality Of Life Decreased; Skin Hypertrophy	Methotrexate			S	Unknown			Novartis
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Imatinib			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13195319	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Femur Fracture; Mobility Decreased; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine	S	Unknown		Concordia
	Leflunomide	S	Oral		Not Reported
	Metformin	C			Not Reported
	Ramipril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13195427	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl (Canada)			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Enablex			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13199422	EXPEDITED (15-DAY)		OT	CA-SA-2015SA109899		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Condition Aggravated; Drug Intolerance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mental Disorder; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Walking Disability	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13199469	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019947		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13199614	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020097		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Solution		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Form- Poweder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2017	13202807	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015029172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Lung Disorder; Pneumonitis; Rheumatoid Arthritis	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow) X 3 Doses		Ucb
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Methotrexate			S	Oral	Up To 25 Mg, Weekly (Qw)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		10 Mg, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported

	Arava			C		Unk			Not Reported
	Prednisone			C		Unk			Not Reported
	Tofacitinib Citrate			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	12908022	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016041565		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pneumonia	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow) X 3		Ucb
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Hydroxychloroquine			S		200 Mg Daily Dose		Not Reported
	Lipitor			C		10 Mg Daily Dose		Not Reported
	Methotrexate			C		2.5 Mg, Weekly (Qw)		Not Reported
	Prednisone			C		5 Mg Daily Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13201406	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000732		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Fatigue; Gastrointestinal Disorder; Mood Altered; Nausea	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Humira			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13201430	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000927		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Right Ventricular Failure	Plaquenil 200 Mg		S	Oral		Concordia
	Salazopyrine		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13201484	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000841			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Reaction	Hydroxychloroquine			S				Concordia
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13201858	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000826		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Aspirin			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Bisoprolol			C				Not Reported
	Glyceryl Trinitrate			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Lansoprazole			C				Not Reported
	Lisinopril			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13203634	EXPEDITED (15-DAY)		OT	CA-SA-2016SA238060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Deformity; Drug Ineffective; Drug Intolerance; Joint Stiffness; Liver Function Test Increased; Retinal Toxicity; Rheumatoid Arthritis	Arava			S	Unknown		Not Reported
	Plaquenil			S	Unknown		Not Reported
	Plaquenil			S	Unknown		Not Reported
	Methotrexate			S	Oral		Not Reported
	Methotrexate			S	Oral		Not Reported
	Folic Acid			C	Unknown		Not Reported
	Sulfasalazine			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13204252	EXPEDITED (15-DAY)		OT	CA-SA-2015SA121451		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Neutropenia; Platelet Count Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Duration 1 Yr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13215951	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020569		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form: Solution Sc, 1 Every 2 Week		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia		S	Subcutaneous		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution Iv	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2017	13216071	EXPEDITED (15-DAY)		OT	CA-SA-2015SA114829		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Intolerance; Eczema; Erythema; Pyrexia; Rash; Rheumatoid Arthritis; Rhinorrhoea; Swelling Face; Therapeutic Response Decreased	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	11403214	EXPEDITED (15-DAY)		OT	CA-SA-2015SA120300		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Dose Is 4-8mg.Kg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

	Ramipril	C	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Lantus	C	Unknown		Not Reported
	Vitamin D2	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Lozide	C	Unknown		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	11529030	EXPEDITED (15-DAY)		OT	CA-SA-2015SA139097		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Loose Tooth; Musculoskeletal Stiffness; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tooth Abscess	Plaquenil			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Sc		Not Reported
	Abatacept			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	12856347	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005211		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Nausea; Pain; Pain In Extremity	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Sulfasalazine			C				Not Reported
	Imuran			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13015516	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865715		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duratin: 6 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gp2013 (Rituximab Biosimilar)			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown	Therapy Duration: 6 Months		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13035636	EXPEDITED (15-DAY)		OT	CA-SA-2016SA224756		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Every 2 Weeks Form: Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Taken From August 2010 Or July 2009, Frequency- Every 4 Weeks		Not Reported
	Orencia			S	Unknown	Frequency- Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13209915	EXPEDITED (15-DAY)		OT	GR-JNJFOC-20170206877		66 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Oral Pigmentation	Simponi			S	Subcutaneous	Not Reported
	Arava			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13210355	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178527		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Advil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13210578	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020159		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Injury; Loss Of Personal	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Subcutaneous Solution		Not Reported

Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13210599	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Erythema; Rheumatoid Arthritis; Rhinorrhoea; Swelling Face	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13210623	EXPEDITED (15-DAY)		OT	CA-SA-2015SA098452		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Joint Swelling; Macule; Mobility Decreased; Pain; Skin Cancer; Swelling	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13211794	EXPEDITED (15-DAY)		OT	CA-SA-2015SA111843		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder; Sleep Disorder	Plaquenil		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituxan		S	Unknown	Form- Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13212440	EXPEDITED (15-DAY)		OT	CA-SA-2015SA117264		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown	Last Dose On 09-Jul (Year Unspecified).		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cortisone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13212970	EXPEDITED (15-DAY)		OT	CA-SA-2015SA134263		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal;	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Leflunomide			S	Unknown	Not Reported
	Methotrexate Sodium			S	Subcutaneous	Not Reported
	Chloroquine			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Xeljanz			S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213336	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020003		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213439	EXPEDITED (15-DAY)		OT	CA-SA-2015SA141878		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213527	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178531		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Advil			S	Unknown	For Years		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213581	EXPEDITED (15-DAY)		OT	CA-SA-2016SA166800		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Naprosyn			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213757	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA019810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown	Form- Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Form- Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Form- Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Form- Solution Subcutaneous		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Humira		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Voltaren		S	Unknown	Not Reported
	Voltaren		S	Unknown	Not Reported
	Voltaren		S	Unknown	Not Reported
	Voltaren		S	Unknown	Not Reported
	Tramadol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213874	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019920		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213888	EXPEDITED (15-DAY)		OT	CA-SA-2017SA022155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213921	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020582		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Sc, 1 Every 2 Week		Not Reported
	Methotrexate			S		Parenteral		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Iv		Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13213976	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020181		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Unknown	Form- Solution Subcuatenous		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13214033	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020581		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling; Loose Tooth; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Tooth Abscess; Toothache	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Unknown	Form- Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13214101	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020151		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Operation; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13216792	EXPEDITED (15-DAY)		HO	CA-ROCHE-1890617		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13219071	EXPEDITED (15-DAY)		LT	CA-TEVA-738159ACC			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Chills; Endotracheal Intubation;	Methotrexate			S	Oral	2.8571 Milligram Daily;		Barr
	Acetaminophen			S	Unknown			Not Reported

Fatigue; Hyperthermia; Hypoxia	Hydroxychloroquine		S	Unknown		Not Reported
	Acebutolol		C			Not Reported
	Bromazepam		C			Not Reported
	Calcium Carbonate		C			Not Reported
	Folic Acid		C			Not Reported
	Fosinopril		C			Not Reported
	Pantoprazole		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13219154	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890021		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 190.0 Day(S)		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13219541	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000769		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Dermatitis Allergic; Drug Ineffective; Pruritus Allergic; Skin Exfoliation; Swelling; Vitamin D Decreased	Plaquenil	S	Unknown		Concordia
	Humira 40mg/0.8ml	S	Subcutaneous		Not Reported
	Vitamin D Nos	C			Not Reported
	Tricor	C			Not Reported
	Zoloft	C			Not Reported
	Pravastatin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13219547	EXPEDITED (15-DAY)		OT	CA-ROCHE-1891282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2017	13220371	EXPEDITED (15-DAY)		OT	GR-CONCORDIA PHARMACEUTICALS		35 YR	Female	GRC

						INC.-GSH201702-000923				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fundoscopy Abnormal; Maculopathy; Optical Coherence Tomography Abnormal; Retinogram Abnormal	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	12958181	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005882		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Drug Ineffective; Fatigue; Grip Strength Decreased; Joint Effusion; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Swelling; Urinary Incontinence	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Leflunomlde			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Arava			C				Not Reported
	Telmisartan			C				Not Reported
	Depomedrol			C				Not Reported
	Meloxicam			C				Not Reported
	Vitamin D2			C				Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)			C				Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	13224414	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000731		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyschromatopsia; Macular Pigmentation; Photopsia; Retinal Degeneration; Retinopathy; Vision Blurred; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	13224477	EXPEDITED (15-DAY)		HO	US-IPCA LABORATORIES LIMITED-IPC201702-000018		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	13224492	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Drug Ineffective; Hand Deformity; Lung Disorder; Pelvic Fracture; Pneumonitis; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	13224503	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	13224535	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Musculoskeletal Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Unevaluable Event	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2017	13224538	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000920		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cystitis; Drug	Plaquenil			S	Unknown			Concordia

Ineffective; Drug Intolerance; Genital Pain; Hysterectomy; Nephrolithiasis; Therapy Interrupted; Unevaluable Event	Enbrel			S	Unknown	Not Reported
	Mtx (Methotrexate)			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Protol			C		Not Reported
	Ibuprofen			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	11311643	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA108461		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Back Disorder; Back Pain; Blister; Decreased Appetite; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Herpes Virus Infection; Infection; Joint Swelling; Localised Infection; Localised Infection; Pain; Pelvic Pain; Renal Failure; Renal Failure; Sepsis; Skin Fissures; Vaginal Infection; Weight Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Xeljanz			S				Not Reported
	Indomethacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fluconazole			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13141117	NON-EXPEDITED			US-PFIZER INC-2017024433		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer

Celebrex	S	Unk	Pfizer
Doxycycline Hyclate	S	Unk	Pfizer
Neurontin	S	Unk	Pfizer
Medrol	S	Unk	Pfizer
Verapamil Hcl	S	Unk	Pfizer
Amitriptyline	S	Unk	Not Reported
Januvia	S	Unk	Not Reported
Oxycontin	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13216090	EXPEDITED (15-DAY)		OT	CA-SA-2015SA137217		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13225777	EXPEDITED (15-DAY)		OT	CA-ROCHE-1891247			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13226292	NON-EXPEDITED			US-PFIZER INC-2017057631		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ibuprofen			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Gold Sodium Thiomalate			S		Unk		Not Reported
	Reflan			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13226853	EXPEDITED (15-DAY)		OT	CA-SA-2015SA149376		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Joint Swelling; Pain In Extremity; Treatment Failure	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13227553	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020510		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Form- Subcutaneous Solution		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form- Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Form- Powder For Solution Itnravenous		Not Reported
	Rituxan			S	Intravenous (not	Form- Solution		Not Reported

						otherwise specified)	Intravenous			
		Simponi			S	Subcutaneous	Form: Solution			Not Reported
		Anakinra			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13227683	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020177		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Drug Ineffective; Exposure During Pregnancy; Exposure To Communicable Disease; Hip Arthroplasty; Joint Effusion; Joint Stiffness; Joint Stiffness; Musculoskeletal Pain; Osteoarthritis; Surgery	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Form- Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Form- Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2017	13227710	EXPEDITED (15-DAY)		OT	CA-SA-2015SA114834		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Intolerance; Eczema; Erythema; Erythema; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Rhinorrhoea; Swelling Face; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown	One And A Half Tablets Per Day For A Week		Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	11530017	NON-EXPEDITED			CA-SA-2015SA103130		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gallbladder Disorder; Headache; Liver Function Test Abnormal; Nausea; Therapeutic Product Effect Decreased; Ulcer	Arava			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold Bond		Y	S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Dose: 0.7 Cc		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13163919	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017038701		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine			S		200 Mg, 2x/Day (5 Days Out Of 7)		Not Reported
	Prednisone			C		5 Mg, 2x/Day (Decreasing Dosage)		Not Reported
	Atorvastatin Calcium			C	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13229139	EXPEDITED (15-DAY)		OT	CA-ROCHE-1892550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	Therapy Duration: 5.0 Year(S)		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	Therapy Duration: 6.0 Month(S)		Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Methotrexate	C	Unknown	25.0 Dosage Forms Nos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13229498	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2017-003396			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteomyelitis Bacterial; Q Fever	Prednisolone			S	Unknown			Bausch And Lomb
	Doxycycline			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13229646	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Ineffective; Drug Intolerance; Joint Stiffness; Liver Function Test Increased; Retinal Toxicity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13231424	EXPEDITED (15-DAY)		OT	GR-SA-2017SA021401		66 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Pigmentation; Oral Pigmentation	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2017	13232019	EXPEDITED (15-DAY)		OT	CA-SA-2014SA140634		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthralgia; Arthralgia; Arthritis; Arthritis; Balance Disorder; Blood Pressure Increased; Bronchitis; Bronchospasm; Chest Pain; Cough;	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Estradot			S	Unknown	Form- Patch		Not Reported
	Actemra			S	Intravenous (not			Not Reported

Dizziness; Dizziness; Fall; Fall; Fatigue; Gastroenteritis; Headache; Headache; Headache; Hepatic Enzyme Increased; Hepatic Enzyme Increased; Hepatic Enzyme Increased; Hepatic Steatosis; Hepatic Steatosis; Hot Flush; Hot Flush; Hypertension; Influenza; Infusion Related Reaction; Joint Swelling; Medication Error; Mobility Decreased; Muscle Strain; Musculoskeletal Discomfort; Musculoskeletal Pain; Nasal Congestion; Nasal Congestion; Nasopharyngitis; Nausea; Nausea; Neutrophil Count Decreased; Oropharyngeal Pain; Oropharyngeal Pain; Oxygen Saturation Decreased; Pain In Extremity; Painful Respiration; Plantar Fasciitis; Poor Quality Sleep; Poor Venous Access; Pruritus; Pruritus; Pyrexia; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis; Tendon Pain; Tracheitis; Vaginal Haemorrhage; Vomiting; Vomiting; Weight Increased			otherwise specified)	
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Prometrium	S	Oral	Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	10168647	EXPEDITED (15-DAY)		OT	US-RANBAXY-2014US-81035		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Retinopathy	Ibuprofen		Y	S	Unknown	Unk		Ranbaxy
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Not Reported
	Nabumetone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13233259	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001084		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Neutropenia; Platelet Count Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13233515	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001050		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13233522	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		57 YR	Female	CAN

						INC.-GSH201702-001055			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Intolerance; Nodule; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Remicade			C				Not Reported
	Orencia			C				Not Reported
	Actemra			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13233554	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001003		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hyperhidrosis; Influenza; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel "Immunex"			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13233893	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000976		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Fatigue; Limb Injury; Skin Atrophy; Skin Laceration	Plaquenil			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen			C				Not Reported
	Cortisone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13234005	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008016		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alveolitis; Pneumonia; Pruritus	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Arthrotec			C				Not Reported
	Lyrica			C				Not Reported
	Ultram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13234103	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893257			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Methotrexate Sodium			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13234336	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Erythema; Rheumatoid Arthritis; Rhinorrhoea; Swelling Face	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2017	13237602	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001082			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Executive Dysfunction; Fatigue; Jc Polyomavirus Test Positive; Neurological Decompensation; Progressive Multifocal Leukoencephalopathy; White Matter Lesion	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13069884	EXPEDITED (15-DAY)		OT	UY-ACTELION-A-US2016-147558		33 YR	Female	URY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Pain; Pain Of Skin; Peripheral Swelling; Rash Macular; Rheumatoid	Ventavis Bayer Schering			S	Respiratory (inhalation)	1 Df, 8id		Bayer
	Evoquin			S	Unknown	Unk		Not Reported

Arthritis; Skin Burning Sensation; Subcutaneous Haematoma; Systemic Lupus Erythematosus; Vaginal Haemorrhage	Tracleer	C	Unk	Not Reported
	Sildenafil	C	Unk	Not Reported
	Digoxin	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Mycophenolate Mofetil	C	Unk	Not Reported
	Loratadine	C	Unk	Not Reported
	Homatropine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13103641	NON-EXPEDITED			US-WATSON-2016-13870			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash; Urticaria	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	Unk, Unknown		Watson
	Diclofenac Sodium (Aellc)			S	Unknown	Unk, Unknown		Watson
	Nortriptyline Hydrochloride (Watson Laboratories)			S	Unknown	Unk, Unknown		Watson
	Prednisone (Watson Laboratories)			S	Unknown	Unk, Unknown		Watson
	Etodolac (Watson Laboratories)			S	Unknown	Unk, Unknown		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13237792	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001058		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous					Not Reported
	Methotrexate Sodium			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13237793	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001089		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Treatment Failure	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13237837	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893817		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Desoximetasone		C	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Zostavax		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238091	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008014		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Condition Aggravated; Drug Intolerance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mental Disorder; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Walking Disability	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238093	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008026		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Wrist	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Deformity	Xeljanz Tablet		S	Oral	Not Reported
	Lyrica		S	Unknown	Not Reported
	Arthrotec Tablet		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Apo-Amitriptyline Tablet		S	Unknown	Not Reported
	Voltaren		S	Unknown	Not Reported
	Elavil Tablet		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238098	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001120		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238100	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001130		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Interstitial Lung Disease	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238165	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893254		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238451	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001123		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Cortisone		C		Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238454	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001126		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13238612	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Imuran			S	Unknown				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13241307	NON-EXPEDITED			US-MYLANLABS-2016M1005886			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Epinephrine			S	Unknown	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Mylan
	Cymbalta			S	Unknown	Unk		Mylan
	Crestor			S	Unknown	Unk		Mylan
	Ceftin /00454603/			S	Unknown	Unk		Mylan
	Codeine			S	Unknown	Unk		Mylan
	Plaquenil /00072602/			S	Unknown	Unk		Mylan
	Neosporin /00038301/			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13244918	EXPEDITED (15-DAY)		OT	CA-ROCHE-1826516		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown	10mg/Ml Vial		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

INC.-GSH201702-001093

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Drug Ineffective; Gastrooesophageal Reflux Disease; Granulomatosis With Polyangiitis; Joint Stiffness; Joint Swelling; Urinary Tract Infection; Vasculitis; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tecta			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cyclobenzaprine Hydrochloride			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Nabilone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Zomig			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13245180	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001129		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Drug Ineffective; Exposure	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

During Pregnancy; Exposure To Communicable Disease; Hip Arthroplasty; Joint Effusion; Joint Stiffness; Joint Stiffness; Musculoskeletal Pain; Osteoarthritis; Surgery	Enbrel	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Ibuprofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	12864344	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 4 Months		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 3 Years On 10/Feb/2016, She Received Last Dose Of Etanercept (Enbrel)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Therapy Duratino: 2 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 5 Months		Not Reported
	Tylenol			S	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Mg/Ml		Not Reported
	Meloxicam			C				Not Reported
	Synthroid			C				Not Reported

	Tylenol #3 (Canada)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	12893073	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016161419		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Intolerance; Hypertensive Crisis; Interstitial Lung Disease; Liver Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13118572	EXPEDITED (15-DAY)		HO, OT	CA-CANTON LABORATORIES, LLC-1062042		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Naprosyn			S	Unknown			Canton Laboratories
	Ketoprofen			C	Unknown			Not Reported
	Omeprazole			C				Not Reported
	Celexa			C				Not Reported
	Crestor			C				Not Reported
	Xeljanz			C	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13157578	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0262		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mobility Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13205286	EXPEDITED (15-DAY)		HO, OT	CN-SA-2017SA020865		32 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Ascites; C-Reactive Protein Increased; Cd4 Lymphocytes Decreased; Computerised Tomogram Abnormal; Condition Aggravated; Diarrhoea; Gamma-Glutamyltransferase Increased; Globulins Increased; Histology Abnormal; Jarisch-Herxheimer Reaction;	Methylprednisolone			S	Intravenous (not otherwise specified)	In The Afternoon		Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Oral	20 Mg In The Morning And 12 Mg In The Afternoon		Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral	20 Mg In The Morning		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	One Single Dose		Not Reported

Lymphadenopathy; Off Label Use; Peritoneal Tuberculosis; Pleural Adhesion; Protein Urine Present; Pulmonary Calcification; Pyrexia; Rash Papular; Red Blood Cell Sedimentation Rate Increased; T-Lymphocyte Count Decreased	Isoniazid	S	Unknown			Not Reported
	Isoniazid	S	Unknown			Not Reported
	Isoniazid	S	Unknown			Not Reported
	Isoniazid	S	Unknown			Not Reported
	Isoniazid	S	Unknown			Not Reported
	Isoniazid	S	Unknown			Not Reported
	Isoniazid	S	Oral			Not Reported
	Isoniazid	S	Oral			Not Reported
	Isoniazid	S	Oral			Not Reported
	Rifampicin	S	Unknown			Not Reported
	Rifampicin	S	Unknown			Not Reported
	Rifampicin	S	Unknown			Not Reported
	Rifampicin	S	Unknown			Not Reported
	Rifampicin	S	Unknown			Not Reported
	Rifampicin	S	Unknown			Not Reported
	Rifampicin	S	Oral			Not Reported
	Rifampicin	S	Oral			Not Reported
	Rifampicin	S	Oral			Not Reported
	Levofloxacin	S	Oral			Not Reported
	Pyrazinamide	S	Unknown			Not Reported
	Pyrazinamide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	One Single Dose		Not Reported
	Ethambutol	S	Oral			Not Reported
	Aminosalicylic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13233598	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001004		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Interstitial Lung Disease	Plaquenil Tablet	S	Oral		Concordia
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Intramuscular		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C			Not Reported
	Naprosyn	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13237648	EXPEDITED (15-DAY)		OT	CA-ROCHE-1829178		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Atasol Plain			C	Unknown	As Required		Not Reported
	Gabapentin			C	Unknown			Not Reported
	Norvasc			C	Unknown	Die, Every 1 Day(S)		Not Reported
	Prednisone			C	Unknown	Every 1 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13242982	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017072376		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyoderma Gangrenosum	Sulfasalazine			S		4 Pills, Daily		Pfizer

	Hydroxychloroquine			S	Oral	2 Pills, Daily			Not Reported
	Humira			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13245321	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-010056		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13245563	EXPEDITED (15-DAY)		HO, OT	BR-ABBVIE-17P-020-1853195-00		54 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug-Induced Liver Injury; Epiglottitis; Extrapulmonary Tuberculosis; Laryngeal Granuloma; Lymph Node Tuberculosis; Pyrexia	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Reuquinol			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Celebra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13245731	EXPEDITED (15-DAY)		DS	CA-ROCHE-1893180		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Peripheral Swelling; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Oral				Not Reported
		Methotrexate Sodium			S	Oral				Not Reported
		Remicade			S	Unknown				Not Reported
		Xeljanz			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246070	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001087		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown	0.6 Millilitre		Not Reported
	Methotrexate			S	Unknown	0.6 Millilitre		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246072	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001114		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Alopecia; Alopecia; Condition Aggravated; Disease Progression; Fungal Skin Infection; Osteoarthritis; Osteoporosis; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246073	EXPEDITED (15-DAY)		OT	CA-CONCORDIA		73 YR	Female	CAN

						PHARMACEUTICALS INC.-GSH201702-001122			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Intolerance; Eczema; Erythema; Pyrexia; Rash; Rheumatoid Arthritis; Rhinorrhoea; Swelling Face; Therapeutic Response Decreased	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246075	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001128		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axillary Mass; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Mouth; Interstitial Lung Disease; Ocular Hyperaemia; Photophobia; Rash; Rash Pruritic; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Meloxicam			C				Not Reported
	Naprosyn			C				Not Reported
	Tylenol 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246076	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001131		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246580	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001086		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eating Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava Tablet			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13248249	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000949		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity; Rash	Plaquenil Tablet	S	Oral		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13248251	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S				Concordia
	Plaquenil Tablet			S				Concordia
	Sodium Aurothtomalate			S	Unknown			Not Reported
	Sodium Aurothtomalate			S				Not Reported
	Sodium Aurothtomalate			S				Not Reported
	Sodium Aurothtomalate			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin			S	Unknown	Powder For Solution For Infusion		Not Reported

	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Naprosyn	S	Unknown		Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Voltaren	S	Unknown		Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2017	13250176	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001052		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Joint Swelling; Macule; Mobility Decreased; Pain; Skin Cancer; Swelling	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide Tablet			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2017	13250177	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001109		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fine Motor Skill	Plaquenil Tablet			S	Unknown			Concordia
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			S	Unknown			Not Reported

Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling	Anakinra		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2017	13250179	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001153		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Plaquenil Tablet			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava Tablet			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2017	13250267	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001081		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Parenteral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2017	13250270	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001115		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Advil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2017	13250271	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001097		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Plaquenil		S	Unknown	Concordia
	Arava		S	Oral	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Not Reported
	Chloroquine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13238094	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008030		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Back Disorder; Back Pain; Blister; Decreased Appetite; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Herpes Virus Infection; Infection; Joint Swelling; Localised Infection; Localised Infection; Pain; Pelvic Pain; Renal Failure; Renal Failure; Sepsis; Skin Fissures; Vaginal Infection; Weight Decreased	Plaquenil			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fluconazole			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250487	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		52 YR	Female	CAN

INC.-E2B_00008017

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250489	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008024		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Malaise; Nasopharyngitis; Oral Herpes; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250492	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001060		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Operation; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250495	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001106		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported
	Lisinopril			C				Not Reported
	Fosamax			C				Not Reported
	Alendronate Sodium/Colecalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250496	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		41 YR	Male	CAN

						INC.-GSH201702-001107			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250498	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001113		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Pain; Pruritus; Rash; Swelling	Plaquenil			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Arava Tablet			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250501	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001119		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Neutropenia; Platelet Count Decreased	Plaquenil Tablet			S				Concordia
	Arava			S				Not Reported
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250502	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001121		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Joint Swelling; Pain In Extremity; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Salazopyrin			S	Oral			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Leflunomide Film Coated Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250503	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001132		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Treatment Failure	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Unknown			Concordia
	Arava Tablet			S	Unknown			Not Reported

	Arava Tablet			S	Unknown	Not Reported
	Desoximetasone			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Methotrexate Sodium			S		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Prednisone			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250611	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001168		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthralgia; Arthralgia; Arthritis; Arthritis; Balance Disorder; Blood Pressure Increased; Bronchitis; Bronchospasm; Chest Pain; Cough; Dizziness; Dizziness; Fall; Fall; Fatigue; Gastroenteritis; Headache; Headache; Headache; Hepatic Enzyme Increased; Hepatic Enzyme Increased; Hepatic Enzyme Increased; Hepatic Steatosis; Hepatic Steatosis; Hot Flush; Hot Flush; Hypertension; Influenza; Infusion Related Reaction; Joint Swelling; Medication Error; Mobility Decreased; Muscle Strain;	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown	Dose Reduced		Concordia
	Arava			S	Unknown			Not Reported
	Estradot			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Musculoskeletal Discomfort; Musculoskeletal Pain; Nasal Congestion; Nasal Congestion; Nasopharyngitis; Nausea; Nausea; Neutrophil Count Decreased; Oropharyngeal Pain; Oropharyngeal Pain; Oxygen Saturation Decreased; Pain In Extremity; Painful Respiration; Plantar Fasciitis; Poor Quality Sleep; Poor Venous Access; Pruritus; Pruritus; Pyrexia; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis; Tendon Pain; Tracheitis; Vaginal Haemorrhage; Vomiting; Vomiting; Weight Increased	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Prometrium		S	Oral		Not Reported
	Methotrexate		C			Not Reported
	Synthroid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250612	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001175		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Treatment Failure	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Anakinra	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250615	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001194		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Intolerance; Eczema; Erythema; Erythema; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Rhinorrhoea; Swelling Face; Therapeutic Response Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250618	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001198		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis;	Plaquenil Tablet			S	Oral			Concordia

Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S	Oral				Not Reported
	Methotrexate Sodium			S	Unknown				Not Reported
	Methotrexate Sodium			S	Oral				Not Reported
	Methotrexate Sodium			S	Oral				Not Reported
	Enbrel			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Advil			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Xeljanz			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250620	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001148		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Arava Tablet			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide Tablet			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Weekly		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250621	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Eye Disorder; Fatigue; Feeling Guilty; Impaired Work Ability; Mouth Ulceration; Oral Candidiasis; Pain; Stomatitis; Thermal Burn	Plaquenil Tablet			S	Oral			Concordia
	Arava Tablet			S	Oral			Not Reported
	Arava Tablet			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Advil			C				Not Reported
	Vesicare			C				Not Reported
	Tylenol 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250623	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001151		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling; Loose Tooth; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Tooth Abscess; Toothache	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250626	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001155		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250673	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diabetes Mellitus; Diarrhoea; Disability; Drug Ineffective; Pain; Swelling	Hydroxychloroquine			S				Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

	Lyrica			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Enbrel			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250674	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008029		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Loose Tooth; Musculoskeletal Stiffness; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tooth Abscess	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Abatacept			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2017	13250676	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001047		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	12710256	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Vimovo			C	Unknown			Not Reported
	Lorazepam			C	Oral	At Bedtime At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	12901774	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2153		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Intolerance; Interstitial Lung Disease; Liver Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Actemra			S	Unknown					Not Reported
	Apo-Hydroxyquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13178932	NON-EXPEDITED			US-PFIZER INC-2017039352		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13195472	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000773		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Decreased Appetite; Erythema Multiforme; Fatigue; Pruritus; Pyrexia; Rash Erythematous; Rash Morbilliform	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13238228	EXPEDITED (15-DAY)		HO	CA-ROCHE-1893865		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Prednisone	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Naproxen	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13250794	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001024			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
End Stage Renal Disease; Ophthalmic Herpes Zoster; Red Blood Cell Count Decreased; Renal Disorder; White Blood Cell Count Decreased	Plaquenil			S				Concordia
	Humira 40 Mg/0.8 Ml			S	Subcutaneous	40 Mg/0.8 Ml		Not Reported
	Humira 40 Mg/0.8 Ml			S				Not Reported
	Humira 40 Mg/0.8 Ml			S				Not Reported
	Celebrex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13250795	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Rash; Swelling; Urticaria	Plaquenil			S	Unknown			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous	40 Mg/0.8ml		Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Millicuries		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Paracetamol			C				Not Reported
	Ibuprofen			C				Not Reported
	Morphine			C				Not Reported

	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13250796	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13251145	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895869		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13251343	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008031		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Blepharospasm; Depressed Mood; Drug Ineffective; Ocular Hyperaemia; Vision Blurred	Plaquenil	S	Oral		Concordia
	Xeljanz	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13251502	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006761		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Blood Test Abnormal; Hepatotoxicity; Injection Site Pain	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1 Df, Total		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13251920	NON-EXPEDITED			US-AMGEN-USASL2017025862			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2017	13253880	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893224		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present;	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Gait Inability; Nausea; Rheumatoid Arthritis; Treatment Failure	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13179900	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2017014100		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthropathy; Bone Erosion; C-Reactive Protein Abnormal; Carpal Tunnel Syndrome; Diarrhoea; Gastrointestinal Disorder; Laryngitis; Rheumatoid Arthritis; Synovitis; Trigger Finger; Weight Increased	Enbrel			S	Unknown	Unk		Amgen
	Cortisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk, 10-25 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 200-400 Mg		Not Reported
	Naproxen			C	Unknown	250 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13237826	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001046			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Swelling	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13254163	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13254229	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Interstitial Lung Disease; Vomiting	Apo-Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20.0 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13254449	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008004		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Cough; Drug Ineffective; Eye Disorder; Gait Disturbance; Malaise; Nasopharyngitis; Pain; Peripheral Swelling; Peripheral Swelling; Pneumonia; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actonel			C				Not Reported
	Ibuprofen			C	Oral			Not Reported
	Vitamin D2			C	Oral			Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13254451	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001045			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Device Issue; Injection Site Bruising; Injection Site Haemorrhage; Injection Site Pain; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Sinusitis; Squamous Cell Carcinoma; Visual Impairment	Plaquenil			S	Unknown			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13254752	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Treatment Noncompliance	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13256161	DIRECT	Y	HO, RI				Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Colitis	Pantoprazole			S				Not Reported
	Cefepime			S				Not Reported
	Ertapenem			S				Not Reported
	Hydroxychloroquinine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2017	13258180	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	12921052	EXPEDITED (15-DAY)		HO	CA-ABBVIE-16K-028-1771776-00		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dyspnoea; Lung Disorder	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13250630	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001163		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Ramipril			C				Not Reported
	Asa			C				Not Reported
	Metformin			C				Not Reported
	Lantus			C				Not Reported
	Vitamin D2			C				Not Reported
	Calcium			C				Not Reported

		Prednisone			C					Not Reported
		Lozide			C					Not Reported
		Naprosyn			C					Not Reported
		Acetylsalicylic Acid			C					Not Reported
		Naproxen			C					Not Reported
		Ergocalciferol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13258331	EXPEDITED (15-DAY)		DS	CA-ROCHE-1895835		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13258373	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749549		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13258953	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895032		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Specific Antibody Present; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13259934	EXPEDITED (15-DAY)		OT	US-SA-2017SA023144			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Hypersensitivity; Insomnia; Muscular Weakness; Neuralgia; Restless Legs Syndrome	Ambien			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Clonidine			S	Unknown	Patch		Not Reported
	Clonidine			S	Unknown	Patch		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13260965	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1865773-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13261504	EXPEDITED (15-DAY)		HO	SG-IPCA LABORATORIES LIMITED-IPC201702-000033		67 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Toxic Epidermal Necrolysis	Hydroxychloroquine Sulfate			S				Ipca
	Cyclosporine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13262030	EXPEDITED (15-DAY)		HO	CA-CANTON LABORATORIES, LLC-1063467		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Naprosyn			S	Unknown			Canton Laboratories
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13262211	EXPEDITED (15-DAY)		OT	CA-ROCHE-1662402		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2017	13262222	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	11621575	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-15K-028-1477929-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	12741495	EXPEDITED (15-DAY)		OT	IT-ROCHE-1829777		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Neutropenia	Mycophenolate Mofetil			S	Oral			Not Reported
	Bactrim			S	Oral	160 Mg + 800 Mg Tablets Half Capsule Per Day 16 Tablets		Not Reported
	Plaquenil			S	Oral	25 Tablets		Not Reported
	Deltacortene			C	Oral	10 Tablets		Not Reported
	Deltacortene			C	Oral			Not Reported
	Deltacortene			C	Oral	5 Mg Tablets 20 Tablets		Not Reported
	Ramipril			C	Oral			Not Reported

Atorvastatin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13212285	EXPEDITED (15-DAY)		HO	IR-JNJFOC-20170206416		67 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tuberculosis	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13245175	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001092		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13254452	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001227			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Hypersensitivity; Insomnia; Muscular Weakness; Neuralgia; Restless Legs Syndrome	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Clonidine			S	Unknown			Concordia
	Clonidine			S	Unknown			Concordia
	Ambien			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2017	13262482	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895842		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	11624411	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477189-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate Injection Bp			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Ativan			C				Not Reported
	Benadryl			C				Not Reported
	Codeine			C				Not Reported
	Cortisone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dilaudid			C				Not Reported
	Enablex			C				Not Reported
	Hydromorphone			C				Not Reported
	Kadian Sustained-Release			C				Not Reported
	Kenalog			C	Intra-articular			Not Reported
	Kineret			C	Subcutaneous			Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C		Metered Dose		Not Reported
	Opioids			C				Not Reported
	Oxyneo Extended-Released			C				Not Reported
	Pantoloc			C				Not Reported
	Restasis			C				Not Reported
	Rituxan			C				Not Reported
	Synthroid			C				Not Reported
	Trimethoprim			C				Not Reported

	Urispas			C						Not Reported
	Vagifem			C	Vaginal					Not Reported
	Gold			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	12104881	NON-EXPEDITED			US-PFIZER INC-2016104953		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Demerol			S		Unk		Not Reported
	Chlorhexidine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	12308608	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745459		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

Prednisone	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Cortisone	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13182790	NON-EXPEDITED			US-PFIZER INC-2016478688		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Urinary Tract Infection	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Synvisc			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13266973	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13269101	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2017077868		55 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported
	Coversyl Plus			C				Not Reported
	Fenbid			C		Unk		Not Reported
	Novorapid			C		Unk		Not Reported
	Paracetamol And Codeine Phosphate			C		Unk		Not Reported
	Perindopril Arginine			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2017	13269898	EXPEDITED (15-DAY)		OT	PHHY2017AU027320			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cardiomegaly; Chest Pain; Dyspnoea Exertional	Myfortic			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Gen-Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2017	12563856	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016091341		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk, Weekly		Amgen
	Prednisone			S	Unknown	40 Mg, Every 1 Day		Not Reported
	Prednisone			S	Unknown	20 Mg, Every 1 Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg,Every 1 Day		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Not Reported
	Sulfasalazine			S	Oral	2 Mg, Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	9308844	EXPEDITED (15-DAY)		OT	RU-ROCHE-1227217			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Hypogammaglobulinaemia ; Neutropenia; Pneumonia	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	10-15 Mg/Kg		Not Reported

	Prednisolone			S	Oral	Average Dose Of 0.80 Mg/Kg		Not Reported
	Ivig			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13228925	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001022		53 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Myopia; Optical Coherence Tomography Abnormal; Retinal Depigmentation; Visual Acuity Tests Abnormal; Visual Field Defect; Visual Impairment	Plaquenil			S	Unknown			Concordia
	Chloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13234124	EXPEDITED (15-DAY)		HO, OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001059		32 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Ascites; C-Reactive Protein Increased; Cd4 Lymphocytes Decreased; Computerised Tomogram Abnormal; Condition Aggravated; Diarrhoea; Gamma-Glutamyltransferase Increased; Globulins	Hydroxychloroquine			S	Unknown			Concordia
	Ethambutol			S	Oral			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Pyrazinamide			S				Not Reported
	Levofloxacin			S	Oral			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Rifampicin			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported

Increased; Histology Abnormal; Jarisch-Herxheimer Reaction; Lymphadenopathy; Off Label Use; Peritoneal Tuberculosis; Pleural Adhesion; Protein Urine Present; Pulmonary Calcification; Pyrexia; Rash Papular; Red Blood Cell Sedimentation Rate Increased; T-Lymphocyte Count Decreased	Isoniazid	S	Unknown		Not Reported
	Isoniazid	S	Oral		Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone	S			Not Reported
	Methylprednisolone	S	Oral		Not Reported
	Methylprednisolone	S	Oral		Not Reported
	Methylprednisolone	S	Oral		Not Reported
	Aminosalicylic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13242778	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1009748			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemic Coma	Metformin			S	Oral	2200 Mg Daily		Not Reported
	Abasaglar			S		10 Iu Daily		Mylan
	Plaquenil			S	Oral	Unk Unk, Qd		Mylan
	Omeprazole			C		Unk		Mylan
	Irbesartan			C		Unk		Mylan
	Clopidogrel			C		Unk		Mylan
	Simvastatin			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2017	13275161	EXPEDITED (15-DAY)		OT	SG-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001312		52 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eye Swelling; Tinnitus	Hydroxychloroquine	S	Unknown	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	12135397	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717291		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Diverticulitis; Diverticulum; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Joint Destruction; Limb Injury; Nausea; Rheumatoid Arthritis; Stomal Hernia	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intracavernous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 6.0 Months		Not Reported
	Plaquenil			C	Oral	Two Tablets		Not Reported
	Xeljanz			C	Oral			Not Reported
	Lorazepam			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Tobradex			C	Unknown	As Directed		Not Reported
	Lotemax			C	Unknown	As Directed		Not Reported
	Oxycodone Hcl			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	12861315	EXPEDITED (15-DAY)		HO	CA-ROCHE-1843584		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 7 Years		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 330 Days		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Therapy Duration: 5 Years		Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C				Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Genteal (Hypromellose)			C				Not Reported
	Lomotil (Canada)			C	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Nortriptyline Hydrochloride			C	Oral			Not Reported
	Omega 3 Fatty Acids			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported
	Tylenol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13275827	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001307		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Plaquenil Tablet			S	Oral			Concordia
	Fragmin			S	Oral			Not Reported
	Contramal			S	Oral			Not Reported
	Ofloxacin			S	Oral			Not Reported
	Calsyn			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13277710	EXPEDITED (15-DAY)		DS, OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000064			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Neuritis; Ototoxicity; Vestibular Disorder	Hydroxychloroquine Sulfate			S				Ipca
	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2017	13279868	DIRECT		DS			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypoaesthesia Oral; Pain; Pruritus; Rash; Rash Erythematous; Rash Pruritic	Hydroxychlor			S	Oral	Quantity:1 Tablet(S);		Zydus Pharm
	Armour Thyroid			C				Not Reported
	Estradiol			C				Not Reported
	Calcium			C				Not Reported
	Glucosamine			C				Not Reported
	Multi Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	12764450	EXPEDITED (15-DAY)		OT	PR-ABBVIE-16K-131-1670547-00		57 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Hernia; Arthralgia; Asthenia; Bone Pain; Cellulitis; Cough; Depressed Mood; Fatigue; Feeling Of Despair; Headache; Lipoma; Lymphoma; Musculoskeletal Discomfort; Pain In Extremity; Pruritus; Rash Macular; Skin Discolouration	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Plaquenil			C	Oral			Not Reported
	Tizadine			C	Oral			Not Reported
	Zoloft			C	Oral			Not Reported
	Synthroid			C	Oral			Not Reported
	Klonopin			C	Oral			Not Reported
	Zocor			C	Oral			Not Reported
	Azulfidine			C	Oral			Not Reported
	Zanaflex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13063903	NON-EXPEDITED			US-PFIZER INC-2016587806		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly (2.5 Mg 4 Tabs A Wk)		Pfizer
	Methotrexate Sodium			S				Pfizer
	Prednisone			S		5 Mg, 2x/Day		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Prednisone			S				Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13281112	EXPEDITED (15-DAY)		OT	CA-ROCHE-1898409		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Tongue Ulceration; Tooth Infection	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Abatacept			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indocin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286738	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001261		55 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl Plus			C				Not Reported
	Fenbid			C				Not Reported
	Novorapid			C				Not Reported
	Paracetamol And Codeine Phosphate			C				Not Reported

		Perindopril Arginine			C						Not Reported
		Simvastatin			C						Not Reported
		Lantus			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286743	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001334		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Tolerance; Fatigue; Hyperhidrosis; Influenza; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel Solution For Injection In Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin D2			C				Not Reported
	Vitamins Nos			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286744	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Hepatotoxicity; Musculoskeletal Disorder; Musculoskeletal Pain; Pain; Pain; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported

	Adalimumab			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286745	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001340		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Disability; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Celebrex			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286746	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Champix			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Unknown	Not Reported
	Rituxan			S	Unknown	Not Reported
	Actemra			S	Unknown	Not Reported
	Cimzia			S	Subcutaneous	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Valacyclovir			C		Not Reported
	Vimovo			C		Not Reported
	Crestor			C		Not Reported
	Oxycocet			C		Not Reported
	Xeljanz			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2017	13286858	EXPEDITED (15-DAY)		HO	CA-ROCHE-1899556		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 330.0 Day(S)		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported

	Actonel	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	12117854	EXPEDITED (15-DAY)		OT	CA-ROCHE-1630803		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Pain; Pruritus; Rash; Swelling	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Stopped.		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Cyclical		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	12370021	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2016-US-005699			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Back Disorder; Bacterial Vaginosis; Fungal Infection; Hypoaesthesia; Muscle Atrophy; Muscle Spasticity; Nail Disorder; Nerve Injury; Oedema; Panic Attack; Peroneal Nerve Palsy; Rash Macular; Skin Discolouration; Skin Exfoliation; Skin Wrinkling; Urticaria; Weight Decreased	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Diflucan			S		Unknown Dose		Not Reported
	Flagyl			S		Unknown Dose		Not Reported
	Plaquenil			S				Not Reported
	Adderall			C		Unk		Not Reported
	Benadryl Allergy			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Cymbalta			C				Not Reported
	Docusate Sodium			C				Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Nifedipine			C				Not Reported
	Oxycodone And Acetaminophen			C				Not Reported
	Tramadol Hcl			C				Not Reported
	Trazodone			C				Not Reported
	Vitamin D3			C				Not Reported
	Adderall			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	12580663	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016093637		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Osteoarthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	12583758	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016094323		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear Of Injection; Rheumatoid Arthritis; Stress; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	15 Mg, Bid		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	12609723	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016098080		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Nephrolithiasis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Celebrex			S	Oral	200 Mg, As Necessary		Not Reported
	Hydromorphone Hydrochloride			C	Unknown	Unk Unk, As Necessary		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287472	EXPEDITED (15-DAY)		OT	JO-IPCA LABORATORIES LIMITED-IPC201702-000069		58 YR	Male	JOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287490	EXPEDITED (15-DAY)		OT	JO-IPCA LABORATORIES LIMITED-IPC201702-000070		62 YR	Male	JOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287511	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201702-000073		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection; Infective Tenosynovitis	Hydroxychloroquine Sulfate			S				Ipca
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287524	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201702-000074		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection; Infective	Hydroxychloroquine Sulfate			S				Ipca

Tenosynovitis	Prednisone			S						Not Reported
	Methotrexate			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287742	EXPEDITED (15-DAY)		DE	PHHY2017US031854			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sandostatin Lar			S	Unknown			Novartis
	Capecitabine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lanreotide			S	Unknown			Not Reported
	Bevacizumab			S	Unknown			Not Reported
	Temozolomide			S	Unknown			Not Reported
	Xelox			S	Unknown			Not Reported
	Sunitinib			S	Unknown	Unk		Not Reported
	Nivolumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287785	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001346			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Arava			S				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287786	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001368			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Ear Infection; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13287788	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Pain In Extremity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Asa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13288008	EXPEDITED (15-DAY)		OT	CA-ROCHE-1899595		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2017	13289141	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-00		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	12682445	EXPEDITED (15-DAY)		OT	CA-AMGEN-KDL157634		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	12890841	EXPEDITED (15-DAY)		HO	CA-CANTON LABORATORIES, LLC-		61 YR	Female	CAN

1058977

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naprosyn			S				Canton Laboratories
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13057277	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP015777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Disability; Drug Ineffective; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	17.5 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13113424	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017006155		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Herpes Zoster; Immobile; Malignant Melanoma;	Methotrexate Sodium			S	Oral	25 Mg (10 Tabs Of 2.5 Mg), Once Weekly		Pfizer

Product Dose Omission; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Oral	1000 Mg, 2x/Day		Pfizer
	Hydroxychloroquine	S	Oral	200 Mg, 2x/Day		Not Reported
	Folic Acid	C		Unk		Not Reported
	Synthroid	C		Unk		Not Reported
	Restasis	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13225702	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017019589		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Mycobacterium Avium Complex Infection; Pneumonia	Benlysta			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Hydroxychloroquine			S		400 Mg, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13270135	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-014648		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemic Coma	Metformin Hydrochloride			S	Oral	2200 Mg, Qd		Bristol Myers Squibb
	Insulin Glargine			S	Unknown	10 Iu, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Unk		Not Reported
	Omeprazole			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13291178	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13293422	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2017M1013664			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Vascular Malformation	Prednisone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Aspirin /00002701/			S	Transplacental			Mylan
	Enoxaparin Sodium			S	Transplacental			Mylan
	Immunoglobulin (Ivig)			S	Transplacental			Mylan
	Rituximab			S	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294226	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000132		65 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294227	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000133		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294228	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000134		38 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294229	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000135		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294230	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000136		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294231	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000137		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Headache; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294232	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000138		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Gait Disturbance; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294233	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000139		16 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Rash	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294234	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000140		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294235	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000141		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294236	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES			Female	FRA

							LIMITED-IPC201702-000142			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294237	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000143		30 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294238	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000144		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Vertigo	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294239	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000145		69 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294240	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000146		50 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294241	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000147		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294242	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000148		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral;	Hydroxychloroquine Sulfate			S				Ipca
Toxicity To Various Agents	Furosemide			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294243	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000149		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294244	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000150		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294245	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000151		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294246	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000152		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294247	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000153		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294248	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000154		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294249	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000168		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Tinnitus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294250	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000169		11 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2017	13294251	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC201702-000170		57 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	12316725	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration 244.0		Not Reported

				Day(S)	
	Cyclosporine	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 4 Years	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 4 Years	Not Reported
	Imuran	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 488.0 Day(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	12687167	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1212		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Nephrolithiasis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral	2x/Day		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydromorph			C	Unknown			Not Reported
	Tamsulosin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	12982262	NON-EXPEDITED			US-PFIZER INC-2016543730		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective	Methotrexate Sodium			S		Unk (6 At 2.5 Per Week Then 8 At 2.5/ Week)		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Meloxicam			C		15 Mg, Daily, As Needed (Prn)		Not Reported
	Methylprednisolone			C		Unk (4 Mg Pack; 21 Pills)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13296695	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001412		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13297073	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS		17 YR	Female	FRA

						INC.-GSH201703-001429			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Suicide Attempt; Weight Decreased	Plaquenil Tablet			S	Oral			Not Reported
	Plaquenil Tablet			S	Oral	Once		Not Reported
	Alprazolam			S	Unknown			Not Reported
	Alprazolam			S	Unknown	Once		Not Reported
	Alprazolam			S	Unknown			Not Reported
	Thalidomide			S	Oral			Not Reported
	Thalidomide			S	Oral	Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13297101	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008053			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hand Deformity; Infection; Pain; Rheumatoid Arthritis; Therapy Non-Responder	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Celebrex			S				Not Reported
	Toradol			S				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13297388	EXPEDITED (15-DAY)		HO	SK-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001417		67 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Papular	Plaquenil			S	Oral			Not Reported
	Aceclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13299529	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016516690		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Chills; Dry Skin; Fatigue; Malaise; Nausea; Pruritus; Pyrexia; Vomiting	Methotrexate Sodium			S	Oral	10 Df, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2017	13300171	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001440		61 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Febrile Neutropenia	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral	Twice A Day		Not Reported
	Plaquenil			S	Oral			Not Reported
	Endoxan			S	Intravenous (not otherwise specified)	First Infusion: 600mg/M^2 (Total 900 Mg)		Not Reported
	Bactrim Forte			C				Not Reported
	Cortancyl			C				Not Reported
	Ramipril			C				Not Reported
	Lovenox			C				Not Reported
	Amlodipine			C				Not Reported
	Kardegic			C				Not Reported
	Atorvastatin			C				Not Reported
	Esomeprazole			C				Not Reported
	Dermoval (Clobetasol Propionate)			C				Not Reported
	Tramadol			C				Not Reported
	Paracetamol			C				Not Reported
	Metoclopramide			C				Not Reported
	Zolpidem			C				Not Reported
	Amlor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	11416332	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015278898		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			S		Unk, 1x/Day, 20 Mg To 2.5 Mg (Taper)		Not Reported
	Naprosyn /00256201/			C		Unk, As Needed		Not Reported
	Tylenol /00020001/			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	11618839	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477030-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertension; Pulmonary Fibrosis; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	12000967	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-HQWYE695901JUN06		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	25 Mg, 2x/Wk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13120667	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0104		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Herpes Zoster; Immobile; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral	2.5 Mg X 10 Tablets		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Multivitamin			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13242479	EXPEDITED (15-DAY)		OT	US-SA-2017SA016221		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Eye Pruritus; Eye Pruritus; Eyelid Oedema; Hypersensitivity; Lacrimation Increased; Peripheral Swelling; Photosensitivity Reaction; Pruritus; Rash; Rash Erythematous; Skin Exfoliation; Swelling; Swelling Face	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Advil	C	Unknown	Dose: 200-800 (Unit Unspecified), One Tablet On And Off	Not Reported
	Advil	C	Unknown	Dose: 200-800 (Unit Unspecified), One Tablet On And Off	Not Reported
	Advil	C	Unknown	Dose: 200-800 (Unit Unspecified), One Tablet On And Off	Not Reported
	Armour Thyroid	C	Unknown	60mg Once In The Morning, Taking Probably 15 Years	Not Reported
	Humira	C	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown	Varies 1-20 Mg	Not Reported
	Prednisone	C	Unknown	Varies 1-20 Mg	Not Reported
	Prednisone	C	Unknown	Varies 1-20 Mg	Not Reported
	Prednisone	C	Unknown	Varies 1-20 Mg	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13258591	EXPEDITED (15-DAY)		DS, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001273		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Vestibular Syndrome; Deafness Neurosensory	Hydroxychloroquine Tablet			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13267752	EXPEDITED (15-DAY)		DS, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001272		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Vestibular Syndrome; Deafness Bilateral	Hydroxychloroquine Tablet			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13300200	EXPEDITED (15-DAY)		OT	CA-ROCHE-1901431		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Gait Disturbance; Joint Range Of Motion Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13300257	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1894952-00		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Increased; Double Stranded Dna Antibody Positive; Injection Site Pain	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Risperidone			C				Not Reported
	Wellbutrin			C				Not Reported
	Verapamil			C				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13300340	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Reactine [Cetirizine Hydrochloride]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13300606	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13301439	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2277		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dry Skin; Fatigue; Malaise; Nausea; Pruritus; Pyrexia; Regurgitation; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13301497	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1449491-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Die		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Enbrel		S	Subcutaneous		Not Reported
					Xeljanz		C			Not Reported
					Methotrexate Sodium		C	Oral		Not Reported
					Methotrexate Sodium		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2017	13303955	NON-EXPEDITED			PHEH2017US005837			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Voltaren-Xr			S	Unknown			Novartis
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	11618799	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1476797-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Rabeprazole Ec			C				Not Reported
	Depo Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	12893854	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013394		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Osteoporosis; Pain; Rash	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Apo-Naproxen			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Mg, Bid		Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	12951047	EXPEDITED (15-DAY)		OT	US-SA-2016SA208769		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ridaura			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Plavix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13275828	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001349		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid	Hydroxychloroquine			S	Unknown			Concordia

Syndrome; Condition Aggravated; Drug Ineffective; Extremity Necrosis; Skin Lesion	Hydroxychloroquine		S	Unknown	Concordia
	Prednisolone		S	Oral	Not Reported
	Acetylsalicylic Acid		S	Unknown	Not Reported
	Iloprost		S	Unknown	Not Reported
	Iloprost		S	Unknown	Not Reported
	Phenprocoumon		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304141	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304237	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001485		66 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Chills; Pyrexia; Rash	Hydroxychloroquine 200 Mg Tablet			S	Oral			Not Reported
	Chloramphenicol			C				Not Reported
	Oculotect			C				Not Reported
	Mizolastine			C				Not Reported
	Pantoprazole			C				Not Reported
	Montelukast			C				Not Reported
	Estriol			C				Not Reported
	Carbomer			C				Not Reported

	Vaseline			C							Not Reported
	Euthyrox			C							Not Reported
	Mometasone			C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304497	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304498	EXPEDITED (15-DAY)		OT	SG-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001443		62 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Periorbital Oedema	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304500	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001487		80 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cold Sweat; Fatigue; Vision Blurred	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Kalcipos-D Forte			C				Not Reported
	Nitrolingual			C				Not Reported
	Panodil			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304730	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2017SP003667			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Mycophenolate Mofetil			S	Unknown	2 G/Day, Unknown		Strides
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg/Day, Unknown		Not Reported
	Methotrexate			S	Unknown	15 Mg/Week, Unk		Not Reported
	Sirolimus			S	Unknown	2 Mg/Day, Unk		Not Reported
	Prednisone /00044702/			C	Unknown	Unk, Unknown		Not Reported
	Prednisone /00044702/			C		Dose Tapered		Not Reported
	Prednisone /00044702/			C	Unknown	Dose Fell Below 20 Mg/Daily, Unk		Not Reported
	Prednisone /00044702/			C	Unknown	Dose Tapered To 10 Mg/Daily, Unk		Not Reported
	Corticosteroids			C	Topical	Unk, Unknown		Not Reported
	Immune Globulin Nos			C	Intravenous (not otherwise specified)	2 G/Kg Over 3 Days ,Every 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304789	EXPEDITED (15-DAY)		OT	US-GILEAD-2017-0255235		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Systemic Lupus Erythematosus	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Uptravi			C				Not Reported
	Revatio			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13304981	NON-EXPEDITED			US-PFIZER INC-2016539091			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Neosporin	S	Unk	Pfizer
	Levofloxacin	S	Unk	Pfizer
	Neomycin Sulfate	S	Unk	Pfizer
	Augmentin	S	Unk, Strength: 500/125	Not Reported
	Amoxicillin	S	Unk	Not Reported
	Antivert	S	Unk	Not Reported
	Bleph	S	Unk , Strength: 10	Not Reported
	Hydrocodone	S	Unk	Not Reported
	Lactose	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Acetaminophen W/Propoxyphene	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	11820435	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675314		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Does Not Tolerate 1 G Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13063060	EXPEDITED (15-DAY)		OT	CA-ROCHE-1631753			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Not Controlling Disease		Not Reported

Abnormal; Liver Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased						And Causing Debilitation And Inability To Perform Daily Activities			
	Humira			S	Subcutaneous	Didn'T Work And Patient Still Symptomatic			Not Reported
	Leflunomide			S	Unknown	Didn'T Work And Patient Still Symptomatic			Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Methotrexate			S	Unknown	Affected Liver Enzymes			Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13309720	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017034607			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Influenza; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cyclosporin			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13320514	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001535		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Insomnia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Plaquenil	S	Unknown		Concordia
	Arava	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Celebrex	S	Unknown		Not Reported
	Lansoprazole	C			Not Reported
	Erythromycin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	9287753	NON-EXPEDITED			US-PFIZER INC-2013145902		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Prednisone			S		Unk		Pfizer
	Aleve			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Excedrin			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Norflex			S		Unk		Not Reported
	Phenergan			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Keflex /00145501/			S		Unk		Not Reported
	Ultracet			S		Unk		Not Reported

Ultram	S	Unk	Not Reported
Relafen	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Excedrin Migraine	S	Unk	Not Reported
Naproxen	S	Unk	Not Reported
Darvocet-N	S	Unk	Not Reported
Centrum	C	1 Df, 1x/Day (Am)	Not Reported
Vitamin D3	C	2 Df, 1x/Day(Am)	Not Reported
Vitamin E	C	2 Df, 1x/Day (Pm)	Not Reported
Biotin	C	2 Df, 2x/Day (2 Capsules Am, 2 Capsules Pm)	Not Reported
Cellcept	C	500 Mg,(3 In Am 2 In Pm)	Not Reported
Lyrica	C	3 Df, 3x/Day (2 Am 2 Noon 2 Pm)	Not Reported
Claritin	C	10 Mg, 2x/Day (1 In Am 1 In Pm)	Not Reported
Klonopin	C	1 Mg, 3x/Day	Not Reported
Dilaudid	C	8 Mg, 12 Daily In Divided Dose	Not Reported
Percocet	C	10/325 Mg, 12 Daily In Divided Dose	Not Reported
Soma	C	350 Mg, Prn (1/2-1 Tab 3xday)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	11618844	EXPEDITED (15-DAY)		DS	CA-ABBVIE-15K-028-1476810-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass;	Humira 40mg/0.8ml			S	Subcutaneous	Duration 2 Years		Not Reported
	Actemra			S	Intravenous (not			Not Reported

Mobility Decreased; Pain; Peripheral Swelling				otherwise specified)		
	Aarava	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral	Duration 3 Years		Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13287790	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001371		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus; Skin Lesion	Hydroxychloroquine			S	Unknown	200-400 Mg/D		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13302023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017092300		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Depressed Mood; Pleural Effusion; Pneumothorax; Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Naproxen			S	Oral	500 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2017	13320729	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK033115			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Voltaren-Xr			S		Unk		Glaxosmithkline

	Celebrex			S	Unk				Not Reported
	Plaquenil			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2017	13327063	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902870		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13258590	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001208			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Pyrexia; Respiratory Tract Infection	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C				Not Reported
	Tylenol			C				Not Reported
	Pantoloc			C				Not Reported
	Elmiron			C				Not Reported
	Actemra			C				Not Reported
	Adalimumab			C				Not Reported

	Abatacept			C						Not Reported
	Etanercept			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13304503	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001533		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Eye Pruritus; Eye Pruritus; Eyelid Oedema; Hypersensitivity; Lacrimation Increased; Peripheral Swelling; Photosensitivity Reaction; Pruritus; Rash; Rash; Rash Erythematous; Skin Exfoliation; Swelling; Swelling Face	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			S	Oral	Twice A Day		Not Reported
	Advil			C				Not Reported
	Armour Thyroid			C				Not Reported
	Humira			C				Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13330474	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001639		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Pancytopenia	Plaquenil			S	Oral			Concordia
	Imeth			S	Oral			Not Reported
	Speciafoldine			C				Not Reported
	Lyrica			C				Not Reported
	Paracetamol			C				Not Reported
	Esomeprazole			C				Not Reported
	Diprosone			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13332573	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001642		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Vimovo			C				Not Reported
	Folic Acid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13332574	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001647		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Disturbance; Limb Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tooth Infection	Plaquenil			S	Unknown			Concordia
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Meloxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2017	13334083	NON-EXPEDITED		OT	US-AMGEN-USASL2017037866			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	12313122	EXPEDITED (15-DAY)		HO	CA-ROCHE-1748847		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Eruption; Drug Ineffective; Fatigue; Femur Fracture; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	12556400	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016090677		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Celebrex			C	Oral	200 Mg, Qd		Not Reported

	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13319938	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0750		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Depressed Mood; Exostosis; Pleural Effusion; Pneumothorax; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13335218	EXPEDITED (15-DAY)		OT	CA-ROCHE-1905466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Enbrel			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13336853	NON-EXPEDITED			US-PFIZER INC-2017106636		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Sulfasalazine	S	Unk		Pfizer
	Arava	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13337024	NON-EXPEDITED			US-PFIZER INC-2017113683			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13341070	DIRECT	Y				24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Hydroxychlor Tab 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13340023	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001664			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13340850	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201703-			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiotoxicity	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13345244	DIRECT		OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder; Toxicity To Various Agents; Visual Acuity Reduced	Plaquenil 400 Mg Daily Damage To The Retini	Y		S	Oral	Quantity:1 Tablet(S);		Concordia
	Hydrochlorothiazide			C				Not Reported
	Tradjenta			C				Not Reported
	Glyburide			C				Not Reported
	Clobetasol Foam			C				Not Reported
	Azathioprine			C				Not Reported
	Atorvastatin			C				Not Reported
	Nystatin Powder			C				Not Reported
	Zaditor			C				Not Reported
	Levothyroxine			C				Not Reported
	Lansoprazole Dr			C				Not Reported
	Lisinopril/Hctz			C				Not Reported
	Bit D			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13095816	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000009		32 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Dizziness;	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

Peripheral Coldness;
Product Counterfeit

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13182469	NON-EXPEDITED			US-PFIZER INC-2017042857		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13344391	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US04123			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Disseminated Intravascular Coagulation; Haemophagocytic Lymphohistiocytosis; Inappropriate Antidiuretic Hormone Secretion; Multiple Organ Dysfunction Syndrome; Rhabdomyolysis; Urinary Retention	Levofloxacin			S	Unknown	Unk		Cipla
	Vancomycin			S	Unknown	Unk		Cipla
	Piperacillin/ Tazobactum			S	Unknown	Unk		Cipla
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Acyclovir			S	Unknown	Unk		Not Reported
	Ampicillin			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Cipla
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Pazopanib			S	Unknown	800 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13344662	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017036926		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness	Enbrel	S	Unknown	Unk, Qwk		Amgen
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine	C	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13345019	NON-EXPEDITED			US-PFIZER INC-2017117896			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rabeprazole			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13346311	EXPEDITED (15-DAY)		OT	US-HORIZON-PRE-0099-2017		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis Of Jaw	Prednisone			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	13346686	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1016695			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrotising Fasciitis	Prednisone			S	Unknown	17 Mg Daily		Not Reported

	Hydroxychloroquine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2017	13348291	NON-EXPEDITED			US-AMGEN-USASP2017037454			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13229502	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000926		40 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Gastrooesophageal Reflux Disease; Haematemesis; Pain In Extremity; Suspected Counterfeit Product	Plaquenil Tablet			S	Oral			Not Reported
	Fen Le			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13331068	EXPEDITED (15-DAY)		HO	AU-ACTELION-A-CH2017-150557		35 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pulmonary Arterial Hypertension	Opsumit			S	Oral	10 Mg, Od		Actelion
	Hydroxychloroquine			S	Oral	400 Mg, Od		Not Reported
	Sildenafil			S	Oral	25 Mg, Tid		Not Reported
	Rivaroxaban			C	Oral	20 Mg, Od		Not Reported
	Lasix			C	Oral	40 Mg, Od		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13349835	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1116		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13351427	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2017085519		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Nerve Compression; Product Use In Unapproved Indication	Gabapentin			S		300 Mg, 1x/Day		Pfizer
	Plaquenil /00072603/			S		400 Mg, 1x/Day		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2017	13354080	DIRECT		OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Plaquenil/Hydroxychloroquine			S	Oral	Quantity:2 Tablet(S);		Ranbaxy
	Zoloft/Sertraline			C				Not Reported
	Vivelle Dot Estrogen Patch			C				Not Reported
	Flonase Nasal Spray			C				Not Reported
	Trazodone			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Calcium Supplement			C				Not Reported

	Magnesium Supplement			C						Not Reported
	Ibuprofen			C						Not Reported
	Omega 3 Supplement			C						Not Reported
	Probiotic			C						Not Reported
	Antihistamine			C						Not Reported
	Decongestant			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13325181	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC-2017088921			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pyelocaliectasis; Congenital Spinal Cord Anomaly; Maternal Exposure During Pregnancy; Pyrexia; Viral Upper Respiratory Tract Infection	Xanax			S	Transplacental	Unk		Pfizer
	Belimumab			S	Transplacental	400 Mg, Cyclic		Not Reported
	Lamictal			S	Transplacental	Unk		Not Reported
	Nicoderm			S	Transplacental	Unk		Not Reported
	Percocet			S	Transplacental	Unk		Not Reported
	Plaquenil			S	Transplacental	Unk		Not Reported
	Vyvanse			S	Transplacental	Unk		Not Reported
	Benzylpenicillin			C	Transplacental	Unk		Not Reported
	Folate			C	Transplacental			Not Reported
	Methotrexate			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13352985	NON-EXPEDITED			US-AMGEN-USASP2017038008		61 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Adalimumab			C	Unknown			Not Reported

	Xeljanz			C	Unknown	5 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353142	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001757		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Chills; Dry Skin; Dry Skin; Fatigue; Malaise; Nausea; Pruritus; Pyrexia; Vomiting	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Iron			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353464	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353779	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001733		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Systemic Lupus Erythematosus	Plaquenil			S	Unknown			Concordia
	Ambrisentan Tablet			S	Unknown			Not Reported

	Uptravi			C						Not Reported
	Revatio			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13353895	NON-EXPEDITED			US-PFIZER INC-2017114168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Mycophenolate Mofetil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Cyclophosphamide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13354039	NON-EXPEDITED		OT	US-AMGEN-USASL2017041892		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Dose Omission; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2017	13355805	EXPEDITED (15-DAY)		HO	US-IPCA LABORATORIES LIMITED-IPC201703-000236		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy; Quadriparesis	Hydroxychloroquine Sulfate			S				Ipca
	Escitalopram			C				Not Reported
	Dapsone			C				Not Reported
	Famotidine			C				Not Reported
	Prednisone			C				Not Reported

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Arava Film Coated Tablet		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13357058	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache; Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Rheumatoid Arthritis; Weight Fluctuation	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Actemra			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13357102	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001819		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Mycobacterium Avium Complex Infection; Pneumonia	Hydroxychloroquine			S				Concordia
	Benlysta			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13357819	NON-EXPEDITED			US-PFIZER INC-2017114057			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S		Unk		Pfizer
	Mycophenolate Mofetil			S		Unk		Not Reported

		Hydroxychloroquine			S		Unk			Not Reported
		Azathioprine			S		Unk			Not Reported
		Cyclophosphamide			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13357838	NON-EXPEDITED			US-PFIZER INC-2017114166			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Mycophenolate Mofetil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Cyclophosphamide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13357901	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017041853			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Toxicity To Various Agents	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13359953	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043050			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form: Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2017	13360139	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form-Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form-Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	12639155	EXPEDITED (15-DAY)		OT	CA-ROCHE-1809565			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Leflunomide			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13147021	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1847712-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13192060	NON-EXPEDITED			US-PFIZER INC-2017050905		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Dry Mouth; Gastrooesophageal Reflux	Xeljanz			S	Oral	5 Mg, 2x/Day Morning And Night		Pfizer

Disease; Lip Swelling; Pollakiuria	Xeljanz Xr	S	11 Mg, Daily	Pfizer
	Xeljanz Xr	S	2 Df, Daily (5.5 2 Daily)	Pfizer
	Hydroxychloroquine	S	200 Mg, 2x/Day	Not Reported
	Pravastatin	C	20 Mg, (For 3 Years) 1x/Day In Evening	Not Reported
	Coreg	C	12.5 Mg, 2x/Day	Not Reported
	Fish Oil	C	Unk	Not Reported
	Calcium	C	Unk	Not Reported
	Red Yeast Rice	C	600 Mg, Unk	Not Reported
	Amoxicillin	C	500 Mg, Unk	Not Reported
	Coq 10	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13203569	EXPEDITED (15-DAY)		OT	CA-SA-2015SA107688		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Intolerance; Musculoskeletal Stiffness; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13287793	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001384		67 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angina Unstable	Plaquenil	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13307549	EXPEDITED (15-DAY)		OT	CA-SA-2017SA036618			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hidradenitis; Staphylococcal Infection	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Cipralex			C	Unknown			Not Reported
	Zantac			C	Unknown			Not Reported
	Tylenol 3			C	Unknown	1-2 Tabs		Not Reported
	Zoledronic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13361678	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001768		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Hydroxychloroquine			S				Concordia
	Metformin			C	Oral	500mg Qam And 1000mg Hs		Not Reported
	Qsymia			C	Oral	3.75 Mg/23 Mg Capsules		Not Reported
	Qsymia			C	Oral	7.5 Mg/46 Mg Capsules		Not Reported
	Qsymia			C	Oral	11.25 Mg/69 Mg Capsules		Not Reported
	Qsymia			C	Oral	15 Mg/92 Mg Capsules		Not Reported
	Qsymia			C	Oral	15 Mg/92 Mg Capsules		Not Reported
	Avapro			C	Oral	125-150 Qd		Not Reported
	Actos			C	Oral			Not Reported

	Invokana				C	Oral				Not Reported
	Victoza				C					Not Reported
	Trilipix				C	Oral				Not Reported
	Crestor				C	Oral				Not Reported
	Vitamin D3				C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13362577	NON-EXPEDITED			US-PFIZER INC-2017124254			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfadiazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13362664	NON-EXPEDITED			US-PFIZER INC-2017123041		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Methotrexate Sodium			S		20 Mg, Unk (2wk)		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Meloxicam			S		15 Mg, Daily		Not Reported
	Meloxicam			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13365584	EXPEDITED (15-DAY)		HO	IT-IPCA LABORATORIES LIMITED-IPC201703-000277		62 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2017	13365600	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201703-000278		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	12348093	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-033793		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Swelling; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Arava			C	Unknown	20 Mg, Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13246191	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006577		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Pain; Pain In Extremity	Apo-Azathioprine			S	Unknown	50 Mg, Tid		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Every One Day		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex

	Celebrex			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13251297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006727		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Drug Ineffective; Drug Intolerance; Palpitations; Rash; Rheumatoid Arthritis; Therapeutic Response Decreased	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13335314	NON-EXPEDITED			US-PFIZER INC-2017106394		62 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Etanercept			S		Unk		Pfizer
	Etanercept			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Adalimumab			S		Unk		Not Reported
	Adalimumab			S				Not Reported
	Hydroxychloroquine Sulphate			S		Unk		Not Reported
	Hydroxychloroquine Sulphate			S				Not Reported
	Leflunomide			S		Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13362590	NON-EXPEDITED			US-PFIZER INC-2017128137			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Nightmare; Palmar Erythema; Plantar Erythema	Lyrica			S		Unk		Pfizer
	Lyrica			S				Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13367404	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001905			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13367463	EXPEDITED (15-DAY)		CA, OT	US-ENDO PHARMACEUTICALS INC-2017-001279			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pyelocaliectasis; Congenital Spinal Cord Anomaly; Foetal Exposure During Pregnancy	Percocet			S	Transplacental	Unk Unk, Unknown		Vintage
	Belimumab			S	Transplacental	Maternal Dose: 400 Mg Cyclically		Not Reported
	Lamictal			S	Transplacental	Unk Unk, Unknown		Not Reported
	Nicoderm			S	Transplacental	Unk Unk, Unknown		Not Reported
	Plaquenil /00072603/			S	Transplacental	Unk Unk, Unknown		Not Reported
	Xanax			S	Transplacental	Unk Unk, Unknown		Not Reported
	Vyvanse			S	Transplacental	Unk Unk, Unknown		Not Reported
	Folate			C	Transplacental	Unk Unk, Unknown		Not Reported
	Penicillin /00000901/			C	Transplacental	Unk Unk, Unknown		Not Reported
	Methotrexate			C	Transplacental	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13368073	NON-EXPEDITED			US-ALEMBIC PHARMACUETICALS LIMITED-2017SCAL000174			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Pain In Extremity; Rash; Swelling	Leflunomide			S		Unk		Alembic
	Humira			S	Subcutaneous	40 Mg/0.8 Ml		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13368242	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Stress	Plaquenil Tablet			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine Phosphate			C				Not Reported
	Paracetamol							
	Actemra			C				Not Reported
	Cimzia			C				Not Reported
	Enbrel			C				Not Reported
	Metformin			C				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13368247	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001914			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Hydroxychloroquine 200 Mg Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13368461	NON-EXPEDITED			US-PFIZER INC-2017127935			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13369066	EXPEDITED (15-DAY)		OT	CA-ROCHE-1906652		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Rosuvastatin Calcium	C	Oral			Not Reported
	Asa	C	Unknown			Not Reported
	Nitroglycerin	C	Unknown	D5w 0.2 Mg/Ml		Not Reported
	Desipramine	C	Unknown			Not Reported
	Clonazepam	C	Oral			Not Reported
	Gabapentin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13370329	EXPEDITED (15-DAY)		OT	CA-SA-2017SA047768		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13371068	EXPEDITED (15-DAY)		HO, OT	AR-BAUSCH-BL-2017-007509		73 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Systemic Scleroderma	Enalapril Maleate			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Not Reported
	Diltiazem			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Amlodipine (Salt Not Specified)			S	Unknown			Not Reported
	Sildenafil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2017	13372198	DIRECT	Y	HO			26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Swelling	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	12705230	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016112898		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein; Diarrhoea; Disability; Drug Ineffective; Fatigue; Gait Disturbance; Joint Swelling; Nausea; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13372541	EXPEDITED (15-DAY)		HO	IR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001942		67 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Prednisolone			S	Unknown	Daily		Concordia
	Prednisolone			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13372542	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13372543	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Quality Of Life Decreased; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine 200 Mg Tablet			S	Unknown			Concordia
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13372546	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001954			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Plaquenil 200 Mg Tablet	S	Unknown		Concordia
	Leflunomide	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2017	13372763	EXPEDITED (15-DAY)		HO, OT	AR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001899		73 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anuria; Drug Ineffective; Generalised Oedema; Hypertension; Microangiopathic Haemolytic Anaemia; Pleural Effusion; Renal Impairment; Scleroderma Renal Crisis; Systemic Scleroderma	Hydroxychloroquine			S	Unknown			Concordia
	Enalapril			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Diltiazem			S	Unknown			Not Reported
	Sildenafil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	12705730	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1518		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported

	Orencia			S	Subcutaneous					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13229915	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2017059779		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Nasopharyngitis	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Folic Acid			S		1 Mg, 2x/Day		Pfizer
	Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cholecalciferol/Vitamin D			S		600 Mg, 2x/Day		Unknown
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Symbicort			C		160/4.5 Mcg Actuation Inhaler		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13335032	EXPEDITED (15-DAY)		OT	CA-BAYER-2017-042296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Aleve			S	Oral	500 Mg, Qd		Bayer
	Methotrexate			S	Unknown	25 Mg, Ow		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13376752	EXPEDITED (15-DAY)		OT	US-TEVA-752984USA		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrotising Fasciitis	Prednisone			S	Unknown	17 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2017	13380789	DIRECT		DE, DS, HO, LT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic; Respiratory Failure	Hydroxychloroquine 200mg Tab Pra			S	Oral			Sanofi
	Lipitor			C				Not Reported
	Lisinopril-Hctz			C				Not Reported
	Metoprol Tarte			C				Not Reported
	Furosemide			C				Not Reported
	Celebrex			C				Not Reported
	Plaquenil			C				Not Reported
	Colace			C				Not Reported
	St. Joseph Asprin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	12652552	NON-EXPEDITED			US-PFIZER INC-2016385824		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Pollakiuria; Pruritus; Urinary Tract Infection; Visual Acuity Reduced	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Tylenol /00020001/			C		Unk		Not Reported

	Prednisone	C	Unk	Not Reported
	Sulfasalazine	C	Unk	Not Reported
	Bactrim	C	Unk	Not Reported
	Aleve	C	Unk	Not Reported
	Losartan	C	Unk	Not Reported
	Vitamin D2	C	Unk	Not Reported
	Folic Acid	C	Unk	Not Reported
	Lisinopril	C	Unk	Not Reported
	Lantus	C	Unk	Not Reported
	Novolog	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13246507	EXPEDITED (15-DAY)		OT	FR-SA-2017SA010103		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Diarrhoea; Gastrointestinal Pain; Hepatitis; Hepatocellular Injury; Nausea; Rash	Plaquenil			S	Oral			Not Reported
	Aubagio			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13250488	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008018		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Intolerance; Musculoskeletal Stiffness; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule;	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13251305	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006781			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported
	Diclofenac			C	Unknown	100 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13251382	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006792		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue;	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.I.W		Not Reported

Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence	Methotrexate	S	Unknown	20 Mg, Q.I.W		Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid		Not Reported
	Plaquenil /00072602/	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13251576	EXPEDITED (15-DAY)		DS, HO	CA-APOTEX-2017AP006767		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actonel			C	Unknown	135.0 Mg, Q.Wk.		Not Reported
	Advair			C	Unknown	500 Mg, Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Qd		Not Reported
	Aspirin /00002701/			C	Unknown	81 Mg, Qd		Not Reported
	Calcium			C	Unknown	500 Mg, Bid		Not Reported
	Citalopram			C	Unknown	30 Mg, Qd		Not Reported
	Docusate Sodium And Senna			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	3000 Df, Qd		Not Reported
	Ferrous Gluconate			C	Oral	300 Mg, Qd		Not Reported
	Folic Acid			C	Oral	5 Mg, Qd		Not Reported

	Hydrochlorothiazide		C	Oral	25 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate		C	Oral	2 Df, Qd	Not Reported
	Olmesartan Medoxomil		C	Unknown	40 Mg, Qd	Not Reported
	Oxybutynin		C	Unknown	2.5 Mg, Qd	Not Reported
	Prednisone		C	Unknown	9 Mg, Qd	Not Reported
	Rabeprazole		C	Unknown	20 Mg, Qd	Not Reported
	Rabeprazole Sodium		C	Oral	20 Mg, Bid	Not Reported
	Senna Alexandrina		C	Unknown	Unk	Not Reported
	Spiriva		C	Unknown	Unk	Not Reported
	Tiotropium Bromide		C	Unknown	18 Mg, Unk	Not Reported
	Tylenol /00020001/		C	Unknown	Unk, Qid	Not Reported
	Vitamin B12 /00056201/		C	Unknown	1500.0 Mg, Qd	Not Reported
	Zinc Gluconate		C	Unknown	25 Mg, Qd	Not Reported
	Zopiclone		C	Unknown	7.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13251602	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006680		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Surgery	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C	Unknown	500 Mg, Tid		Not Reported
	Apo-Prednisone			C	Unknown	5 Mg, Unk		Not Reported
	Budesonide			C	Unknown	200 Mg, Unk		Not Reported
	Cefuroxime Axetil			C	Unknown	500 Mg, Unk		Not Reported
	Fluorouracil			C	Unknown	5 %, Unk (Every 1 Hour)		Not Reported

	Humira	C	Unknown			Not Reported
	Hydrochlorothiazide	C	Unknown	25 Mg, Qd		Not Reported
	Nebivolol Hydrochloride	C	Unknown	10 Mg, Qd		Not Reported
	Oseltamivir	C	Unknown	75 Mg, Unk		Not Reported
	Azithromycin	C	Unknown	250 Mg, Unk		Not Reported
	Azithromycin	C	Unknown	250 Mg, Unk		Not Reported
	Prednisone	C	Unknown			Not Reported
	Remicade	C	Unknown			Not Reported
	Winpred	C	Unknown	1 Mg, Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13251634	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP006607		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Arthroplasty; Knee Arthroplasty; Mobility Decreased; Pain; Swelling	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1500 Mg, Bid		Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13254077	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Rheumatoid Arthritis	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported

		Methotrexate		C	Oral	20 Mg, Q.Wk.			Not Reported
		Methotrexate		C	Unknown	Unk			Not Reported
		Xeljanz		C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13254189	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006747		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Diarrhoea; Drug Ineffective; Drug Intolerance; Fatigue; Menorrhagia; Nausea; Tinnitus	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Tid		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Not Reported
	Gold			S	Unknown	50 Mg, Cyclical		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13254725	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006694		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Emphysema; Hand Deformity; Joint Swelling; Nausea; No Adverse Event; Rheumatoid Arthritis	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Zostavax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13330473	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-			Female	CAN

001606

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hidradenitis; Staphylococcal Infection	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Cipralex			C				Not Reported
	Zantac			C				Not Reported
	Tylenol 3			C				Not Reported
	Zoledronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13332572	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Pleural Effusion; Polyarthritis	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Inh			C				Not Reported
	Vitamin B6			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2017	13380268	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001940			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fluid Retention; Pain; Rash; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

			Sulfasalazine		S	Unknown			Not Reported
			Leflunomide		S	Unknown			Not Reported
			Metformin		C				Not Reported
			Methotrexate		C				Not Reported
			Xeljanz		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	8885604	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2012269190		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Dyspepsia; Dyspnoea; End Stage Renal Disease; Impaired Gastric Emptying; Injection Site Bruising; Joint Swelling; Ophthalmic Herpes Zoster; Peripheral Swelling; Protein Urine Present; Red Blood Cell Count Decreased; Renal Disorder; Skin Laceration; Weight Decreased; Wheezing; White Blood Cell Count Decreased	Celebrex			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Humira			S		40 Mg, 2x/Week (40mg/0.8ml)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly (40mg/0.8ml)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Detrol La			C		Unk		Not Reported
	Estradiol			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Zopidem			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13165113	EXPEDITED (15-DAY)		DS, HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000641		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Vestibular Syndrome; Audiogram Abnormal; Deafness; Deafness Bilateral; Neuritis	Plaquenil			S	Unknown			Concordia
	Metoject			C				Not Reported
	Cortancyl			C				Not Reported
	Speciafoldine			C				Not Reported
	Anafranil			C				Not Reported
	Inexium			C				Not Reported
	Oestrogel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13195307	EXPEDITED (15-DAY)		DS, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000806			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Vestibular Syndrome; Audiogram Abnormal; Deafness; Deafness Bilateral; Neuritis	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13339997	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001648		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catheter Site Erythema; Emphysema; Gas Gangrene; Joint Range Of Motion Decreased; Necrotising Fasciitis; Pain; Pyrexia; Staphylococcal Infection; Subcutaneous Emphysema; Swelling; Tenderness	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Sulindac			C				Not Reported
	Albuterol			C				Not Reported
	Gabapentin			C				Not Reported
	Tramadol			C		Every 8 Hours For 14 Days		Not Reported
	Misoprostol			C				Not Reported

		Ramipril			C					Not Reported
		Rosuvastatin			C					Not Reported
		Cetirizine			C					Not Reported
		Ranitidine			C					Not Reported
		Teriparatide			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13384951	DIRECT		DS			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Lipase Increased	Plaquenil			S	Oral			Concordia
	Zoloft			C				Not Reported
	Lamictal			C				Not Reported
	Gabapentin			C				Not Reported
	Mobic			C				Not Reported
	Protonix			C				Not Reported
	Hydrocodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13385893	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002005		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13385899	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002035		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Lichenoid Keratosis; Lichenoid Keratosis	Plaquenil	S	Oral		Concordia
	Plaquenil	S	Oral		Concordia
	Plaquenil	S	Oral		Concordia
	Plaquenil	S	Oral		Concordia
	Kardegic	C			Not Reported
	Tareg	C			Not Reported
	Stagid	C			Not Reported
	Isoptine	C			Not Reported
	Cortancyl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13385901	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002037		66 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Cutaneous Symptom; Lip Swelling; Liver Function Test Increased; Pyrexia; Swollen Tongue	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Pantoprazol			C				Not Reported
	Thyrax			C				Not Reported
	Mizollen			C				Not Reported
	Montelukast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13386922	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002003		29 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depression; Pain Of Skin; Rash Pruritic; Suicidal Ideation	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13386931	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-		11 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; C-Reactive Protein Increased; Headache; Heart Rate Increased; Pharyngitis Streptococcal; Pyrexia; Vomiting	Plaquenil			S	Oral			Concordia
	Cortancyl			S	Oral			Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2017	13387388	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2017M1019765			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Malaise; Psychomotor Hyperactivity	Methotrexate			S	Subcutaneous	10 Mg Weekly		Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	200mg/Day (4mg/Kg/Day)		Not Reported
	Folic Acid			C	Oral	5mg; 24 H After Methotrexate		Mylan
	Methylprednisolone			C	Oral	8mg/Day; In The First 2 Weeks; Then 4 Mg/Day For A Further 2 Weeks		Mylan
	Methylprednisolone			C	Oral	4 Mg/Day For 2w; Later, Administered During Exacerbations Only For A Short Time (Dose Not Stated)		Mylan
	Pravastatin			C	Unknown	After Dinner		Mylan
	Amlodipine			C	Unknown	5 Mg Daily		Mylan
	Aspirin /00002701/			C	Unknown	At Lunch Time		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13389144	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002088			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Liver Function Test Abnormal; Liver Function Test Increased	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Metformin			C				Not Reported
	Lansoprazole			C				Not Reported
	Doxazosin			C				Not Reported
	Asa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	9103257	NON-EXPEDITED			US-PFIZER INC-2013061248		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Linezolid			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Fluticasone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13380404	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1909121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Infection; Weight Decreased	Actemra	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Discontinued	Not Reported
	Plaquenil	S	Unknown	6 Days Per Week	Not Reported
	Arava	S	Unknown		Not Reported
	Prednisone	S	Unknown	2 To 5 Mg Od	Not Reported
	Enbrel	S	Unknown	Discontinued	Not Reported
	Cimzia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Vimovo	C	Unknown	Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13394534	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002079		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Pain; Pain; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Methotrexate Sodium				S	Subcutaneous				Not Reported
	Xeljanz				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13395758	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002106		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Interaction; Feeling Hot; Inflammation; Pruritus; Rash	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prolia			S	Subcutaneous			Not Reported
	Cortisone			C				Not Reported
	Synthroid			C				Not Reported
	Triazide			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13397278	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010697		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13398290	EXPEDITED (15-DAY)		OT	PHHY2014US143098		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Dysarthria; Hyporeflexia; Hypotonia; Overdose; Somnolence	Lioresal Intratecal			S	Intrathecal	962 Ug, Per Day		Not Reported
	Lioresal Intratecal			S	Intrathecal	872.8 Ug, Qd		Not Reported
	Lioresal Intratecal			S	Intrathecal	826.4 Ug, Qd		Not Reported
	Lisinopril			S	Unknown			Novartis
	Simvastatin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Novolog			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Evoxac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2017	13398760	EXPEDITED (15-DAY)		HO	IT-IPCA LABORATORIES LIMITED-IPC201703-000347		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychomotor Hyperactivity	Hydroxychloroquine Sulfate			S				Ipca
	Folic Acid			C	Oral			Not Reported
	6-Methylprednisolone			C				Not Reported
	6-Methylprednisolone			C				Not Reported
	Pravastatin			C				Not Reported
	Amlodipine			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	12915772	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1772059-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	12921997	EXPEDITED (15-DAY)		DS	CA-ABBVIE-16K-028-1775337-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Flagyl			S	Intravenous (not otherwise specified)			Not Reported

	Norfloxacin	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13340295	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001713		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Creatine Phosphokinase Increased; C-Reactive Protein Increased; Condition Aggravated; Dyspnoea; Fatigue; Hypotonia; Magnetic Resonance Imaging Abnormal; Magnetic Resonance Imaging Brain Abnormal; Medication Error; Muscular Weakness; Myalgia; Myopathy; Quadriparesis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Levetiracetam			C	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			C				Not Reported
	Escitalopram			C				Not Reported
	Dapsone			C				Not Reported
	Famotidine			C				Not Reported
	Acyclovir			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13398901	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002045		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported

	Leflunomide			S	Unknown					Not Reported
	Xeljanz			C						Not Reported
	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13398965	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002112		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diffuse Alopecia; Headache; Psoriasis	Plaquenil			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Effexor			C				Not Reported
	Levothyrox			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13399363	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002121		63 YR	Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Opacity	Plaquenil Tablet			S	Oral	1 Tablet Daily And 2 Tablets Daily Alternatively		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2017	13399721	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-00		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy; Quadriparesis	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2017	12912957	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1772048-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13287792	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001377		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Diarrhoea; Gastrointestinal Pain; Hepatitis; Hepatocellular Injury; Nausea; Rash	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Aubagio			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13348482	EXPEDITED (15-DAY)		HO	US-CELGENEUS-USA-2017034487		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Infection; Abdominal Pain; Acute Kidney Injury	Abraxane			S	Intravenous drip	100 Milligram/Sq. Meter		Not Reported
	Abraxane			S	Intravenous drip	100 Milligram/Sq. Meter		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gemcitabine			S	Intravenous drip	1000 Milligram/Sq. Meter		Not Reported
	Gemcitabine			S	Intravenous drip	1000 Milligram/Sq. Meter		Not Reported
	Gemcitabine			S	Unknown	1000 Milligram/Sq. Meter		Not Reported
	Gabapentin			C	Oral	100 Milligram		Not Reported

Gabapentin	C	Oral	100 Milligram	Not Reported
Lorazepam	C	Oral	.5 Milligram	Not Reported
Lorazepam	C	Unknown	.5 Milligram	Not Reported
Lorazepam	C	Unknown	.5 Milligram	Not Reported
Omeprazole	C	Oral	20 Milligram	Not Reported
Ondansetron	C	Oral	8 Milligram	Not Reported
Ondansetron	C	Unknown	24 Milligram	Not Reported
Ondansetron	C	Unknown	12 Milligram/Milliliters	Not Reported
Ondansetron	C	Unknown	24 Milligram	Not Reported
Ondansetron	C	Unknown	24 Milligram	Not Reported
Ondansetron	C	Unknown	24 Milligram	Not Reported
Oxycodone	C	Oral	5 Milligram	Not Reported
Prochlorperazine	C	Oral	10 Milligram	Not Reported
Prochlorperazine	C	Oral	40 Milligram	Not Reported
Prochlorperazine	C	Oral	40 Milligram	Not Reported
Scopolamine	C	Unknown	.5 Milligram	Not Reported
Glycopyrrolate	C	Unknown	1.2 Milligram/Milliliters	Not Reported
Hydromorphone	C	Unknown	2.4 Milligram	Not Reported
Hydromorphone	C	Unknown	3.6 Milligram	Not Reported
Hydromorphone	C	Unknown		Not Reported
Hydromorphone	C	Unknown	8 Milligram/Milliliters	Not Reported
Hydralazine	C	Unknown	10 Milligram	Not Reported
Hydralazine	C	Unknown	10 Milligram	Not Reported
Lactated Ringers	C	Unknown	250 Milliliter	Not Reported
Cefepime	C	Unknown	1 Gram	Not Reported
Furosemide	C	Unknown	10 Milligram/Milliliters	Not Reported
Dextrose	C	Unknown	4800 Milliliter	Not Reported
Dextrose	C	Oral		Not Reported
Insulin Aspart	C	Unknown	0-6 Units	Not Reported

Insulin Aspart	C	Unknown	0-6 Units	Not Reported
Dextrosew/Sodium Chloride	C	Unknown	5% & 0.9%	Not Reported
Fosaprepitant Dimeglumine	C	Unknown	250 Milliliter	Not Reported
Cisplatin	C	Unknown	250 Milliliter	Not Reported
Dexamethasone	C	Unknown	4 Milligram/Milliliters	Not Reported
Dexamethasone	C	Unknown	10 Milligram/Milliliters	Not Reported
Potassium Chloride	C	Unknown	40 Milliequivalents	Not Reported
Potassium Chloride	C	Unknown	60 Milliequivalents	Not Reported
Albumin	C	Unknown	25 Percent	Not Reported
Albumin	C	Unknown	25 Percent	Not Reported
Metoclopramide	C	Unknown		Not Reported
Metoclopramide	C	Unknown	5 Milligram/Sq. Meter	Not Reported
Metoclopramide	C	Unknown	5 Milligram/Sq. Meter	Not Reported
Metoclopramide	C	Unknown		Not Reported
Lopramide	C	Unknown	16 Milligram	Not Reported
Piperacillin Tazobactam	C	Unknown	13.5 Gram	Not Reported
Piperacillin Tazobactam	C	Unknown	13.5 Gram	Not Reported
Famotidine	C	Unknown	20 Milligram	Not Reported
Sodium Chloride	C	Unknown	1000 Milliliter	Not Reported
Sodium Chloride	C	Unknown	1000 Milliliter	Not Reported
Sertraline	C	Unknown	50 Milligram	Not Reported
Sertraline	C	Unknown	25 Milligram	Not Reported
Sertraline	C	Unknown	25 Milligram	Not Reported
Fentanyl	C	Unknown	25 Microgram	Not Reported
Fentanyl	C	Unknown	4 Microgram	Not Reported
Fentanyl	C	Unknown	4 Microgram	Not Reported
Acetaminophen	C	Unknown	650 Milligram	Not Reported
Acetaminophen	C	Unknown	2600 Milligram	Not Reported
Magnesium Hydroxide	C	Oral	800 Milligram	Not Reported

Vancomycin	C	Oral	1 Gram		Not Reported
Alteplase	C	Unknown	1 Milligram		Not Reported
Calcium Carbonate	C	Unknown	1500 Milligram		Not Reported
Oxycodone Ir	C	Unknown	30 Milligram		Not Reported
Oxycodone Ir	C	Unknown	40 Milligram		Not Reported
Oxycodone Ir	C	Unknown	60 Milligram		Not Reported
Docusate Sodium	C	Unknown	200 Milligram		Not Reported
Ceftriaxone	C	Intravenous drip	1 Gram		Not Reported
Ceftriaxone	C	Intravenous drip	3 Gram		Not Reported
Creon	C	Unknown	3 Capsule		Not Reported
Amlodipine	C	Unknown	5 Milligram		Not Reported
Lansoprazole	C	Unknown	15 Milligram		Not Reported
Enoxaparin	C	Unknown	40 Milligram		Not Reported
Senna	C	Unknown	17.2 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13358263	EXPEDITED (15-DAY)		HO, LT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001825		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Activated Partial Thromboplastin Time Prolonged; Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Asthenia; Blood Albumin Decreased; Blood Lactate Dehydrogenase Increased; Blood Lactic Acid Increased; Blood Osmolarity Decreased; Blood Triglycerides	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Pazopanib			S				Not Reported

Increased; C-Reactive Protein Increased; Chills; Diarrhoea; Diarrhoea; Disseminated Intravascular Coagulation; Drug Ineffective; Dyspnoea; Encephalopathy; Haemoglobin Decreased; Haemophagocytic Lymphohistiocytosis; Headache; Hepatosplenomegaly; Hyperferritinaemia; Hypofibrinogenaemia; Hyponatraemia; Hypotension; Inappropriate Antidiuretic Hormone Secretion; Influenza Like Illness; Interleukin-2 Receptor Increased; International Normalised Ratio Increased; Iron Binding Capacity Total Decreased; Lipase Increased; Mental Status Changes; Multiple Organ Dysfunction Syndrome; Natural Killer Cell Count Decreased; Nausea; Neck Pain; Oropharyngeal Pain; Pancytopenia; Procalcitonin; Prothrombin Time Prolonged; Pyrexia; Tachycardia; Thrombocytopenia; Transferrin Decreased; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13380681	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthralgia; Condition Aggravated; Diarrhoea; Disability; Drug Ineffective; Drug Ineffective; Hypoaesthesia; Rheumatoid Arthritis; Rheumatoid Nodule; Weight Decreased	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			S	Unknown	2 To 5 Mg Daily		Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Actonel			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vimovo			C				Not Reported
	Myochrysine			C				Not Reported
	Cimzia			C				Not Reported
	Actemra			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13408047	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017049828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Prednisone			C	Intramuscular	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13408231	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002077			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil 200 Mg			S				Concordia
	Lodine			S				Not Reported
	Arava			S				Not Reported
	Humira			S				Not Reported
	Prednisone			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Seroquel			C				Not Reported
	Ativan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13408232	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002158		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrobiosis Lipoidica Diabeticorum	Hydroxychloroquine			S		200 Mg Twice Daily		Concordia
	Etanercept			S	Subcutaneous			Not Reported
	Diclofenac			C		50 Mg 3 Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13409024	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wrong Product Administered	Plaquenil Hydrochloroquine			S				Not Reported
	Plaqterol Plus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2017	13409957	NON-EXPEDITED			US-PFIZER INC-2017148913		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13412929	NON-EXPEDITED			US-AMGEN-USASP2017049852			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Infection; Nasopharyngitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13416612	EXPEDITED (15-DAY)		HO	SE-PURDUE PHARMA-GBR-2017-0044485		26 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase; Analgesic Drug Level Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Gamma-Glutamyltransferase Increased; International Normalised Ratio Increased; Overdose; Suicide Attempt; Toxicity	Oxycontin			S	Oral	120 Mg		Purdue
	Oxycontin			S				Purdue
	Alvedon			S	Oral	53.2 G, Single		Not Reported
	Betapred			S	Oral	500 Mg, Single		Not Reported
	Plaquenil /00072602/			S	Oral	4 G, Single		Not Reported
	Citalopram			S	Oral	800 Mg, Single		Not Reported
	Alcohol			S	Oral	Unk		Not Reported
	Lamotrigine			C				Not Reported
	Saroten			C				Not Reported

To Various Agents	Stilnoct	C		Not Reported
	Paraflex /00041601/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13418884	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002145		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Plaquenil			S	Oral			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13419069	EXPEDITED (15-DAY)		OT	CA-ROCHE-1914424		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Cortisone			C				Not Reported
	Xeljanz			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13419785	NON-EXPEDITED			US-PFIZER INC-2017151396			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13420210	EXPEDITED (15-DAY)		HO	PL-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002161		38 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous; Rash Papular	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2017	13420394	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-014490		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catheter Site Erythema; Emphysema; Joint Range Of Motion Decreased; Necrotising Fasciitis; Pain; Pyrexia; Staphylococcal Sepsis; Subcutaneous Emphysema; Swelling; Tachycardia; Tenderness	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported
	Sulindac/Sulindac Sodium			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tramadol			C	Oral			Not Reported
	Misoprostol			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Cetirizine			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Teriparatide			C	Unknown			Not Reported
	Ropivacaine			C	Unknown			Not Reported
	Chlorhexidine			C	Unknown			Not Reported
	Isopropanol			C	Unknown			Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)			Not Reported
	Fentanyl			C	Transdermal			Not Reported

		Ketamine			C	Unknown				Not Reported
		Midazolam Hydrochloride			C	Unknown				Not Reported
		Mepivacaine			C	Unknown				Not Reported
		Tramadol			C	Unknown				Not Reported
		Fentanyl			C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13390482	NON-EXPEDITED			US-PFIZER INC-2017140578			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421610	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017052360		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Drug Intolerance; Fatigue; Headache; Tinnitus	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421713	EXPEDITED (15-DAY)		HO	CH-CONCORDIA PHARMACEUTICALS		83 YR	Male	CHE

INC.-GSH201704-002162

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous	Hydroxychloroquine			S	Oral			Not Reported
	Aspirin Cardio			C				Not Reported
	Zanidip			C				Not Reported
	Atenolol			C				Not Reported
	Pantoprazol			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421857	NON-EXPEDITED			US-PFIZER INC-2017149492			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421860	NON-EXPEDITED			US-PFIZER INC-2017149533			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13421906	NON-EXPEDITED			US-PFIZER INC-2017149488		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Poor Quality Sleep; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Oral	1000 Mg, 3x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13422830	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2017M1021338			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Liver Function Test Abnormal; Liver Function Test Increased	Atorvastatin			S	Unknown	80 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Mylan
	Plaquenil			S	Unknown	200 Mg, Unk		Mylan
	Asa			C		25 Mg		Mylan
	Doxazosin			C		5 Mg		Mylan
	Lansoprazole			C		Every Morning		Mylan
	Metformin			C		1000 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2017	13425020	EXPEDITED (15-DAY)		DE, OT	DE-IPCA LABORATORIES LIMITED-IPC201607-000600		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Cardiomyopathy; Cardiotoxicity	Hydroxychloroquine Sulfate			S				Ipca
	Sildenafil			C				Not Reported
	Iloprost			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13360149	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017056609		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Imuran /00001501/			S		Unk		Not Reported
	Cellcept /01275102/			S		Unk		Not Reported

	Gold	S		Unk	Not Reported
	Tacrolimus	S		Unk, Daily	Not Reported
	Rituxan	S		Unk	Not Reported
	Prednisone	C	Oral	17 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13425097	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002112		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diffuse Alopecia; Headache; Psoriasis	Plaquenil			S	Oral			Concordia
	Seresta			C				Not Reported
	Effexor			C				Not Reported
	Levothyrox			C				Not Reported
	Zolpidem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13425337	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002218			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Gastrooesophageal Reflux Disease; Infection; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426528	EXPEDITED (15-DAY)		HO	GB-DRREDDYS-GER/UKI/17/0088527			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Liver Function Test Abnormal; Liver	Atorvastatin			S				Not Reported
	Plaquenil			S				Not Reported

Function Test Increased	Plaquenil	S	Unknown			Not Reported
	Asa	C		25 Mg		Not Reported
	Doxazosin	C		5 Mg		Not Reported
	Lansoprazole	C		Every Morning		Not Reported
	Metformin	C		1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426583	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002247		38 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Suicidal Ideation	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426585	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002288			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Foetal Exposure During Pregnancy	Prednisolone			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Methylprednisolone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Mycophenolate Mofetil			S	Transplacental			Not Reported
	Rituximab			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426716	EXPEDITED (15-DAY)		LT, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002249		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Gestational Diabetes; Glucose Tolerance Impaired; Sepsis; Staphylococcal Sepsis	Prednisolone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Tacrolimus			S				Not Reported
	Tacrolimus			S				Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13426718	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone			C				Not Reported
	Xeljanz			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13429136	EXPEDITED (15-DAY)		HO	PHHY2017GB049773			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Liver Function Test Abnormal; Liver Function Test Increased	Atorvastatin			S	Unknown	80 Mg, Unk		Novartis
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Asa			C	Unknown	25 Mg, Unk		Not Reported
	Doxazosin			C	Unknown	5 Mg, Unk		Not Reported
	Lansoprazole			C	Unknown	Every Morning		Not Reported
	Metformin			C	Unknown	1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13367086	EXPEDITED (15-DAY)		HO	IN-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001896		50 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Skin Abnormal; Dermatitis Exfoliative Generalised; Erythema; Lymphocytic Infiltration; Nail Ridging; Parakeratosis; Pruritus; Rash Erythematous; Skin Exfoliation; Skin Exfoliation; Skin Lesion; Skin Plaque	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13417547	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2017145642			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arrhythmia; Liver Function Test Abnormal; Liver Function Test Increased	Atorvastatin		S	Unknown	80 Mg, Unk	Pfizer
	Plaquenil		S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil		S	Unknown	200 Mg, 1x/Day	Not Reported
	Doxazosin		C		5 Mg, Unk	Not Reported
	Metformin		C		1000 Mg, Unk	Not Reported
	Lansoprazole		C		Unk, 1x/Day (Every Morning)	Not Reported
	Asa		C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2017	13431021	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017052600		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Bursitis; Crepitations; Drug Ineffective; Enthesopathy; Pain; Rheumatoid Arthritis; Scar	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Maxzide			C	Oral	25 Mg, Qd		Not Reported
	Maxzide			C	Oral	25 Mg, Qd		Not Reported
	Maxzide			C	Oral	25 Mg, Qd		Not Reported
	Flexeril			C	Oral	10 Mg, Q8h (As Needed)		Not Reported
	Flexeril			C	Oral	10 Mg, Q8h (As Needed)		Not Reported
	Amitriptyline			C	Oral	50 Mg, (2 Tablets Everyday)		Not Reported
	Amitriptyline			C	Oral	50 Mg, (2 Tablets Everyday)		Not Reported
	Amitriptyline			C	Oral	50 Mg, (2 Tablets Everyday)		Not Reported
	Gold Sodium Thiomalate			C	Unknown	50 Mg/Ml, Unk		Not Reported
	Remicade			C	Intravenous (not	Unk		Not Reported

						otherwise specified)				
		Medrol			C	Oral	4 Mg, Unk			Not Reported
		Ansaid			C	Oral	100 Mg, Tid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	12198882	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA055875		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Arava			S	Oral			Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Omega 3			C	Unknown			Not Reported
	Diphenoxylate			C	Unknown	2.5/0.025 Mg		Not Reported
	Vitamin D2			C	Unknown	Dose:400 Unit(S)		Not Reported
	Actonel			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Every Four Weeks		Not Reported
	Calcium			C	Unknown			Not Reported

Xeljanz	C	Oral		Not Reported
Biotin	C	Unknown		Not Reported
Vitamin D Nos/Calcium Pantothenate/Vitamin B Nos/Ferrous Fumarate/Retinol/Ascorbic Acid	C	Unknown		Not Reported
D-Alpha [Alfacalcidol]	C	Unknown		Not Reported
Nicotinamide	C	Unknown		Not Reported
Pyridoxine Hydrochloride	C	Unknown		Not Reported
Retinol	C	Unknown		Not Reported
Sodium Ascorbate/Ergocalciferol/Thiamine Mononitrate/Retinol Palmitate/Riboflavin/Nicotinamide	C	Unknown		Not Reported
Sodium	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown		Not Reported
Thiamine Hydrochloride	C	Unknown		Not Reported
Vitamine B12	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
D-Alpha Tocopherol	C	Unknown		Not Reported
Diphenoxylate Hydrochloride	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown		Not Reported
Loperamide Hydrochloride	C	Unknown		Not Reported
Nasonex	C	Nasal	Spray, Metered Dose	Not Reported
Nortriptyline Hydrochloride	C	Oral		Not Reported
Pantoprazole	C	Unknown		Not Reported
Trazodone Hydrochloride	C	Oral		Not Reported
Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2017	13380788	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0505		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Malaise; Oesophageal Disorder; Rheumatoid Arthritis; Throat Cancer; Thrombosis; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2017	13442147	EXPEDITED (15-DAY)		OT	IR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-031247		30 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Caesarean Section; Maternal Exposure During Pregnancy; Premature Delivery; Product Use Issue	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Iloprost			S	Unknown	1 Df, Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2017	13442513	EXPEDITED (15-DAY)		HO	PHHY2017SE052803		26 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Analgesic Drug Level Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Gamma-Glutamyltransferase Increased; International Normalised Ratio Increased; Overdose; Suicide Attempt; Toxicity To Various Agents	Citalopram			S	Unknown			Novartis
	Oxycontin			S	Unknown			Not Reported
	Betapred			S	Unknown			Not Reported
	Alvedon			S	Oral	665 Mg, Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2017	13443226	EXPEDITED (15-DAY)		HO	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-137754			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Liver Function Test Abnormal; Liver Function Test Increased	Atorvastatin			S	Unknown	80 Mg, Unk		Sun
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Asa			C	Unknown	25 Mg		Not Reported
	Doxazosin			C	Unknown	5 Mg		Not Reported
	Lansoprazole			C	Unknown	Every Morning		Not Reported
	Metformin			C	Unknown	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2017	13445708	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1023065			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During	Prednisone			S	Unknown	10 Mg Per Day		Not Reported

Pregnancy; Lupus Nephritis; Premature Delivery	Prednisone		S	Unknown	25 Mg Per Day		Not Reported
	Hydroxychloroquine		S	Unknown	200mg Per Day		Not Reported
	Methyldopa		S	Unknown			Not Reported
	Aspirin /00002701/		S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13419154	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002160		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Computerised Tomogram Abnormal; Drug Intolerance; Dyspnoea; Mycobacterium Tuberculosis Complex Test Positive; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13445953	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002327		62 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Quality Of Life Decreased	Plaquenil			S	Unknown			Not Reported
	Imatinib			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446142	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002369			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis	Plaquenil		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446199	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002316			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Rheumatoid Arthritis; Urticaria	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446274	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002334			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Erythematous	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446678	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002410			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Haematoma; Muscular Weakness; Myalgia; Pruritus; Urinary Tract Infection	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Meticorten			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446692	NON-EXPEDITED			CA-AMGEN-CANSP2017043307			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13446760	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1021843			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Product Use In Unapproved Indication; Sepsis; Tuberculosis	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13447513	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1023092			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Lupus Nephritis; Premature Delivery	Prednisone			S	Unknown	7.5mg		Not Reported
	Azathioprine			S	Unknown	150mg		Not Reported
	Hydroxychloroquine			S	Unknown	400mg Per Day		Not Reported
	Methyldopa			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13447517	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1023082			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Exposure During Pregnancy; Lupus Nephritis; Premature Delivery	Prednisone	S	Unknown	5mg		Not Reported
	Prednisone	S	Unknown	10mg		Not Reported
	Azathioprine	S	Unknown	100mg		Not Reported
	Azathioprine	S	Unknown	150mg Daily		Not Reported
	Hydroxychloroquine	S	Unknown	200mg Per Day		Not Reported
	Methyldopa	S	Unknown			Not Reported
	Aspirin /00002701/	S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2017	13448041	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1023423			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress; Premature Baby	Prednisone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Aspirin /00002701/			S	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13451243	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002457		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation;	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Gabapentin			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Fentanyl	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Omega 3	C		Not Reported
	Diphenoxylate	C		Not Reported
	Vitamin D Nos	C		Not Reported
	Actonel	C		Not Reported
	Prednisone	C		Not Reported
	Aclasta	C		Not Reported
	Calcium	C		Not Reported
	Xeljanz	C		Not Reported
	Biotin	C		Not Reported
	No Drug Name	C		Not Reported
	D-Alpha Tocopherol	C		Not Reported
	Nicotinamide	C		Not Reported
	Pyridoxine Hydrochloride	C		Not Reported
	Retinol	C		Not Reported
	No Drug Name	C		Not Reported
	Sodium	C		Not Reported
	Ascorbic Acid	C		Not Reported
	Thiamine Hydrochloride	C		Not Reported
	Vitamine B12	C		Not Reported
	Vitamin D3	C		Not Reported
	D-Alpha Tocopherol	C		Not Reported
	Diphenoxylate Hydrochloride	C		Not Reported
	Ergocalciferol	C		Not Reported
	Esomeprazole	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Loperamide Hydrochloride	C		Not Reported
	Nasonex	C		Not Reported
	Nortriptyline Hydrochloride	C		Not Reported
	Pantoprazole	C		Not Reported
	Trazodone Hydrochloride	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13451579	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS			Female	USA

INC.-GSH201704-002414

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Heart Transplant	Plaquenil 200 Mg Tablet			S				Concordia
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13451698	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002413			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Malaise; Visual Impairment	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2017	13452120	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002473		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Plaquenil Tablet			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Infection; Nausea; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C			Not Reported
	Omega 3	C			Not Reported
	Prednisone	C			Not Reported
	Trazodone Hydrochloride	C			Not Reported
	Tylenol	C			Not Reported
	Nasonex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13129999	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2677		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Intervertebral Disc Protrusion; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13421850	EXPEDITED (15-DAY)		HO, LT, OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002176		29 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Tongue Abnormal; Squamous Cell Carcinoma Of The Tongue; Tongue Ulceration	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported
	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13455913	EXPEDITED (15-DAY)		OT	JP-IPCA LABORATORIES LIMITED-IPC201704-000498			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13455919	EXPEDITED (15-DAY)		OT	JP-IPCA LABORATORIES LIMITED-IPC201704-000501			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13455945	EXPEDITED (15-DAY)		OT	JP-IPCA LABORATORIES LIMITED-IPC201704-000502			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Pneumococcal	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13455973	EXPEDITED (15-DAY)		OT	JP-IPCA LABORATORIES LIMITED-IPC201704-000504			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Hydroxychloroquine Sulfate			S				Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457839	EXPEDITED (15-DAY)		OT	SA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002476			Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Guillain-Barre Syndrome	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457887	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138646			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Prednisone			S	Transplacental			Mutual
	Hydroxychloroquine			S	Transplacental	400 Mg, Daily		Ipca
	Methyldopa			S	Transplacental			Sun
	Acetylsalicylic Acid			S	Transplacental			Sun
	Azathioprine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457888	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138644		29 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Live Birth; Premature Delivery	Prednisone			S	Unknown			Mutual
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Methyldopa			S	Unknown			Sun
	Acetylsalicylic Acid			S	Unknown			Sun
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457913	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138645		20 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Live Birth; Premature Delivery	Prednisone			S	Unknown	10 Mg, Daily		Mutual
	Prednisone			S	Unknown	Unk		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Methyldopa			S	Unknown			Sun
	Acetylsalicylic Acid			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457915	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138635		39 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Live Birth; Premature Delivery	Prednisone			S	Unknown			Mutual
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Ipca
	Methyldopa			S	Unknown			Sun
	Acetylsalicylic Acid			S	Unknown			Sun
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457917	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138651			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth	Prednisone			S	Transplacental	10 Mg, Daily		Mutual

Weight Baby; Premature Baby	Prednisone		S	Transplacental	Unk		Mutual
	Hydroxychloroquine		S	Transplacental	Unk		Ipca
	Hydroxychloroquine		S	Transplacental	Unk		Ipca
	Methyldopa		S	Transplacental			Sun
	Acetylsalicylic Acid		S	Transplacental			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457920	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138650			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Prednisone			S	Transplacental			Mutual
	Hydroxychloroquine			S	Transplacental	200 Mg, Daily		Ipca
	Methyldopa			S	Transplacental			Sun
	Acetylsalicylic Acid			S	Transplacental			Sun
	Azathioprine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13458027	EXPEDITED (15-DAY)		OT	HK-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002468		26 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus; Drug Ineffective; Inappropriate Schedule Of Product Administration; Lupus Nephritis; Retinal Vasculitis; Skin Lesion; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Dapsone			S	Topical			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13458119	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002465		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Disorder; Drug Ineffective; Movement Disorder; Pain In Extremity; Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Fentanyl			C				Not Reported
	Minocycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13012074	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0805		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Back Pain; Body Fat Disorder; Costochondritis; Drug Ineffective; Mass; Pain In Extremity; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	Went From 4 To 2 Pills		Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Tiazac			C	Unknown			Not Reported

	Metformin	C	Unknown	Not Reported
	Xenical	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13241910	NON-EXPEDITED			US-PFIZER INC-2017071090		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Meperidine Hcl			S		Unk		Unknown
	Risedronate Sodium			S		Unk		Not Reported
	Ketorolac Tromethamine			S				Pfizer
	Azathioprine			S		Unk		Not Reported
	Bleph-10			S		Unk		Not Reported
	Gold Sodium Thiomalate			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Nabumetone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Scopolamine Hydrobromide			S		Unk		Not Reported
	Sodium Sulamyd			S		Unk		Not Reported
	Sulfamethoxazole			S		Unk		Not Reported
	Transderm-Scop			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13357981	NON-EXPEDITED			US-PFIZER INC-2017121072			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated	Enbrel		S	Unk	Pfizer
	Methotrexate Sodium		S	Unk	Pfizer
	Humira		S	Unk	Not Reported
	Plaquenil		S	Unk	Not Reported
	Orencia		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13404053	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017048153			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inguinal Hernia; Osteoarthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported
	Folic Acid			C	Unknown	1 Mg, Qd		Not Reported
	Finasteride			C	Unknown	5 Mg, Qd		Not Reported
	Alfuzosin			C	Unknown	10 Mg, Qd		Not Reported
	Dexilant			C	Unknown	60 Mg, Qd		Not Reported
	Sotalol			C	Unknown	40 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13409880	NON-EXPEDITED			US-PFIZER INC-2017148640		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Rufinamide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

	Orencia			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13440680	EXPEDITED (15-DAY)		HO, OT	IT-ROCHE-1916311		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Mycobacterium Tuberculosis Complex Test Positive; Off Label Use	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13460822	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002471			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13461066	EXPEDITED (15-DAY)		OT	US-ZYDUS-014619		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Face Oedema; Histoplasmosis; Infective Tenosynovitis; Joint Swelling; Night Sweats; Pain; Peripheral Swelling; Skin Disorder; Soft Tissue Swelling	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13461071	EXPEDITED (15-DAY)		OT	US-ZYDUS-014616		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bacterial Infection; Condition Aggravated; Histoplasmosis; Infective Tenosynovitis; Joint Swelling; Wound	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13461170	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002519		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Alendronic Acid			C				Not Reported
	Atenolol			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Calcichew D3			C				Not Reported
	Zapain			C				Not Reported
	Hylo-Tear			C				Not Reported
	Ranitidine			C				Not Reported
	Salivix Pastille			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13462118	EXPEDITED (15-DAY)		OT	CA-SA-2017SA069532			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inguinal Hernia; Osteoarthritis; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Methotrexate	C		Not Reported
Folic Acid	C		Not Reported
Finasteride	C		Not Reported
Alfuzosin	C		Not Reported
Sotalol	C		Not Reported
Dexilant	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	12856042	EXPEDITED (15-DAY)		HO, OT	SG-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005158		37 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antiphospholipid Syndrome; Blood Pressure Systolic Increased; Condition Aggravated; Exposure During Pregnancy; Foetal Growth Restriction; Haematoma; Haemolysis; Hepatic Enzyme Increased; Hypertension; Platelet Count Decreased; Postpartum Haemorrhage; Premature Separation Of Placenta; Proteinuria; Pyrexia; Retained Products Of Conception; Sepsis; Stillbirth; Thrombocytopenia; Thunderclap Headache; Vaginal Haemorrhage	Hydroxychloroquine			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13162284	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000666		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intervertebral Disc Protrusion; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Pantoloc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13466346	EXPEDITED (15-DAY)		OT	CA-ROCHE-1920832			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2017	13469086	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017170133		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Advil			S	Oral	Unk, As Needed		Pfizer
	Prednisone			S		10 Mg, Daily		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13192744	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017051058		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Nasopharyngitis; Psychotic Disorder	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Plaquenil			S	Oral	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13228924	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001020		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Cimzia			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13409765	EXPEDITED (15-DAY)		OT	US-ORION CORPORATION ORION PHARMA-TREX2017-1017		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Histoplasmosis; Tenosynovitis	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13449593	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016229301		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Still'S Disease	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13470687	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002567			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inguinal Hernia; Osteoarthritis; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Alfuzosin			C				Not Reported
	Sotalol			C				Not Reported
	Dexilant			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Finasteride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13471353	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002479		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil			S	Oral			Not Reported
	Daiphen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13471940	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

INC.-GSH201704-002516

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neutropenia	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2017	13472581	EXPEDITED (15-DAY)		HO	AU-PFIZER INC-2017114136		63 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Malaise	Enbrel			S		20 Mg, Weekly		Unknown
	Methotrexate			S		20 Mg, Weekly On Fridays		Pfizer
	Hydroxychloroquine Sulphate			S		200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2017	13246068	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008015		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Plaquenil Tablet			S	Oral			Not Reported
	Plaquenil Tablet			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tecta			S	Oral			Not Reported
	Voltaren			S	Oral			Not Reported
	Voltaren			S	Oral			Not Reported
	Synthroid			S	Unknown			Not Reported

	Lisinopril	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2017	13483866	EXPEDITED (15-DAY)		DE, HO, OT	US-ENDO PHARMACEUTICALS INC-2017-002189		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Bundle Branch Block; Completed Suicide; Extensor Plantar Response; Gastrointestinal Sounds Abnormal; Hyperthermia; Muscle Twitching; Myoclonus; Respiratory Arrest; Rhabdomyolysis; Serotonin Syndrome; Unresponsive To Stimuli	Tranylcypromine			S	Oral	Unk Unk, Unknown		Par
	Olanzapine			S	Oral	Unk Unk, Unknown		Par
	Amlodipine Besylate Tablets			S	Oral	Unk Unk, Unknown		Vintage
	Levothyroxine Sodium			S	Oral	Unk Unk, Unknown		Par
	Lisinopril			S	Oral	Unk Unk, Unknown		Not Reported
	Sertraline			S	Oral	Unk Unk, Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unk Unk, Unknown		Not Reported
	Buspirone			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2017	13483915	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002591		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			C				Not Reported

	Cymbalta			C						Not Reported
	Hydromorphone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2017	13484015	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002522			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Norvasc			C				Not Reported
	Naproxen			C				Not Reported
	Synthroid			C				Not Reported
	Amitriptyline			C				Not Reported
	Calcium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13484412	EXPEDITED (15-DAY)		HO	AU-AMGEN-AUSSP2017041950		63 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Malaise	Enbrel			S	Unknown	20 Mg, Weekly		Amgen
	Methotrexate			S	Unknown	20 Mg, Weekly On Fridays		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2017	13488293	EXPEDITED (15-DAY)		OT	PHHY2017US058301			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Graft Versus Host Disease In Skin; Atypical Fibroxanthoma; Basal Cell	Ciclosporin			S	Unknown			Novartis
	Ciclosporin			S				Novartis

Carcinoma; Carcinoma In Situ; Chronic Graft Versus Host Disease; Chronic Graft Versus Host Disease In Skin; Glomerulonephritis Membranous; Spindle Cell Sarcoma; Squamous Cell Carcinoma; Squamous Cell Carcinoma Of Skin	Ciclosporin	S			Novartis
	Ciclosporin	S			Novartis
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Psoralon (Dithranol)	S	Unknown		Not Reported
	Psoralon (Dithranol)	S			Not Reported
	Cyclophosphamide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	12313518	EXPEDITED (15-DAY)		HO	CA-ROCHE-1748838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13213220	EXPEDITED (15-DAY)		OT	CA-SA-2015SA137211		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Feeling Abnormal; Gastrointestinal Disorder; Headache;	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Thirst; Tremor; Tremor; Upper Respiratory Tract Infection	Methotrexate Sodium	S	Oral			Not Reported
	Cortisone	C	Unknown			Not Reported
	Wellbutrin	C	Unknown	Strength: 300 Mg		Not Reported
	Apo-Naproxen	C	Unknown	Strength: 500 Mg, Form: Ec Tab		Not Reported
	Apo-Prednisone	C	Unknown	Strength: 5 Mg		Not Reported
	Ergocalciferol	C	Oral	Vitamin D2 1,000 Unit/Ml [2000 Daily]		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Leucovorin Calcium	C	Unknown	Strength: 5 Mg		Not Reported
	Tecta	C	Unknown	Strength: 40 Mg		Not Reported
	Ascorbic Acid	C	Oral			Not Reported
	Pantoprazole	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13220382	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0449		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Nasopharyngitis; Psychotic Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			C	Unknown	2 Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13490910	NON-EXPEDITED			US-APOTEX-2016AP010138			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Exposure During Pregnancy	Allopurinol Tablets Usp			S	Unknown	5 Mg, Qd		Apotex
	Enalapril			S	Unknown	5 Mg, Daily		Apotex
	Enalapril			S				Apotex

			Cellcept /01275102/	S	Oral	1000 Mg, Bid			Not Reported
			Cellcept /01275102/	S					Not Reported
			Prednisone	S	Unknown	10 Mg, Daily			Not Reported
			Prednisone	S	Unknown	20 Mg, Daily			Not Reported
			Hydroxychloroquine	S	Unknown	400 Mg, Qd			Not Reported
			Hydroxychloroquine	S					Not Reported
			Lovenox	S	Subcutaneous	60 Mg, Qd			Not Reported
			Calcium W/Vitamin D /00944201/	S	Unknown	600/400mg Twice Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13492022	EXPEDITED (15-DAY)		OT	PHHY2017GB061186			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Mycophenolate Mofetil			S	Transplacental	500 Mg, Bid		Novartis
	Tacrolimus			S	Transplacental	2 Mg, Bid		Not Reported
	Tacrolimus			S	Unknown	3 Mg, Bid		Not Reported
	Azathioprine			S	Transplacental	50 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	75 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Mg, Unk		Not Reported
	Coal Tar			S	Transplacental			Not Reported
	Vancomycin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	500 Mg Per Dose		Not Reported
	Intravenous Human Immunoglobulin			S	Transplacental	0.4 G/Kg, Qd		Not Reported
	Chlorhexidine			S	Transplacental			Not Reported
	White Soft Paraffin			S	Transplacental			Not Reported
	Mupirocin			S	Transplacental	Unk		Not Reported
	Insulin			S	Transplacental	Unk		Not Reported

	Gliclazide			S	Transplacental				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13492180	EXPEDITED (15-DAY)		DS	AU-DRREDDYS-AUS/AUS/17/0089875			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Spontaneous Urticaria; Condition Aggravated	Fexofenadine			S				Not Reported
	Cetirizine			S				Not Reported
	Ranitidine			S				Not Reported
	Montelukast			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2017	13492254	NON-EXPEDITED			US-PFIZER INC-2017181564		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13496709	EXPEDITED (15-DAY)		HO, OT	SG-IPCA LABORATORIES LIMITED-IPC-2017-SG-000102		37 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Deep Vein Thrombosis; Exposure During Pregnancy; Foetal Growth Restriction; Hellp Syndrome; Sepsis; Thrombocytopenia; Thunderclap Headache	Hydroxychloroquine			S		Unk		Ipca
	Low-Molecular Weight Heparin			C		1 Mg/Kg/Day		Not Reported
	Aspirin			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13496742	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-000091		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S		8 Mg/Kg, For 25 Years		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13496747	EXPEDITED (15-DAY)		OT	DK-IPCA LABORATORIES LIMITED-IPC-2017-DK-000177			Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Exposure During Pregnancy; Tinnitus	Hydroxychloroquine			S	Oral	200 Mg, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13496829	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017054985		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown	Unk		Not Reported
	Sulfa (Sulfadiazine)			S	Unknown	Unk		Not Reported
	Silver			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Cortisone			C		20 Mg, Qd (In Decreasing Dose)		Not Reported
	Tylenol			C		Unk Unk, As Necessary		Not Reported

Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Hydroxychloroquine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13497111	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-000164		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Dystrophy	Hydroxychloroquine			S		400 Mg/Day For 8 Years		Ipca
	Hydroxychloroquine			S		200 Mg/Day For 2 Years		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2017	13497281	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-000166		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Hydroxychloroquine			S		400 Mg, Per Day, For 17 Years		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2017	13498870	DIRECT		LT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Back Pain; Balance Disorder; Blood Creatinine Increased; Blood Urine Present; Dizziness; Haemoglobin Decreased; Headache; Heart Rate Increased; Influenza Like Illness; Neck Pain; Pruritus; Pyrexia; Visual Impairment	Hydroxychoroquine 200 Mg			S	Oral	Quantity:90 Tablet(S); Dalily Oral		Zydus Pharm
	Indomethacin			C				Not Reported
	Doxepin			C				Not Reported
	Qvar			C				Not Reported
	Triamcinolone Ointment			C				Not Reported
	Ketotifen Fumarate			C				Not Reported
	Doxylamine Melatonin			C				Not Reported
	B6/B12/Folate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	11391075	EXPEDITED (15-DAY)		OT	CA-SA-2015SA103140		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Gallbladder Disorder; Headache; Infection; Liver Function Test Increased; Nausea; Oral Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure; Ulcer	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Lost Control		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	12172123	EXPEDITED (15-DAY)		OT	CA-SA-2016SA047209		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; C-Reactive Protein Increased; Cough; Drug Ineffective; Ear Infection; Fatigue; Headache; Migraine; Nasopharyngitis; Nausea; Non-Cardiac Chest Pain; Pneumonia	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Celebrex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13103505	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877703		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Still'S Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13250500	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001117		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Plaquenil Tablet			S	Oral			Not Reported
	Plaquenil Tablet			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tecta			S	Oral			Not Reported
	Voltaren			S	Oral			Not Reported

	Xeljanz			S	Unknown					Not Reported
	Depo-Medrol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13499455	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1025677			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy; Premature Labour; Staphylococcal Sepsis	Azathioprine			S	Unknown	50 Mg Per Day; Later Increased To 75 Mg/Day		Not Reported
	Azathioprine			S	Unknown	75 Mg Daily		Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisolone			S	Oral	20 Mg/Day		Not Reported
	Prednisolone			S	Oral	30 Mg Daily		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13499537	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1026330			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Foetal Exposure During Pregnancy; Premature Baby	Azathioprine			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Mycophenolate Mofetil			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2017	13499693	EXPEDITED (15-DAY)		OT	US-SA-2017SA077165		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Retinal Toxicity; Skin Hyperpigmentation	Chloroquine (Salt Not Specified)		S	Unknown	Not Reported
	Minocycline Hydrochloride		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Mycophenolate Mofetil		S	Unknown	Not Reported
	Triamcinolone Acetonide		S	Unknown	Not Reported
	Allopurinol		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Thalidomide		S	Unknown	Not Reported
	Adalimumab		S	Unknown	Not Reported
	Cyclosporine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13237044	EXPEDITED (15-DAY)		OT	CA-SA-2015SA137206		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Mobility Decreased; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	10 Mg For 2 Weeks, Then 15 Mg For 3 Weeks, Then 20 Mg For 3 Months		Not Reported
	Cortisone			C	Unknown			Not Reported
	Wellbutrin Xl			C	Unknown	Strength: 300mg		Not Reported
	Apo-Naproxen			C	Unknown	Strength: 500mg		Not Reported
	Apo-Prednisone			C	Unknown	Strength: 5mg		Not Reported
	Ergocalciferol			C	Oral	1,000 Unit/Ml Oral Tabs (2000 Daily)		Not Reported
	Folic Acid			C	Unknown			Not Reported

Leucovorin Calcium	C	Unknown	Strength: 5mg		Not Reported
Tecta	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Vitamin C	C	Oral			Not Reported
Pantoprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13254110	EXPEDITED (15-DAY)		DE, OT	UY-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-134175		36 YR	Female	URY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrotising Fasciitis Streptococcal; Septic Shock	Prednisone			S	Unknown	60 Mg, Daily		Mutual
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13501815	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002630			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2017	13502334	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002648			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13230255	EXPEDITED (15-DAY)		CA, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Foetal Exposure During Pregnancy; Intraventricular Haemorrhage Neonatal; Premature Baby; Teratogenicity	Mycophenolate Mofetil			S	Transplacental			Westward
	Mycophenolate Mofetil			S	Transplacental			Westward
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Low-Molecular-Weight Heparin			C	Transplacental			Not Reported
	Aspirin			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13250614	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001193		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Gallbladder Disorder; Headache; Infection; Liver Function Test Increased; Nausea; Oral Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure; Ulcer	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13431734	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017053362		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Depression; Diarrhoea; Drug Ineffective; Increased Appetite; Neuropathy Peripheral; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Prozac			S	Unknown	40 Mg, Qd		Not Reported
	Prozac			S	Unknown	20 Mg, Qd		Not Reported
	Pennsaid			C	Topical	2 Pumps Per Joint Q12hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13507071	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0732		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cystitis; Drug Intolerance; Guillain-Barre Syndrome; Product Complaint; Urinary Tract Disorder; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13507268	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002629		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Lymphopenia; Neutropenia	Plaquenil			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13507433	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201704-		22 YR	Male	FRA

002654

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Thrombocytopenia	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13508003	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002681		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil 200 Mg			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Vancomycin			C				Not Reported
	Naprosyn			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2017	13508876	EXPEDITED (15-DAY)		OT	US-SA-2017SA076014			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Seizure	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13070551	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006545		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palatal Oedema	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13250497	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001110		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Thirst; Tremor; Tremor; Upper Respiratory Tract Infection	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Cortisone			C				Not Reported
	Wellbutrin			C				Not Reported
	Apo-Naproxen			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Ergocalciferol			C	Oral	2000 Unit/Ml Daily		Not Reported
	Folic Acid			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Tecta			C				Not Reported
	Ascorbic Acid			C	Oral			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13381286	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010615		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; C-Reactive Protein Increased; Cough; Drug Ineffective; Ear Infection; Fatigue;	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Oral			Concordia
	Arava			S	Unknown			Not Reported

Headache; Migraine; Nasopharyngitis; Nausea; Non-Cardiac Chest Pain; Pneumonia	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Methotrexate Sodium		S	Oral		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Methotrexate Sodium		S	Oral		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Celebrex		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13484367	EXPEDITED (15-DAY)		OT	IN-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002590		19 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Cardiomegaly; Dyspnoea; Heart Rate Increased; Heart Sounds Abnormal; Pericardial Effusion; Pyrexia; Rales; Red Blood Cell Sedimentation Rate Increased; Respiratory Rate Increased; Tuberculosis; Venous Pressure Jugular Increased	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13515326	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1762681-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Humira 40mg/0.8ml			S	Subcutaneous	Duration: 730 Unknown		Not Reported
	Orencia			S	Unknown	Duration: 730 Unknown		Not Reported
	Enbrel			S	Unknown	Duration: 730 Unknown		Not Reported

Ineffective; Encephalitis; Hypoaesthesia	Methotrexate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	Duration: For More Than Three Months		Not Reported
	Leflunomide	S	Unknown	Duration: More Than 3 Months		Not Reported
	Pregabalin	C	Oral	At Bedtime		Not Reported
	Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13515451	EXPEDITED (15-DAY)		OT	US-HORIZON-PRE-0181-2017		13 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Laboratory Test Abnormal; T-Lymphocyte Count Decreased	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2017	13515752	EXPEDITED (15-DAY)		HO	PHHY2017US062532		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral T-Cell Lymphoma Unspecified	Tacrolimus			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	12837868	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1949		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Osteoarthritis;	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Pantoprazole			S	Unknown			Not Reported

Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Plaquenil		S	Oral	Not Reported
	Prinivil		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Synthroid		S	Unknown	Not Reported
	Voltaren		S	Oral	Not Reported
	Voltaren		S	Oral	Not Reported
	Folic Acid		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13250613	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001177		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Mobility Decreased; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Plaquenil Tablet			S	Oral	At Bedtime		Not Reported
	Arava Film Coated Tablet			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	10 Mg For 2 Weeks		Not Reported
	Methotrexate Sodium			S	Oral	15mg For 3 Weeks		Not Reported
	Methotrexate Sodium			S	Oral	20mg For 3 Months		Not Reported
	Wellbutrin Xlj 300 Mg Tablet			C				Not Reported
	Apo-Naproxen			C				Not Reported
	Apo-Prednisone 5 Mg Tablet			C				Not Reported
	Ergocalciferol Tablet			C	Oral	1000 Unit/Ml , 2000 Unit Daily		Not Reported
	Folic Acid			C				Not Reported
	Leucovorin Calcium Tablet			C		1 Tab A Week		Not Reported
	Tecta Tablet			C		1 Tab A Day		Not Reported
	Sulfasalazine			C				Not Reported
	Vitamin C			C	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13502676	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002652		13 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; T-Cell Receptor Gene Rearrangement Test; T-Lymphocyte Count Decreased	Hydroxychloroquine			S	Transplacental			Concordia
	Prednisone			S	Transplacental			Not Reported
	Prednisone			S	Transplacental	100 Milligram Once		Not Reported
	Azathioprine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13510353	EXPEDITED (15-DAY)		OT	FR-ABBVIE-17K-056-1956268-00			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Cutaneous Lupus Erythematosus; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Purinethol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pentasa			C		1 Df In The Morning And 1 Df In The Evening		Not Reported
	Vitamin D2			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13516415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038069		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Erythema; Infection;	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb

Malaise; Pyrexia; Rash; Vomiting	Arava		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Neoral		S	Unknown		Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Prednisone		C	Unknown	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13516450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038375		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13517303	EXPEDITED (15-DAY)		OT	PHHY2017FR065540			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Evans Syndrome; Product Use In Unapproved Indication	Ciclosporin			S	Unknown			Novartis
	Ciclosporin			S				Novartis
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S				Not Reported

		Azathioprine			S	Unknown					Not Reported
		Azathioprine			S						Not Reported
		Hydroxychloroquine			S	Unknown					Not Reported
		Hydroxychloroquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13518201	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2017M1026964			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral T-Cell Lymphoma Unspecified; Respiratory Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13518863	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1000 G, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13518989	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1965811-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2017	13521470	DIRECT		DS, HO, OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dyspnoea; Movement Disorder; Muscle Disorder; Pain; Porphyria; Prescribed Overdose; Skin Disorder; Skin Irritation; Vomiting	Hydroxychloroquine	Y		S	Oral	Quantity:60 Tablet(S);		Northstar
	Probiotic			C				Not Reported
	Aloe			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2017	13519795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1960661-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Consciousness; Mobility Decreased	Arava		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Kineret		S	Subcutaneous	100mg Per Syringe Single Use - Preservative Free	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2017	13519907	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1961404-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	4x2.5mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Zopiclone			C						Not Reported
	Folic Acid			C						Not Reported
	Pantoprazole Magnesium			C						Not Reported
	Tenofovir Disoproxil Fumarate			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2017	13519934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038138		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Cellcept /01275102/			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2017	13520026	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-039000		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Drug Intolerance; Fatigue; Headache; Tinnitus	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	11 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2017	12957719	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-097111		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fatigue; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Arava			S	Unknown	1 Df, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2017	13520435	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038213		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Intolerance; Rheumatoid Arthritis; Type 2 Diabetes Mellitus; Wound Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	12629598	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2016GSK077295			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Adverse Event; Arthralgia; Bleeding Time Prolonged; Blood Test Abnormal; Cataract Operation; Circumstance Or Information Capable Of Leading To Medication Error; Dyspnoea; Flatulence; Hypertension; Inappropriate Schedule Of Product Administration; Influenza; Medication Error; Pain; Platelet Count Decreased; Pneumonia; Product Availability Issue; Product Dose Omission; Respiratory Disorder; Swelling; Swelling; Tachycardia; Underdose; Underdose; Visual Impairment; Weight Increased	Benlysta	S	920 Mg, Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Reuquinol	S	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Mycophenolate Mofetil	C	Unk	Not Reported
	Calcium Carbonate	C	Unk	Not Reported
	Vitamin D Nos	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13484003	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-33078		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fungal Infection; Swelling; Tenosynovitis	Prednisone			S	Unknown			Aurobindo
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520781	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-1966154-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis	Apo-Sulfasalazine			S	Unknown	Not Reported
	Apo-Hydroxyquine			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Cimzia			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported
	Simponi			S	Subcutaneous	Not Reported
	Xeljanz			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520818	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965659-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Cortisone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520823	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1965981-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520837	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-1965674-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520854	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965680-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Unevaluable Event	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C				Not Reported
	Amoxil			C				Not Reported
	Bacillus Calmette-Guerin Bcg			C				Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520923	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1966162-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Acetylsalicylic Acid W/Clopidogrel			S	Unknown			Not Reported
	Acetylsalicylic Acid			S				Not Reported

Vomiting; Weight Decreased	W/Clopidogrel			
	Acetylsalicylic Acid	S		Not Reported
	W/Clopidogrel			
	Acetylsalicylic Acid	S		Not Reported
	W/Clopidogrel			
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Gold	S		Not Reported
	Gold	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Motrin	S	Unknown	Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported
	Tramadol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13520930	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1966139-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Cirrhosis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13521036	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1966094-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13521306	NON-EXPEDITED			US-PFIZER INC-2017192800			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Celebrex			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Azithromycin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Cipro			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Tetanus Toxoid Adsorbed (Vaccine)			S		Unk		Not Reported
	Entex			S		Unk		Not Reported
	Entex			S				Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13521562	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017068534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C		50 Mg, Qd		Not Reported

Tylenol Arthritis	C	Unk Unk, As Necessary	Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13521844	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1966119-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrogram Abnormal; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Rotator Cuff Syndrome; Shoulder Arthroplasty; Synovial Disorder; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13522804	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1965807-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13522877	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17P-028-1965802-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13523093	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017068109		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, (Every 8 Weeks)		Not Reported
	Methotrexate Sodium			S	Oral	2.5 Mg, Qwk (8 Tablets Weekly)		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Tramadol			S	Oral	50 Mg, Q6h		Not Reported
	Tramadol			S	Oral	(2-4 Daily) As Necessary		Not Reported
	Citalopram			C	Oral	20 Mg, Qd		Not Reported
	Vitamin B 12			C	Oral	1000 Mug, Qd		Not Reported
	Famotidine			C	Oral	20 Mg, Bid		Not Reported
	Fluconazole			C	Oral	150 Mg, Qd		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported

	Omeprazole			C	Oral	40 Mg, Qd			Not Reported
	Zyrtec			C	Oral	10 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13524251	EXPEDITED (15-DAY)		OT	US-SA-2017SA081311		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Drug Intolerance; Fatigue; Headache; Tinnitus	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2017	13526166	DIRECT		HO, LT			47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Hypersensitivity; Pruritus; Rash; Swelling Face	Hydroxychloroquine Sulfate	Y		S	Oral	Quantity:500 Tablet(S);		Ranbaxy
	Adarax			C				Not Reported
	Xanax			C				Not Reported
	Prednisone			C				Not Reported
	Men-Phor Anti Itching Lotion			C				Not Reported
	Triamcinolone Acetonide Cream			C				Not Reported
	Desondie			C				Not Reported
	Aveeno Oatmeal Bath			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13516888	NON-EXPEDITED			US-PFIZER INC-2017149035			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Enbrel	S		Unk	Pfizer
	Enbrel	S		Unk, Weekly (50 Q Wk)	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Leflunomide	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13525715	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965741-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13525789	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017067846			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Pruritus; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Folic Acid			C	Oral	3 Mg, Qd				Not Reported
	Nexium			C	Oral	20 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13525818	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-17K-028-1966110-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13526035	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-17K-028-1965778-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Celebrex			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13526042	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965686-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13526192	NON-EXPEDITED			US-AMGEN-USASP2017067842			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Infection	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	200 Mg, Unk (For Three		Not Reported

						Months)				
	Aspirin			S	Unknown	Unk				Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13526234	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965715-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13527798	NON-EXPEDITED			US-PFIZER INC-2017193117		58 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Soma			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13527839	NON-EXPEDITED			US-PFIZER INC-2017192618			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2017	13528765	EXPEDITED (15-DAY)		CA, OT	US-SHIRE-US201709837		< 1 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pyelocaliectasis; Congenital Spinal Cord Anomaly; Foetal Exposure During Pregnancy; Pyrexia; Viral Upper Respiratory Tract Infection	Vyvanse			S	Transplacental	Unk, Unknown		Shire
	Belimumab			S	Transplacental	400 Mg, Other (Cyclically)		Not Reported
	Lamictal			S	Transplacental	Unk, Unknown		Not Reported
	Nicoderm			S	Transplacental	Unk, Unknown		Not Reported
	Percocet /00446701/			S	Transplacental	Unk, Unknown		Not Reported
	Plaquenil /00072603/			S	Transplacental	Unk, Unknown		Not Reported
	Xanax			S	Transplacental	Unk, Unknown		Not Reported
	Folate			C	Transplacental	Unk, Unknown		Not Reported
	Penicillin /00000901/			C	Transplacental	Unk, Unknown		Not Reported
	Methotrexate			C	Transplacental	Unk, Unknown		Not Reported
	Prenatal Vitamins /02014401/			C	Transplacental	Unk, Unknown		Not Reported
	Stool Softener			C	Transplacental			Not Reported
	Corticosteroid Nos			C	Transplacental	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13130602	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017021951		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Pneumonia; Renal Impairment	Lyrica			S		150 Mg, Daily (3 Per Day)		Pfizer
	Lyrica			S		150 Mg, Daily		Pfizer
	Lyrica			S		50 Mg, 3x/Day		Pfizer

	Norvasc	S	2.5 Mg, 1x/Day	Pfizer
	Prednisone	S	40 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	400 Mg, 1x/Day	Not Reported
	Duexis	S	Unk, 3x/Day, ([Famotidine 26.6 Mg]/[Ibuprofen 800 Mg])	Not Reported
	Levothyroxine	C	125 Ug, 1x/Day	Not Reported
	Liothyronine	C	5 Ug, 3x/Day	Not Reported
	Misoprostol	C	100 Ug, 2x/Day	Not Reported
	Allegra	C	180 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13351115	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043098		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Laryngitis; Malaise; Pneumonia; Product Dose Omission	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13356068	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043412		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain;	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown	Form: Solution		Not Reported

Peripheral Swelling; Swelling	Subcutaneous

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13356124	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA043145		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Malaise; Osteomyelitis; Pneumonia	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13502714	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000821		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Hyperaemia; Hypoaesthesia Oral; Lip Swelling; Stevens-Johnson Syndrome; Visual Impairment	Plaquenil Tablet			S	Oral	400 Mg Qd And 200 Mg Qd, Alternately.		Not Reported
	Prograf			S	Unknown	At 2 Mg Daily And At 3 Mg Daily From 13/Jan/2016		Not Reported
	Prednisolone			C	Oral			Not Reported
	Prednisolone			C				Not Reported
	Edirol			C				Not Reported
	Nexium			C				Not Reported
	Fosamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13530477	EXPEDITED (15-DAY)		OT	CA-ROCHE-1930538		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance;	Cellcept			S	Unknown			Not Reported

Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Ciclosporin			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Imuran			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13530584	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-1966120-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13530702	EXPEDITED (15-DAY)		OT	CA-ROCHE-1931732			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Daily		Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2017	13531714	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002834			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Bursitis; Crepitations; Drug Ineffective; Enthesopathy; Eye Disorder; Pain; Rheumatoid Arthritis; Scar	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Gold Sodium Thiomalate			C				Not Reported
	Hydrochlorothiazide/Triamterene			C				Not Reported
	Flexeril			C				Not Reported
	Amitriptyline			C				Not Reported
	Remicade			C				Not Reported
	Medrol			C				Not Reported
	Ansaid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13492119	EXPEDITED (15-DAY)		OT	IT-ACCORD-050872		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia Macrocytic; Neuroendocrine Tumour	Methotrexate		S	Subcutaneous	Accord
	Hydroxychloroquine		S		Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2017	13537249	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2016M1026652			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Cardiomyopathy; Hypotension; Renal Impairment	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Ramipril			S	Unknown	5 Mg, Bid		Not Reported
	Carvedilol			S		25 Mg, Bid		Not Reported
	Torasemide			S	Unknown	10 Mg, Qd		Not Reported
	Spironolactone			S	Unknown	25 Mg, Qd		Not Reported
	Sildenafil			C	Unknown			Mylan
	Iloprost			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13540353	EXPEDITED (15-DAY)		LT	PHHY2017US066521		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis	Hydroxychloroquine			S	Unknown			Novartis
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Pazopanib			C	Unknown			Not Reported
	Vancomycin			C	Unknown			Not Reported
	Piperacillin+Tazobactam			C	Unknown			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Acyclovir			C	Unknown			Not Reported
	Levofloxacin			C				Not Reported
	Ampicillin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13541226	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015110797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Methotrexate Sodium			S		Max 15/Week		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072603/			S		400 (Units Unspecified), 1x/Day		Not Reported
	Naproxen			S		Unk		Not Reported
	Leflunomide			S		10 (Units Unspecified), 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13541751	EXPEDITED (15-DAY)		CA, OT	DE-GLAXOSMITHKLINE-DE2017GSK070457			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital	Tacrolimus			S	Transplacental	60 Mg, Bid		Glaxosmithkline
	Rivaroxaban			S				Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Glaxosmithkline
	Ramipril			S	Transplacental			Glaxosmithkline
	Torasemide			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Glaxosmithkline
	Ezetimibe			S				Glaxosmithkline
	Acetylsalicylic Acid			S	Transplacental			Glaxosmithkline
	Salbutamol			S	Transplacental			Glaxosmithkline
	Metamizole			S	Transplacental			Glaxosmithkline
	Aliskiren			S	Transplacental			Not Reported
	Rituximab			S	Transplacental			Not Reported
	Cyclophosphamid			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2017	13543384	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1974237-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Duration : 08 Months		Not Reported
	Lyrica			C	Oral			Not Reported
	Marijuana			C				Not Reported
	Orencia			C				Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	12664535	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016390676		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Age-Related Macular Degeneration; Retinal Toxicity	Lyrica			S	Oral	100 Mg, Twice A Day		Pfizer
	Lyrica			S		Unk		Pfizer
	Plaquenil			S	Oral	200 Mg, Twice A Day		Not Reported
	Tramadol			C		Unk		Not Reported
	Coraspin			C		Unk		Not Reported
	Enbrel			C		50 Mg, Unk		Not Reported
	Effexor Xr			C		Unk		Not Reported
	Somacid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13361389	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001871		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Laryngitis; Malaise; Pneumonia; Product Dose Omission	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13361544	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001880		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection	Plaquenil Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13367325	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001890		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Dyspnoea; Hypersensitivity; Mobility Decreased; Neutropenia; Synovitis	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Weekly		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13368241	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001895		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported
	Arava Tablet			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13447476	EXPEDITED (15-DAY)		HO	IT-TEVA-758366ACC		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Herpes Zoster; Mycobacterium Tuberculosis Complex Test Positive; Off Label Use; Sepsis; Tuberculosis	Mycophenolate Mofetil			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S				Not Reported
	Pyrazinamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13543469	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1972850-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Dependence; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Ineffective; Fibromyalgia; Foot Operation; Gait Disturbance; Hip Arthroplasty; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To A General Medical Condition; Temperature Intolerance; Therapeutic Product Effect Incomplete	Gold	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13543473	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1974246-00		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13543664	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002922		34 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased; Thrombocytopenia	Hydroxychloroquine 200 Mg Tablet			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisolon			C				Not Reported
	Folsan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13543994	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1974207-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Codeine			C				Not Reported
	Fentanyl			C				Not Reported
	Gold			C				Not Reported
	Levofloxacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13545940	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-1971634-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate Sodium		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13545951	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-3035050		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Gait Disturbance; Joint Swelling	Methotrexate Sodium			S				Unknown
	Plaquenil /00072602/			S				Not Reported
	Amitriptyline			C				Not Reported
	Calcium /00405001/			C				Not Reported
	Citalopram			C				Not Reported
	Pantoloc /01263204/			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin C /00008001/			C				Not Reported
	Vitamin D /00107901/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13546069	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1971669-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	C		Not Reported
	Ciclosporin	C		Not Reported
	Minocycline	C		Not Reported
	Penicillamine	C		Not Reported
	Prednisone	C		Not Reported
	Tocilizumab	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2017	13546417	EXPEDITED (15-DAY)		HO, OT	FR-BAXTER-2017BAX019971		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Polyneuropathy; Chorioretinitis; Deafness Bilateral; Deafness Neurosensory; Haemophagocytic Lymphohistiocytosis; Mast Cell Activation Syndrome; Meningitis Aseptic; Myopathy; Sepsis; Septic Shock	Endoxan 1000 Mg, Poudre Pour Solution Injectable			S	Intravenous (not otherwise specified)	First Cycle		Baxter
	Endoxan 1000 Mg, Poudre Pour Solution Injectable			S	Intravenous (not otherwise specified)	Second Cycle		Baxter
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cortancyl			C	Unknown			Not Reported
	Zelitrex			C	Unknown			Not Reported

	Bactrim	C	Unknown		Not Reported
	Xanax	C	Unknown		Not Reported
	Inexium	C	Unknown		Not Reported
	Diffu K	C	Unknown		Not Reported
	Topalgic (France)	C	Unknown		Not Reported
	Lovenox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13367165	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001891		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Malaise; Osteomyelitis; Pneumonia	Plaquenil Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13547968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1971699-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Swelling	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Ibuprofen			C				Not Reported

	Morphine			C						Not Reported
	Pertussis Vaccine			C						Not Reported
	Prednisone			C						Not Reported
	Sulfamethoxazole And Trimethoprim			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13549441	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-140588		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Disease	Atorvastatin			S	Unknown			Sun
	Furosemide			S	Unknown			Sun
	Lisinopril			S	Unknown			Sun
	Metoprolol			S	Unknown			Sun
	Prednisone			S	Unknown			Mutual
	Mycophenolate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Ipca
	Aspirin			S	Unknown			Sun
	Ticagrelor			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13549465	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002883			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rash; Urticaria	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13550194	EXPEDITED (15-DAY)		LT	PHHY2017US067220		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Loss Of Consciousness	Prednisone			S	Unknown			Novartis
	Mycophenolate Mofetil			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Ticagrelor			C	Unknown			Not Reported
	Metoprolol Succinate			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13550301	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2017M1028449			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	800 Mg Daily		Not Reported
	Prednisone			S	Unknown			Not Reported
	Pazopanib			S	Unknown	800 Mg Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2017	13550720	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1973015-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
	Alendronate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Codeine			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate Sodium			S	Oral	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab			S	Unknown	Not Reported
	Ciclosporin			C		Not Reported
	Prednisone			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	12859926	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-E2B_00007867		72 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Blood Sodium Decreased; Eye Pruritus; Fatigue; Lethargy; Lower Respiratory Tract Infection; Viral Upper Respiratory Tract Infection	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oroxine			C				Not Reported
	Karvea			C				Not Reported
	Somac			C				Not Reported
	Aspirin			C				Not Reported
	Methotrexate			C				Not Reported
	Karvezide			C				Not Reported
	Crestor			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13119501	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1819553-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Drug Ineffective; Investigation Abnormal; Joint Swelling; Loss Of Personal Independence In Daily Activities; Peripheral Swelling; Rheumatoid Arthritis; Sleep Disorder; Synovitis	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Myochrysine	C	Intramuscular		Not Reported
	Orencia	C			Not Reported
	Actemra	C			Not Reported
	Xeljanz	C			Not Reported
	Celebrex	C			Not Reported
	Methotrexate	C			Not Reported
	Septra	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13165139	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1850398-00		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Ineffective; Dry Eye; Intervertebral Disc Protrusion; Ocular Hyperaemia	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13318777	EXPEDITED (15-DAY)		HO	FR-ORION CORPORATION ORION PHARMA-TREX2017-0770			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration Bone Marrow Abnormal; Axonal Neuropathy; Epstein-Barr Virus Infection Reactivation; Pancytopenia; Product Use In Unapproved Indication; Sialoadenitis	Imeth			S	Oral	Strength: 10 Mg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Speciafoldine			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported

	Diprosone	C	Unknown		Not Reported
	Kardegic	C	Unknown	Strength: 75 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13512062	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002728		9 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Skin Abnormal; Blister; Epidermal Necrosis; Mucosal Inflammation; Productive Cough; Pyrexia; Rash; Skin Exfoliation; Stevens-Johnson Syndrome	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone Hemisuccinate			S	Intravenous (not otherwise specified)	2 Milligram(S)/Kilogram;Every 12 Hours		Not Reported
	Methylprednisolone Hemisuccinate			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Furosemide			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide			S				Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide			S				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13550192	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1973678-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

	Leflunomide			S	Unknown	10 (Units Unspecified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13553213	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-015152		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Dyspnoea; Lung Infiltration; Lymphadenopathy; Lymphadenopathy Mediastinal; Peripheral T-Cell Lymphoma Unspecified Stage Iv; Rales; Respiratory Distress; Respiratory Failure	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13553507	EXPEDITED (15-DAY)		OT	CA-ROCHE-1934813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13554490	EXPEDITED (15-DAY)		HO	CA-ABBVIE-17K-028-1973680-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Terminal State; Thrombosis	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituximab	C		Not Reported
	Hydroxychloroquine	C		Not Reported
	Methotrexate	C		Not Reported
	Ilaris	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13554662	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086193		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sarcoidosis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Form: Tablet (Enteric Coated)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2017	13554948	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016138991		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Colitis; Drug Intolerance; Gastrointestinal Disorder; Nausea; Pneumonia Cryptococcal; Sedation; Somnolence	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg		Not Reported
	Cortisone			C		15 Mg, 1x/Day		Not Reported
	Tylenol Arthritis			C		Unk		Not Reported
	Prednisone			C		5 Mg, Daily		Not Reported
	Avalide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13286742	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Condition Aggravated; Drug Ineffective; Drug Resistance; Gastrointestinal Disorder; Rheumatoid Arthritis; Transaminases Increased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			C				Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13559964	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002997		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Oedema	Plaquenil			S	Oral			Not Reported

Peripheral	Betadine		S	Transdermal	Not Reported
	Hydrocortisone		C		Not Reported
	Irbesartan		C		Not Reported
	Previscan (Fluindione)		C		Not Reported
	Ogast		C		Not Reported
	Levothyrox		C		Not Reported
	Oxycontin		C		Not Reported
	Oxynorm		C		Not Reported
	Doliprane		C		Not Reported
	Desogestrel		C		Not Reported
	Remicade		C		Not Reported
	Cortancyl		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13560299	NON-EXPEDITED			US-PFIZER INC-2017216122			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Minoxidil			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Aldomet			S		Unk		Not Reported
	Dapsone			S		Unk		Not Reported
	Hydralazine			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561003	NON-EXPEDITED			US-ROCHE-1236452		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Naprosyn			S	Unknown			Not Reported
	Ultram			S	Unknown			Not Reported
	Ultracet			S	Oral			Not Reported
	Aspirin			S	Unknown			Not Reported

Flexeril (United States)	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported
Levaquin	S	Unknown	Not Reported
Motrin	S	Unknown	Not Reported
Orphenadrine Citrate	S	Unknown	Not Reported
Phenergan	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Relafen	S	Unknown	Not Reported
Keflex	S	Unknown	Not Reported
Paxil	S	Unknown	Not Reported
Cymbalta	S	Unknown	Not Reported
Acetylsalicylic Acid	S	Unknown	Not Reported
Darvocet	S	Unknown	Not Reported
Aleve	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Neurontin (United States)	S	Unknown	Not Reported
Zoloft	S	Unknown	Not Reported
Biotin	C	Oral	Not Reported
Vitamin D3	C	Oral	Not Reported
Tocopherol	C	Oral	Not Reported
Cellcept	C	Unknown	Not Reported
Soma (United States)	C	Oral	Not Reported
Claritin	C		Not Reported
Klonopin	C		Not Reported
Dilaudid	C		Not Reported
Percocet	C		Not Reported
Lyrica	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561237	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		63 YR	Female	CAN

INC.-GSH201705-003026

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sarcoidosis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2017	13561490	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011908			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Disorder; Chest Pain; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Apo-Esomeprazole			S	Unknown	40 Mg, Qd		Apotex
	Apo Folic Acid			S	Unknown	1 Df, Bid		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Apotex
	Apo Prednisone Tab 5mg			S	Unknown	5 Mg, Qd		Apotex
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Actemra			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Golden Seal /01446501/			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2017	13559190	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1976095-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Foot Deformity; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Marijuana			C		Marijuana Brownie		Not Reported
	Celebrex			C				Not Reported
	Wellbutrin			C				Not Reported
	Vitamin D2			C				Not Reported
	Risedronate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2017	13562996	EXPEDITED (15-DAY)		OT	PHHY2017US067983		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Degeneration; Retinopathy	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	12901864	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2155		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury;	Methotrexate (Trade Name			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Fall; Nausea; Vomiting	Unknown)					
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Arava	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Cyclic		Not Reported
	Orencia	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13512083	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002731			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Retinal Toxicity; Skin Hyperpigmentation	Hydroxychloroquine			S	Unknown			Concordia
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Thalidomide			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13535992	NON-EXPEDITED			US-PFIZER INC-2017199985			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13566587	EXPEDITED (15-DAY)		HO, LT	US-HORIZON-PRE-0203-2017		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13566776	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002971		53 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Discomfort; Tinnitus	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13566927	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002990		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13566970	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003003		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Takecab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13567088	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017074094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported
	Tylenol			C		Unk Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13570200	NON-EXPEDITED			US-MAYNE PHARMA-2016MYN002099			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash; Urticaria	Hydroxychloroquine Sulfate (Watson Laboratories)			S	Unknown	Unk, Unknown		Not Reported
	Diclofenac Sodium (Aellc)			S	Unknown	Unk, Unknown		Not Reported
	Nortriptyline Hydrochloride			S	Unknown	Unk, Unknown		Mayne
	Prednisone (Watson Laboratories)			S	Unknown	Unk, Unknown		Not Reported
	Etodolac (Watson Laboratories)			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13570564	EXPEDITED (15-DAY)		OT	CA-ROCHE-1936674			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2017	13571882	DIRECT	Y	LT, RI, OT			46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Rash	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13333895	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017109338		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration Bone Marrow Abnormal; Axonal Neuropathy; Epstein-Barr Virus Infection Reactivation; Pancytopenia; Product Use In Unapproved Indication; Sialoadenitis	Imeth			S	Oral	15 Mg, Weekly		Pfizer
	Plaquenil			S	Oral	200 Mg, 3x/Day		Not Reported
	Speciafoldine			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Diprosone			C		Unk		Not Reported
	Kardegic			C		75 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13570715	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003029		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Cholelithiasis; Dizziness; Headache; Nausea	Plaquenil			S	Oral	Alternated Between 200 Mg And 400 Mg Every Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13571129	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003046		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Sulfa (Sulfadiazine)			S	Unknown			Not Reported
	Silver			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Cortisone			C				Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13571160	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003050		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Hydroxychloroquine	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2017	13573497	EXPEDITED (15-DAY)		HO, OT	US-TEVA-770703USA		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Pazopanib			S	Unknown	800 Mg Daily		Not Reported
	Azathioprine			S	Unknown	800 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13085522	NON-EXPEDITED			US-PFIZER INC-2016603099		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Malaise; Stress	Xeljanz			S		5 Mg, Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Xeljanz			S		1.5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 2x/Day (Am, Pm)		Pfizer
	Methotrexate Sodium			S	Intramuscular	1 Ml, Weekly		Unknown
	Methotrexate Sodium			S	Intramuscular	Unk, Weekly (0.7 Cc		Unknown

			Weekly)	
	Folic Acid	S	1 Mg, Daily (6 Daily 6 Days)	Pfizer
	Folic Acid	S	Unk, 1x/Day (Greater Than 1mg)	Pfizer
	Folic Acid	S	7 Mg, 1x/Day (Am)	Pfizer
	Hydroxychloroquine	S	200 Mg, 2x/Day (1 Am 1 Pm)	Not Reported
	Hydroxychloroquine	S	300 Mg, Daily [200 Mg Am, 100 Mg Pm]	Not Reported
	D3	S	1000 Iu, Daily (1 Df, Daily, Am)	Not Reported
	D3	S	Unk (1000 Tab Am)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13575304	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003119		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13575500	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003004			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Atrophy; Cardiomyopathy; Decreased Appetite; Diarrhoea; Gastrointestinal Disorder; Mental Impairment; Muscle Discomfort; Nervousness; Palpitations; Rash; Weight Decreased	Plaquenil 200 Mg Tablet	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13575511	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003047		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Plaquenil			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13576408	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-01		13 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
False Positive Investigation Result; Foetal Exposure During Pregnancy	Azathioprine			S	Transplacental			Eurohealth International
	Hydroxychloroquine			S	Transplacental			Hikma
	Prednisone			S	Transplacental			Westward
	Prednisone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13576697	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK077092			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Systemic Lupus Erythematosus	Benlysta	S	Unk		Glaxosmithkline
	Plaquenil	S	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13576987	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017171782		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome; Neutropenia	Novatrex			S	Oral	2 Df, Weekly		Pfizer
	Plaquenil /00072603/			S	Oral	2 Df, Daily		Not Reported
	Metformin Mylan			S	Oral	500 Mg, 3x/Day		Not Reported
	Xultophy			S	Subcutaneous	14 Df, Daily		Not Reported
	Allopurinol Merck			S	Oral	100 Mg, Daily		Not Reported
	Ultibro Breezhaler			S	Respiratory (inhalation)	1 Df, Daily		Not Reported
	Folic Acid Arrow			S	Oral	5 Mg, Daily		Not Reported
	Irbesartan Mylan			S	Oral	300 Mg, Daily		Not Reported
	Clopidogrel Mylan			S	Oral	75 Mg, Daily		Not Reported
	Amlodipine Merck-Generics			S	Oral	5 Mg, Daily		Not Reported
	Victoza			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2017	13577838	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20170522393		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy; Fall	Xarelto			S	Oral			Not Reported
	Hydroxychloroquine Phosphate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13441326	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002370			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Plaquenil			S	Oral			Not Reported
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13495698	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-542089		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Xultophy			S	Subcutaneous	Unk (14 Dose Steps)		Novo Nordisk
	Novatrex /00113801/			S	Oral	2 Df, Qw		Not Reported
	Plaquenil /00072603/			S	Oral	2 Df, Qd (In Evening)		Not Reported
	Metformine Mylan			S	Oral	500 Mg, Tid		Not Reported
	Allopurinol Merck			S	Oral	100 Mg, Qd		Not Reported
	Ultibro Breezhaler			S	Respiratory (inhalation)	1 Puff, Qd (In Morning)		Not Reported
	Acide Folique Arrow			S	Oral	5 Mg, Qd (In Morning)		Not Reported
	Irbesartan Mylan			S	Oral	300 Mg, Qd		Not Reported
	Clopidogrel Mylan			S	Oral	75 Mg, Qd (In Morning)		Not Reported
	Amlodipine Merck-Generics			S	Oral	5 Mg, Qd (In Morning)		Not Reported
	Tazocilline			C	Unknown	Unk		Not Reported
	Victoza			C	Unknown	Unk		Novo Nordisk

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13581477	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-015236		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Rigidity; Activated Partial Thromboplastin Time Prolonged; Acute Kidney Injury; Agitation; Alanine Aminotransferase	Azathioprine			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported
	Pazopanib			S	Unknown			Not Reported

Increased; Aspartate Aminotransferase Increased; Asthenia; Blood Albumin Decreased; Blood Creatinine Increased; Blood Fibrinogen Decreased; Blood Lactate Dehydrogenase Increased; Blood Lactic Acid Increased; Blood Osmolarity Decreased; Blood Triglycerides Increased; C-Reactive Protein Increased; Chills; Coagulopathy; Diarrhoea; Dyspnoea; Haemophagocytic Lymphohistiocytosis; Headache; Hepatosplenomegaly; Hyponatraemia; Hypotension; Influenza Like Illness; Interleukin-2 Receptor Increased; International Normalised Ratio Increased; Iron Binding Capacity Total Decreased; Lipase Increased; Liver Function Test Abnormal; Mental Status Changes; Multi-Organ Disorder; Nausea; Neck Pain; Oropharyngeal Pain; Pancytopenia; Platelet Count Decreased; Procalcitonin Increased; Pyrexia; Rhabdomyolysis; Serum Ferritin Increased; Tachycardia; Thrombocytopenia; Transferrin Decreased;	Levofloxacin	C	Unknown	Not Reported

Urinary Retention;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2017	13582661	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1031474			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	25mg/Week And Then Reduced		Not Reported
	Methotrexate			S	Unknown	20mg/Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	20mg/Day And Increased		Mylan
	Prednisone			C	Unknown	30mg/Day		Mylan
	Alendronic Acid			C	Unknown	70mg/Week		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2017	13583467	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010628		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Colitis; Drug Intolerance; Gastrointestinal Disorder; Impaired Self-Care; Nausea; Nausea; Pneumonia Cryptococcal; Rheumatoid Arthritis; Sedation; Somnolence	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Avalide			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Cortisone			C				Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2017	13585497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017224361		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Toxicity	Methotrexate Sodium			S				Pfizer

	Hydroxychloroquine	S	200 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2017	13531804	NON-EXPEDITED		OT	US-AMGEN-USASP2017068656		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Injection Site Reaction; Nasopharyngitis; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Prednisolone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2017	12919752	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1771812-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Impaired Work Ability; Joint Swelling; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2017	13135586	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1839878-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral		Not Reported
	Hydroxychloroquine			S	Oral		Not Reported
	Rituxan			S	Unknown		Not Reported
	Actemra			S	Unknown		Not Reported
	Sulfasalazine			C	Oral		Not Reported
	Prednisone			C	Oral		Not Reported
	Folic Acid			C			Not Reported
	Synthroid			C			Not Reported
	Restasis			C			Not Reported
	Multivitamins			C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2017	13589148	EXPEDITED (15-DAY)		OT	US-ROCHE-1938166			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2017	13589306	EXPEDITED (15-DAY)		OT	CA-ROCHE-1936184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Hypoglycaemia; Lymphoma; Thyroid Disorder	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2017	13590288	EXPEDITED (15-DAY)		OT	CA-ROCHE-1940986		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C				Not Reported
	Amoxil			C				Not Reported
	Bacillus Calmette Guerin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2017	13591205	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1989065-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported
	Clobetasol Propionate			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2017	13492878	NON-EXPEDITED			US-AMGEN-USASL2017062402		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Injection Site Bruising; Insomnia	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2017	13502216	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002615		82 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Plaquenil			S	Oral	Daily, Few Month		Not Reported
	Novatrex			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Xultophy			S	Subcutaneous	At Bedtime		Not Reported

	Allopurinol			S	Oral					Not Reported
	Ultibro			S						Not Reported
	Folic Acid			S	Oral					Not Reported
	Irbesartan			S	Oral					Not Reported
	Clopidogrel			S	Oral					Not Reported
	Amlodipine			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2017	13539282	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017208923		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Injection Site Reaction; Nasopharyngitis; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2017	13593280	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011526		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Erythema Multiforme; Pyrexia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	11114374	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1439029		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister Infected; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Fluctuation;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Blood Pressure Increased; Bronchitis; Cellulitis; Cellulitis; Eye Infection; Foot Fracture; Hypotension; Infusion Related Reaction; Ingrowing Nail; Limb Injury; Nail Infection; Neuropathy Peripheral; Neuropathy Peripheral; Osteomyelitis; Peripheral Vascular Disorder; Plasma Cell Myeloma; Postoperative Wound Infection; Renal Impairment; Retinal Disorder; Uterine Disorder; Uterine Polyp; Vasculitis; Weight Increased; Wrong Technique In Product Usage Process	Hydroxychloroquine	S	Unknown			Not Reported
	Actemra	S	Subcutaneous			Not Reported
	Celebrex	S	Unknown			Not Reported
	Ciprolex	C				Not Reported
	Folic Acid	C				Not Reported
	Ativan	C	Unknown	Prn		Not Reported
	Tylenol Arthritis	C				Not Reported
	Seroquel	C				Not Reported
	Methotrexate	C				Not Reported
	Clonazepam	C				Not Reported
	Plaquenil	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	12162163	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-112744			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Pantoprazole			S	Unknown	Unk		Sun
	Folic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Methotrexate			S	Unknown	Unk		Not Reported
	Aleve			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Calcium D Pantothenate/Nicotinamide/Pyridoxine Hcl/Riboflavin/Thiamine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13595025	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941642		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13599579	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941645		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13505346	EXPEDITED (15-DAY)		HO	US-SUNOVION-2017SUN001829			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Utibron			S	Respiratory (inhalation)	1 Puff, Qd		Sunovion
	Novatrex			S	Oral	2 Df, Weekly		Not Reported
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Metformin Mylan			S	Oral	500 Mg, Tid		Not Reported
	Xultophy			S	Subcutaneous	100 U/Ml + 3.6 Mg/Ml, Hs		Not Reported
	Allopurinol Merck			S	Oral	100 Mg, Qd		Not Reported
	Folic Acid Arrow			S	Oral	5 Mg, Qd		Not Reported
	Irbesartan Mylan			S	Oral	300 Mg, Qd		Not Reported
	Clopidogrel Mylan			S	Oral	75 Mg, Qd		Not Reported
	Amlodipine Merck-Generics			S	Oral	5 Mg, Qd		Not Reported
	Prevenar			C				Not Reported
	Pneumo 23			C				Not Reported
	Movicol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13599721	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941651		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13599798	EXPEDITED (15-DAY)		OT	CA-ROCHE-1939789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Drug Intolerance; Glaucoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Methotrexate			C	Unknown	Manufacturer Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13600278	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003217			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13600784	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003235		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Pneumonia; Trigeminal Neuralgia	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13600785	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003236			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13600786	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003251			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pharyngeal Swelling	Plaquenil Tablet			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13603239	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA097864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Form:Solution		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13228849	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017022177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Fluid Retention; Memory Impairment; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13549170	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002927		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil Tablet			S	Oral	1 Tablet Daily And 2 Tablets Daily Alternately		Not Reported
	Plaquenil Tablet			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13560095	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003022		84 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Ataxia; Balance Disorder; Blood Osmolarity Increased; C-Reactive Protein Increased; Confusional State; Csf	Hydroxychloroquine			S	Unknown			Not Reported

Glucose Decreased; Csf Protein Increased; Csf White Blood Cell Count Increased; Depressed Level Of Consciousness; Dysarthria; Dysdiadochokinesis; Dysmetria; Encephalitis; Encephalitis; Hyponatraemia; Inappropriate Antidiuretic Hormone Secretion; Intention Tremor; Nystagmus; Pleocytosis; Polymerase Chain Reaction Positive; Somnolence; Varicella Zoster Virus Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13603923	EXPEDITED (15-DAY)		OT	CA-ROCHE-1942001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Drug Hypersensitivity; Drug Ineffective; Furuncle; Hand Deformity; Ovarian Neoplasm; Rheumatoid Arthritis; Therapeutic Response Decreased	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13608251	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-047542			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported
	Clobetasol Propionate E			C	Unknown			Not Reported
	Advil /00044201/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609543	NON-EXPEDITED			US-APOTEX-2016AP013553			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Apotex
	Mycophenolate Mofetil			S				Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Q.H.S.		Not Reported
	Prilosec /00661201/			S	Unknown	40 Mg, Qd		Not Reported
	Lovenox			S	Unknown	80 Mg, Daily		Not Reported
	Lovenox			S				Not Reported
	Unisom /00000402/			S	Unknown	Unk, Q.H.S.		Not Reported
	Prenatal Vitamins /07426201/			S	Unknown	1 Df, Daily		Not Reported
	Tizanidine			C	Unknown			Not Reported
	Tizanidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2017	13609704	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1719338US		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Injection Site Reaction; Nasopharyngitis; Urinary Tract Infection	Prednisolone Acetate, 1.0%			S				Allergan
	Enbrel			S				Not Reported
	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13492279	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20170424335		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Premature Separation Of Placenta	Durogesic			S	Transdermal			Not Reported
	Orencia			S	Unknown	At 12 Weeks Of Amenorrhea.		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Oral	At 12 Weeks Of Amenorrhea.		Not Reported
	Plaquenil			S	Oral			Not Reported
	Cortancyl			S	Oral	In Morning		Not Reported
	Aprovel			S	Oral	0/0/1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13610231	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003293		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Retinopathy; Visual Impairment	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13610233	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003296		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Retinopathy	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13611636	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-048950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2017	13613668	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-17K-163-1996417-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Femur Fracture; Rheumatoid Arthritis; Road Traffic Accident; Systemic Lupus Erythematosus; Upper Limb Fracture	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	12801386	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13575481	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003126		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Ataxia; Balance Disorder; Balance Disorder; Headache; Neurotoxicity; Paraesthesia; Paraesthesia; Paraesthesia; Tinnitus; Tinnitus; Vestibular Disorder; Visual Field Defect; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Aspirin			C				Not Reported
	Crestor			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13615478	NON-EXPEDITED			US-PFIZER INC-2017244164		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Benzathine Benzylpenicillin	S	Unk		Pfizer
	Plaquenil /00072602/	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13615569	NON-EXPEDITED			US-PFIZER INC-2017244462			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13616181	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Exposure Via Breast Milk; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Imuran			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2017	13618202	EXPEDITED (15-DAY)		OT	CA-SA-2017SA097504		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Hypertension; Insomnia; Pain; Rash; Seronegative Arthritis; Therapeutic Product Effect	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown			Not Reported

Decreased; Therapeutic Product Effect Incomplete; Visual Impairment	Xeljanz			C	Oral					Not Reported
	Venlafaxine Hydrochloride			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13433987	EXPEDITED (15-DAY)		HO	CA-SA-2017SA060884		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Localised Infection; Malaise; Pleurisy; Pneumonia	Sodium Aurothiomalate			S	Intramuscular	Solution		Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13441240	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138238		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Sepsis; Tuberculosis	Mycophenolate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisone			S	Unknown	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13620693	NON-EXPEDITED			US-AMGEN-USASP2017084633			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13621280	NON-EXPEDITED			US-PFIZER INC-2017243818		85 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Arava			S		Unk		Not Reported
	Arava			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13624834	EXPEDITED (15-DAY)		HO, OT	US-TEVA-775185USA		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Xeljanz Xr			S	Unknown	10 Milligram Daily;		Not Reported
	Clopidogrel			C				Not Reported
	Metoprolol			C				Not Reported
	Simvastatin			C				Not Reported
	Aspirin			C				Not Reported
	Aspirin			C				Not Reported
	Folic Acid			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2017	13625339	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003359		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Plaquenil			S	Oral			Concordia

Diarrhoea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava 10 Milligram Film Coated Tablet	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13516192	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-036454		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy; Premature Separation Of Placenta; Product Use Issue	Orencia			S	Unknown	Unk, Qmo		Bristol Myers Squibb
	Loxen L P			S	Oral	50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Cortancyl			S	Oral	20 Mg, Qd		Not Reported
	Durogesic			S	Transdermal	50 Mg, Qh; Every 3 Days		Not Reported
	Aprovel			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13538646	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002840		74 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13598144	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003218			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use Issue;	Hydroxychloroquine			S	Unknown			Concordia

Systemic Lupus Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13613034	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20170529341			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Durogesic			S	Transplacental			Not Reported
	Orencia			S	Transplacental	At 12 Weeks Of Amenorrhea.		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Transplacental	At 12 Weeks Of Amenorrhea		Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Aprovel			S	Transplacental	0/0/1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13623508	EXPEDITED (15-DAY)		LT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003283		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bundle Branch Block Right; Cardiac Failure; Cardiac Hypertrophy; Syncope	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Hizaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13623677	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003339			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carbon Dioxide Increased;	Plaquenil			S				Not Reported

Cough; Dyspnoea; Pulmonary Function Test Abnormal; Rheumatoid Arthritis	Xeljanz				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13624111	EXPEDITED (15-DAY)		OT	US-ZYDUS-015374		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cystoid Macular Oedema; Macular Cyst; Maculopathy; Night Blindness; Retinal Degeneration; Toxicity To Various Agents; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown	Cumulative Dose Of 2,774 G		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13624898	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003327			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Systemic Lupus Erythematosus	Plaquenil			S				Concordia
	Benlysta			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13625589	EXPEDITED (15-DAY)		DS	NO-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003353			Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Fatigue; Maculopathy; Night Blindness; Photophobia; Photosensitivity Reaction;	Plaquenil			S	Oral			Concordia
	Brufen			C				Not Reported
	Naprosyn			C				Not Reported
	Prednisolon			C				Not Reported

Vision Blurred; Visual Impairment	Tolvon	C	Not Reported
	Venlafaxine	C	Not Reported
	Valium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13625591	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-049662			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Orencia			S	Transplacental	Unk, Qmo		Bristol Myers Squibb
	Loxen L P			S	Transplacental	50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Transplacental	200 Mg, Bid		Not Reported
	Cortancyl			S	Transplacental	20 Mg, Qd		Not Reported
	Durogesic			S	Transplacental	50 Mg, Qh; Every 3 Days		Not Reported
	Aprovel			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2017	13632554	EXPEDITED (15-DAY)		DS	CA-ROCHE-1945340			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	12162907	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2016SE23123		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Nexium			S	Oral				Not Reported
	Nexium			S	Oral				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Tofacitinib			S	Oral				Not Reported
	Tofacitinib			S	Oral				Not Reported
	Tofacitinib			S	Oral				Not Reported
	Tofacitinib			S	Oral				Not Reported
	Gabapentin			S	Unknown				Not Reported
	Folic Acid			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Sulfasalazine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13580102	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13617987	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA100571			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Tuberculosis Complex	Plaquenil			S	Oral			Not Reported

Test Positive; Nerve Injury; Rheumatoid Arthritis	Arava	S	Oral			Not Reported
	Arava	S	Oral			Not Reported
	Methotrexate	C	Oral	15-25 Mg		Not Reported
	Methotrexate	C	Subcutaneous			Not Reported
	Prednisone	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Aldactone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13625588	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003305			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome	Plaquenil			S	Oral			Concordia
	Oxycodone			C				Not Reported
	Cymbalta			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13637722	EXPEDITED (15-DAY)		LT	PHHY2017FR079585		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Postpartum Haemorrhage; Uterine Atony; Uterine Inversion; Uterine Scar	Oxytocin			S	Unknown	Unk		Not Reported
	Oxytocin			S	Unknown	Dose Increased Up To 17.5 Mu/Min		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13638179	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2017SE58735			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Nexium			S	Oral			Astrazeneca
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Arava			C	Unknown			Not Reported
	Golden Seal			C				Not Reported
	Remicade			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2017	13638485	EXPEDITED (15-DAY)		OT	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2017-BI-03			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dysphagia; Rheumatoid Arthritis; Sjogren'S Syndrome; Thyroid Gland Scan Abnormal; Vomiting	Mobic			S	Unknown			Boehringer Ingelheim
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640230	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003379		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Plaquenil			S	Oral			Concordia
	Cortancyl			C				Not Reported
	Zoledronate			C				Not Reported
	Calcidose Vitamine D3			C				Not Reported

		Pantoprazole			C						Not Reported
		Fludex (Indapamide)			C						Not Reported
		Actiskenan			C						Not Reported
		Lyrica			C						Not Reported
		Doliprane			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640232	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003407		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cough; Drug Hypersensitivity; Fatigue; Immune System Disorder; Infusion Related Reaction; Oxygen Saturation Decreased; Pyrexia; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actonel			C				Not Reported
	Coversyl			C				Not Reported
	Dexilant			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Prednisone			C				Not Reported
	Pregabalin			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640233	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003302		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Oral			Concordia
	Apo-Amitriptyline			S	Unknown			Not Reported

	Arthrotec	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640239	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003401		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain Lower; Arthralgia; Asthenia; Barium Enema Abnormal; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Body Temperature Decreased; Disease Susceptibility; Dry Throat; Eye Disorder; Fatigue; Musculoskeletal Stiffness; Oedema Peripheral; Palpitations; Polyp	Hydroxychloroquine			S	Oral			Concordia
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Amlodipine Besilate			C				Not Reported
	Ativan			C				Not Reported
	Celebrex			C				Not Reported
	Diltiazem			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640240	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640267	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003402		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Chondropathy; Drug Ineffective; Dysphonia; Erythema; Hernia Repair; Hyperhidrosis; Influenza Like Illness; Joint Swelling; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Pyrexia; Swelling Face; Unevaluable Event	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640268	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003304		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Drug Intolerance; Hypertensive Crisis; Interstitial Lung Disease; Liver Disorder	Hydroxychloroquine	S	Oral		Concordia
	Actemra	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Diclofenac	C			Not Reported
	Nexium	C			Not Reported
	Rituxan	C			Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2017	13640272	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003364		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Blood Pressure Increased; Discomfort; Heart Rate Increased; Osteoarthritis; Pruritus; Urticaria	Hydroxychloroquine			S	Oral			Concordia
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Ventolin			C				Not Reported
	Zenhale			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	11285006	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015201152		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cellulitis; Drug Ineffective; Drug Intolerance; Myalgia; Nausea	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Plaquenil			S	Oral	400 Mg, Daily		Not Reported
	Arava			S	Oral	10 Mg, Daily		Not Reported
	Prednisone			S		5-15mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13489392	EXPEDITED (15-DAY)		OT	US-PFIZER INC-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tooth Abscess; Tooth Infection	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13611480	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017239375		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Nerve Injury; Renal Function Test Abnormal; Tuberculin Test Positive	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Oral	15-25 Mg		Pfizer
	Plaquenil			S	Oral	400 Mg, Daily		Not Reported
	Arava			S	Oral	10 Mg, Daily		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Prednisone			S		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13640750	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported
	Tylenol			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13640754	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003306		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13640824	EXPEDITED (15-DAY)		OT	CA-ROCHE-1944509			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13640908	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13640913	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003438		37 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Disorder; Paraesthesia	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13641207	EXPEDITED (15-DAY)		DS	CA-ROCHE-1944964		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock;	Actemra			S	Subcutaneous			Not Reported

Mass; Pain; Peripheral Swelling; Physical Disability	Humira		S	Subcutaneous	40 Mg/0.8 Ml		Not Reported
	Apo-Hydroxyquine		S	Oral			Not Reported
	Enbrel		S	Subcutaneous			Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Xeljanz		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13641248	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003442		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Belimumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13641249	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003446		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Hypertension; Insomnia; Pain; Rash; Seronegative Arthritis; Therapeutic Product Effect	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			C				Not Reported
	Methotrexate			C				Not Reported
	Reactine (Cetirizine Hydrochloride)			C				Not Reported

Decreased; Therapeutic Product Effect Incomplete; Visual Impairment	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2017	13645466	EXPEDITED (15-DAY)		OT	CA-ROCHE-1944534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown	40mg/0.8 Ml		Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Folic			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13216105	EXPEDITED (15-DAY)		OT	CA-SA-2015SA107674		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Cellulitis; Drug Ineffective; Drug Intolerance; Myalgia; Nausea; Rheumatoid Arthritis	Plaquenil	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Prednisone	S	Unknown	Dose- 5-15 Mg	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13251345	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001165		20 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil			S	Oral			Concordia
	Baktar			C				Not Reported
	Prograf			C				Not Reported
	Imuran			C				Not Reported
	Urinorm			C				Not Reported
	Alfarol			C				Not Reported
	Prorenal			C				Not Reported
	Bonalon			C				Not Reported
	Juvela N			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Amlodipine Od			C				Not Reported
	Sarpogrelate			C				Not Reported
	Lixiana			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13508249	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002702		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Exposure During Pregnancy; Foetal Growth Restriction; Premature Separation Of Placenta	Plaquenil 200 Mg Tablet	S	Oral		Concordia
	Cortancyl	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Loxen Lp	S	Oral		Not Reported
	Durogesic	S	Cutaneous		Not Reported
	Aprovel	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13614526	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1656			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Cell Carcinoma	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13645733	EXPEDITED (15-DAY)		DE, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0916		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Demyelination; Seizure	Methotrexate			S	Unknown	15-25 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200-400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2017	13645873	EXPEDITED (15-DAY)		OT	CA-ROCHE-1949414		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	11485779	EXPEDITED (15-DAY)		HO, OT	BR-ROCHE-1098505		60 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Blood Urea Abnormal; Contusion; Depression; Dysphagia; Dyspnoea; Emphysema; Gait Disturbance; Headache; Herpes Zoster; Hypoaesthesia; Ill-Defined Disorder; Muscular Weakness; Musculoskeletal Disorder; Off Label Use; Oral Herpes; Pain; Panic Disorder; Paraesthesia; Pharyngeal Disorder; Renal Disorder; Rheumatoid Arthritis; Sensation Of Foreign Body; Sluggishness; Swelling; Therapeutic Response Decreased; Tinnitus; Tremor; Visual Impairment	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Most Recent Dose Of Rituximab Infusion		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	1 Tablet In The Morning And 1 At Night		Not Reported
	Prednisone			S	Unknown			Not Reported
	Clonazepam			S	Unknown	At Night.		Not Reported
	Clonazepam			S				Not Reported
	Enbrel			S	Unknown			Not Reported

	Amitriptyline	C	Unknown	Night		Not Reported
	Codeine	C	Unknown			Not Reported
	Alprazolam	C	Unknown			Not Reported
	Deflazacort	C	Unknown			Not Reported
	Propranolol	C	Unknown	2 Tablets In The Morning And 1 At Night		Not Reported
	Methotrexate	C	Unknown	3 Tablets In The Morning And 3 At Night		Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13614850	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017021750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Cimzia			S	Subcutaneous			Ucb
	Humira			S	Subcutaneous	40 Mg / 0.8 Ml		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13635508	NON-EXPEDITED			US-PFIZER INC-2017250601		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Cellcept			S		Unk		Not Reported
	Cellcept			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13649664	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1717		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Mycobacterium Tuberculosis Complex Test Positive; Nerve Injury; Renal Impairment; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral	15-25 Mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13650240	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1994469-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Nausea; Rheumatoid	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Arthritis; Therapeutic Product Effect Decreased; Vomiting	Plaquenil		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Enbrel		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13650379	EXPEDITED (15-DAY)		OT	CA-ROCHE-1947673			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13651530	EXPEDITED (15-DAY)		OT	US-BAYER-2017-105340			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Atrial	Acetylsalicylic Acid(<=100 Mg)		Y	S	Transplacental	81 Mg Once Daily		Bayer
	Mycophenolate Mofetil			S	Transplacental	1,000 Mg Twice Daily		Not Reported

Septal Defect; Foetal Exposure During Pregnancy; Intraventricular Haemorrhage; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Right Ventricular Hypertrophy; Tricuspid Valve Incompetence	Mycophenolate Mofetil		S	Transplacental	500 Mg Twice Daily	Not Reported
	Prednisone		S	Transplacental	10 Mg/D	Not Reported
	Hydroxychloroquine		S	Transplacental	200 Mg/D	Not Reported
	Heparin		S	Transplacental	65 Mg Twice Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13651741	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017090094		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence; Pulmonary Hypertension; Tricuspid Valve Incompetence	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydrochlorothiazide			S	Oral	12.5 Mg, 1x/Day		Not Reported
	Irbesartan Hydrochloride			S	Oral	300 Mg, 1x/Day		Not Reported
	Bisoprolol			S	Oral	5 Mg, 2x/Day		Not Reported
	Plaquenil /00072603/			S	Oral	200 Mg, 2x/Day		Not Reported
	Sulfasalazine			S	Oral	400 Mg, 2x/Day		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2017	13653976	EXPEDITED (15-DAY)		OT	GR-AMGEN-GRCSP2017089887		53 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Neutropenia	Enbrel			S	Unknown	50 Mg, Weekly		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	12891035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Sulfasalazie			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	4omg/0.8ml		Not Reported
	Methotrexate /00113802/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Cortisone /00014602/			C	Subcutaneous			Not Reported
	Diclofenac /00372302/			C	Subcutaneous	100 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	12891264	EXPEDITED (15-DAY)		DS, HO, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005369			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Motor-Sensory Axonal Neuropathy; Asthenia; Ataxia; Fall; Gait Disturbance; Impaired Quality Of Life; Pain In Extremity; Pain In Extremity; Pelvic Pain;	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine 200 Mg Tablet			S				Concordia

Polyneuropathy; Skin Disorder; Somnolence; Spinal Pain; Tendon Pain

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13628309	EXPEDITED (15-DAY)		DS	CA-JNJFOC-20170602995		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13645713	EXPEDITED (15-DAY)		OT	AU-ORION CORPORATION ORION PHARMA-17_00002410		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13649845	EXPEDITED (15-DAY)		OT	CA-ABBVIE-14K-028-1268257-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Malaise; Nausea; Rheumatoid	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Arthritis; Vomiting	Methotrexate			S	Oral	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13654429	EXPEDITED (15-DAY)		OT	CA-ROCHE-1949976			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13654444	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003517			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Renal Impairment	Hydroxychloroquine	S	Unknown	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13654491	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2001826-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13655177	EXPEDITED (15-DAY)		OT	CA-ROCHE-1949953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13655459	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Drug Ineffective; Joint Swelling; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pyrexia	Plaquenil			S	Oral			Concordia
	Myochrysine			S	Intramuscular			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13656254	EXPEDITED (15-DAY)		OT	US-ZYDUS-015430			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Degeneration	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13656262	EXPEDITED (15-DAY)		OT	US-ZYDUS-015431			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Degeneration	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13657249	EXPEDITED (15-DAY)		OT	BR-MYLANLABS-2017M1036003			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Borderline Leprosy; Tuberculoid Leprosy; Type 1 Lepra Reaction	Prednisone			S	Unknown	40 Mg/Day		Not Reported
	Prednisone			S	Unknown	15mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg/Day		Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G/Day		Not Reported
	Cyclophosphamide			S	Other	500-1000 Mg/M2/Month; Seven Infusions Totally		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13657748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1944521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2017	13660510	DIRECT		DS			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Therapy Cessation; Urticaria	Hydroxycloriquine 200mg	S	Oral	Quantity:30 Tablet(S); Daily Oral	Sanofi
	Metformin Er	C			Not Reported
	Hyosciamine	C			Not Reported
	Zofran	C			Not Reported
	Miralax	C			Not Reported
	Ibuprofen	C			Not Reported
	Vitamin D Nos	C			Not Reported
	Daily Vitamin	C			Not Reported
	Turmeric	C			Not Reported
	Acidophilus	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13565892	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017074810		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergy To Vaccine; Alopecia; Arthralgia; Bursitis; Drug Ineffective; Epicondylitis; Fall; Fibromyalgia; Gastrointestinal Disorder; Hypertension; Injection Site Irritation; Iron Deficiency Anaemia; Leukopenia; Lung Hyperinflation; Musculoskeletal Pain; Osteopenia; Osteoporosis; Rheumatoid Arthritis; Rotator Cuff Syndrome; Sjogren'S Syndrome; Tooth Loss	Enbrel			S	Unknown	Unk		Amgen
	Afluria			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	11 Mg, Qd		Not Reported
	Humira			S	Unknown			Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	2.5 Mg, 6 Tablets Once A Week		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Triamcinolone Acetonide			C		0.1 %, Bid		Not Reported
	Atorvastatin			C		10 Mg, Qd		Not Reported
	Omeprazole			C		40 Mg, Qd		Not Reported
	Slow Release Iron			C		45 Mg, Unk		Not Reported
	Amlodipine Besylate			C		5 Mg, Qd		Not Reported

	Losartan Potassium	C		100 Mg, Qd	Not Reported
	Pentoxifylline	C		400 Mg, Tid	Not Reported
	Sulfasalazine	C	Oral	500 Mg, Bid	Not Reported
	Sulfasalazine	C		2 G, Qd	Not Reported
	Folic Acid	C	Oral	1 Mg, Qd	Not Reported
	Leflunomide	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13611477	NON-EXPEDITED			US-PFIZER INC-2017243599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13658199	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1734		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence; Pulmonary Hypertension; Pulmonary Valve Incompetence; Tricuspid Valve Incompetence	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Irbesartan Hydrochloride			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13658611	EXPEDITED (15-DAY)		OT	CA-ROCHE-1949943		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13658786	EXPEDITED (15-DAY)		OT	US-ZYDUS-015432			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Degeneration	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662785	DIRECT		OT			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Watson
	Praluent			S				Not Reported
	Carvedilol			C				Not Reported
	Clopidogrel			C				Not Reported
	Diazepam			C				Not Reported
	Eliquis			S				Not Reported

			Premarin			C				Not Reported
			Furosemide			C				Not Reported
			Plaquenil			S				Not Reported
			Levothyroxine			C				Not Reported
			Losartan			C				Not Reported
			Methotrexate			C				Not Reported
			Pantoprazole			C				Not Reported
			Metan-X			C				Not Reported
			Ranexa			C				Not Reported
			Prednisone			C				Not Reported
			Mag Oxide			C				Not Reported
			D 3			C				Not Reported
			Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2017	13662357	EXPEDITED (15-DAY)		DE	US-TORRENT-00003053		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Intentional Overdose; Toxicity To Various Agents	Cetirizine			S				Unknown
	Hydroxychloroquine			S				Unknown
	Hydroxyzine			S				Unknown
	Paracetamol			S				Unknown
	Butalbital			S				Unknown
	Caffeine			S				Unknown
	Meloxicam			S				Unknown
	Amlodipine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13662846	EXPEDITED (15-DAY)		DS	CA-ROCHE-1950658		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Arava			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Orencia			S	Subcutaneous	Therapy Duration: 7 Months		Not Reported

Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13663402	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown	Therapy Duration: 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13665976	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2017-018604		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Folic Acid			S	Unknown			Not Reported
	Diclofenac			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Lisinopril Dihydrate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	20mg 1 Every Week		Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

		Synthroid			S	Unknown				Not Reported
		Tecta			S	Oral				Not Reported
		Xeljanz			S	Oral				Not Reported
		Gold			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	11507275	EXPEDITED (15-DAY)		OT	CA-SA-2015SA139096		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Frequency: Q2w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13124186	EXPEDITED (15-DAY)		HO, OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000411		24 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Ineffective; Methaemoglobinaemia; Oedema Peripheral; Oedema Peripheral; Off Label Use; Panniculitis; Skin Plaque; Skin Ulcer	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Colchicine			S				Not Reported
	Dapsone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13204204	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA114805		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Malaise; Pain; Post Procedural Complication; Sensory Loss; Swelling; Therapeutic Product Effect Incomplete; Thrombosis; Thrombosis; Unevaluable Event	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Chloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13204467	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019895		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Gallbladder Disorder; Headache; Infection; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Ulcer	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13211675	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020575		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13215770	EXPEDITED (15-DAY)		DS	CA-SA-2017SA020107		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13250178	EXPEDITED (15-DAY)		OT	CA-CONCORDIA		58 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cellulitis; Drug Ineffective; Drug Intolerance; Myalgia; Nausea; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Leflunomide Tablet			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13425285	EXPEDITED (15-DAY)		HO	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002214		26 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Analgesic Drug Level Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Gamma-Glutamyltransferase Increased; International Normalised Ratio Increased; Overdose; Poisoning; Suicide Attempt; Toxicity To Various Agents	Plaquenil			S				Concordia
	Alvedon			S	Oral			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Betapred			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Lamotrigine			C				Not Reported
	Saroten			C				Not Reported
	Stilnoct			C				Not Reported
	Paraflex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13447258	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002466			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Myochrysine			S	Parenteral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13457702	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002325		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Localised Infection; Malaise; Pleurisy; Pneumonia	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13610041	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-		50 YR	Female	USA

003290

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dry Skin; Erythema; Macule; Malaise; Pain; Pain; Paraesthesia; Pruritus; Pustule; Pyrexia; Rash; Rash; Skin Exfoliation; Skin Exfoliation; Skin Lesion; Subcorneal Pustular Dermatosis; White Blood Cell Count Increased	Hydroxychloroquine			S	Oral			Concordia
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13617831	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003285		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Haematuria; Rebound Effect; Skin Lesion	Hydroxychloroquine			S	Unknown			Concordia
	Cyclophosphamide			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Chlorambucil			S	Unknown			Not Reported
	Alendronate			C				Not Reported
	Alendronate			C				Not Reported
	Etanercept			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13641246	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Tuberculosis Complex Test Positive; Nerve Injury; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported
	Synthroid			C				Not Reported
	Aldactone			C				Not Reported
	Bactrim			C				Not Reported
	Keflex			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13641324	NON-EXPEDITED			US-AMGEN-USASP2017085133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13667338	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Prevacid			C				Not Reported
	Coversyl			C				Not Reported
	Asa			C				Not Reported
	Salbutamol			C				Not Reported
	Spiriva			C				Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C				Not Reported
	Lipitor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13668419	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003568		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Injection Site Reaction; Respiratory Tract Infection; Urinary Tract Infection; Viral Upper Respiratory Tract Infection	Plaquenil			S				Concordia
	Prednisolone			S				Concordia
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13669163	EXPEDITED (15-DAY)		OT	US-SA-2017SA109376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Consciousness; Mobility Decreased	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13669227	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-01		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Ataxia; Balance Disorder; Headache; Hypoaesthesia; Neurotoxicity; Paraesthesia; Tinnitus; Vestibular Disorder; Vision Blurred	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13669883	EXPEDITED (15-DAY)		OT	CA-SA-2017SA106049		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Drug	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Ineffective; Exposure To Communicable Disease; Joint Effusion; Joint Stiffness; Musculoskeletal Pain; Osteoarthritis	Enbrel			S	Subcutaneous					Not Reported
	Enbrel			S	Subcutaneous					Not Reported
	Enbrel			S	Unknown					Not Reported
	Enbrel			S	Unknown					Not Reported
	Ibuprofen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2017	13670363	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020089		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Form; Solution Sc		Not Reported
	Humira			S	Subcutaneous	Form: Solution Sc		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown	1 Every 4 Wk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13215699	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA114798		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Diarrhoea; Drug Intolerance; Hypoaesthesia; Pain; Post Procedural Complication; Swelling; Therapeutic Product Effect Incomplete;	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

Thrombosis	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13296778	EXPEDITED (15-DAY)		OT	CA-ROCHE-1901266		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Sodium/Clavulanate Potassium			C				Not Reported
	Amoxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13300820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902134		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Parenteral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13320228	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902937		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Amoxicillin Sodium/Clavulanate Potassium			C				Not Reported
	Amoxil			C				Not Reported
	Bacillus Calmette Guerin			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13672747	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201706-		37 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13673840	EXPEDITED (15-DAY)		OT	CA-ROCHE-1950665		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2017	13674325	EXPEDITED (15-DAY)		HO	CA-ROCHE-1952686		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ramipril			C				Not Reported
	Naproxen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Lantus			C				Not Reported
	Lozide			C				Not Reported
	Metformin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13215916	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020141		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Methotrexate				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13421828	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13583490	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003142		65 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Eczema; Pruritus; Rash Erythematous	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13675418	EXPEDITED (15-DAY)		OT	AU-ABBVIE-17P-008-1911173-00			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Madarosis; Transfusion	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13676508	EXPEDITED (15-DAY)		OT	CA-ROCHE-1953242		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13676527	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003676		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13676530	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003716		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13676531	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003717			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2017	13677202	EXPEDITED (15-DAY)		OT	PHHY2017AU090788			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective	Imatinib			S	Unknown			Novartis
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13680647	EXPEDITED (15-DAY)		OT	CA-ROCHE-1953382		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Infliximab		S	Unknown		Not Reported
					Methotrexate		S	Oral		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Orencia		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13680697	EXPEDITED (15-DAY)		OT	CA-ROCHE-1953350		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13680959	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003741			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pruritus	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13680960	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003742			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Benzathine Benzyipenictliin Suspension For Injection			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13685129	EXPEDITED (15-DAY)		HO	TW-MYLANLABS-2017M1037054			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13685557	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016379411		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Diarrhoea; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea	Methotrexate Sodium			S	Oral	1 G, 2x/Day		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13686172	NON-EXPEDITED			US-ROCHE-1052646		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Protein Total Decreased;	Cellcept			S	Oral			Not Reported

Therapy Interrupted	Plaquenil			S	Oral	Not Reported
	Enalapril			S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2017	13686856	EXPEDITED (15-DAY)		HO, OT	SA-BAUSCH-BL-2017-019708		24 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bronchopleural Fistula; Maternal Exposure During Pregnancy; Pneumonia Staphylococcal	Prednisolone			S	Unknown			Bausch And Lomb
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2017	13443316	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1943413-00		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Heart Rate Increased; Hypertension	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2017	13687624	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003602		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis Infective; Blood Uric Acid Decreased; Blood Uric Acid Increased; Candida Infection; Crystal Urine Present; Fungal Skin Infection; Gastrointestinal	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Biotin			C				Not Reported

Bacterial Infection; Gastrointestinal Candidiasis; Hepatotoxicity; Hypertension; Liver Disorder; Renal Disorder; Retinal Disorder; Toxicity To Various Agents; Vitamin B12 Deficiency; White Blood Cell Count Decreased	Curcuma Xanthorrhiza	C		Not Reported
	Curcumin	C		Not Reported
	Iron	C		Not Reported
	Milk Thistle	C		Not Reported
	Prednisone	C		Not Reported
	Rivotril	C		Not Reported
	Vitamin B12	C		Not Reported
	Vitamin B6	C		Not Reported
	Zinc	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13044934	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2643		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Nausea; Nodule; Osteoarthritis; Thyroid Cancer	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13215928	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020216		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

Enzyme Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Arava	S	Oral			Not Reported
	Certolizumab Pegol	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Form- Solution Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Form- Solution Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Neoral	S	Unknown			Not Reported
	Prograf	S	Unknown			Not Reported
	Prograf	S	Oral			Not Reported
	Prograf	S	Oral			Not Reported
	Rapamune	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Form- Powder For Solution Intravenous		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Azathioprine	C	Unknown			Not Reported
	Imuran	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13286989	EXPEDITED (15-DAY)		OT	CA-ROCHE-1900087		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

		Methotrexate Sodium			S	Oral				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Orencia			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13457321	EXPEDITED (15-DAY)		OT	CA-SA-2017SA063893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Erosion; Drug Ineffective; Drug Intolerance; Joint Swelling; Nausea; Osteoarthritis; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Thrombocytosis; Thrombosis; Weight Decreased	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Codeine			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Actonel			C	Oral			Not Reported
	Vitamin D2			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13553440	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2017073674		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Femur Fracture; Platelet Count Decreased; Road Traffic Accident; Therapeutic Product Effect Decreased; Upper Limb Fracture	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13580460	EXPEDITED (15-DAY)		OT	US-009507513-1705USA012427		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergy To Vaccine; Alopecia; Arthralgia; Bursitis; Drug Ineffective; Epicondylitis; Fall; Fibromyalgia; Gastrointestinal Disorder; Hypertension; Injection Site Irritation; Iron Deficiency Anaemia; Leukopenia; Lung Hyperinflation; Musculoskeletal Pain; Osteopenia; Osteoporosis; Rheumatoid Arthritis; Rotator Cuff Syndrome; Sjogren'S Syndrome; Tooth Loss	Methotrexate			S	Oral	2.5 Mg, 6 Tablets Once A Week		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Fosamax			S		Unk		Merck
	Enbrel			S				Not Reported
	Afluria			S				Not Reported
	Cymbalta			S				Not Reported
	Xeljanz			S		11 Mg, Qd		Not Reported
	Humira			S				Not Reported
	Duloxetine Hydrochloride			S				Not Reported
	Gabapentin			S				Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Triamcinolone Acetonide			C				Not Reported
	Atorvastatin			C				Not Reported
	Omeprazole			C				Not Reported
	Iron (Unspecified)			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Cozaar			C				Merck
	Pentoxifylline			C				Not Reported
	Sulfasalazine			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2017	13691114	NON-EXPEDITED			US-ROCHE-765868		10 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic	Cellcept			S	Oral	Other Indication: Sle (Systemic Lupus Erythematous).		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	12854764	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP012836		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Apo-Celecoxib			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Apotex
	Apo-Pregabalin			S	Unknown	Unk		Not Reported
	Misoprostol			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk (Capsule)		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid (2 Every 1 Day)		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Not Specified)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Diclofenac W/Misoprostol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	12953553	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007912		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Malaise; Nausea; Pain In Extremity; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased;	Plaquenil			S	Oral	1 Every 1day(S)		Concordia
	Erythromycin			S	Unknown			Not Reported
	Arava			S	Oral	1 Every 1 Day(S)		Not Reported
	Flagyl			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

Staphylococcal Infection; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate Sodium		S	Oral	Not Reported
	Norfloxacin		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Ceclor		S	Unknown	Not Reported
	Celebrex		S	Oral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Misoprostol		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692242	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1953989		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692290	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003784		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Erythromycin			S	Unknown			Not Reported
	Plaquenil Tablet			S	Oral	1 Every 1 Day(S)		Concordia
	Humira			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Metronidazole 5 Mg/Ml Injection			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692292	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003791		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Erythromycin			S	Unknown			Not Reported
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported

	Celebrex	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Metronidazole	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Demerol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692320	EXPEDITED (15-DAY)		DS	CA-ROCHE-1953963			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692480	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003768		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Hydroxychloroquine			S				Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13692925	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003776		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Drug Ineffective; Exposure To	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Communicable Disease; Joint Effusion; Joint Stiffness; Musculoskeletal Pain; Osteoarthritis	Enbrel	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Ibuprofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13693905	DIRECT		OT			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma; Iritis; Scleral Disorder	Hydrochloroquine Sulfate Tab 200mg			S	Oral	2 Pills One A Day, By Mouth		Prasco
	Levothyroxine			C				Not Reported
	Prednisone			C				Not Reported
	Prednisolone Acetate			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Zyflamend			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694047	NON-EXPEDITED			US-AMGEN-USASP2017095633			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C		20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694242	NON-EXPEDITED			US-MYLANLABS-2016M1040569		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia Oral	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694243	NON-EXPEDITED			US-MYLANLABS-2016M1033235			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Qd		Mylan
	Hydroxychloroquine Sulfate Tablets, Usp			S				Mylan
	Multivitamin /00097801/			C		Unk		Mylan
	Vitamin D /00107901/			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694244	NON-EXPEDITED			US-MYLANLABS-2016M1042299		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	400 Mg, Qd		Mylan
	Morphine			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694245	NON-EXPEDITED			US-MYLANLABS-2016M1028728			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Dyspnoea; Hypersensitivity; Pain	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694246	NON-EXPEDITED			US-MYLANLABS-2016M1043806		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reaction To Excipient; Swelling Face; Swollen Tongue	Hydroxychloroquine			S	Oral	200 Mg, Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694247	NON-EXPEDITED			US-MYLANLABS-2016M1046783		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrooesophageal Reflux Disease	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694248	NON-EXPEDITED			US-MYLANLABS-2016M1047366		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Feeling Abnormal; Hypersensitivity; Nausea; Palpitations; Tachycardia	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694249	NON-EXPEDITED			US-MYLANLABS-2016M1041651			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Pain; Paraesthesia	Hydroxychloroquine Sulfate Tablets, Usp			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2017	13694250	NON-EXPEDITED			US-MYLANLABS-2017M1000936		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Dyspnoea; Fatigue; Mucosal Inflammation	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Qd		Mylan
	Ascorbic Acid/Calcium Pantothenate/Ergocalciferol/Nicotinamide/Pyridoxine Hydrochloride/Retinol/Ribo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	11987608	EXPEDITED (15-DAY)		HO	CA-ROCHE-1623671		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infusion Related Reaction; Pneumonia; Sarcoidosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13234419	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000989		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise	Hydroxychloroquine			S	Oral			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Prednisone			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13250627	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001159		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Plaquenil Tablet	S	Unknown		Concordia
	Arava Tablet	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13250629	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001162		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Rheumatoid Arthritis	Plaquenil			S	Oral	Twice A Day		Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13625337	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003335			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

		Prednisone			C					Not Reported
		Simponi			C					Not Reported
		Xeljanz			C					Not Reported
		Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13691597	EXPEDITED (15-DAY)		OT	CA-SA-2017SA109559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Retinal Degeneration; Retinal Toxicity; Vertigo	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13695997	EXPEDITED (15-DAY)		OT	CA-ROCHE-1954519			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown	Apo Folic Acid, 5 Mg Tablet		Not Reported
	Apo-Sulfasalazine			S	Unknown	500 Mg Tablet		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Orencia			S	Subcutaneous				Not Reported
		Reactine (Cetirizine Hydrochloride)			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Methotrexate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13696329	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder; Leukopenia	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2017	13696330	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)				
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13070735	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007953		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Fatigue; Foot Fracture; Joint Swelling; Malaise; Nausea; Skin Depigmentation; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	Weekly		Not Reported
	Cortisone			C				Not Reported
	Cortisone			C		2.5 Mg Every Other Day		Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13224728	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000993		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate			S	Oral					Not Reported
	Orencia			S	Subcutaneous					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13233913	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001053		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13234330	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001048		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13234359	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008021		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13238450	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001111		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Plaquenil			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Arava			C				Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Rituxan			C				Not Reported
	Cimzia			C				Not Reported
	Acetaminophen			C				Not Reported
	Tylenol			C				Not Reported
	Folic Acid			C				Not Reported
	Indapamide			C				Not Reported

	Coversyl			C						Not Reported
	Pantoloc			C						Not Reported
	Calcium			C						Not Reported
	Vitamin D Nos			C						Not Reported
	Humira			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13246582	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001125			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Drug Ineffective; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomycosis	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Orencia			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13248248	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008020		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Arthropathy;	Plaquenil Tablet			S	Oral			Concordia

Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Malaise; Pain; Post Procedural Complication; Sensory Loss; Swelling; Therapeutic Product Effect Incomplete; Thrombosis; Thrombosis; Unevaluable Event	Arava	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Remicade	S	Unknown		Not Reported
	Chloroquine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13248253	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Cozaar			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13250266	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001056		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Gallbladder Disorder; Headache; Infection; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Rheumatoid Arthritis; Stomatitis;	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Ulcer	Myochrysine	S	Intramuscular			Not Reported
	Xeljanz	S	Oral	Twice A Day		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Celebrex	C				Not Reported
	Prednisone	C				Not Reported
	Humira	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13250494	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001079		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13250504	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001134		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Ovarian	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Prograf	S	Unknown	Not Reported
	Prograf	S	Oral	Not Reported
	Prograf	S	Oral	Not Reported
	Rapamune	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Azathioprine	C		Not Reported
	Imuran	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13250624	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001152		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Lactate Dehydrogenase Increased; Butterfly Rash; Chills; Gamma-Glutamyltransferase Increased; Hepatic Cyst; Hepatic Haematoma;	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S				Concordia
	Dapsone			S	Oral			Not Reported
	Dapsone			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Calcium			C				Not Reported
	Levothyroxine			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Zopiclone			C				Not Reported

Jaundice; Liver Function Test Increased; Pyrexia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13250631	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001164		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Cellulitis; Condition Aggravated; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Frustration Tolerance Decreased; Insomnia; Musculoskeletal Stiffness; Oral Allergy Syndrome; Pain In Extremity; Tinnitus	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil			C				Not Reported
	Eltroxin			C				Not Reported
	Ergocalciferol			C		2000 U Od		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13521318	NON-EXPEDITED			US-PFIZER INC-2017192257		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Adalimumab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13641472	EXPEDITED (15-DAY)		OT	SG-SUN PHARMACEUTICAL INDUSTRIES LTD-		37 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Separation Of Placenta; Stillbirth	Aspirin			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisolone			S	Unknown	Unk		Taro
	Immunoglobulin (Ivig)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13665720	EXPEDITED (15-DAY)		DE, OT	FR-EDENBRIDGE PHARMACEUTICALS, LLC-FR-2017EDE00007		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hepatitis; Hepatitis Cholestatic; Hypoxia; Lymphopenia; Pain; Pneumocystis Jirovecii Pneumonia; Tracheal Dilatation	Prednisolone Sodium Phosphate			S	Oral	40 Mg, Qd		Edenbridge Pharmaceuticals
	Hydroxychloroquine			S		200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13699686	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction; Visual Impairment	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13699914	EXPEDITED (15-DAY)		HO, OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003823		58 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Mastectomy	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Valmetrol-3			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13700315	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2017-GB-001210		88 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Hydroxychloroquine			S		200 Mg, Daily		Ipca
	Leflunomide			S		20 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported
	Methotrexate			S		15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13700446	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2017-GB-001206		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia	Hydroxychloroquine			S		200 Mg, Daily		Ipca
	Leflunomide			S		20 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2017	13700474	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES		50 YR	Female	GBR

						LIMITED-IPC-2017-GB-001212			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia	Hydroxychloroquine			S		200 Mg, Unk		Ipca
	Leflunomide			S		20 Mg, Unk		Not Reported
	Leflunomide			S		10 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13233492	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000995		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13233914	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001061		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dyspepsia; Dyspepsia; Malaise; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13233944	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000996		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13250180	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001160		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Drug	Hydroxychloroquine 200 Mg			S	Oral			Concordia
	Leflunomide Tablet			S	Oral			Not Reported

Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Unknown				Not Reported
	Anakinra			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13250616	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001195		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Diarrhoea; Drug Intolerance; Hypoaesthesia; Pain; Post Procedural Complication; Swelling; Therapeutic Product Effect Incomplete; Thrombosis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13250625	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001154		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Oral			Concordia
	Asa			S	Unknown			Not Reported

Intolerance; Dry Mouth; Joint Range Of Motion Decreased; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Swelling; Synovitis	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actonel	C		Not Reported
	Calcium Carbonate	C		Not Reported
	Ergocalciferol			
	Citalopram	C		Not Reported
	Domperidone	C		Not Reported
	Folic Acid	C		Not Reported
	Gabapentin	C		Not Reported
	Gliclazide	C		Not Reported
	Lipitor	C		Not Reported
	Nifedipine	C		Not Reported
	Pantoprazole Sodium Sesquihydrate	C		Not Reported
	Synthroid	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13600789	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003263		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergy To Vaccine; Alopecia; Arthralgia; Bursitis; Drug Ineffective; Epicondylitis; Fall; Fibromyalgia; Gastrointestinal Disorder; Hypertension; Injection Site Irritation; Iron Deficiency Anaemia; Leukopenia; Lung Hyperinflation;	Plaquenil			S	Oral			Concordia
	Gabapentin			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Mg, 6 Tablets		Not Reported
	Methotrexate			S	Oral			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Musculoskeletal Pain; Osteopenia; Osteoporosis; Rheumatoid Arthritis; Rotator Cuff Syndrome; Sjogren'S Syndrome; Tooth Loss	Enbrel	S	Unknown		Not Reported
	Cymbalta	S	Unknown		Not Reported
	Afluria	S	Unknown		Not Reported
	Triamcinolone Acetonide	C			Not Reported
	Atorvastatin	C			Not Reported
	Omeprazole	C			Not Reported
	Slow Release Iron	C			Not Reported
	Amlodipine Besylate	C			Not Reported
	Losartan Potassium	C			Not Reported
	Pentoxifylline	C			Not Reported
	Sulfasalazine	C			Not Reported
	Folic Acid	C			Not Reported
	Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13612857	EXPEDITED (15-DAY)		OT	US-ELI_LILLY_AND_COMPANY-US201705010376		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Pressure Increased; Bursitis; Epicondylitis; Fall; Fibromyalgia; Gastrointestinal Disorder; Iron Deficiency Anaemia; Leukopenia; Lung Hyperinflation; Musculoskeletal Pain; Musculoskeletal Pain; Osteopenia; Osteoporosis; Rheumatoid Arthritis; Rotator Cuff Syndrome; Sjogren'S Syndrome; Tooth Loss	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Duloxetine Hydrochloride			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Xeljanz			S	Unknown	11 Mg, Daily		Not Reported
	Humira			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly (1/W)		Not Reported
	Fosamax			S	Unknown	Unk, Unknown		Not Reported
	Gabapentin			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk, Unknown		Not Reported
	Afluria			S	Unknown	Unk, Unknown		Not Reported
	Triamcinolone Acetonide			C	Unknown	Unk, Unknown		Not Reported
	Atorvastatin			C	Unknown	Unk, Unknown		Not Reported
	Omeprazole			C	Unknown	Unk, Unknown		Not Reported
	Slow Release Iron			C	Unknown	Unk, Unknown		Not Reported

	Amlodipine Besylate	C	Unknown	Unk, Unknown		Not Reported
	Losartan Potassium	C	Unknown	Unk, Unknown		Not Reported
	Pentoxifylline	C	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine	C	Unknown	Unk, Unknown		Not Reported
	Folic Acid	C	Unknown	Unk, Unknown		Not Reported
	Leflunomide	C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13704225	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1955852		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Duloxetine Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13704303	EXPEDITED (15-DAY)		OT	CA-ROCHE-1955882		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated	Actemra			S	Unknown	Therapy Duration: 3 Years		Not Reported

Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan		S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months	Not Reported
	Arava		S	Unknown	5 Months	Not Reported
	Cimzia		S	Subcutaneous	Therapy Duration: 2 Years	Not Reported
	Enbrel		S	Unknown	Therapy Duration: 730 ?	Not Reported
	Enbrel		S	Unknown	Therapy Duration: 731 ?	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Therapy Duration: 5 Months	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Therapy Duration: 6 Years	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Therapy Duration: 8 Years	Not Reported
	Leflunomide		S	Unknown	Therapy Duration: 5 Months	Not Reported
	Methotrexate		S	Unknown	Therapy Duration: 8 Years	Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years	Not Reported
	Simponi		S	Subcutaneous	Therapy Duration: 2 Months	Not Reported
	Arthrotec		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Imuran		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13704321	EXPEDITED (15-DAY)		OT	CA-ROCHE-1955303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Enbrel				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13704702	NON-EXPEDITED			US-AMGEN-USASP2017097996			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Increased Tendency To Bruise; Injection Site Discolouration; Injection Site Pain; Visual Acuity Reduced	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13704869	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001170		44 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Oral Blood Blister; Thrombocytopenia	Hydroxychloroquine			S		Unk		Ipca
	Aceclofenac			S		100 Mg, Unk		Not Reported
	Paracetamol			C		500 Mg, Unk		Not Reported
	Leflunomide Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13705083	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003836			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus	Plaquenil			S				Concordia
	Fabrazyme			S	Intravenous (not otherwise specified)	130		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13705084	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003840		84 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema	Plaquenil Tablet			S	Oral			Concordia
	Vitamin B12			C				Not Reported
	Pantoprazole			C				Not Reported
	Aldactazine			C				Not Reported
	Pulmicort			C				Not Reported
	Stagid			C				Not Reported
	Ventoline			C				Not Reported
	Cordarone			C				Not Reported
	Sevikar			C				Not Reported
	Alpress			C				Not Reported
	Natispray			C				Not Reported
	Doliprane			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2017	13706515	NON-EXPEDITED			US-PFIZER INC-2017282196		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13378002	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043533		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal;	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported

Mucosal Inflammation; Pneumonia; Treatment Failure	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Unknown	Form: Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Cortisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13709948	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003898			Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Pustular Psoriasis	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2017	13716425	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Surgery; Therapy Cessation	Folic Acid 1mg Generic			S	Oral			Unknown
	Hydrochloroquine			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2017	13713832	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-02162			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Quality Of Life	Ranitidine			S	Unknown	150 Mg, Bid		Not Reported
	Cetirizine			S	Unknown	Quadruple-Dosed		Novel Labs
	Fexofenadine			S	Unknown	Quadruple-Dosed		Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13460706	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Erosion; Drug Ineffective; Drug Intolerance; Joint Swelling; Nausea; Osteoarthritis; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Thrombocytosis; Thrombosis; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actonel			C				Not Reported
	Codeine			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13715758	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Drug	Erythromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Concordia

Ineffective; Nausea; Urticaria	Arava		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate Sodium		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13715887	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003891		63 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fundoscopy Abnormal; Glare; Optical Coherence Tomography Abnormal; Retinopathy; Visual Acuity Reduced; Visual Field Defect; Visual Impairment	Hydroxychloroquine			S	Unknown			Concordia
	Omeprazole			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13716383	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-144675		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Combined Immunodeficiency; Foetal Exposure During Pregnancy	Prednisone			S	Transplacental	10 Mg, Daily		Mutual
	Hydroxychloroquine			S	Transplacental	200 Mg, Bid		Ipca
	Prednisone			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	50 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13718154	EXPEDITED (15-DAY)		OT	PHHY2017US093212		13 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During	Prednisone			S	Unknown	10 Mg, Qd		Novartis

Pregnancy; T-Cell Receptor Gene Rearrangement Test; T-Lymphocyte Count Decreased	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Azathioprine			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	100 Mg,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13719950	EXPEDITED (15-DAY)		HO, OT	CN-MYLANLABS-2017M1039896			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis; Pneumonia; Skin Bacterial Infection	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2017	13719954	EXPEDITED (15-DAY)		HO, OT	CN-MYLANLABS-2017M1039935			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis; Pneumonia; Skin Bacterial Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	12470327	EXPEDITED (15-DAY)		OT	CA-ROCHE-1776829		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	Interrupted On 29/Jun/2016		Not Reported

	Arava	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Prednisone	C	Unknown	Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13672657	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00012342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Pneumonia	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Rituxan			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported
	Mucosil			C				Not Reported
	Actemra			C				Not Reported
	Cortisone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720177	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003876		44 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fundoscopy Abnormal; Maculopathy; Retinogram Abnormal; Retinopathy; Visual Field Defect; Visual Field Tests Abnormal; Visual Impairment	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported
	Omeprazole			C				Not Reported
	Loratadine			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720302	EXPEDITED (15-DAY)		OT	GR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003894		53 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Neutropenia	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13720303	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003969		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13722119	NON-EXPEDITED			US-PFIZER INC-2017285111		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methylprednisolone			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13722653	NON-EXPEDITED			US-JNJFOC-20170519289		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Incorrect Dose Administered; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Therapeutic Response Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Citalopram			C	Oral			Not Reported
	Cyanocobalamine			C	Oral			Not Reported
	Famotidine			C	Oral			Not Reported
	Fluconazole			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Zyrtec			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13723719	NON-EXPEDITED		OT	US-JNJFOC-20170525613			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Treatment Failure	Simponi		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Clobetasol Propionate		C	Unknown	Not Reported
	Advil		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725400	NON-EXPEDITED			US-PFIZER INC-2017288644		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725409	NON-EXPEDITED			US-PFIZER INC-2017288958		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725495	NON-EXPEDITED			US-PFIZER INC-2017288827		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725854	EXPEDITED (15-DAY)		OT	CA-SA-2017SA122055		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown	Form:Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13056504	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015796		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Apotex
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13059485	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015784		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Apo-Leflunomide	S	Unknown	20 Mg, Qd		Apotex
	Apo-Sulfasalazie	S	Unknown	1 G, Bid		Not Reported
	Chloroquine	S	Unknown	250 Mg, Qd		Not Reported
	Arava	S	Oral	20 Mg, Qd		Not Reported
	Enbrel	S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Unknown	250 Mg, Qd		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13341112	NON-EXPEDITED		OT	US-AMGEN-USASL2017036694		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hernia; Mobility Decreased; Renal Failure; Renal Impairment	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13536411	NON-EXPEDITED			US-PFIZER INC-2017202442		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methylprednisolone Acetate			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Tramadol			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Flonase			S		Unk		Not Reported
	Seroquel			S		Unk		Not Reported

Plaquenil /00072602/	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13575570	EXPEDITED (15-DAY)		HO, LT, OT	MY-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-140700		24 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Pulmonary Embolism	Acetylsalicylic Acid			S	Unknown	75 Mg, Daily		Sun
	Acetylsalicylic Acid			S	Unknown	150 Mg, Daily		Sun
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Ipca
	Enoxaparin Sodium			S	Subcutaneous	80 Mg, Qd, At Night		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	100 Mg, Qd, In The Morning		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	80 Mg, Bid (1 Mg/Kg/Dose)		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13636305	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1941633			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200mg Daily More, Started More Than 1 Year Ago		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Started More Than 1 Year Ago		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13692289	EXPEDITED (15-DAY)		DS, HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003780		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Nausea; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Staphylococcal Infection; Vomiting; Vomiting	Erythromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Flagyl			S	Unknown			Not Reported
	Misoprostol			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13699687	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Retinal Degeneration; Retinal Toxicity; Vertigo	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13713224	EXPEDITED (15-DAY)		HO, OT	SA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003827		24 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Bronchopleural Fistula; Exposure During Pregnancy; Pneumonia Staphylococcal	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13727809	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003961			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Retinal Toxicity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13728074	NON-EXPEDITED			US-PFIZER INC-2017294279		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13728906	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001279			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tendon Disorder	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S				Ipca
	Glimepiride			S		2 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13729142	NON-EXPEDITED			US-PFIZER INC-2017294484		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral	Methotrexate Sodium			S	Oral	8 Df, Weekly (8 Tablets Once A Week, Same Day Each Week)		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Meloxicam			S	Oral	15 Mg, Daily		Not Reported
	Meloxicam			S				Not Reported
	Meloxicam			S				Not Reported
	Meloxicam			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Daily		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jul-2017	13730061	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2017M1040220			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Hypokalaemia; Overdose; Pupils Unequal; Suicide Attempt; Toxicity To	Hydroxychloroquine			S	Unknown	42 Tablets Of 200 Mg		Not Reported

Various Agents;
Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2017	13692291	EXPEDITED (15-DAY)		DS, HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003787		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Nausea; Pain In Extremity; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased; Staphylococcal Infection; Vomiting	Erythromycin			S	Unknown			Not Reported
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Flagyl			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Misoprostol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2017	13735713	DIRECT	Y	OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Product Substitution Issue	Hydroxychloroquine			S					Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2017	13735719	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Therapeutic Product Effect Decreased	Hydroxychloroquine			S				Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2017	13735721	DIRECT	Y	OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue; Therapeutic Product Effect Decreased	Hydroxychloroquine			S				Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2017	13734334	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001315			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Metformin			S		1000 Mg, Unk		Ipca
	Hydroxychloroquine Sulfate			S		300 Mg, Unk		Ipca
	Zopiclone			S				Not Reported
	Aceclofenac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2017	13734437	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ureteric Obstruction	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine Tablets			S		300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2017	13735564	DIRECT		DS, HO, OT			59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Mood Altered; Psychotic Disorder	Plaquinil, Hydroxychloroquine			S	Oral	Other Strength:Mg;Quantity:2 Tablet(S);		Not Reported
	Montelukast Sod			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);		Not Reported
	Geodon			C				Not Reported
	Benztropine			C				Not Reported
	Lorazepam			C				Not Reported
	Trintellix			C				Not Reported
	Trazadone			C				Not Reported
	Skelaxin			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Stool Softener			C				Not Reported
	Calcium			C				Not Reported
	Fish Oil			C				Not Reported
	Turmeric			C				Not Reported
	Cranbury			C				Not Reported
	Multivitamin			C				Not Reported
	B6			C				Not Reported
	D3			C				Not Reported
	Magnesium			C				Not Reported
	Enteric Coated 81mg Aspirin			C				Not Reported
	Zyrtec			C				Not Reported
	Flonase			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13059038	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015771		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Migraine; Nausea; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Arava			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Mg, 1 Every 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13673301	EXPEDITED (15-DAY)		HO	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003678		29 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bicarbonate Decreased; Blood Lactic Acid Increased; Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Hypotension; Intentional Overdose; Loss Of Consciousness; Mydriasis; Overdose; Pupils Unequal; Torsade De Pointes; Ventricular Tachycardia	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral	Once		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13735045	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES			Unknown	IND

LIMITED-IPC-2017-IN-001435

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Metformin			S		Unk		Ipca
	Hydroxychloroquine Tablets			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13735615	EXPEDITED (15-DAY)		OT	CA-ROCHE-1959793		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide (Canada)			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Ramipril			C	Unknown					Not Reported
	Metformin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13735745	NON-EXPEDITED			US-AMGEN-USASP2017101260		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13735965	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001517			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Priapism	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		200 Mg, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13736019	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001523			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Wound Dehiscence	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13736104	NON-EXPEDITED			US-AMGEN-USASP2017101252			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2017	13738669	NON-EXPEDITED		OT	US-SAOL THERAPEUTICS-0700763568		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Dysarthria; Hyporeflexia; Hypotonia; Overdose; Somnolence	Lioresal			S		962 Mg, \Day		Saol Therapeutics
	Lioresal			S	Intrathecal	872.8 Mg, \Day		Saol Therapeutics
	Lioresal			S	Intrathecal	826.4 Mg, \Day		Saol Therapeutics
	Lisinopril			S				Not Reported
	Levothyroxine			S				Not Reported
	Simvastatin			S				Not Reported
	Gabapentin			S				Not Reported
	Novolog			S				Not Reported
	Plaquenil			S				Not Reported
	Evoxac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13045997	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016587353		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Fear Of Injection; High Density Lipoprotein Increased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nephrolithiasis; Red Blood Cell Sedimentation Rate Increased	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13060325	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Neuropathy Peripheral; Osteoarthritis; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Sulfasalazie			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Actonel			C	Unknown	135 Mg, Q.Wk.		Not Reported
	Advair			C	Unknown			Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Ascorbic Acid			C	Unknown	1000 Mg, Qd		Not Reported
	Aspirin /00002701/			C	Unknown	81 Mg, Qd		Not Reported
	Calcium			C	Unknown	500 Mg, Bid		Not Reported
	Citalopram			C	Unknown	30 Mg, Qd		Not Reported
	Ergocalciferol			C	Unknown	3000.0 Df, Qd		Not Reported
	Ferrous Gluconate			C	Unknown	300 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	Unk, Qd		Not Reported

	Hydrochlorothiazide	C	Unknown	25 Mg, Qd		Not Reported
	Olmesartan Medoxomil	C	Unknown	40 Mg, Qd		Not Reported
	Prednisone	C	Unknown	9 Mg, Qd		Not Reported
	Rabeprazole	C	Unknown	20 Mg, Qd		Not Reported
	Senna Alexandrina	C	Unknown	Unk		Not Reported
	Vitamin B-12	C	Unknown	1500 Mg, Qd		Not Reported
	Tiotropium Bromide	C	Unknown	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk, Qid		Not Reported
	Zinc Gluconate	C	Unknown	25 Mg, Qd		Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13705528	EXPEDITED (15-DAY)		HO, LT	PHHY2017CA095438			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Novartis
	Methotrexate			S				Novartis
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13713810	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003856		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Fluorescence Angiogram Abnormal; Fundoscopy Abnormal; Macular Cyst; Maculopathy; Night Blindness; Optical Coherence Tomography Abnormal; Retinal Degeneration; Retinal Degeneration; Retinogram Abnormal; Retinopathy; Toxicity To Various Agents; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13739928	NON-EXPEDITED			US-PFIZER INC-2017295916		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective	Dilantin	S	Unk	Pfizer
	Neurontin	S	Unk	Pfizer
	Dalmane	S	Unk	Not Reported
	Elavil	S	Unk	Not Reported
	Lortab	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Relafen	S	Unk	Not Reported
	Restoril	S	Unk	Not Reported
	Tegretol	S	Unk	Not Reported
	Tocilizumab	S	Unk	Not Reported
	Ultram	S	Unk	Not Reported
	Vicodin	S	Unk	Not Reported
	Lasix	S	Unk	Not Reported
	Advair	C	Unk ([Fluticasone Propionate:: 250 Mcg]/ [Salmeterol Xinafoate: 50 Mcg] Dose Powder For Inhalation)	Not Reported
	Albuterol Sulfate	C	Unk (1.25mg/3ml Solution For Nebulization)	Not Reported
	Ammonium Lactate	C	Unk	Not Reported
	Amoxicillin	C	500 Mg, Unk	Not Reported
	Amoxicillin And Clavulanate Potassium	C	Unk	Not Reported
	Azithromycin	C	250 Mg, Unk	Not Reported
	Budesonide	C	(0.5mg/2 Ml Suspension For Nebulization	Not Reported
	Cefpodoxime	C	200 Mg, Unk	Not Reported
	Cephalexin	C	250 Mg, Unk	Not Reported
	Depo-Medrol	C	2.22 Ml, Daily (Everyday By Injection Route For 7 Days	Not Reported

Dexamethasone	C			Not Reported
Endocet	C	Oral	1 Df, 4x/Day (Every 6 Hours By Oral Route For 30 Days	Not Reported
Fluconazole	C			Not Reported
Fluzone	C		Unk (2013-2014(Pf) 45 Mcg (15mcg X 3)/0.5 Ml Intramuscular Syringe	Not Reported
Furosemide	C			Not Reported
Furosemide	C		40 Mg, Unk	Not Reported
Hydrocodone Bitartrate And Acetaminophen	C	Oral	1 Df, 4x/Day	Not Reported
Hydrocodone Bitartrate And Acetaminophen	C	Oral	1 Df, 4x/Day (Every 6 Hours	Not Reported
Hydrocodone/Homatropine	C		Unk (5 Mg-1.5 Mg/Ml)	Not Reported
Methylprednisolone	C		4 Mg, Unk (Take As Directed	Not Reported
Metoprolol Tartrate	C		25 Mg, Unk	Not Reported
Metronidazole	C	Topical	Unk (0.75 % Topical Gel)	Not Reported
Morphine	C	Oral	30 Mg, 2x/Day(Every 12 Hours)	Not Reported
Omeprazole	C		20 Mg, Unk	Not Reported
Polymyxin B Sulfate And Trimethoprim Ophthalm	C		Unk (10000 Unit - 1 Mg/Ml)	Not Reported
Pravastatin	C		40 Mg, Unk	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk (100 Mg Intravenous Solution Infuse 5 Mg/Kg Over 2 Hours Every 8 Weeks)	Not Reported
Ropinirole	C		0.25 Mg, Unk	Not Reported
Ropinirole	C		0.5 Mg, Unk	Not Reported
Silver Sulfadiazine	C	Topical	Unk (Topical Cream)	Not Reported
Sulfamethoxazole And Trimethoprim	C		Unk	Not Reported

Synthroid	C		100 Ug, Unk	Not Reported
Synthroid	C		125 Ug, Unk	Not Reported
Tubersol	C	Intradermal	0.1 Ml, Unk (Tubersol 5 Tub. Unit/0.1 Ml)	Not Reported
Trazodone	C		50 Mg, Unk	Not Reported
Ventolin	C		Unk (90 Mcg/Actuation Aerosol Inhaler)	Not Reported
Verapamil	C		240 Mg, Unk (24 Hr Capsule)	Not Reported
X-Viate	C	Topical	Unk (Topical Cream	Not Reported
Fluoxetine	C		20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13740043	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001532			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Echinococciasis	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine Tablets			S		300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13740091	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001540			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporosis	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13741025	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea Exertional	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		400 Mg, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13741235	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003898		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Pustular Psoriasis	Hydroxychloroquine			S	Oral			Concordia
	Naproxen			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13741236	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003989		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2017	13741664	NON-EXPEDITED			US-PFIZER INC-2017296326		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	12917868	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1774740-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported

Gold	S		Not Reported
Gold	S		Not Reported
Gold	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Arava	S		Not Reported
Arava	S		Not Reported
Aspirin	S	Unknown	Not Reported
Aspirin	S		Not Reported
Aspirin	S		Not Reported
Aspirin	S		Not Reported
Voltaren	S	Unknown	Not Reported
Voltaren	S		Not Reported
Voltaren	S		Not Reported
Voltaren	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Motrin	S	Unknown	Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Naprosyn	S	Unknown	Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Tramadol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13446101	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002404		22 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Erythema; Hepatic Function Abnormal; Lymphadenopathy; Pyrexia; Rash	Plaquenil			S	Unknown			Concordia
	Sulfamethoxazole Trimethoprim			S	Unknown			Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13743926	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001288			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Skin Discolouration	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca
	Albendazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13743965	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001710			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Neuralgia	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		200 Mg, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744026	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001720			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hiatus Hernia	Metformin			S		500 Mg, Unk		Ipca

	Hydroxychloroquine Sulphate 200mg Tablet			S		200 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744085	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001580			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744090	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001743			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatic Neoplasm	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca
	Zopiclone			S				Not Reported
	Aceclofenac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744116	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001750			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Movement Disorder	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca
	Albendazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744188	EXPEDITED (15-DAY)		OT	IN-IPCA			Unknown	IND

						LABORATORIES LIMITED-IPC-2017-IN-001764			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Volvulus	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca
	Aceclofenac			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744407	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001650			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis Superficial	Metformin			S		1000 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca
	Aceclofenac			S				Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744410	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003972		49 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swollen Tongue	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Losartan			C				Not Reported
	Prednisolone			C				Not Reported
	Trombyl			C				Not Reported
	Bisoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744411	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003976		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy	Plaquenil 200 Mg Tablet			S	Oral	3 Times A Day		Concordia
	Doxycycline			S	Oral			Not Reported
	Macrogol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744412	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003977		72 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Pneumonia; Skin Disorder	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744413	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003984			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744599	NON-EXPEDITED			US-AMGEN-USASP2017103876		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

Plaquenil	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13744655	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001778			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Left Ventricular Failure	Metformin			S		500 Mg, Unk		Ipca
	Hydroxychloroquine			S		300 Mg, Unk		Ipca
	Aceclofenac			S		Unk		Not Reported
	Zopiclone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2017	13746049	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017103919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13118731	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1772931-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Musculoskeletal Pain;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Treatment Failure	Arava		S	Unknown	Not Reported
	Cellcept		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Gold		S	Unknown	Not Reported
	Lyrica		S	Oral	Not Reported
	Methotrexate Sodium		S	Intra-arterial	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C		Not Reported
	Piroxicam		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13360087	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020229		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Drug Ineffective; Feeling Jittery; Joint Swelling; Limb Discomfort; Malaise; Musculoskeletal Disorder; Neck Pain; Night Sweats; Peripheral Swelling; Peripheral Swelling; Pustular Psoriasis; Synovitis; Tachycardia; Unevaluable Event	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Cimzia			S	Unknown	Form; Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Asa			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Form Solution Subcutaneous		Not Reported

Sulfasalazine	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Calcium	C	Oral		Not Reported
Celebrex	C			Not Reported
Elavil	C			Not Reported
Ergocalciferol	C	Oral		Not Reported
Leucovorin Calcium	C	Oral		Not Reported
Lorazepam	C	Oral		Not Reported
Pantoprazole	C			Not Reported
Magnesium	C			Not Reported
Prednisone	C			Not Reported
Prednisone	C	Oral		Not Reported
Valtrex	C			Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Form: Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13709949	EXPEDITED (15-DAY)		HO	IL-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003899		69 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Plaquenil			S				Concordia
	Quinidine Bisulfate			C				Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13748151	EXPEDITED (15-DAY)		OT	PL-BAXTER-2017BAX025443		43 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Body Temperature Increased; Erythema; Erythema; Face Oedema	Uromitexan		S	Intravenous (not otherwise specified)		Not Reported
	Endoxan		S	Intravenous (not otherwise specified)		Baxter
	Encorton		S	Oral		Not Reported
	Plaquenil		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13748810	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Drug Ineffective; Eye Disorder; Joint Swelling; Joint Swelling; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Nodule	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13749468	EXPEDITED (15-DAY)		DS, OT	US-DRREDDYS-USA/USA/17/0091639		10 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Acanthosis Nigricans; Anaemia; Chronic Graft Versus Host Disease; Dehydration; Diarrhoea; Extremity Contracture; Hyperglycaemia; Partial Lipodystrophy	Tacrolimus			S	Oral			Not Reported
	Sirolimus			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Methylprednisone			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported
	Daclizumab			S	Unknown			Not Reported

						Megestrol Acetate	S	Oral	Not Reported
						Hydroxychloroquine	S	Oral	Not Reported
						Sodium Bicarbonate	C	Oral	Not Reported
						Aciclovir	C	Oral	Not Reported
						Furosemide	C	Oral	Not Reported
						Dapsone	C	Oral	Not Reported
						Penicillin V	C	Oral	Not Reported
						Voriconazole	C	Oral	Not Reported
						Enalapril	C	Oral	Not Reported
						Clonidine	C	Transdermal	0.1mg Transdermal Patch Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13751815	EXPEDITED (15-DAY)		HO	CA-SA-2017SA125203		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mobility Decreased; Nerve Compression	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13752040	NON-EXPEDITED			US-PFIZER INC-2017304182		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13752195	EXPEDITED (15-DAY)		HO	CA-CIPHER-2017-CA-000613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Arava			S	Unknown			Not Reported
	Naprosyn			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Diclofenac			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Tramadol Hydrochloride			S				Cipher
	Humira			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2017	13753243	EXPEDITED (15-DAY)		OT	NL-TEVA-784555ACC		72 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Pneumonia; Skin Disorder	Hydroxychloroquine Dragee 200mg			S	Oral	400 Milligram Daily;		Teva
	Methotrexaat Tablet 10mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13423400	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015047149		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Elbow Deformity; Gastrointestinal Disorder; Headache; Hepatic Enzyme Increased; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	2 G, 1x/Day		Pfizer
	Prednisone			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported

Hydroxychloroquine	S	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13753056	EXPEDITED (15-DAY)		HO, LT	CA-BAXTER-2017BAX027727		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Azathioprine			S	Unknown	Dosage Form: Not Specified		Not Reported
	Cellcept			S	Unknown	Dosage Form: Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	Dosage Form: Not Specified		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Acetaminophen			C	Unknown	Dosage Form: Not Specified		Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methyl Prednisolone Sodium Succinate			C	Unknown			Not Reported
	Methyl Prednisolone Sodium Succinate			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13754439	DIRECT		DS			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration	Plaquenil 200mg Unknown			S	Oral	Pills Daily Po	10 YR	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13755274	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX027736		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage; Pharyngeal Oedema; Rash; Swollen Tongue	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			C	Subcutaneous	Dosage Form Not Specified		Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	Dosage Form Not Specified		Not Reported
	Remicade			C	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13755482	NON-EXPEDITED			US-PFIZER INC-2017304829		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk		Pfizer
	Sulfasalazine	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13755535	NON-EXPEDITED			US-PFIZER INC-2017302924		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13755597	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004059		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Plaquenil			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Imuran			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13756243	EXPEDITED (15-DAY)		CA, OT	US-STRIDES ARCOLAB LIMITED-2017SP010735			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Foetal Exposure During Pregnancy; Intraventricular Haemorrhage Neonatal; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Right Ventricular Hypertrophy; Tricuspid Valve Incompetence	Prednisolone			S	Transplacental	Unk		Not Reported
	Mycophenolate Mofetil			S	Transplacental	1000 Mg, Bid		Strides
	Mycophenolate Mofetil			S	Transplacental	500 Mg, Bid		Strides
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2017	13756321	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017221650		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Rash; Red Cell Distribution Width Increased; Swelling Face	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S	Oral	10 Mg, Daily		Not Reported
	Gold			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2017	10973402	EXPEDITED (15-DAY)		OT	CA-ROCHE-1516383		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acarodermatitis; Allergic Bronchitis; Arthralgia; Blood Pressure Increased; Drug Ineffective; Drug Ineffective; Headache; Heart Rate Increased; Hypotension; Infusion Related Reaction; Insulin Resistance; Joint Swelling; Nasopharyngitis; Nephrolithiasis; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Thyroid Disorder; Underdose; Urinary Tract Infection; Weight Increased	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Lipitor	C			Not Reported
	Humira	C			Not Reported
	Ezetrol	C			Not Reported
	Plaquenil	C	Unknown	Started On Sept 8th (Flaring On Humira)	Not Reported
	Plaquenil	C	Oral		Not Reported
	Pantoloc	C	Oral		Not Reported
	Baby Aspirin	C	Unknown	(Since Leg Amputation Blood Clot)	Not Reported
	Ramipril	C	Unknown	Previous Kidney Failure - Taking As Prophylactic	Not Reported
	Ramipril	C	Oral		Not Reported
	Tapazole	C	Unknown	For Thyroid	Not Reported
	Tylenol	C			Not Reported
	Prolia	C	Unknown	For Osteoporosis/Osteopenia - As Prevention	Not Reported
	Ciprofloxacin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13394668	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002108		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pain; Product Substitution Issue; Treatment Failure	Plaquenil			S	Oral			Concordia
	Ezetrol			S	Oral			Not Reported
	Naprosyn			C				Not Reported
	Salazopyrin			C				Not Reported
	Synthroid			C				Not Reported
	Tecta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13668432	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Leukopenia; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13757518	EXPEDITED (15-DAY)		OT	CA-ROCHE-1960914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Q Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13757977	NON-EXPEDITED			US-AMGEN-USASP2017104343		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759321	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004062		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759323	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004072			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759326	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004082		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759351	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004054		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Headache; Heart Rate Decreased; Herpes Virus Infection; Infusion Related Reaction; Pain; Weight Increased	Hydroxychloroquine			S	Oral			Concordia
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
	Metoprolol			C				Not Reported
	Valtrex			C				Not Reported
	Acetaminophen			C				Not Reported
	Alendronate			C				Not Reported
	Alocril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759356	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-		60 YR	Female	CAN

004064

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Polyarthritis; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759361	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004009		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759362	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004031		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankylosing Spondylitis; Oral Mucosal Eruption; Rash; Skin Exfoliation; Therapeutic Product Effect Decreased	Hydroxychloroquine		S	Oral	Concordia
	Adalimumab		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759365	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004050		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Headache; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13759368	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004053		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2017	13760644	EXPEDITED (15-DAY)		OT	US-TEVA-787742USA		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Nausea	Methotrexate			S	Unknown	10mg Per Week		Barr
	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	12919644	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1773766-00		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Coronary Artery Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypersensitivity; Hypoaesthesia; Nodule; Peripheral Swelling; Rash	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C				Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13157306	EXPEDITED (15-DAY)		HO, LT	JP-CONCORDIA PHARMACEUTICALS INC.-E2B_00007997		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Pain; Pericarditis; Pyrexia	Plaquenil		S	Oral	Concordia
	Plaquenil		S	Oral	Concordia
	Bayaspirin		C		Not Reported
	Cellcept		C		Not Reported
	Prograf		C		Not Reported
	Gaster		C		Not Reported
	Anplag		C		Not Reported
	Mucosta		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13385892	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002004			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Gait Disturbance; Joint Swelling	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Calcium			C				Not Reported
	Citalopram			C				Not Reported
	Pantoloc			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13385894	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002021		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Prinivil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Sulfasalazine		S	Oral	Not Reported
	Synthroid		S	Unknown	Not Reported
	Voltaren		S	Oral	Not Reported
	Voltaren		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13386923	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002010		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Cimzia			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13386925	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002017		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous					Not Reported
	Methotrexate Sodium			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13397190	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002109		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Weekly		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13441009	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1100		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Headache; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Oral				Not Reported
		Arava			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13761656	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1590104-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Drug Intolerance; Hip Arthroplasty; Hypertensive Crisis; Interstitial Lung Disease; Joint Arthroplasty; Liver Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Voltaren			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13762065	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004086			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Femur Fracture; Platelet Count Decreased; Road Traffic Accident; Upper Limb Fracture	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13762068	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004140		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13762363	NON-EXPEDITED			US-PFIZER INC-2017305239		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13762427	NON-EXPEDITED			US-PFIZER INC-2017305954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13763690	NON-EXPEDITED			US-AMGEN-USASP2017105606		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen

	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Simponi			S	Unknown				Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13764953	NON-EXPEDITED			US-PFIZER INC-2017305783		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2017	13765095	NON-EXPEDITED			US-PFIZER INC-2017310500		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	11003362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1373299-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hypertension; Rheumatoid Arthritis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Weight Increased	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Etanercept		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13250493	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001062		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Drug Ineffective; Feeling Jittery; Joint Swelling; Limb Discomfort; Malaise; Musculoskeletal Disorder; Neck Pain; Night Sweats; Peripheral Swelling; Peripheral Swelling; Pustular Psoriasis; Synovitis; Tachycardia; Unevaluable Event	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Calcium			C				Not Reported
	Celebrex			C				Not Reported
	Elavil			C				Not Reported
	Ergocalciferol			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Lorazepam			C				Not Reported
	Pantoprazole			C				Not Reported
	Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Valtrex			C				Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13385896	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002031		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Folic Acid			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			S	Unknown			Not Reported
	Voltaren			S	Oral			Not Reported
	Voltaren			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tecta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13735421	NON-EXPEDITED			US-PFIZER INC-2017294974		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13741491	EXPEDITED (15-DAY)		OT	IT-SA-2017SA121737		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypertensive Crisis; Neutropenia	Arava				S	Oral			Not Reported
	Hydroxychloroquine Sulfate				S	Oral			Not Reported
	Esomeprazole Sodium				C				Not Reported
	Dibase				C				Not Reported
	Nerixia				C				Not Reported
	Palexia				C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13766975	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017106802		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthma; Back Disorder; Blood Cholesterol Increased; Blood Count Abnormal; Drug Ineffective; Dyspareunia; Hypertension; Micturition Urgency; Muscle Spasms; Nervousness; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Effexor			S	Oral	150 Mg, Unk, Two Capsules Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13767010	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017108104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Rheumatoid Arthritis; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13767764	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Unevaluable Event	Plaquenil Tablet			S	Oral			Concordia
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Calcium			C				Not Reported
	Dorzolamide Hydrochloride Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C				Not Reported
	Furosemide			C				Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Zingiber Officinale			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13767792	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017307055		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Sulfasalazine			S		500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13767992	NON-EXPEDITED			US-AMGEN-USASP2017106771		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13768226	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-015769		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Drug Ineffective; Drug Intolerance; Nausea; Psoriatic Arthropathy; Rash Maculo-Papular; Skin Exfoliation	Methotrexate			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13768718	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US12275			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Amlodipine			S	Unknown	Unk		Invagen
	Hydralazine Hcl			S	Unknown	Unk		Invagen
	Prednisone			S	Oral	60 Mg, Daily		Not Reported
	Prednisone			S	Oral	80 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13769777	NON-EXPEDITED			US-AMGEN-USASP2017105543			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown	11 Mg, Qwk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13769978	EXPEDITED (15-DAY)		OT	AU-SA-2017SA129296		99 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Madarosis; Transfusion	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2017	13770441	DIRECT	Y				27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Discomfort; Product Substitution Issue	Hydroxychloroquine			S	Oral	Other Dose:Mg;	1 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13761954	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		59 YR	Female	CAN

PHARMA-TREX2017-1514

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Blood Creatinine Increased; Drug Eruption; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Haemoglobin Concentration Decreased; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13770969	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-064441			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Xeljanz			S	Unknown	Unk, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771063	NON-EXPEDITED		HO	US-STRIDES ARCOLAB LIMITED-2016SP013582			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hepatitis; Malaise	Mycophenolate Mofetil			S		1000 Mg, Bid		Strides
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Not Reported
	Monoclonal Antibodies			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771279	NON-EXPEDITED			US-ASTRAZENECA-2017SE73566		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
	Keflex			S	Unknown	Unk		Not Reported
	Nortriptyline			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771334	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2016SP017338			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	1000 Mg, Bid		Strides
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771592	NON-EXPEDITED			US-PFIZER INC-2017309046			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Chlorzoxazone			S		Unk		Not Reported
	Digoxin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Ranitidine Hcl			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771610	NON-EXPEDITED			US-PFIZER INC-2017309864			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Lamictal			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771743	NON-EXPEDITED			US-PFIZER INC-2017311861			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13771763	NON-EXPEDITED			US-PFIZER INC-2017315178		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13772885	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-1010422		84 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; General Physical Health Deterioration; Pancytopenia; Weight Decreased	Methotrexate Sodium			S	Oral	7.5 Mg, Weekly		Pfizer
	Hydroxychloroquine			S	Oral	300 Mg, 1x/Day		Not Reported
	Colchicine			C	Unknown	Not Reported, Not Reported		Not Reported
	Diltiazem			C	Oral	Not Reported, Not Reported		Not Reported
	Enalapril			C	Oral	Not Reported, Not Reported		Not Reported
	Folic Acid			C	Oral	Not Reported, Not Reported		Not Reported
	Fosamax			C	Oral	Not Reported, Not Reported		Not Reported
	Furosemide			C	Oral	Not Reported, Not Reported		Not Reported
	Metformin			C	Oral	Not Reported, Not Reported		Not Reported
	Synthroid			C	Oral	Not Reported, Not Reported		Not Reported

	Vitamin D /00107901/		C	Oral	Not Reported, Not Reported		Not Reported
	Warfarin		C	Oral	Not Reported, Not Reported		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13774104	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-1575654		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Oesophageal Spasm	Methotrexate Sodium			S	Oral	15 Mg, Freq: 1 Week, Interval :1		Unknown
	Plaquenil /00072602/			S	Oral	200 Mg, Strength: 200 Mg, Freq: 1 Day, Interval: 1		Not Reported
	Risedronate Sodium			S	Oral	35 Mg, Freq: 1 Week, Interval: 1		Not Reported
	Folic Acid			C	Oral	5 Mg, Freq: 1 Week, Interval: 1		Not Reported
	Prednisolone			C	Oral	10 Mg, Freq: 1 Day, Interval: 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13775589	EXPEDITED (15-DAY)		OT	CA-SA-2017SA128570		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13776247	EXPEDITED (15-DAY)		OT	MX-BAYER-2017-133952			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Acetylsalicylic Acid(<=100 Mg)			S	Transplacental	At The 6th Week Of Gestation		Bayer
	Nadroparin			S	Transplacental	0.6 Ml, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2017	13777307	NON-EXPEDITED			US-AMGEN-USASP2017108040		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13385898	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002034			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthralgia; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; C-Reactive Protein Increased; Drug	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

Ineffective; Impaired Work Ability; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Increased; Synovitis; Type 2 Diabetes Mellitus	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Naproxen	C		Not Reported
	Cortisone	C		Not Reported
	Omeprazole	C		Not Reported
	Folic Acid	C		Not Reported
	Levothyroxine Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13583466	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003158			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arrhythmia; Arrhythmia; Cardiac Disorder; Condition Aggravated; Discomfort; Dizziness; Feeling Hot; Hypotonia; Macular Degeneration; Performance Status Decreased; Quality Of Life Decreased; Sleep Disorder	Plaquenil Tablet			S	Oral			Concordia
	Estradot			C				Not Reported
	Mirena			C				Not Reported
	Progynova			C				Not Reported
	Sotalol "Mepha"			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13699367	NON-EXPEDITED			US-AMGEN-USASP2017096108		28 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Dry Skin; Erythema; Feeling Hot;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen

Inflammation; Irritable Bowel Syndrome; Joint Warmth; Pruritus; Skin Irritation; Tenderness	Plaquenil	S	Unknown	Unk		Not Reported
	Nexium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13734257	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017101697		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Off Label Use; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Synovitis; Treatment Failure; Type V Hyperlipidaemia	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Prolia			S	Unknown			Amgen
	Aranesp			C	Unknown	200 Mug, Q6wk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Qwk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Everyday		Not Reported
	Oxycodone			C	Unknown	10 Mg, Unk		Not Reported
	Abilify			C	Unknown	5 Mg, Unk		Not Reported
	Advair			C		Unk		Not Reported
	Atenolol			C	Oral	25 Mg, Qd		Not Reported
	Buffered Aspirin			C		325 Mg, Qid		Not Reported
	Crestor			C	Oral	10 Mg, Everyday		Not Reported
	Cytomel			C	Oral	5 Mug, Qd		Not Reported
	Dorzolamide Hcl			C		Unk		Not Reported

Duloxetine Hcl	C	Unknown	60 Mg, Bid	Not Reported
Duoneb	C	Unknown	Unk Unk, As Necessary	Not Reported
Famotidine	C		40 Mg, Qhs	Not Reported
Finasteride	C	Unknown	5 Mg, Unk	Not Reported
Furosemide	C		20 Mg, Once Daily As Necessary	Not Reported
Gabapentin	C		400 Mg, Four Times A Day	Not Reported
Leflunomide	C		20 Mg, Unk	Not Reported
Lovaza	C		4 Mg, Per Day	Not Reported
Medrol	C		4 Mg, Unk	Not Reported
Myrbetriq	C		50 Mg, Unk	Not Reported
Nexium	C		40 Mg, Unk	Not Reported
Omega 3	C		1000 Mg, Unk	Not Reported
Oxycodone Hcl	C		10 Mg, Tid	Not Reported
Prochlorperazine Maleate	C		10 Mg, Unk	Not Reported
Relpax	C		40 Mg, Unk	Not Reported
Singulair	C	Unknown	10 Mg, Unk	Not Reported
Soma	C	Unknown	350 Mg, As Necessary	Not Reported
Sulfazine Ec	C	Oral	500 Mg, Bid	Not Reported
Synthroid	C	Oral	225 Mug, Daily Dose	Not Reported
Tamsulosin Hcl	C		0.4 Mg, Unk	Not Reported
Topamax	C	Oral	100 Mg, Bid	Not Reported
Topiramate	C	Unknown	150 Mg, Bid	Not Reported
Triamterene/Hctz	C	Oral	1 Df, Bid	Not Reported
Voltaren	C	Topical	Unk	Not Reported
Xalatan	C		Unk	Not Reported
Zyrtec Allergy	C		10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13735369	NON-EXPEDITED			US-PFIZER INC-			Female	USA

2017296539

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13745102	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004005			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Azithromycin			C				Not Reported
	Steroids			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13771057	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003895			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Palpitations; Therapeutic Response Changed	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13777591	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX028284		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Procytox (Cyclophosphamide)			S	Unknown	Dosage Form: Not		Baxter

	2000mg/Vial					Specified			
	Methotrexate Sodium			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Celebrex			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778237	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2139		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778593	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003968		62 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Oedema; Visual Acuity Reduced	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Predonine			C				Not Reported
	Mucosta			C				Not Reported
	Edirol			C				Not Reported
	Bonalon			C				Not Reported
	Prograf			C				Not Reported
	Calcium Lactate			C				Not Reported
	Urso			C				Not Reported
	Bezatol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778595	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS		73 YR	Male	FRA

INC.-GSH201707-004158

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Plaquenil Tablet			S	Oral			Concordia
	Acebutolol			C				Not Reported
	Kardegic			C				Not Reported
	Nicorandil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778597	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004186		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mobility Decreased; Nerve Compression	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778598	EXPEDITED (15-DAY)		DS	NO-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004227		45 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Dizziness; Headache; Hypoacusis; Insomnia; Migraine; Tinnitus	Plaquenil			S	Oral			Concordia
	Nexium			C				Not Reported
	Provera			C				Not Reported
	Selo-Zok			C				Not Reported
	Neurontin			C				Not Reported
	Lisinopril			C				Not Reported
	Imigran			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778600	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004233		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Neurologic Neglect Syndrome	Plaquenil			S	Oral			Concordia
	Cortancyl			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778601	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004306			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Pepto-Bismol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778739	NON-EXPEDITED			US-PFIZER INC-2017311670		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778782	NON-EXPEDITED			US-PFIZER INC-2017314244		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13778904	NON-EXPEDITED			US-PFIZER INC-2017314277		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jul-2017	13779310	NON-EXPEDITED			US-AMGEN-USASP2017108295		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Keflex			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	12556740	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC-2015001107		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Cardiomyopathy; Seizure	Methotrexate Sodium	S	15-25 Mg Weekly For More Than 25 Years		Pfizer
	Hydroxychloroquine	S	200-400 Mg Daily For More Than 14 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13153002	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007990		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Gait Disturbance; Haemorrhage; Herpes Zoster; Hypoaesthesia; Joint Lock; Joint Swelling; Mobility Decreased; Peripheral Swelling; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Concordia
	Naproxen			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13741789	NON-EXPEDITED			US-PFIZER INC-2017298409			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13780092	EXPEDITED (15-DAY)		OT	CA-ROCHE-1963543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Increased; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Abatacept		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Etanercept		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Levothyroxine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13780353	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004185		76 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Malaise; Pruritus	Hydroxychloroquine			S	Oral			Concordia
	Adizem-Sr			C				Not Reported
	Alendronic Acid			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Calcium Vitamin D			C				Not Reported
	Felodipine			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisolone Acetate			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13780354	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004243		30 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Exposure During Pregnancy; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13780663	NON-EXPEDITED			US-PFIZER INC-2017316013		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13780673	NON-EXPEDITED			US-PFIZER INC-2017315964		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13781214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-064152		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			C	Unknown	0.8 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13781707	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-3185257		77 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Syncope	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	50 Mg, Freq: 2 Day; Interval: 1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13783303	NON-EXPEDITED			US-PFIZER INC-2017316498		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2017	13784365	EXPEDITED (15-DAY)		HO, LT	PHHY2017US107074		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes; Toxicity To Various Agents; Ventricular Extrasystoles	Hydroxychloroquine			S	Unknown	60 G, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13566990	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-CONCORDIA PHARMACEUTICALS		21 YR	Female	USA

INC.-GSH201705-003023

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Asthenia; Brain Oedema; Computerised Tomogram Abnormal; Csf Protein Increased; Csf White Blood Cell Count Increased; Drug Ineffective; Haemorrhagic Cerebral Infarction; Hyporesponsive To Stimuli; Lethargy; Mental Status Changes; Pyrexia; Tachycardia; Varicella Zoster Virus Infection; Viral Vasculitis; Vith Nerve Paralysis	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Aciclovir			S	Unknown			Not Reported
	Aciclovir			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Isoniazid			C				Not Reported
	Pyridoxine			C				Not Reported
	Ethambutol			C				Not Reported
	Pyrazinamide			C				Not Reported
	Rifampin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13709019	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003855		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Drug Ineffective; Nausea; Off Label Use; Rash Maculo-Papular; Skin Exfoliation	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13735557	NON-EXPEDITED			US-PFIZER INC-2017296739		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unk		Pfizer
	Sulfasalazine	S	Unk		Pfizer
	Humira	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13766871	NON-EXPEDITED			US-PFIZER INC-2017310613		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13785952	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX028655		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Humira			S	Subcutaneous	Strength:40 Mg/0.8 Ml		Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Fentanyl	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Levofloxacin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13785992	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2017SP001415			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Mycophenolate Mofetil			S		Unk		Strides
	Mycophenolate Mofetil			S				Strides
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13788894	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004251		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13788898	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004307		99 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Madarosis; Transfusion	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported

	Humira			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13788900	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004340		81 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Back Pain; Decreased Appetite; Dyspnoea; Ear Pain; Eye Pain; Headache; Hyperhidrosis; Muscular Weakness; Nausea; Rash Macular; Rash Pruritic; Tremor; Visual Impairment	Plaquenil			S	Oral			Concordia
	Apomorphine Hydrochloride			C				Not Reported
	Azilect			C				Not Reported
	Cartia (Acetylsalicylic Acid)			C				Not Reported
	Colofac			C				Not Reported
	Ezetrol			C				Not Reported
	Karvezide			C				Not Reported
	Madopar			C				Not Reported
	Motilium			C				Not Reported
	Ostelin Vitamin D			C				Not Reported
	Panadeine [Codeine Phosphate;Paracetamol]			C				Not Reported
	Pantoprazole			C				Not Reported
	Sinemet			C				Not Reported
	Spiriva			C				Not Reported
	Symbicort Turbuhaler			C				Not Reported
	Ventolin			C				Not Reported
	Zoloft			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13788903	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004376		69 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Chills; Fatigue	Hydroxychloroquine			S	Oral			Concordia
	Calcichew D3			C				Not Reported
	Prednisolon			C				Not Reported
	Methotrexate			C				Not Reported
	Foliumzuur			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13789357	NON-EXPEDITED			US-AMGEN-USASP2017109567		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuralgia	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13789782	EXPEDITED (15-DAY)		OT	PHHY2017CA107306		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown			Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13790058	NON-EXPEDITED			US-PFIZER INC-2017320010		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported

	Prednisone				S		Unk				Not Reported
	Plaquenil				S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13790500	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2016SP015602			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	1000 Mg, Bid		Strides
	Hydroxychloroquine Sulfate			S		300 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13790501	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2017SP001416			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Mycophenolate Mofetil			S		Unk		Strides
	Mycophenolate Mofetil			S				Strides
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13791105	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-1261265		50 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Hepatic Steatosis; Liver Function Test Increased	Methotrexate Sodium			S	Oral	20 Mg,Freq:1 Week ;Interval: 1.		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg,Freq:1 Day;Interval:2.		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13791213	EXPEDITED (15-DAY)		HO, LT	GB-PFIZER INC-1272346		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Disorder; Contusion; Diarrhoea; Full Blood Count Abnormal; Haematemesis; Thrombocytopenia	Methotrexate Sodium			S	Oral	25 Mg,Freq: 1 Week; Interval: 1		Pfizer
	Gabapentin			S	Oral	600 Mg,Freq: 1 Day; Interval: 4		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Omeprazole			S	Oral	20 Mg,Freq: 1 Day; Interval: 2		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Unk		Not Reported
	Venlafaxin			S	Oral	75 Mg,Freq: 1 Day; Interval: 2		Not Reported
	Benzydamine			C				Not Reported
	Flucloxacillin			C				Not Reported
	Metronidazole			C				Not Reported
	Miconazole			C				Not Reported
	Nystatin			C				Not Reported
	Scheriproct /00212301/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2017	13791359	EXPEDITED (15-DAY)		OT	PHHY2017CA108030		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count Decreased	Voltaren			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Novartis
	Sulfasalazine			S	Unknown	1000 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	12735085	NON-EXPEDITED			US-AMGEN-USASP2016119632		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C		11 Mg, Unk		Not Reported
	Humira			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13229837	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Hepatotoxicity; Liver Function Test Increased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13614445	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1644		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Arava			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13621276	NON-EXPEDITED			US-PFIZER INC-2017244239		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S	Oral	200 Mg, Daily With Food		Not Reported
	Arava			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13659447	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017090779			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Humira			S	Unknown			Not Reported
	Sulfasalazine			C		500 Mg, Tid		Not Reported
	Leflunomide			C	Unknown	Unk Unk, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13720489	EXPEDITED (15-DAY)		HO	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201707-003893		27 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bicarbonate	Hydroxychloroquine			S	Unknown	Equivalent To 155 Mg Of		Concordia

Decreased; Blood Glucose Decreased; Blood Lactic Acid Increased; Blood Ph Decreased; Blood Pressure Decreased; Coma Scale Abnormal; Electrocardiogram Qt Prolonged; Hypokalaemia; Loss Of Consciousness; Mydriasis; Pupils Unequal; Sinus Rhythm; Torsade De Pointes; Toxicity To Various Agents; Ventricular Tachycardia	Hydroxychloroquine		S	Oral	Hydroxychloroquine Base				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13735478	NON-EXPEDITED			US-PFIZER INC-2017296560		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira Pen			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Meloxicam			S		15 Mg, Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13793951	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004366		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate	Hydroxychloroquine			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Sulfasalazine		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13793954	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004368		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13793957	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004373		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13793959	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Pain; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794070	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK115138		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Methotrexate			S				Glaxosmithkline
	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794107	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK115180		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia; Skin Hyperpigmentation; White Blood Cell Count	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Methotrexate			S	Subcutaneous			Glaxosmithkline
	Sulfasalazine			S		1000 Mg, Qd		Not Reported
	Arava			S		20 Mg, Unk		Not Reported

Decreased	Plaquenil	S	200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794378	NON-EXPEDITED			US-PFIZER INC-2017320315		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794405	NON-EXPEDITED			US-PFIZER INC-2017319945			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794414	NON-EXPEDITED			US-PFIZER INC-2017320753		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			C		Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794514	NON-EXPEDITED			US-PFIZER INC-2017321730		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk		Pfizer
	Leflunomide	S	Unk		Not Reported
	Hcq	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794567	NON-EXPEDITED			US-PFIZER INC-2017322170		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13395056	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002105		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Depressed Mood; Drug Ineffective; Influenza; Pain	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13395112	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002120		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash; Skin Exfoliation; Skin Plaque	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13725757	NON-EXPEDITED			US-PFIZER INC-2017290135		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13734670	EXPEDITED (15-DAY)		OT	PR-ABBVIE-17K-131-2031057-00			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Dyspepsia; Joint Stiffness; Le Cells Present; Musculoskeletal Stiffness; Therapeutic Response Shortened	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13744936	NON-EXPEDITED			US-PFIZER INC-2017297014		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk (10+Yrs Ago)		Pfizer

Sulfasalazine	S	Unk	Pfizer
Enbrel	S	Unk	Pfizer
Plaquenil	S	Unk (10+Yrs Ago)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13755595	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004034		53 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis; Neutropenia	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S				Concordia
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Esomeprazole Sodium			C				Not Reported
	Dibase			C				Not Reported
	Nerixia			C				Not Reported
	Palexia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13778662	EXPEDITED (15-DAY)		DE, HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004228			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Hydroxychloroquine			S	Unknown			Concordia
	Aspirin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797602	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2016SP011077			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy	Mycophenolate Mofetil	S	Oral	1000 Mg, Bid	Strides
	Allopurinol	S		5 Mg, Daily	Not Reported
	Prednisolone	S		10 Mg Prior To Pregnancy	Not Reported
	Prednisolone	S		20 Mg, Daily	Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg, Daily	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Enalapril	S		5 Mg, Daily	Not Reported
	Enalapril	S			Not Reported
	Lovenox	S	Subcutaneous	60 Mg, Daily	Not Reported
	Calcium + Vit D	S		600mg Calcium/ 400mg Vit.D	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797614	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2015SP000076			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	1500 Mg, Bid		Strides
	Mycophenolate Mofetil			S				Strides
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Not Reported
	Morphine			S	Oral	20 Mg, Bid		Not Reported
	Morphine			S		15 Mg, Bid		Not Reported
	Zolpidem			S		10 Mg, Prn		Not Reported
	Atenolol			S		25 Mg/Day		Not Reported
	Benazepril			S	Oral	40 Mg, Qd		Not Reported
	Percocet			S	Oral	5/325 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797821	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-		25 YR	Female	CAN

004359

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13797916	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004416			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Nausea; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Pariet			C				Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2017	13801948	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2052781-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported

	Prednisone				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13397321	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002123		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Plaquenil			S	Oral			Concordia
	Folic Acid			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Tecta			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			S	Unknown			Not Reported
	Voltaren			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13659504	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK091384			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Benlysta			S		528 Mg, Unk		Glaxosmithkline
	Mycophenolate			S		Unk		Glaxosmithkline
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13744970	NON-EXPEDITED			US-PFIZER INC-2017296474		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

No Adverse Event	Methotrexate Sodium		S	Unk		Pfizer
	Humira		S	Unk		Not Reported
	Hydroxychloroquine		S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13778749	NON-EXPEDITED			US-PFIZER INC-2017310312		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13804332	EXPEDITED (15-DAY)		HO	CA-ABBVIE-17K-028-2052129-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13804428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2052742-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Ibuprofen			C				Not Reported
	Morphine			C				Not Reported
	Pertussis Vaccine			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13804878	NON-EXPEDITED			US-PFIZER INC-2017324895		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13804992	NON-EXPEDITED			US-PFIZER INC-2017324891		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Cuprimine			S		Unk		Not Reported

	Gold			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13805089	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2053122-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13805431	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2016SP012116			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	2500 Mg Per Day		Strides
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Not Reported
	Ferrous Gluconate			S		325 Mg, Per Day		Strides
	Omeprazole			S		20 Mg, Qd		Not Reported
	Azathioprine			S		50 Mg, Bid		Not Reported
	Plaquenil /00072603/			S		200 Mg, Bid		Not Reported
	Prenatal Vitamins /07499601/			S		1 Tablets, Qd		Not Reported
	Calcium Vitamin D			S		1 Tablets, Bid		Not Reported
	Losartan			S		100 Mg, Qd		Not Reported
	Micronor			S		0.35 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13805441	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2016SP006028			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	1500 Mg, Bid		Strides
	Hydroxychloroquine Sulfate			S		200 Mg, Unk		Not Reported
	Prednisolone			S		15 Mg, Daily		Not Reported
	Azathioprine			S		75 Mg, Daily		Not Reported
	Doxylamine			C		10 Mg, 2 Tablets In The Evening		Not Reported
	Pyridoxine			C		10 Mg, 2 Tablets In The Evening		Not Reported
	Prenatal Vitamins /02014401/			C		1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jul-2017	13807519	EXPEDITED (15-DAY)		HO	CA-ABBVIE-17K-028-2052866-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2017	13812763	EXPEDITED (15-DAY)		HO	DE-ROCHE-1970338		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Arthroplasty	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexat			S	Unknown			Not Reported
	Methotrexat			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Roactemra			C	Subcutaneous			Not Reported
	Orencia			C	Unknown			Not Reported
	Sulfasalazin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2017	13812778	NON-EXPEDITED			US-AMGEN-USASP2017112947		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	600 Mg, Unk		Not Reported
	Flector			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2017	13812866	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-17K-028-2053116-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Disability; Drug Ineffective; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Treatment Failure	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Celebrex	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13071713	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016576767		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Mood Altered; Nausea	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13673299	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003604			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Oedema	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13735701	NON-EXPEDITED			US-AMGEN-USASP2017101228			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contusion; Drug Ineffective; Joint Stiffness; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	2.5 Mg, 6 Times/Wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13778603	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004308		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13780736	NON-EXPEDITED			US-PFIZER INC-2017320037		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13813003	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-2052853-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Humira 40mg/0.8ml	S	Subcutaneous		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown	Various Dosages (10 Mg, 12 Mg And 12.5 Mg) Chronology Unclear, Route Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Various Dosages (10 Mg, 15 Mg And 17.5 Mg) Chronology Unclear	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13813103	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-2053151-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Deafness	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Diclofenac Potassium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Motrin	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13813150	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Grip Strength Decreased; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13813808	NON-EXPEDITED			US-PFIZER INC-2017326831		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13814063	NON-EXPEDITED			US-PFIZER INC-2017327130		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817388	EXPEDITED (15-DAY)		OT	PHHY2017TW112124		64 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817389	EXPEDITED (15-DAY)		OT	PHHY2017TW112123		71 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817391	EXPEDITED (15-DAY)		OT	PHHY2017TW112125		42 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclosporin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817402	EXPEDITED (15-DAY)		OT	PHHY2017TW112128		43 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817404	EXPEDITED (15-DAY)		OT	PHHY2017TW112119		75 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817405	EXPEDITED (15-DAY)		OT	PHHY2017TW112120		56 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2017	13817409	EXPEDITED (15-DAY)		OT	PHHY2017TW112130		78 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	12649869	EXPEDITED (15-DAY)		OT	PHHY2016FR110946		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fundoscopy Abnormal; Retinogram Abnormal; Visual Acuity Reduced	Lamisil			S	Oral	Unk		Novartis
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Aprovel			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	12883902	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016146973		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Desoximetasone			C		5 Mg, Qd		Not Reported
	Arava			C	Unknown	10 Mg, Qd		Not Reported
	Celecoxib			C	Oral	200 Mg, Bid		Not Reported
	Cortisone			C		5 Mg, Od		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13527849	NON-EXPEDITED			US-PFIZER INC-2017192294		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		400 Mg, 1x/Day (At Bed Time)		Not Reported
	Methotrexate			C		20 Mg, Weekly (Once A Week)		Not Reported
	Xeljanz Xr			C		11 Mg, Daily		Not Reported

	Alendronate Sodium			C		70 Mg, Weekly (Once A Week)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13761366	NON-EXPEDITED			US-PFIZER INC-2017308183		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13780909	EXPEDITED (15-DAY)		OT	AT-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004304		26 YR	Female	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Double Stranded Dna Antibody Positive; Histology Abnormal; Hypoalbuminaemia; Hypocomplementaemia; Phospholipidosis; Proteinuria	Hydroxychloroquine			S	Unknown			Concordia
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13819487	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP016151		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Chelonae Infection	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820105	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2056351-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820684	EXPEDITED (15-DAY)		OT	PHHY2017TW112138		63 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820697	EXPEDITED (15-DAY)		OT	PHHY2017TW112135		60 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pulmonary Tuberculosis; Tuberculosis	Methotrexate		S	Unknown		Novartis
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Ciclosporin		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820702	EXPEDITED (15-DAY)		OT	PHHY2017TW112136		59 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820708	EXPEDITED (15-DAY)		OT	PHHY2017TW112137		80 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820712	EXPEDITED (15-DAY)		OT	PHHY2017TW110305		52 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820731	EXPEDITED (15-DAY)		OT	PHHY2017TW112139		56 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapulmonary Tuberculosis; Tuberculosis	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13820745	EXPEDITED (15-DAY)		OT	PHHY2017TW112132		67 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis	Methotrexate			S	Unknown			Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13821116	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2056335-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13821148	EXPEDITED (15-DAY)		LT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004466		56 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Hydroxychloroquine			S	Oral			Concordia
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13821746	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2051293-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bunion Operation; Foot Deformity; Gait Disturbance; Hip Arthroplasty; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Response Shortened	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Centrum Silver			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported
	Biotin			C	Oral			Not Reported
	Fluticasone Propionate			C		50 Mcg/Act Two Sprays Each Nostril Once Daily		Not Reported
	Amoxicillin			C	Oral	4 Tabs By Mouth 1 Hour		Not Reported

							Prior To Dental Appointment			
	Lisinopril And Hydrochlortiazide			C	Oral	20-12.5 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822055	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1046695			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy; Quadriparesis	Hydroxychloroquine			S	Unknown	400 Mg Daily		Not Reported
	Prednisone			C	Unknown	10mg Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822193	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046737			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G		Not Reported
	Rituximab			S	Unknown	1 G		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822337	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046748			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	1.5 G		Not Reported
	Rituximab			S	Unknown	1 G		Mylan

	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822344	NON-EXPEDITED		HO	US-STRIDES ARCOLAB LIMITED-2017SP007428			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lung Consolidation; Lymphadenopathy; Lymphadenopathy Mediastinal; Off Label Use; Peripheral T-Cell Lymphoma Unspecified Stage Iv; Respiratory Distress; Respiratory Failure	Tacrolimus			S	Unknown	Unk		Strides
	Hydroxychloroquine			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822435	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046727			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown	1 G		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822436	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046746			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown	2 G		Not Reported
	Mycophenolate Mofetil	S	Unknown	3 G		Not Reported
	Rituximab	S	Unknown	1 G		Mylan
	Cyclophosphamide	S	Intravenous (not otherwise specified)	750 G		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822450	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1046755			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes	Hydroxychloroquine			S	Oral	60 Grams		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822620	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046815			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown	1 G		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822701	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046890			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose	Not Reported
	Prednisolone			S	Unknown	High-Dose	Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Azathioprine			S	Unknown		Not Reported
	Rituximab			S	Unknown	1 G	Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2017	13822714	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1046800			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	2 G		Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G		Not Reported
	Rituximab			S	Unknown	1 G		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	12251856	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600105-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Pain; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dyspepsia; Infection; Mobility Decreased; Rheumatoid	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported

Arthritis; Therapeutic Product Effect Decreased	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Myochrysine		C	Intramuscular		Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13074832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2658		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Mood Altered; Nausea	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13722052	NON-EXPEDITED			US-PFIZER INC-2017284128		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13756046	NON-EXPEDITED			US-PFIZER INC-2017303355		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13823202	EXPEDITED (15-DAY)		OT	AU-AMGEN-AUSSP2017114830			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Pollakiuria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13823212	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2056383-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13823785	NON-EXPEDITED			US-PFIZER INC-2017327182		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13823874	NON-EXPEDITED			US-PFIZER INC-2017330710		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13823903	NON-EXPEDITED			US-PFIZER INC-2017332473		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Humira			S		Unk		Not Reported
	Humira			S				Not Reported
	Arava			S		Unk		Not Reported
	Arava			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13824029	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-002005		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes	Hydroxychloroquine			S	Oral	60 G, Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2017	13824384	EXPEDITED (15-DAY)		HO	US-IPCA LABORATORIES LIMITED-IPC-2017-US-002009			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy; Myositis	Hydroxychloroquine			S		400 Mg, Daily		Ipca
	Prednisone			C		10 Mg, Daily		Not Reported
	Prednisone			C		60 Mg, Daily		Not Reported
	Prednisone			C		30 Unk, Daily		Not Reported
	Prednisone			C		60 Unk, Daily		Not Reported
	Mycophenolate Mofetil			C		250 Mg, Bid		Not Reported
	Cefazolin			C				Not Reported
	Levetiracetam			C	Intravenous (not otherwise specified)	1500 Mg, Bid		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	1000 Mg, Daily		Not Reported
	Acyclovir			C				Not Reported
	Escitalopram			C				Not Reported
	Dapsone			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	10687011	NON-EXPEDITED			US-AMGEN-USASL2014101084		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Drug Ineffective; Injection Site Reaction	Enbrel	S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13400783	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1909976-00		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Hypertension; Joint Swelling; Rheumatoid Factor Positive; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Prednisone			C				Not Reported
	Valsartan			C				Not Reported
	Cortisone			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13764988	NON-EXPEDITED			US-PFIZER INC-2017310104		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Keflex			S		Unk		Not Reported

Ceclor	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported
Humira	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13793956	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004370		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Hypertrophy; Cardiomyopathy; Dyspnoea Exertional; Right Ventricular Dilatation; Right Ventricular Failure	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13827755	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Haematochezia; Joint Swelling; Prostatic Disorder	Plaquenil			S	Oral			Concordia
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13827757	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chorioretinopathy	Plaquenil		S	Oral		Concordia
	Enbrel		S	Unknown		Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13827758	EXPEDITED (15-DAY)		DE, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004479		91 DAY	Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Product Use Issue	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828072	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004471		64 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Facial Paresis; Headache; Muscle Atrophy; Muscular Weakness	Hydroxychloroquine			S	Oral			Concordia
	Amlodipin			C				Not Reported
	Carbamazepine			C				Not Reported
	Diclofenac			C				Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Lansoprazole			C				Not Reported
	Losartan			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828125	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-2057719-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828377	NON-EXPEDITED			US-PFIZER INC-2017333238		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zoloft			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer
	Paxil			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Vivactil			S		Unk		Not Reported
	Parnate			S		Unk		Not Reported
	Emsam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828715	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2017SP011391			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Hypogammaglobulinaemia ; Off Label Use	Prednisolone			S	Unknown	Low-Dose		Not Reported
	Prednisolone			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G, Unknown		Strides
	Mycophenolate Mofetil			S	Unknown	3 G, Unknown		Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown	1 G, Cyclical		Not Reported
	Rituximab			S				Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Cyclical		Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828717	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2017SP011385			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication; Hypogammaglobulinaemia ; Off Label Use	Tacrolimus			S	Unknown	Unk		Strides
	Tacrolimus			S				Strides
	Mycophenolate Mofetil			S	Unknown	3 G, Unknown		Strides
	Mycophenolate Mofetil			S	Unknown	2 G, Unknown		Strides
	Prednisolone			S	Unknown	Unknown (Low Dose)		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown	1 G, Cyclical		Not Reported
	Rituximab			S				Not Reported
	Cyclophosphamide			S	Intravenous (not	750 Mg, Cyclical		Not Reported

					otherwise specified)				
	Cyclophosphamide			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828721	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2017SP011389			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication; Hypogammaglobulinaemia ; Off Label Use	Prednisolone			S	Unknown	(Low Dose), Unk		Not Reported
	Prednisolone			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	1.5 G, Unknown		Strides
	Mycophenolate Mofetil			S				Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown	1 G, Cyclical		Not Reported
	Rituximab			S	Unknown	1 G, Cyclical		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Cyclical		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Cyclical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828756	EXPEDITED (15-DAY)		OT	AU-ORION CORPORATION ORION PHARMA-TREX2017-2225			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Pollakiuria	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828808	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-			Unknown	GBR

2017SP011411

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Mycophenolate Mofetil			S	Unknown	1.5 G, Unknown		Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828810	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2017SP011409			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication; Off Label Use	Mycophenolate Mofetil			S	Unknown	2 G, Unknown		Strides
	Mycophenolate Mofetil			S				Strides
	Prednisolone			S	Unknown	Unknown		Not Reported
	Prednisolone			S	Unknown	Unknown (Low Dose)		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13828943	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2017SP011437			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication; Off Label Use	Mycophenolate Mofetil			S	Unknown	2 G, Unknown		Strides
	Mycophenolate Mofetil			S				Strides
	Prednisolone			S	Unknown	Low Dose		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13829915	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2056101-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13829977	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004526			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Gold			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13830000	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2059850-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13831292	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2056200-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Loss Of	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Xeljanz			S	Oral				Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13831436	EXPEDITED (15-DAY)		OT	US-TEVA-792855USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Dyspnoea; Haemoglobin Decreased; Joint Stiffness	Methotrexate			S	Oral	Six 2.5mg Tablets		Barr
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			S	Unknown			Not Reported
	Triamterene Hctz			C	Oral	75mg/50mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13832251	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz 5mg Pfizer			S	Oral			Pfizer
	Hydroxychloroquine 200mg Generic			S	Oral	Frequency - 2 Tabs Daily		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2017	13833323	NON-EXPEDITED			US-AMGEN-USASP2017114314		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13767015	NON-EXPEDITED			US-AMGEN-USASP2017105986		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13833677	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-2056133-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13833977	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011463		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fundoscopy Abnormal; Retinogram Abnormal; Visual Acuity Reduced	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lamisil			S	Oral			Not Reported
	Aprovel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13834282	NON-EXPEDITED			US-PFIZER INC-2017334279		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13834523	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-2060390-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported

Onychomadesis; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835265	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060858-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835462	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060465-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Malaise; Pain; Peripheral Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Acetaminophen/Diphenhydramine Hydrochloride			S	Unknown			Not Reported

Somnolence; Visual Impairment	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835695	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00013		35 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S		1g, Unk, 2 Doses Given 1-2 Weeks Apart		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835759	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE		42 YR	Unknown	GBR

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LLC-GB-2017EDE00013

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Prednisolone Sodium Phosphate			S				Edenbridge Pharmaceuticals
	Mycophenolate Mofetil			S		3 G, Unk		Not Reported
	Mycophenolate Mofetil			S		2 G, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tacrolimus			S		Unk		Not Reported
	Tacrolimus			S				Not Reported
	Rituximab			S		1 G, Unk, 2 Doses 1-2 Weeks Apart		Not Reported
	Cyclophosphamide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835775	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00013		55 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Prednisolone Sodium Phosphate			S				Edenbridge Pharmaceuticals
	Mycophenolate Mofetil			S		2 G, Unk		Not Reported
	Mycophenolate Mofetil			S		3 G, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S		1 G, Unk, 2 Doses 1-2 Weeks Apart		Not Reported

	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835819	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00014		45 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Prednisolone Sodium Phosphate			S				Edenbridge Pharmaceuticals
	Mycophenolate Mofetil			S		1.5 G, Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S		1 G, Unk, 2 Doses 1-2 Weeks Apart		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835831	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060886-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835836	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00014		53 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S		1 G, Unk, 2 Doses 1-2 Weeks Apart		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835842	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00014		22 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Prednisolone Sodium Phosphate			S				Edenbridge Pharmaceuticals
	Mycophenolate Mofetil			S		3 G, Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S		1 G, Unk, 2 Doses 1-2 Weeks Apart		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2017	13835850	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00014		46 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S		1 G, Unk, 2 Doses 1-2 Weeks Apart		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2017	13270869	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1882868-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Mobility Decreased; Neurological Procedural Complication; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	400/200 Mg, During Five Year		Not Reported
	Arava			C				Not Reported
	Plaquenil			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2017	13837780	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060512-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported

Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Warfarin	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	11945329	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415569		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Lower Respiratory Tract Infection; Rheumatoid Arthritis; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13363830	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1909253-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Methotrexate			C						Not Reported
	Prednisolone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13718178	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP013781		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Apo-Rosuvastatin			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13757446	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2036024-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Rheumatoid	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

Arthritis; Spinal Pain;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13777267	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017108305		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Pain; Drug Ineffective; Dyspepsia; Headache; Increased Tendency To Bruise; Insomnia; Myalgia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Orencia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13837884	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060521-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Amoxicillin Sodium/Clavulanate			C				Not Reported

	Potassium (Non-Abbvie)					
	Amoxil	C				Not Reported
	Bacillus Calmette-Guerin Bcg (Non-Abbvie)	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13837915	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-17K-028-2060433-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo-Bisoprolol			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Norflox			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythro E C			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838004	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-2060822-00		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Ibuprofene			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838072	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060355-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Tylenol			S	Unknown	Not Reported
	Synthroid			C		Not Reported
	Methotrexate			C		Not Reported
	Meloxicam			C		Not Reported
	Leflunomide			C		Not Reported
	Acetaminophen And Codeine Phosphate			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838164	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060490-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			C				Not Reported
	Acetaminophen/Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838493	EXPEDITED (15-DAY)		OT	CA-ROCHE-1970598			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	Frequency: Day 1 And Day 15		Not Reported
	Rituxan			S				Not Reported
	Cellcept			S	Oral	1000-3000 Od		Not Reported
	Cellcept			S				Not Reported
	Myfortic			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Motilium			C				Not Reported
	Cymbalta			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838536	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-2059755-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838718	NON-EXPEDITED		OT	US-PFIZER INC-2017336806			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838755	NON-EXPEDITED			US-PFIZER INC-2017335009			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838890	NON-EXPEDITED			US-PFIZER INC-2017303853		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Procaine Hydrochloride			S		Unk		Unknown
	Bumetanide			S		Unk		Unknown
	Xanax			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Metoprolol Tartrate			S		Unk		Unknown
	Fentanyl			S		Unk		Not Reported
	Lasix			S		Unk		Not Reported
	Digoxin			S		Unk		Not Reported
	Asa			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

		Ketoconazole			S		Unk			Not Reported
		Oxycodone-Acet			S		Unk			Not Reported
		Carafate			S		Unk			Not Reported
		Mirtazapine			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13838894	NON-EXPEDITED			US-PFIZER INC-2017336955			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13839506	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060378-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Clonazepam			C				Not Reported
	Desipramine			C				Not Reported
	Gabapentin			C	Oral			Not Reported

	Nitroglycerin			C						Not Reported
	Rosuvastatin Calcium			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13839642	NON-EXPEDITED			US-AMGEN-USASP2017117283		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13841460	EXPEDITED (15-DAY)		HO, OT	US-TEVA-794134USA		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes	Hydroxychloroquine			S	Oral	60 Grams		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2017	13842246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2060871-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13380444	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-023176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13449266	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017161079		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Hypersensitivity; Pneumonitis; Pneumothorax	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Gold			S		Injections		Not Reported
	Naproxen			C	Oral	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13455944	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027829			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Toxicity To Various Agents	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13777288	NON-EXPEDITED			US-AMGEN-USASP2017107618		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Cimzia	S	Unknown	400 Mg, Unk		Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13788902	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004372		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease	Hydroxychloroquine 200 Mg Tablet			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13821147	EXPEDITED (15-DAY)		OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004445		58 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenocarcinoma; Disease Progression; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13842343	NON-EXPEDITED			US-AMGEN-USASP2017117208		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13842380	EXPEDITED (15-DAY)		OT	US-CONCORDIA			Female	USA

PHARMACEUTICALS INC.-GSH201708-004564

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dysphagia; Rheumatoid Arthritis; Sjogren'S Syndrome; Thyroid Disorder; Vomiting	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Mobic			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13842488	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2059827-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Duration- 275		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13842998	EXPEDITED (15-DAY)		DS	CA-ABBVIE-17K-028-2059515-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disability; Drug Ineffective; Musculoskeletal Stiffness;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported

Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Prednisone		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13843401	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2017M1048032			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Torsade De Pointes; Toxicity To Various Agents	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	Ingested Amount Not Stated		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13843527	NON-EXPEDITED			US-AMGEN-USASP2017116435		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd (Upto 28 Days, 28 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13844341	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-015994		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2017	13844369	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-016001		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Lymphadenopathy; Abdominal Pain; Blood Creatine Phosphokinase Increased; Blood Immunoglobulin G Increased; Blood Immunoglobulin M Increased; C-Reactive Protein Increased; Dyspnoea; Encephalopathy; Epstein-Barr Virus Infection; Eye Movement Disorder; Fatigue; Generalised Tonic-Clonic Seizure; Haemophagocytic Lymphohistiocytosis; Herpes Simplex Encephalitis; Hypotonia; Inflammatory Marker Increased; Leukocytosis;	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Mycophenolic Acid			C	Unknown			Not Reported

Malaise; Mental Status Changes; Muscular Weakness; Myalgia; Myopathy; Neurological Decompensation; Neuropsychiatric Lupus; Nodular Rash; Oedema Peripheral; Pancytopenia; Pupils Unequal; Pyrexia; Quadriparesis; Red Blood Cell Sedimentation Rate Increased; Respiratory Failure; Retroperitoneal Lymphadenopathy; Staphylococcal Infection; Systemic Lupus Erythematosus; Tachycardia; Thrombosis; Transaminases Increased; Unresponsive To Stimuli

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	11745563	EXPEDITED (15-DAY)		DS, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-106124		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril			S	Unknown	Unk		Sun
	Pantoprazole			S	Oral	Unk		Sun
	Pantoprazole			S	Unknown			Sun
	Pantoprazole			S	Unknown			Sun
	Pantoprazole			S	Unknown			Sun
	Diclofenac			S	Oral	75 Mg, Bid		Sun
	Diclofenac			S	Oral	150 Mg, Qd		Sun
	Sulfasalazine			S	Oral	500 Mg, Qd		Sun
	Sulfasalazine			S	Oral	500 Mg, Bid		Sun

	Sulfasalazine	S	Oral	2 G, Qd	Sun
	Methotrexate	S	Subcutaneous	20 Mg, 1/Week	Not Reported
	Methotrexate	S	Subcutaneous	80 Mg, 1/Week	Not Reported
	Folic Acid	S	Unknown	Unk	Sun
	Tecta	S	Oral	Unk	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Voltaren Sr	S	Oral	75 Mg, Bid	Not Reported
	Voltaren Sr	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	200 Mg, Qd	Not Reported
	Xeljanz	S	Oral	20 Mg, Qd	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Apo-Lisinopril	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Depo-Medrol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13567986	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2017JPN069126		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; General Physical Health Deterioration; Headache; Malaise; Nausea; Renal Disorder; Renal Impairment; Toxic Encephalopathy; Toxicity To Various Agents; Vomiting	Valtrex			S	Oral	3000 Mg, 1d		Glaxosmithkline
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Tacrolimus Hydrate			S	Oral	Unk		Not Reported
	Tacrolimus Hydrate			S	Oral	Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Calonal			C		Unk		Not Reported
	Scopolamine Butylbromide			C		Unk		Not Reported
	Predonine			C		Unk		Not Reported

	Loxonin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13758252	NON-EXPEDITED			US-PFIZER INC-2017306111		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13758373	NON-EXPEDITED			US-PFIZER INC-2017307241		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Imuran			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13771636	NON-EXPEDITED			US-PFIZER INC-2017312472		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13847546	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2059865-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13848876	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-02		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Chelonae Infection	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13849459	EXPEDITED (15-DAY)		OT	PHHY2017CA115251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13849481	EXPEDITED (15-DAY)		CA	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004605			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip; Foetal Exposure During Pregnancy	Plaquenil Tablet			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13849513	NON-EXPEDITED			US-PFIZER INC-2017341064		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Sulfasalazine			S		Unk			Pfizer
	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13849516	NON-EXPEDITED			US-PFIZER INC-2017338336		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13849640	NON-EXPEDITED			US-PFIZER INC-2017340051			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13852160	NON-EXPEDITED			GXBR2017US001806			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	2 Df, Qd		Novartis

	Vitamin B12			C	Unknown	Unk				Not Reported
	Vitamin D2			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2017	13853610	NON-EXPEDITED			GXBR2017US002185			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Screen False Positive	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	1 Df, Bid		Novartis
	Valtrex			C	Oral	1 G, Qd		Not Reported
	Ibuprofen			C	Oral	Unk, Prn (As Needed)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	11848645	EXPEDITED (15-DAY)		OT	CA-ROCHE-1597030		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 5 Months		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	12684684	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016108442		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Metoprolol			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen Sodium			C		Unk		Not Reported
	Rosuvastatin Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	12810481	EXPEDITED (15-DAY)		OT	CA-ROCHE-1837479		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Pain	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Tylenol			C	Unknown	As Required		Not Reported

	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	12884705	EXPEDITED (15-DAY)		OT	CA-ROCHE-1720106		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Deformity; Pain; Pneumonia; Swelling	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	12949039	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016158769		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Rituxan			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Fiorinal			C		Unk		Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13794623	NON-EXPEDITED			US-PFIZER INC-2017322221		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Enbrel	S	Unk		Pfizer
	Ibuprofen	S	Unk		Pfizer
	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13820730	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-068240		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Local Reaction; Psoriasis; Sinusitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13852308	NON-EXPEDITED			US-PFIZER INC-2017343601		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13853914	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2064770-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Headache; Increased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Tendency To Bruise; Insomnia; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Myalgia; Neck Pain; Pain In Extremity; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Xeljanz Xr	C			Not Reported
	Orencia	C	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13855552	NON-EXPEDITED			US-PFIZER INC-2017341038		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Depo-Medrol			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13855906	NON-EXPEDITED			US-AMGEN-USASP2017117977		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856011	EXPEDITED (15-DAY)		OT	PHHY2017CA113087		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Sodium Aurothiomalate Injection Bp	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Novartis
	Leflunomide	S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Enbrel	S	Unknown	50 Mg, Qw		Not Reported
	Arava	S	Unknown	25 Mg, Qw		Not Reported
	Actemra	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856211	EXPEDITED (15-DAY)		OT	GB-TEVA-794423ROM		53 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Teva
	Rituximab			S	Unknown	1 G		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856212	EXPEDITED (15-DAY)		OT	GB-TEVA-794425ROM		46 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Teva
	Rituximab			S	Unknown	1 G		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856218	EXPEDITED (15-DAY)		OT	GB-TEVA-794422ROM		35 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Teva
	Prednisolone			S	Unknown	High-Dose		Teva
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown	1 G		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856229	EXPEDITED (15-DAY)		OT	GB-TEVA-794432ROM		55 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Teva
	Mycophenolate Mofetil			S	Unknown	2 G		Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G		Not Reported
	Rituximab			S	Unknown	1 G		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856230	EXPEDITED (15-DAY)		OT	GB-TEVA-794429ROM		42 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown	2 G		Not Reported

	Mycophenolate Mofetil			S	Unknown	3 G			Not Reported
	Tacrolimus			S	Unknown				Actavis
	Rituximab			S	Unknown	1 G			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg			Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856231	EXPEDITED (15-DAY)		OT	GB-TEVA-794424ROM		22 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Teva
	Mycophenolate Mofetil			S	Unknown	3 G		Not Reported
	Rituximab			S	Unknown	1 G		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856242	EXPEDITED (15-DAY)		OT	GB-TEVA-794434ROM		45 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypogammaglobulinaemia	Prednisolone			S	Unknown	Low Dose		Teva
	Mycophenolate Mofetil			S	Unknown	1.5 G		Not Reported
	Rituximab			S	Unknown	1 G		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 G		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856245	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201717258			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 G, Unk		Shire
	Human Normal Immunoglobulin			S				Shire
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 1x/2wks		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Week		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg/Kg, 1x/Day:Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, 1x/Week		Not Reported
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, 1x/Week		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, 1x A Month		Not Reported
	Prednisone			S	Oral	3 Mg,2x/Day:Bid		Not Reported
	Prednisone			S	Oral	5 Mg,2x/Day:Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, 1x/Day:Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, 1x/2wks		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13856329	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-071623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pruritus; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2017	13858550	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Feeling Hot; Haemorrhage; Hepatic Enzyme Increased; Pain; Pruritus; Rash; Skin Discolouration	Hydroxychloroquine Sulfate			S	Oral	Quantity:1 Tablet(S);		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	12691294	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016403985		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S				Not Reported
	Apo-Metoprolol			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Sulfasalazine			S		500 Mg, Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen Sodium			C		Unk		Not Reported

	Rosuvastatin Calcium			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13764256	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017309058		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acrochordon; Dry Eye; Eye Pain; Eye Swelling; Eyelid Pain; Superficial Injury Of Eye; Visual Impairment	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		400 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, Weekly		Not Reported
	Gabapentin			C		300 Mg, 1x/Day For A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13771741	NON-EXPEDITED			US-PFIZER INC-2017311919		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13839609	NON-EXPEDITED			US-AMGEN-USASP2017116472		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13857672	EXPEDITED (15-DAY)		OT	US-ABBVIE-17P-163-2063995-00		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Cervical Spinal Stenosis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Essential Hypertension; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Lumbar Spinal Stenosis; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Syncope; Type V Hyperlipidaemia	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Prolia			S	Unknown			Not Reported
	Prolia			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Aranesp			C				Not Reported
	Oxycodone			C				Not Reported
	Abilify			C				Not Reported
	Advair			C				Not Reported
	Atenolol			C				Not Reported
	Buffered Aspirin			C				Not Reported
	Crestor			C				Not Reported
	Cytomel			C				Not Reported
	Dorzolamide Hcl			C				Not Reported
	Duloxetine Hcl			C				Not Reported
	Duoneb			C				Not Reported
	Famotidine			C				Not Reported
	Finasteride			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Leflunomide			C				Not Reported

	Lovaza	C	Not Reported
	Medrol	C	Not Reported
	Myrbetriq	C	Not Reported
	Nexium	C	Not Reported
	Omega 3	C	Not Reported
	Oxycodone Hcl	C	Not Reported
	Prochlorperazine Maleate	C	Not Reported
	Relpax	C	Not Reported
	Singulair	C	Not Reported
	Soma	C	Not Reported
	Sulfazine Ec	C	Not Reported
	Synthroid	C	Not Reported
	Tamsulosin Hcl	C	Not Reported
	Topamax	C	Not Reported
	Topiramate	C	Not Reported
	Triamterene/Hctz	C	Not Reported
	Voltaren	C	Not Reported
	Xalatan	C	Not Reported
	Zyrtec Allergy	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13858167	EXPEDITED (15-DAY)			US-IPCA LABORATORIES LIMITED-IPC201503-000180			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Muscle Spasms; Pruritus	Hydroxychloroquine Sulfate Tablets, Usp			S		Unk,Unk,Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13858169	EXPEDITED (15-DAY)			US-IPCA LABORATORIES LIMITED-IPC201702-000026			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Malaise	Hydroxychloroquine Sulfate Tablets, Usp			S		200,Mg,One Day		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13858385	EXPEDITED (15-DAY)		DE, HO	IN-PFIZER INC-2016020815		28 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningoencephalitis Amoebic	Methotrexate Sodium			S		Unk		Unknown
	Prednisolone			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13859252	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017119609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebrovascular Accident; Drug Ineffective; Memory Impairment; Musculoskeletal Pain; Myocardial Infarction; Peripheral Swelling	Enbrel			S	Unknown			Amgen
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13859508	NON-EXPEDITED			US-PFIZER INC-2017343606		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13859777	NON-EXPEDITED			US-PFIZER INC-2017345575		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13860442	NON-EXPEDITED			US-AMGEN-USASP2017119021			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13860558	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2063980-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2017	13861027	NON-EXPEDITED		OT	US-PFIZER INC-2017344388			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tuberculous Pleurisy	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2017	13862218	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017119156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Pain; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2017	13862467	EXPEDITED (15-DAY)		OT	CA-ROCHE-1976505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Malaise; Therapeutic Product Ineffective; Wheezing	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	11127133	EXPEDITED (15-DAY)		DE, OT	US-ROCHE-1579503			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia Supraventricular; Decreased Appetite; Diarrhoea; Embolism; Fatigue; Myocardial Infarction; Neutropenia; Pulmonary Embolism	Bevacizumab			S	Intravenous (not otherwise specified)			Not Reported
	Leucovorin			S	Intravenous (not otherwise specified)			Not Reported
	Oxaliplatin			S	Intravenous (not otherwise specified)			Not Reported
	5-Fu			S	Intravenous bolus			Not Reported
	5-Fu			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	12640601	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015038764		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Fall; Feeling Hot; Joint Effusion; Local Reaction; Wrist Fracture	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Prednisone			S		On And Off		Not Reported
	Humira			S		40 Mg, Unk		Not Reported
	Simponi			S		50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13593950	EXPEDITED (15-DAY)		OT	CA-ROCHE-1937330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia;	Rituxan			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Celebrex	S	Unknown			Not Reported
	Enbrel	S	Unknown	Discontinued		Not Reported
	Salazopyrine	S	Unknown	Discontinued		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Loperamide	C	Oral	2mg/1-2-Tabs 4x Per Day; Ongoing		Not Reported
	Align	C	Unknown	Align Digestive Aid		Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13774903	NON-EXPEDITED			US-AMGEN-USASP2017106896			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13786037	NON-EXPEDITED			US-AMGEN-USASP2017109559		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Arava	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd (30 Days)		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd (14 Days)		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd (Upto 28 Days) 5 Refills		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13840876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017336265		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombosis	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S		500 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine /00072603/			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13862429	EXPEDITED (15-DAY)		OT	PHHY2017CA118904		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13863384	NON-EXPEDITED			US-PFIZER INC-2017344852		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Nausea	Methotrexate Sodium		S		Unk	Pfizer
	Sulfasalazine		S		Unk	Pfizer
	Plaquenil		S		Unk	Not Reported
	Azathioprine		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13863464	NON-EXPEDITED			US-PFIZER INC-2017348030		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13863519	NON-EXPEDITED			US-PFIZER INC-2017347955		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	0.8 Injection, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	0.80 Cc Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	0.8 Ml, Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13863580	NON-EXPEDITED			US-PFIZER INC-2017349285		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13864900	NON-EXPEDITED			US-AMGEN-USASP2017120539		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2017	13865051	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2017DEP001651		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S		Unk		Depomed
	Desoximetasone			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13771142	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2115		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acrochordon; Dry Eye; Eye Allergy; Eye Pain; Eye Pruritus; Eye Swelling; Eyelid Pain; Visual	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Impairment	Folic Acid			C	Oral				Not Reported
	Gabapentin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13813860	NON-EXPEDITED			US-PFIZER INC-2017326799		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13868439	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975856		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13868670	NON-EXPEDITED			US-PFIZER INC-2017345057		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Oxycodone Hydrochloride			S		Unk		Pfizer
	Hydrocodone Cp			S		Unk		Not Reported

	Hcq				S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13868734	NON-EXPEDITED			US-PFIZER INC-2017349644			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13868992	NON-EXPEDITED			US-PFIZER INC-2017352042		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13869168	NON-EXPEDITED			US-PFIZER INC-2017347657			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2017	13869330	EXPEDITED (15-DAY)		OT	CA-SA-2017SA147721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13615477	NON-EXPEDITED			US-PFIZER INC-2017244632		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Peripheral Swelling; Synovitis; Tenderness	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Actemra			S		8 Mg/Kg, As Needed (Every 4 Weeks)		Not Reported
	Actemra			S		162 Mg, As Needed (Once A Week)		Not Reported
	Omeprazole			C		20 Mg, 2x/Day		Not Reported
	Ibuprofen			C	Oral	1 Df, 2x/Day (800)		Not Reported
	Vinate Care			C		1 Df, As Needed (29- 1 Mg Tablet 1 Tablet Once A Day)		Not Reported
	Folic Acid			C		2 Mg, As Needed (Once A Day)		Not Reported
	Hydrochlorothiazide			C		12.5 Mg, As Needed (1		Not Reported

				Capsule Once A Day)	
Prednisone	C	Oral	10 Mg (4 Tabs), As Needed	Not Reported
Prednisone	C	Oral	7.5 Mg (3 Tabs), As Needed	Not Reported
Prednisone	C	Oral	5 Mg (2 Tabs), As Needed	Not Reported
Prednisone	C	Oral	2.5 Mg (Once A Day), As Needed	Not Reported
Prednisone	C		10 Mg (2 Tabs), As Needed	Not Reported
Prednisone	C		1-2 Tabs, As Needed	Not Reported
Prednisone	C		5 Mg (Once A Day), As Needed	Not Reported
Vitamin D2	C		2000 Iu, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13793953	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004367		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871026	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002119		60 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dermatitis Exfoliative; Enanthema; Erythema; Erythema Multiforme; Oedema; Rash	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871030	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004616			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Malaise	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871033	EXPEDITED (15-DAY)		OT	SG-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004659		84 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Wheezing	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13871870	EXPEDITED (15-DAY)		HO, LT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-02		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Electrocardiogram Qt Prolonged; Hypocalcaemia; Hypokalaemia; Intentional Overdose; Torsade De Pointes	Hydroxychloroquine			S	Oral			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13872352	NON-EXPEDITED			US-PFIZER INC-2017347584		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective	Sulfasalazine		S	Unk	Pfizer
	Enbrel		S	Unk	Pfizer
	Hydroxychloroquine		S	Unk	Not Reported
	Arava		S	Unk	Not Reported
	Humira		S	Unk	Not Reported
	Cimzia		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13872369	NON-EXPEDITED			US-PFIZER INC-2017349593		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13872465	NON-EXPEDITED			US-PFIZER INC-2017347714		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13872606	NON-EXPEDITED			US-PFIZER INC-2017352033		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2017	13873104	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-797946USA		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Clostridial Sepsis; Death; Failure To Thrive; Gastrointestinal Injury; General Physical Health Deterioration; Haematocrit Decreased; Haemoglobin Decreased; Localised Oedema; Malaise; Product Expiration Date Issue; Product Physical Issue; Respiratory Distress; Weight Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Morphine Sulfate			C	Unknown	Crushed Through Feeding Tube		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13531620	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002832			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonitis; Pneumothorax	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Naproxen			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13805035	NON-EXPEDITED			US-PFIZER INC-2017324871		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Humira	S	Unk	Not Reported
	Cimzia	S	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13842289	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2017116391		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Blood Uric Acid Decreased; Eye Disorder; Feeling Abnormal; Pain; Psoriatic Arthropathy; Sciatica; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13875706	EXPEDITED (15-DAY)		OT	US-ROCHE-1975065		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Arthralgia; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Off Label Use; Osteoarthritis; Osteopenia; Pain;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prolia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Spondyloarthropathy; Synovitis; Treatment Failure; Type V Hyperlipidaemia	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Abilify	C	Unknown		Not Reported
	Advair	C			Not Reported
	Atenolol	C	Unknown		Not Reported
	Buffered Aspirin	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Cytomel	C	Unknown		Not Reported
	Dorzolamide Hcl	C			Not Reported
	Duloxetine Hcl	C	Unknown		Not Reported
	Duoneb	C			Not Reported
	Famotidine	C	Unknown		Not Reported
	Finasteride	C	Unknown		Not Reported
	Furosemide	C			Not Reported
	Gabapentin	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Lovaza	C	Unknown		Not Reported
	Medrol	C	Unknown		Not Reported
	Myrbetriq	C	Unknown		Not Reported
	Nexium	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Oxycodone Hcl	C	Unknown		Not Reported
	Prochlorperazine Maleate	C	Unknown		Not Reported
	Relpax	C	Unknown		Not Reported
	Singulair	C	Unknown		Not Reported
	Soma	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown	Sulfasalazine Ec	Not Reported
	Synthroid	C	Unknown		Not Reported
	Tamsulosin Hcl	C	Unknown		Not Reported

					Topamax	C	Unknown		Not Reported
					Topiramate	C	Unknown		Not Reported
					Triamterene/Hctz	C	Unknown		Not Reported
					Voltaren	C	Unknown		Not Reported
					Xalatan	C			Not Reported
					Zyrtec Allergy	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13876265	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017121443		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13876837	NON-EXPEDITED			US-AMGEN-USASP2017121536		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13877762	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2017CA119746		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown	Unk		Not Reported
	Ilaris			S	Unknown	Unk		Not Reported
	Ilaris			S	Unknown	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Not Specified		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Not Specified	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2017	13879483	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017122215		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cholecystectomy; Constipation; Drug Hypersensitivity; Drug Ineffective; Fall; Fatigue; Fibromyalgia; Hypertension; Joint Injury; Nasal Congestion; Nasal Injury; Nephrolithiasis; Rheumatoid Arthritis; Spinal Fracture; Vomiting; Weight Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	2.5 Mg, Qwk (8 Tablets)		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Voltaren			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported
	Orencia			C	Subcutaneous	125 Mg, Qwk		Not Reported
	Folic Acid			C	Oral	2 Df, Qd		Not Reported
	Losartan			C	Oral	50 Mg, Qd		Not Reported
	Oxycodone			C	Oral	10/325 Mg Q6h		Not Reported

	Oxycodone	C	Oral	10/325 Mg Prn		Not Reported
	Prednisone	C	Oral	5 Mg, Bid		Not Reported
	Prednisone	C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	12948671	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2295		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Effusion; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13767893	NON-EXPEDITED			US-PFIZER INC-2017307591			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Unk		Pfizer

	Orencia			S	Subcutaneous	Unk			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Hydroxychloroquine			S		Unk			Not Reported
	Cimzia			S		Unk			Not Reported
	Xeljanz Xr			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13813782	NON-EXPEDITED			US-PFIZER INC-2017327452		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Azulfidine			S		1 G, 3x/Day (Tid)		Pfizer
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13832737	NON-EXPEDITED			US-PFIZER INC-2017336834		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13862537	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004636		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13879934	NON-EXPEDITED			US-AMGEN-USASP2017122987		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown			Not Reported
	Cipro			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13880017	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004705			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13880581	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-073638		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13881147	EXPEDITED (15-DAY)		DE, HO	CH-ROCHE-1980199		66 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Sepsis; Diverticular Perforation; Multiple Organ Dysfunction Syndrome; Peritonitis Bacterial	Mabthera			S	Intravenous drip			Not Reported
	Prednisolon			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Calcimagon D3			C	Unknown			Not Reported
	Lisitril			C	Unknown			Not Reported
	Vi-De 3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13882889	NON-EXPEDITED			US-PFIZER INC-2017355457		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2017	13883185	EXPEDITED (15-DAY)		OT	US-SA-2017SA149651		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Off Label Use; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Synovitis; Treatment	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prolia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Failure; Type V Hyperlipidaemia	Remicade	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Abilify	C	Unknown	Not Reported
	Advair	C	Unknown	Not Reported
	Atenolol	C	Unknown	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Crestor	C	Unknown	Not Reported
	Cytomel	C	Unknown	Not Reported
	Dorzolamide Hydrochloride	C	Unknown	Not Reported
	Duloxetine Hydrochloride	C	Unknown	Not Reported
	Duoneb	C	Unknown	Not Reported
	Famotidine	C	Unknown	Not Reported
	Finasteride	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Lovaza	C	Unknown	Not Reported
	Medrol	C	Unknown	Not Reported
	Myrbetriq	C	Unknown	Not Reported
	Nexium	C	Unknown	Not Reported
	Omega 3	C	Unknown	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Not Reported
	Prochlorperazine Maleate	C	Unknown	Not Reported
	Relpax	C	Unknown	Not Reported
	Singulair	C	Unknown	Not Reported
	Soma	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Tamsulosin Hydrochloride	C	Unknown	Not Reported

	Topamax	C	Unknown	Not Reported
	Topiramate	C	Unknown	Not Reported
	Hydrochlorothiazide/Triamterene	C	Unknown	Not Reported
	Voltaren	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Oxycodone	C	Unknown	Not Reported
	Zyrtec	C	Unknown	Not Reported
	Aranesp	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	12316674	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1748895		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Fatigue; Malaise; Osteomyelitis; Pleurisy; Pneumonia; Red Blood Cell Sedimentation Rate Increased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 6 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13838895	NON-EXPEDITED			US-PFIZER INC-2017336520		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13884597	NON-EXPEDITED			US-AMGEN-USASP2017124038		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13884877	NON-EXPEDITED			US-AMGEN-USASP2017123646		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Abnormal; Myalgia	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13885565	NON-EXPEDITED			US-PFIZER INC-2017356740		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Sulfasalazine	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported
	Humira	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13887875	EXPEDITED (15-DAY)		OT	AT-MYLANLABS-2017M1051339			Unknown	AUT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Mylan
	Azathioprine			C	Unknown			Mylan
	Mycophenolate Mofetil			C	Unknown			Mylan
	Rituximab			C	Unknown			Mylan
	Cyclophosphamide			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13889249	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2076143-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13905549	DIRECT		HO			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Rash; Skin Exfoliation; Stevens-Johnson Syndrome; Therapy Cessation	Hydroxychloroquine 200mg Tablets			S	Oral	Quantity:1 ;		Not Reported
	Vitamin D Nos			C				Not Reported
	Ocuvite			C				Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	7456107	NON-EXPEDITED			US-ROCHE-713502		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Actemra			S	Intravenous (not otherwise specified)	Form: Infusion		Not Reported
	Arava			S	Oral	Dose: 20 Daily		Not Reported
	Plaquenil			S	Oral	Dose:250		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13031960	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2016CA011332			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Inflectra			S	Unknown	Unk		Celltrion
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Simponi			S	Subcutaneous	Unk				Not Reported
	Orencia			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13758325	NON-EXPEDITED			US-PFIZER INC-2017305803			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13823384	NON-EXPEDITED			US-AMGEN-USASP2017114402		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13852362	NON-EXPEDITED			US-PFIZER INC-2017343571		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13863457	NON-EXPEDITED			US-PFIZER INC-2017345209		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prinivil			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Salsalate			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Avapro			S		Unk		Not Reported
	Disalcid			S		Unk		Not Reported
	Forteo			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Miacalcin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13889700	NON-EXPEDITED			US-AMGEN-USASP2017124535		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Codeine			S	Unknown	Unk		Not Reported
	Betadine			S	Unknown	Unk		Not Reported
	Iodine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13890678	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017316903		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13890826	EXPEDITED (15-DAY)		HO	FR-ROCHE-1978552		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use; Product Use In Unapproved Indication; Pyrexia	Cellcept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortancyl			C				Not Reported
	Inexium			C				Not Reported
	Cacit D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13890832	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004761		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Prolia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Decreased; Insomnia; Off Label Use; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Synovitis; Treatment Failure; Type V Hyperlipidaemia	Xeljanz	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S		Not Reported
	Furosemide	C		Not Reported
	Abilify	C		Not Reported
	Advair	C		Not Reported
	Atenolol	C		Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Crestor	C		Not Reported
	Cytomel	C		Not Reported
	Dorzolamide Hydrochloride	C		Not Reported
	Duloxetine Hydrochloride	C		Not Reported
	Duoneb	C		Not Reported
	Famotidine	C		Not Reported
	Finasteride	C		Not Reported
	Gabapentin	C		Not Reported
	Lovaza	C		Not Reported
	Medrol	C		Not Reported
	Myrbetriq	C		Not Reported
	Nexium	C		Not Reported
	Omega 3	C		Not Reported
	Oxycodone Hydrochloride	C		Not Reported
	Prochlorperazine Maleate	C		Not Reported
	Relpax	C		Not Reported
	Singulair	C		Not Reported
	Soma	C		Not Reported
	Sulfasalazine	C		Not Reported
	Synthroid	C		Not Reported
	Tamsulosin Hydrochloride	C		Not Reported
	Topamax	C		Not Reported
	Topiramate	C		Not Reported
	Hydrochlorothiazide/Triamterene	C		Not Reported
	Voltaren	C		Not Reported
	Xalatan	C		Not Reported
	Oxycodone	C		Not Reported
	Zyrtec	C		Not Reported

	Aranesp			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13891271	NON-EXPEDITED			US-PFIZER INC-2017360003		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13891344	EXPEDITED (15-DAY)		OT	CA-SA-2017SA150212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5iw:Five Days Per Week		Not Reported
	Methotrexate			C	Oral			Not Reported
	Tocilizumab			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13893671	EXPEDITED (15-DAY)		OT	CA-SA-2017SA141605			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative Arthritis; Urinary Tract Obstruction	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	Dose: 400mg With 200 Mg Q 2 Days		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13851805	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2064022-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13895536	NON-EXPEDITED		OT	US-ENDO PHARMACEUTICALS INC-2016-005870			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Chills; Drug Ineffective; Hallucination; Pain; Seizure	Prednisone Tablets			S	Unknown			Vintage
	Prednisone Tablets			S	Unknown	Higher Dose		Vintage
	Prednisone Tablets			S	Unknown	Higher Dose		Vintage
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

	Methotrexate			S					Not Reported
	Reclast			S	Unknown	One Time Infusion That Lasts One Year			Not Reported
	Reclast			S					Not Reported
	Reclast			S					Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine			S					Not Reported
	Hydroxychloroquine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13895600	NON-EXPEDITED			US-PFIZER INC-2017359358			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2017	13896802	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017356839			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	12416785	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016251226		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Insomnia; Joint Swelling; Malaise; Meniere'S Disease; Pain;	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Plaquenil /00072602/			S		400 Mg, Daily		Not Reported
	Tylenol 3			C		Unk		Not Reported

Peripheral Swelling	Omeprazole	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13224878	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000951			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Ineffective	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Morphine			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13343285	EXPEDITED (15-DAY)		HO, OT	AR-PFIZER INC-2017110435		73 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Blood Pressure Increased; Cardiac Disorder; Dizziness; Generalised Oedema; Headache; Microangiopathic Haemolytic Anaemia; Oliguria; Pleural Effusion; Product Use In Unapproved Indication; Renal Failure; Respiratory Disorder; Vomiting	Sildenafil Citrate			S		Unk		Pfizer
	Diltiazem Hcl			S		Unk		Unknown
	Hidroxicloroquina			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13570470	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1980576-00		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Fear Of Injection; Photopsia; Retinal Degeneration; Retinal Toxicity; Vitreous Floaters; Weight Fluctuation; Weight Fluctuation	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Cymbalta		C		Not Reported
	Cymbalta		C		Not Reported
	Cymbalta		C		Not Reported
	Tirosint		C		Not Reported
	Tirosint		C		Not Reported
	Tirosint		C		Not Reported
	Oxycodone		C		Not Reported
	Fentanyl		C		Not Reported
	Metoprolol		C		Not Reported
	Estropipate		C		Not Reported
	Temazepam		C		Not Reported
	Dexilant		C		Not Reported
	Methocarbamol		C		Not Reported
	Lasix		C		Not Reported
	Atorvastatin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13786184	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2162		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13824661	NON-EXPEDITED			US-PFIZER INC-2017329156			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer

	Augmentin			S		Unk			Not Reported
	Plaquenil			S		Unk			Not Reported
	Levaquin			S		Unk			Not Reported
	Oxycodone			S		Unk			Not Reported
	Oxycodone And Acetaminophen			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13834332	NON-EXPEDITED			US-PFIZER INC-2017332519		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13838861	NON-EXPEDITED			US-PFIZER INC-2017336401		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13849482	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004617		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Off Label Use; Post Inflammatory	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported

Pigmentation Change; Sjogren'S Syndrome; Skin Lesion	Prednisone			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13875702	NON-EXPEDITED			US-AMGEN-USASP2017122362		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Immune Responsiveness; Injection Site Pruritus; Injection Site Swelling; Pain In Extremity; Peripheral Swelling; Skin Laceration	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13899819	NON-EXPEDITED			US-AMGEN-USASP2017125961		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13900663	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP016905			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis;	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira	S	Subcutaneous			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Diclofenac	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13900958	EXPEDITED (15-DAY)		HO, LT, OT	US-APOTEX-2017AP016771		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Ineffective; Treatment Noncompliance	Mycophenolate Mofetil			S	Unknown			Apotex
	Sertraline Hydrochloride			S	Unknown	25 Mg, Daily		Apotex
	Midazolam Hydrochloride Injection			S	Intravenous drip	Unk		Apotex
	Midazolam Hydrochloride Injection			S	Intravenous drip	15 Mg, Q.H.		Apotex
	Haloperidol			S	Intramuscular			Apotex
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Lorazepam			S	Intravenous (not otherwise specified)	24 Mg, Per Day		Not Reported
	Esmolol			C	Intravenous drip	Unk Unk, Prn		Not Reported
	Esmolol			C	Unknown	Unk, Prn		Not Reported
	Flumazenil			C	Unknown			Not Reported
	Ketamine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13901126	NON-EXPEDITED			US-AMGEN-USASP2017125925		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13901406	NON-EXPEDITED			US-AMGEN-USASP2017125708			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Disorder; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13901720	EXPEDITED (15-DAY)		OT	PHHY2017CA124492		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Ciclosporin			S	Unknown			Novartis
	Leflunomide			S	Unknown			Not Reported

Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, 01 Every 01 Weeks		Not Reported
Hydroxychloroquine	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Unk		Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
Xeljanz	C	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902209	NON-EXPEDITED			US-AMGEN-USASP2017126640		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Simponi Aria			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902582	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017126588		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Back Pain; Central Pain Syndrome;	Enbrel			S	Unknown	Unk		Amgen

Headache; Muscle Swelling; Musculoskeletal Stiffness; Nausea; Oral Pain; Pain In Extremity; Polyarthritis; Porokeratosis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Plaquenil	S	Oral	200 Mg, Bid, One Tablet By Mouth Twice A Day	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz Xr	S	Oral	11 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Ambien Cr	C		12.5 Mg, Qd 1 Every Bedtime	Not Reported
	Insulin	C		Unk Unk, Qwk As Directed	Not Reported
	Methotrexate Sodium	C	Subcutaneous	250 Mg, Qwk	Not Reported
	Calcium	C		500 Mg, Qd	Not Reported
	Mtx	C		Unk	Not Reported
	Omega 3	C		1000 Mg, Qd	Not Reported
	Omeprazole	C		40 Mg, Qd	Not Reported
	Vitamin B12	C		12.75 Ml, Unk Twice A Month	Not Reported
	Folic Acid	C		2 Mg, Qd	Not Reported
	Gabapentin	C	Oral	100 Mg, Qhs	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902723	EXPEDITED (15-DAY)		OT	CA-ROCHE-1980935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Simponi			S	Unknown	Tried For 4 Months (Dec-		Not Reported

							Mar)			
		Plaquenil			S	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902733	EXPEDITED (15-DAY)		OT	CA-ROCHE-1980914		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2 In 1 Day		Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)	1000mg, 2 In 1 Day		Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902841	EXPEDITED (15-DAY)		DE	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004736			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Infection; Photosensitivity Reaction	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13902845	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral	400mg Five Days Per Week		Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13903010	NON-EXPEDITED			US-AMGEN-USASP2017124217		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2017	13903471	NON-EXPEDITED			US-PFIZER INC-2017363014			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

		Prednisone			S		Unk			Not Reported
		Simponi			S		Unk			Not Reported
		Humira			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	12395260	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016063933		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Methotrexate Sodium			S	Intramuscular	25 Mg, Qwk		Not Reported
	Prednisone			S	Unknown	5 Mg, Every Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Cimzia			S	Unknown	200 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid (2x/Day)		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13004529	EXPEDITED (15-DAY)		OT	CA-ROCHE-1862072			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Inflectra			S	Intravenous (not	Then Every 6 Weeks For		Not Reported

							otherwise specified)	12 Months	
					Crestor	C	Oral		Not Reported
					Ezetrol	C	Oral		Not Reported
					Aspirin	C	Unknown		Not Reported
					Plavix	C	Oral		Not Reported
					Nitro Patch	C	Transdermal		Not Reported
					Niaspan	C			Not Reported
					Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13021620	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016171515		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13864251	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported

Arthritis; Urinary Tract Obstruction	Leflunomide			S	Oral				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Azathioprine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13894029	EXPEDITED (15-DAY)		OT	CA-HIKMA PHARMACEUTICALS CO. LTD-2017CA010955			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Infliximab Hospira			S	Unknown			Celltrion
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904204	NON-EXPEDITED			US-AMGEN-USASP2017128039		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen

	Plaquenil			S	Unknown	Unk				Not Reported
	Humira			S	Unknown	Unk				Not Reported
	Leflunomide			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904264	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004766		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Pyrexia	Plaquenil			S	Oral			Concordia
	Cellcept			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cacit D3			C				Not Reported
	Cortancyl			C				Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904265	EXPEDITED (15-DAY)		DS	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004789		64 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Chest Discomfort; Chest Pain; Dyspnoea Exertional	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Sulfarlem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904266	EXPEDITED (15-DAY)		HO	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004817		18 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus	Plaquenil 200 Mg Tablet			S	Oral			Concordia

Erythematosus	Plaquenil 200 Mg Tablet	S	Oral	1 To 2 Oral Tablets Of 200 Mg Of Hydroxychloroquine Sulfate Every 24 Hours (Monday To Friday) And 1		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904334	NON-EXPEDITED			US-AMGEN-USASP2017126609		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Enbrel			S	Unknown			Amgen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904644	NON-EXPEDITED			US-PFIZER INC-2017365649		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904714	NON-EXPEDITED			US-PFIZER INC-2017365646		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904735	NON-EXPEDITED			US-PFIZER INC-2017365554		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Keflex			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13904840	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017127335		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13905699	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2057548-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

					Orencia		S	Unknown		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13905925	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004843		35 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enalapril			C				Not Reported
	Seretide			C				Not Reported
	Sildenafil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2017	13907025	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2017-001060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Folic Acid			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Fosamax		S	Unknown		Not Reported
					Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
					Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**		**503B Facility**	**Age**	**Sex**	**Country**
25-Aug-2017	13907128	EXPEDITED (15-DAY)		OT		CA-BAUSCH-BL-2017-025079				Female	CAN
Preferred Term		**Product**	**Comp.**	**OTC**	**Role**	**Route**		**Dosage Text**	**Duration**	**Mfr**	
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure		Diclofenac Potassium			S	Oral				Bausch And Lomb	
		Folic Acid			S	Unknown				Not Reported	
		Lisinopril			S	Unknown				Not Reported	
		Methotrexate Sodium			S	Subcutaneous				Not Reported	
		Plaquenil			S	Oral				Not Reported	
		Sodium Aurothiomalate			S	Unknown				Not Reported	
		Sulfasalazine			S	Oral				Not Reported	
		Synthroid			S	Unknown				Not Reported	
		Tecta			S	Oral				Not Reported	
		Xeljanz			S	Unknown				Not Reported	
		Depo-Medrol			C	Intramuscular		Suspension Intra-Articular		Not Reported	
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**		**503B Facility**	**Age**	**Sex**	**Country**
25-Aug-2017	13907172	EXPEDITED (15-DAY)		OT		CA-BAUSCH-BL-2017-025084				Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2017	13028900	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016174639		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Hypersensitivity; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Celebrex			C	Oral	Unk		Not Reported

	Prednisone			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2017	13053560	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016179483		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2017	13908393	NON-EXPEDITED			US-AMGEN-USASP2017122909		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Humira			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2017	13913542	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Xeljanz 5mg Pfizer	S	Oral		Pfizer
	Hydroxychloroquine 200mg	S	Oral		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	12959419	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016162529		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Atrial Fibrillation; Bone Pain; Disability; Fibromyalgia; Malaise; Pain; Pain In Extremity; Retinopathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tooth Fracture	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			C	Oral	1 Gram, Twice Daily		Not Reported
	Celebrex			C	Oral	100 Mg, Daily		Not Reported
	Morphine			C	Unknown	10 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13100020	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876560			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral	Therapy Duration: 365.0		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	Therapy Duration: 549.0		Not Reported

	Orencia		S	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Folic Acid		C	Oral		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown		Not Reported
	Prednisone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13758376	NON-EXPEDITED			US-PFIZER INC-2017307929		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Levothyroxine Sodium			S		Unk		Pfizer
	Nexium			S		Unk		Unknown
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Nortriptyline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13773156	NON-EXPEDITED			US-AMGEN-USASP2017106791			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13783309	NON-EXPEDITED			US-PFIZER INC-2017320076		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13823389	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004473		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyponatraemia; Neutropenia; Sopor	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Gladio			S	Oral			Not Reported
	Gladio			S	Oral			Not Reported
	Tenormin			C				Not Reported
	Zanedip			C				Not Reported
	Tareg			C				Not Reported
	Limpidex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13832200	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017116102		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Herpes Zoster; Liver Function Test Increased; Mechanical Ventilation	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	200 Mg, Qd				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13880378	NON-EXPEDITED		OT	US-AMGEN-USASP2017122854		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Mouth Ulceration; Musculoskeletal Pain; Oral Candidiasis; Osteoarthritis; Peripheral Swelling; Polyarthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	300 Mg, Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13908864	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004850		60 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13908996	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982395		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13909126	NON-EXPEDITED			US-AMGEN-USASP2017125751			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13909405	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP016944			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Apo-Diclo (Diclofenac Sodium)			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Acetylsalicylic Acid W/Ascorbic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13909612	NON-EXPEDITED			US-PFIZER INC-2017365292			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil	S	Unk	Not Reported
	Cimzia	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13909702	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP016953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Apo-Diclofenac			S	Unknown			Apotex
	Apo-Diclofenac			S				Apotex
	Apo-Diclofenac			S				Apotex
	Apo-Diclofenac			S				Apotex
	Apo-Tramadol			S	Unknown			Apotex
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin			S	Unknown			Not Reported
	Motrin			S				Not Reported

	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Naprosyn /00256201/	S	Unknown		Not Reported
	Naprosyn /00256201/	S			Not Reported
	Naprosyn /00256201/	S			Not Reported
	Naprosyn /00256201/	S			Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S	Unknown		Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13267219	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0610		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13785319	NON-EXPEDITED			US-AMGEN-USASP2017107635			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Local Reaction; Psoriasis;	Enbrel			S	Unknown	Unk		Amgen

Sinusitis; Unevaluable Event	Arava		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		C		Unk	Not Reported
	Methotrexate		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13835270	NON-EXPEDITED		OT	US-AMGEN-USASP2017115131		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Dyspepsia; Insomnia; Mass; Parotid Gland Enlargement; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Amlodipine			S	Unknown	5 Mg, Qd		Not Reported
	Potassium Chloride			S	Unknown	20 Meq, Qd		Not Reported
	Morphine Hcl			S	Unknown	Unk		Not Reported
	Penicillin (Benzylpenicillin)			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13852389	NON-EXPEDITED			US-PFIZER INC-2017343690			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13868745	NON-EXPEDITED			US-PFIZER INC-2017349453		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13872604	NON-EXPEDITED			US-PFIZER INC-2017351121		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13876121	NON-EXPEDITED			US-PFIZER INC-2017353757		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Benzonatate			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Betadine			S		Unk		Not Reported

	Iodine			S		Unk				Not Reported
	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13913560	NON-EXPEDITED			US-AMGEN-USASP2017128871		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13914324	NON-EXPEDITED			US-PFIZER INC-2017371918		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13914914	NON-EXPEDITED			US-AMGEN-USASP2017128458		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

Cimzia	S	Unknown	Unk			Not Reported
Plaquenil	S	Unknown	Unk			Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13915113	EXPEDITED (15-DAY)		CA, DE, HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004866			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomaly Of Orbit, Congenital; Anotia; Anterior Displaced Anus; Camptodactyly Congenital; Congenital Anomaly; Congenital Foot Malformation; Congenital Hand Malformation; Congenital Nose Malformation; Conjunctival Disorder; Cranial Sutures Widening; Ear Malformation; Foetal Exposure During Pregnancy; Hydrocephalus; Hypocalvaria; Hypotelorism Of Orbit; Low Set Ears; Macrocephaly; Respiratory Distress; Small For Dates Baby; Syringomyelia	Hydroxychloroquine			S	Transplacental			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Transplacental			Not Reported
	Prednisone			S				Not Reported
	Enalapril			S	Transplacental			Not Reported
	Amlodipine (Salt Not Specified)			S	Transplacental			Not Reported
	Cyclophosphamide			S	Transplacental			Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13915114	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004867			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Drug Intolerance; Ototoxicity; Rash	Hydroxychloroquine			S	Oral		Concordia
	Methotrexate			C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13915547	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982329		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			C	Oral	Therapy Duration: 365 Days		Not Reported
	Leflunomide			C	Oral	Therapy Duration: 549 Days		Not Reported
	Orencia			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13915767	EXPEDITED (15-DAY)		DE, HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-002656			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Condition Aggravated; Death; Disease Progression; Disturbance	Hydroxychloroquine Sulfate 200mg Tablets, Usp			S		Unk		Ipca
	Fentanyl			S				Not Reported
	Propofol			S				Not Reported
	Antibiotics			S				Not Reported

In Attention; Mental Disorder; Pelvic Pain; Renal Failure; Toxicity To Various Agents; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13915817	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982421		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Align			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13915967	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2017-001465			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Prednisone Tablets			S	Unknown	Unk Unk, Unknown		Vintage
	Arava			S	Unknown	20 Mg, Daily		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, Bid		Not Reported
	Seroquel			C				Not Reported

	Ativan			C						Not Reported
	Iodine			C						Not Reported
	Humira			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13916243	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1999089-00		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Ulcer; Panic Attack; Sinusitis; Vision Blurred	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Belbuca			C				Not Reported
	Baclofen			C				Not Reported
	Levothyroxine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Adderall			C				Not Reported
	Prozac			C				Not Reported
	Trulance			C				Not Reported
	Quetiapine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13917844	NON-EXPEDITED			US-PFIZER INC-2017367927		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13359976	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043326		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Arava			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Humira	S	Unknown	Frequency: 1 Every 2 Week Form: Solution Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Rituxan	S	Unknown	Form: Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13615612	NON-EXPEDITED			US-PFIZER INC-2017244626		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day (Bid)		Pfizer
	Plaquenil			S	Oral	400 Mg, Daily		Not Reported
	Leflunomide			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13779536	NON-EXPEDITED			US-AMGEN-USASP2017107472		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk (60 For 30		Not Reported

Days)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13802799	NON-EXPEDITED		OT	US-AMGEN-USASP2017111917		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Wound Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13875303	EXPEDITED (15-DAY)		OT	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004702		42 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Anti-Cyclic Citrullinated Peptide Antibody Positive; Erythema; Erythema; Face Oedema; Leukocytosis; Papule; Pustule; Pyrexia; Rash Erythematous; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Skin Lesion; Skin Plaque	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13881210	NON-EXPEDITED			US-PFIZER INC-2017357818		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Immune Responsiveness; Injection Site Pruritus; Injection Site Swelling; Pain In Extremity; Peripheral Swelling; Skin Laceration	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13919307	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004882		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyspnoea; Infectious Pleural Effusion; Mycobacterium Fortuitum Infection; Off Label Use; Pyrexia	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13920071	NON-EXPEDITED			US-PFIZER INC-2017368376		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13920076	NON-EXPEDITED			US-PFIZER INC-2017368993		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Aleve			C		Unk		Not Reported
	Motrin			C		Unk		Not Reported
	Diclofenac			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13920224	NON-EXPEDITED			US-PFIZER INC-2017371878		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13920283	NON-EXPEDITED			US-PFIZER INC-2017372046		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2017	13923994	DIRECT	Y	HO			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain; Cholangitis; Nausea; Pyrexia; Rash; Rash; Vomiting	Hydroxychloroquine	S	Oral			Concordia
	Abraxane	S	Intravenous (not otherwise specified)	283 Mg, Day 1,8,15 Iv, Every 28 Day		Celgene
	Decexamethasone	C				Not Reported
	Gemzar	C				Not Reported
	Granisetron	C				Not Reported
	Famotidine	C				Not Reported
	Fluoxetine	C				Not Reported
	Furosemide	C				Not Reported
	Losartan	C				Not Reported
	Metoprolol	C				Not Reported
	Multivitamin	C				Not Reported
	Xarelto	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13172293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886139		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13359854	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043336		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Response Decreased; Treatment Failure	Leflunomide			S	Unknown	20,Unk			Not Reported
	Plaquenil			S	Oral				Not Reported
	Celebrex			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous			Not Reported
	Methotrexate			S	Unknown				Not Reported
	Methotrexate Sodium			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13360186	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043023		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13360690	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043008		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy;	Leflunomide			S	Unknown			Not Reported

Arthropathy; Bone Disorder; Drug Ineffective; Hip Arthroplasty; Infection; Lower Limb Fracture; Osteonecrosis; Post Procedural Infection; Therapeutic Product Effect Decreased	Plaquenil	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13813841	NON-EXPEDITED			US-PFIZER INC-2017327509		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13885581	NON-EXPEDITED			US-PFIZER INC-2017357540		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13923574	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Herpes Zoster; Liver Function Test Increased; Mechanical Ventilation	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13923989	NON-EXPEDITED			US-PFIZER INC-2017372054			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13924699	NON-EXPEDITED			US-AMGEN-USASP2017129400			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13925628	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE JAPAN K.K.-2017CA011522			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, 1/Week		Celltrion
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, 1/Week		Not Reported
	Humira			S	Subcutaneous	400 Mg, 1/Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13925852	NON-EXPEDITED			US-PFIZER INC-2017372223		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13926366	NON-EXPEDITED			US-AMGEN-USASP2017128742		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel		S	Unknown	Unk	Amgen
	Plaquenil		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Xeljanz Xr		C	Oral	11 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2017	13927303	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-2089605-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Levothyroxine			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Oral	75.0 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200.0 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500.0 Mg, Qd		Not Reported
	Tecta			S	Oral			Not Reported
	Xeljanz			S	Unknown	Unk, Bid		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	12885019	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013281		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Cholesterol Increased; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder;	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	25 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	25 Mg, Qd		Apotex

Grip Strength Decreased; Headache; Hypertension; Joint Swelling; Nausea	Sulfasalazine		S	Oral	1 G, Bid	Not Reported
	Enbrel		S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium		S	Oral	2.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium		S	Oral	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium		S	Subcutaneous	25 Mg, Unk	Not Reported
	Etanercept		S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Hydrochlorothiazide		C	Unknown	5 Mg, Qd	Not Reported
	Leucovorin /00566701/		C	Oral	5 Mg, Unk	Not Reported
	Orencia		C	Unknown	Unk	Not Reported
	Oxycodone		C	Unknown	Unk	Not Reported
	Quinapril		C	Unknown	40 Mg, Qd	Not Reported
	Rosuvastatin		C	Unknown	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	12891630	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013462		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Swelling	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			C	Oral	50 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13100036	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877137		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13359967	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13359991	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043186			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Diarrhoea; Drug Ineffective; Drug	Arava			S	Oral			Not Reported

Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Hydroxychloroquine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Desoximetasone	C	Oral			Not Reported
	Methotrexate	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13360024	EXPEDITED (15-DAY)		DS	CA-SA-2017SA043234		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Dyspnoea; Hypersensitivity; Mobility Decreased; Neutropenia; Synovitis	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Upto 20 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13360696	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043255		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate Sodium	S	Oral			Not Reported
	Prednisone	S	Unknown			Not Reported
	Simponi	S	Unknown	Form: Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13360764	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA042989			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Balance Disorder; Bursitis; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Dry Mouth; Fall; Hand Deformity; Hypoaesthesia; Intervertebral Disc Operation; Joint Range Of Motion Decreased; Malaise; Muscle Tightness; Musculoskeletal Pain; Nausea; Nerve Compression; Nocturnal Dyspnoea; Pain In Extremity; Pruritus; Respiratory Disorder; Skin Wound; Spinal Cord Compression; Swelling; Therapeutic Product Effect Incomplete; Tracheostomy; Wound	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Frequency: 1 Every 2 Weeks		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral	Duration: 74 (Unit Unspecified)		Not Reported

Complication; Wound Infection Staphylococcal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13646893	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003496		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Doliprane			S	Oral			Not Reported
	Chronadalate			S	Oral			Not Reported
	Cortancyl			C				Not Reported
	Kardegic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13681122	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP013133			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Apo-Mycophenolate			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Enbrel			S	Subcutaneous			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cellcept /01275102/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13813152	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004447		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mycobacterium Chelonae Infection; Pruritus; Skin Plaque	Hydroxychloroquine		S	Unknown		Concordia
	Prednisone		S	Unknown		Not Reported
	Mycophenolate Sodium		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13838682	NON-EXPEDITED			US-PFIZER INC-2017334730		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13903549	NON-EXPEDITED			US-PFIZER INC-2017363648		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13927861	NON-EXPEDITED			US-PFIZER INC-2017369355			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk	Pfizer
	Humira	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Folic Acid	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13928012	NON-EXPEDITED			US-AMGEN-USASP2017130936		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13928824	EXPEDITED (15-DAY)		DE, HO, LT, OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004874		24 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Coma; Csf White Blood Cell Count Increased; Drug Dependence; Drug Ineffective; Headache; Musculoskeletal Stiffness; Off Label Use; Pseudomonas Infection; Pyrexia; Therapeutic Response Decreased; Type 2 Lepra Reaction; Vomiting Projectile	Hydroxychloroquine			S	Unknown			Concordia
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported

	Levofloxacin			S	Unknown		Not Reported
	Meropenem			S	Unknown		Not Reported
	Ceftriaxone			S	Unknown		Not Reported
	Cyclophosphamide			S	Unknown		Not Reported
	Leflunomide			S	Unknown		Not Reported
	Rifampin			C			Not Reported
	Clofazimine			C			Not Reported
	Dapsone			C			Not Reported
	Thalidomide			C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13929638	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004981			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Pneumonia	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13929808	NON-EXPEDITED			US-AMGEN-USASP2017130930		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13929840	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL			Female	DEU

INDUSTRIES LTD-
2017RR-148918

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dyspnoea; Head Discomfort; Hyperthyroidism; Hypoaesthesia; Hypokinesia; Paraesthesia; Pharyngeal Swelling; Tinnitus; Tremor	Alendronsaure Basics Einmal Wochentlich 70mg Tabletten			S	Unknown	Unk		Sun
	Quensyl 200 Mg			S	Oral	1-0-1; (2-0-1)		Not Reported
	Sufasalazin			C	Unknown			Not Reported
	Ass			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Prednisolone			C	Unknown	2.5 Mg, Unk		Not Reported
	Vitamin D Nos			C	Unknown	Unk		Not Reported
	Pantoprazol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2017	13930453	NON-EXPEDITED			US-PFIZER INC-2017375886		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Medrol			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	12148091	NON-EXPEDITED			US-PFIZER INC-2016108434		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	12716062	NON-EXPEDITED			US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-01			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rash; Urticaria	Methotrexate			S	Unknown			Roxane
	Oxycodone			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			S	Unknown			Roxane

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13178710	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013284		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis; Liver Disorder	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13588963	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1937352		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea;	Cellcept			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			C	Unknown	15-50 Mg Currently On 50 Mg. Since 15/Mar/2017 50 Mg Per Day For 4 Weeks Then Slow Taper		Not Reported
	Prednisone			C	Unknown	5-20 Mg		Not Reported

Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Baby Aspirin		C	Unknown		Not Reported
	Colchicine		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13692325	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1864		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13779817	NON-EXPEDITED			US-AMGEN-USASP2017107579		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13838859	NON-EXPEDITED			US-PFIZER INC-2017337146		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13881932	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Finger Deformity; Malaise; Pain; Pulmonary Fibrosis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13890834	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004772		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Cutaneous Lupus Erythematosus; Condition Aggravated; Drug Ineffective; Herpes Zoster; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Tacrolimus			S	Topical			Not Reported
	Ilomedin			S				Not Reported
	Belimumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13891310	NON-EXPEDITED			US-PFIZER INC-2017357178		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13923575	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004972			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13931570	EXPEDITED (15-DAY)		OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004875		48 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Hydroxychloroquine			S				Concordia
	Acetazolamide			S				Not Reported
	Acetazolamide			S				Not Reported
	Methotrexate			S				Not Reported
	Etanercept			S				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13931959	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1986450			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13932104	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Hydroxychloroquine	S	Unknown	Concordia
	Ramipril	S	Oral	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13932171	NON-EXPEDITED			US-PFIZER INC-2017378686		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13932455	EXPEDITED (15-DAY)		OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005005		53 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pulmonary Fibrosis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Adalat Oros			C				Not Reported
	Galvus Met			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2017	13932692	NON-EXPEDITED			US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-02			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Arthralgia; Joint Swelling; Pain In Extremity; Rash	Methotrexate	S	Oral	Westward
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Aleve	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Ortho Tri-Cyclen	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	9917411	NON-EXPEDITED			US-PFIZER INC-2014047798			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Calan			S		Unk		Pfizer
	Ciprofloxacin			S				Unknown
	Procardia			S		Unk		Pfizer
	Glucose			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Dolobid			S		Unk		Not Reported
	Trimpex			S		Unk		Not Reported
	Voltaren			S		Unk		Not Reported
	Tetanus			S		Unk		Not Reported
	Ziac			S		Unk		Not Reported
	Brimonidine			S		Unk		Not Reported
	Macrodantin			S		Unk		Not Reported
	Cardizem			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported

	Lopressor	S	Unk	Not Reported
	Motrin	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Macrobid	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	10796331	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1538458		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Clostridium Difficile Infection; Diarrhoea; Eye Disorder; Fatigue; Gastrointestinal Disorder; Ill-Defined Disorder; Impaired Healing; Localised Infection; Malaise; Osteomyelitis; Pleurisy; Pneumonia; Pneumonitis; Postoperative Wound Infection; Red Blood Cell Sedimentation Rate Increased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquinol			S	Unknown	Therapy Duration: 6 Years		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13059536	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015773		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Mirtazapine			S	Unknown	15 Mg, Unk		Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Sulfasalazine			S	Unknown			Not Reported

	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Lyrica		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown	25 Mg, Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13254330	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006769		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13767883	NON-EXPEDITED			US-PFIZER INC-2017307967		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Local Reaction; Psoriasis; Sinusitis; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

	Humira	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13860246	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004622		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Erythema; Pruritus; Rash; Skin Exfoliation; Swelling Face	Hydroxychloroquine			S				Concordia
	Losartan			C				Not Reported
	Occuvite			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13909646	NON-EXPEDITED			US-PFIZER INC-2017369490		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13934400	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1986471			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported

	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Intra-arterial	Not Reported
	Methotrexate Sodium	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13934652	NON-EXPEDITED			US-AMGEN-USASP2017132757			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13934718	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2057591-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13936770	NON-EXPEDITED			US-PFIZER INC-2017381239			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13936771	NON-EXPEDITED			US-PFIZER INC-2017381309		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer

	Arava	S		Unk		Not Reported
	Plaquenil	S		Unk		Not Reported
	Cimzia	S		Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2017	13937166	EXPEDITED (15-DAY)		OT	PHHY2017FR127833		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Toxicity To Various Agents	Furosemide			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	11880804	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015329328		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Condition Aggravated; Diarrhoea; Fall; Gait Disturbance; Haemorrhage; Herpes Zoster; Hypoaesthesia; Joint Lock; Joint Swelling; Mobility Decreased; Rib Fracture; Skin Lesion; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Plaquenil			S		200 Mg, 1x/Day		Not Reported
	Naproxen			C		Unk		Not Reported
	Tylenol			C		Unk, Every 4 Hrs		Not Reported
	Acetaminophen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13058361	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015755		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Azathioprine Tablets			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13368244	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001909		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13368248	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001938		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Response Decreased; Treatment Failure	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13372545	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001953		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspnoea; Hypersensitivity; Mobility Decreased; Neutropenia; Synovitis	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13372548	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		84 YR	Female	CAN

						INC.-GSH201703-001980			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Hydroxychloroquine 200 Mg Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13372765	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001957		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Arthropathy; Bone Disorder; Drug Ineffective; Hip Arthroplasty; Infection; Lower Limb Fracture; Osteonecrosis; Post Procedural Infection; Therapeutic Product Effect Decreased	Plaquenil 200 Mg Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			C				Not Reported
	Hydromorphone			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13376309	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Hydroxychloroquine 200 Mg Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13380269	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001958		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Atrial Fibrillation; Chest Pain; Chills; Dyspnoea; Headache; Heart Rate Increased; Hypotension; Mouth Ulceration; Musculoskeletal Stiffness; Night Sweats; Oropharyngeal Pain; Pyrexia	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral	Daily		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Flecainide			C				Not Reported
	Gabapentin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13380270	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001983			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Balance Disorder; Bursitis; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Dry Mouth; Fall; Hand Deformity; Hypoaesthesia; Intervertebral Disc Operation; Joint Range Of Motion Decreased; Malaise; Muscle Tightness; Musculoskeletal Pain; Nausea; Nerve Compression; Nocturnal Dyspnoea; Pain In Extremity; Pruritus; Respiratory Disorder; Skin Wound; Spinal Cord Compression; Swelling; Therapeutic Product Effect Incomplete; Tracheostomy; Wound Complication; Wound Infection Staphylococcal	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Every Other Week		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13854591	EXPEDITED (15-DAY)		DE	CN-ACTELION-A-CH2017-157422		23 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericardial Effusion; Respiratory Failure; Right	Tracleer			S	Oral	125 Mg, Bid		Actelion

Atrial Enlargement; Right Ventricular Enlargement; Right Ventricular Failure; Tricuspid Valve Incompetence	Hydroxychloroquine	S	Unknown	0.1 G, Bid		Not Reported
	Prednisone	S	Unknown	30 Mg, Qd		Not Reported
	Methylprednisolone	S	Unknown	80 Mg, Bid		Not Reported
	Medrol	C		48 Mg, Qd		Not Reported
	Mycophenolate Mofetil	C		100 Mg, Qd		Not Reported
	Tacrolimus	C		1 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13868766	NON-EXPEDITED			US-PFIZER INC-2017349400		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13871032	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004637		65 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis C	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13871563	NON-EXPEDITED			US-AMGEN-USASP2017121529		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13904750	NON-EXPEDITED			US-PFIZER INC-2017366264		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939277	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017133367		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthroscopy; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	12.5 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939478	NON-EXPEDITED			US-PFIZER INC-2017378859		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium			S		Unk				Pfizer
	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939581	NON-EXPEDITED			US-PFIZER INC-2017383086		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939583	NON-EXPEDITED			US-PFIZER INC-2017381076		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939594	NON-EXPEDITED			US-PFIZER INC-2017382940		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939701	EXPEDITED (15-DAY)		LT	AU-ACCORD-057950			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Methotrexate			S				Accord
	Montelukast			S				Accord
	Plaquenil			S				Not Reported

	Azathioprine			S						Not Reported
	Xolair			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939917	EXPEDITED (15-DAY)		OT	RU-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004979		29 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Ptosis; Iiird Nerve Paresis	Plaquenil			S	Oral			Concordia
	Prednisolon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939918	EXPEDITED (15-DAY)		HO	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005011		68 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Albumin Decreased; Complement Factor C3 Decreased; Complement Factor C4 Decreased; Creatinine Urine Decreased; Cytomegalovirus Duodenitis; Duodenal Ulcer; Haematochezia; Haematuria; Henoch-Schonlein Purpura; Hypersensitivity Vasculitis; Infection Reactivation; Kidney Fibrosis; Malaise; Off Label Use; Palpable Purpura; Proteinuria; Rash; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Cisplatin			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Etoposide			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13939932	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP006876		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	428 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1500 Mg, Bid		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Percocet /00446701/			C	Unknown	Unk		Not Reported
	Percocet /00446701/			C				Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Oxycodone Terephthalate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13940750	NON-EXPEDITED			US-AMGEN-USASP2017134595		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Hypersensitivity; Injection Site Reaction; Liver Function Test Increased; Swollen Tongue; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Auranofin			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Humira			S	Unknown	Unk			Not Reported
	Leflunomide			S	Unknown	Unk			Not Reported
	Rituximab			C		Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2017	13943152	NON-EXPEDITED			US-AMGEN-USASP2017132025		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Cyclosporin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13368246	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer;	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Inflammation; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13372764	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001955		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13758374	NON-EXPEDITED			US-PFIZER INC-2017305734		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

	Orencia	S	Unk		Not Reported
	Rituxan	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13929380	NON-EXPEDITED			US-AMGEN-USASP2017130925		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Nausea; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13945065	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005096		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Back Pain; Central Pain Syndrome; Headache; Muscle Swelling; Musculoskeletal Stiffness; Nausea; Oral Pain; Pain In Extremity; Polyarthritis; Porokeratosis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Plaquenil Tablet			S		One Tablet By Mouth Twice A Day		Concordia
	Enbrel			S				Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ambien Cr			C				Not Reported
	Insulin			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Calcium			C				Not Reported
	Mtx			C				Not Reported

		Omega 3			C						Not Reported
		Omeprazole			C						Not Reported
		Vitamin B12			C						Not Reported
		Folic Acid			C						Not Reported
		Gabapentin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13945074	EXPEDITED (15-DAY)		OT	US-SA-2017SA159563		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Herpes Zoster; Liver Function Test Increased; Mechanical Ventilation	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13945348	NON-EXPEDITED			US-PFIZER INC-2017380897		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13945945	EXPEDITED (15-DAY)		OT	MX-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-148822			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Acetylsalicylic Acid			S	Transplacental	Unk		Sun
	Prednisone			S	Transplacental	5 Mg, Daily		Mutual
	Hydroxychloroquine			S	Transplacental	200 Mg, Daily		Ipca
	Nadroparin			S	Transplacental	0.6 Ml, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2017	13945946	EXPEDITED (15-DAY)		OT	MX-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-148813		36 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Acetylsalicylic Acid			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	5 Mg, Daily		Mutual
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Nadroparin			S	Subcutaneous	0.6 Ml, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13419551	NON-EXPEDITED			US-CELGENEUS-USA-2017039712		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Sinusitis	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Oral			Not Reported
	Topicort			C	Topical			Not Reported
	Taclonex			C	Topical			Not Reported

	Celebrex			C	Oral					Not Reported
	Decadron			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13813831	NON-EXPEDITED			US-PFIZER INC-2017327417		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Oral	20 Mg, Weekly(Once A Week)		Not Reported
	Prednisone			S		5 Mg, Daily		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13833889	NON-EXPEDITED			US-AMGEN-USASP2017114949		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Lipenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13895925	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004783			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid	Plaquenil			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia

Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Leflunomide		S	Oral	Not Reported
	Leflunomide		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Penicillin		S	Unknown	Not Reported
	Aspirin		S	Unknown	Not Reported
	Tylenol		C		Not Reported
	Pregabalin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13898375	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017126284			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk Unk, Qwk (Friday)		Amgen
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Prednisone			C		9 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13913865	NON-EXPEDITED			US-PFIZER INC-2017365725		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13923862	NON-EXPEDITED			US-PFIZER INC-2017375693		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Cyclosporin			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13939502	NON-EXPEDITED			US-PFIZER INC-2017379184		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13947335	NON-EXPEDITED			US-AMGEN-USASP2017134664		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13947446	NON-EXPEDITED			US-AMGEN-USASP2017133723		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13947896	NON-EXPEDITED			US-AMGEN-USASP2017134610			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13947939	NON-EXPEDITED			US-PFIZER INC-2017383092		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948125	NON-EXPEDITED			US-PFIZER INC-2017387217		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948143	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005135			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Herpes Zoster; Liver Function Test Increased; Mechanical Ventilation	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13948313	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Male	CAN

INC.-GSH201709-005076

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Mobility Decreased; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Zostavax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13813935	NON-EXPEDITED			US-PFIZER INC-2017328477		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Lipenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13821520	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-009507513-1707USA012436		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Bypass; Overdose; Suicide Attempt	Prinivil			S	Oral	40 Mg, Qd		Merck
	Benztropine Mesylate			S	Oral	1 Mg, Bid (Twice A Day)		Merck
	Methotrexate			S		8 Tablets, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Not Reported

	Hydroxychloroquine Sulfate	S			Not Reported
	Folic Acid	S	1 Mg, Qd		Not Reported
	Fluoxetine	S	20 Mg, Once Daily		Not Reported
	Prazosin	S	1 Mg, Tid		Not Reported
	Prazosin	S			Not Reported
	Prazosin	S			Not Reported
	Prazosin	S			Not Reported
	Sucralfate	S	4 G, Qd (Daily)		Not Reported
	Primidone	S	50 Mg, Bid		Not Reported
	Primidone	S			Not Reported
	Olanzapine	S	15 Mg, Qd		Not Reported
	Olanzapine	S			Not Reported
	Pantoprazole	S	40 Mg, Qd		Not Reported
	Hydroxyzine	S	25 Mg, Tid		Not Reported
	Hydroxyzine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13838914	NON-EXPEDITED			US-PFIZER INC-2017338938		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13859746	NON-EXPEDITED			US-PFIZER INC-2017345908		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13868329	NON-EXPEDITED			US-AMGEN-USASP2017121426			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13904517	EXPEDITED (15-DAY)		DE, OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004837		66 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Distension; Abdominal Pain; Abdominal Sepsis; Diverticular Perforation; Multiple Organ Dysfunction Syndrome; Peritonitis Bacterial	Plaquenil			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Mabthera			S	Intravenous drip			Not Reported
	Calcimagon-D3			C				Not Reported
	Lisitril Comp			C				Not Reported
	Vi-De 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13932844	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2017133050		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cytopenia; Renal Failure; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	Unk			Not Reported
	Prednisone			C	Oral	5 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952283	NON-EXPEDITED			US-AMGEN-USASP2017136264		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Liver Function Test Increased; Rash	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952660	EXPEDITED (15-DAY)		OT	CA-ROCHE-1990184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952945	EXPEDITED (15-DAY)		OT	CA-ROCHE-1989628		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown	Not Reported
	Acetaminophen			S	Unknown	Not Reported
	Dilaudid			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13953114	EXPEDITED (15-DAY)		OT	US-ROCHE-1988515			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthroscopy; Cholecystectomy; Constipation; Drug Hypersensitivity; Fall; Fatigue; Fibromyalgia; Fractured Coccyx; Hypertension; Joint Injury; Nasal Congestion; Nasal Injury; Nephrolithiasis; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Ineffective; Vomiting; Weight Increased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	8 Tablets		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Voltaren			S	Unknown			Not Reported
	Cimzia			C				Not Reported
	Orencia			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13953490	NON-EXPEDITED			US-PFIZER INC-2017384980		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Etodolac			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13955550	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyspepsia; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13658923	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-143238		12 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Borderline Leprosy; Tuberculoid Leprosy	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Mycophenolate			S	Unknown	3 G, Daily		Not Reported
	Prednisone			S	Unknown	15 Mg, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13957244	EXPEDITED (15-DAY)		OT	CA-ROCHE-1990242		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960427	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005136			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2017	13960764	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017822		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Cranial Nerve Injury; Drug Hypersensitivity; Herpes Zoster; Nodule; Pain In Extremity; Rheumatoid Factor Positive; Synovitis	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13762397	NON-EXPEDITED			US-PFIZER INC-2017304539		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil Sulfate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Methotrexate Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13858421	NON-EXPEDITED			US-AMGEN-USASP2017119033		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis; Drug Ineffective; Fatigue; Infection; Musculoskeletal Stiffness; Neck Pain; Pain	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13881933	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004737		37 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mechanical Urticaria; Urticaria; Urticaria	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Bassado			S	Oral			Not Reported
	Dicloreum			S	Oral			Not Reported

	Medrol		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13962660	EXPEDITED (15-DAY)		OT	CA-ROCHE-1991452		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Lozide (Canada)			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13962962	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017872		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex

Drug Intolerance; Rheumatoid Arthritis; Type 2 Diabetes Mellitus; Wound Infection	Apo-Leflunomide	S	Unknown	Unk		Apotex
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Naprosyn /00256201/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13963024	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005101		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil Tablet			S	Oral	Every Other Day		Concordia
	Plaquenil Tablet			S	Oral	Every Other Day		Concordia
	Plaquenil Tablet			S	Oral	Every Other Day		Concordia
	Plaquenil Tablet			S	Oral	Every Other Day		Concordia
	Rapiacta			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Bisphosphonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13963026	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005112		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13963027	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011846		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Limb Injury; Pelvic Fracture; Staphylococcal Infection; Wound	Hydroxychloroquine			S				Concordia
	Xeljanz			S		5 M Twice A Day		Not Reported
	Methotrexate Sodium			S		2.5 Mg, 5 Per Week		Not Reported
	Leucovorin			S				Not Reported
	Meloxicam			S		7.5, 2 Per Day		Not Reported
	Protonix			C				Not Reported
	Montelukast			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13963079	NON-EXPEDITED			US-PFIZER INC-2017391371		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13964113	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Omeprazole			C				Not Reported
	Irbesartan			C				Not Reported
	Diltiazem			C				Not Reported

	Trazodone			C						Not Reported
	Levothyroxine			C						Not Reported
	Bupropion			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2017	13965646	NON-EXPEDITED			US-PFIZER INC-2017391753		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oral Pain	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Metoprolol Tartrate			C	Oral	50 Mg, 2x/Day [Take 1 Tablet By Oral Route 2 Tablet Times Every Day With Meals]		Not Reported
	Ambien			C	Oral	Take 1 Tablet By Oral Route Every Day At Bedtime		Not Reported
	Aspirin			C	Oral	Take 1 Tablet By Oral Route Every Day		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Sertraline			C	Oral	Take 1 Tablet By Oral Route 2 Times Every Day		Not Reported
	Furosemide			C	Oral	Take 1 Tablet By Oral Route Every Day		Not Reported
	Actemra			C	Intravenous (not otherwise specified)	Infuse (8 Mg/Kg) By Intravenous Route Every 4 Weeks Over Not To Exceed 800 Mg Per Infusion		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13535369	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011518			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Colitis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling	Apo-Amlodipine	S	Oral	5 Mg, Qd		Apotex
	Apo-Amlodipine	S	Oral	5 Mg, Unk		Apotex
	Depo-Medrol	S	Intramuscular	120 Mg, Unk		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Asacol	C	Unknown	800 Mg, 3 Every 1 Day		Not Reported
	Atacand Plus	C	Unknown	Unk, Qd		Not Reported
	Bisoprolol Fumarate	C	Unknown	2.5 Mg, Unk		Not Reported
	Cholecalciferol	C	Unknown	Unk, Qd		Not Reported
	Ferrous Gluconate	C	Oral	300 Mg, Unk		Not Reported
	Folic Acid	C	Oral	5 Mg, Unk		Not Reported
	Methotrexate Sodium	C	Unknown	Unk, Q.Wk.		Not Reported
	Tylenol /00020001/	C	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13849512	NON-EXPEDITED			US-PFIZER INC-2017340837		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13902842	EXPEDITED (15-DAY)			CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004744		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Plaquenil			S	Oral			Concordia

	Calcium			C					Not Reported
	Xeljanz			C					Not Reported
	Tylenol			C					Not Reported
	Humira			C					Not Reported
	Enbrel			C					Not Reported
	Rituxan			C					Not Reported
	Orencia			C					Not Reported
	Arava			C					Not Reported
	Actemra			C					Not Reported
	Cimzia			C					Not Reported
	Prednisone			C					Not Reported
	Folic Acid			C					Not Reported
	Mtx			C					Not Reported
	Kenalog			C					Not Reported
	Remicade			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13909420	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2017127816		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicectomy; Cardiac Ablation; Depressed Mood; Finger Deformity; Gastrointestinal Disorder; Headache; Hysterectomy; Influenza Like Illness; Limb Discomfort; Nausea; Pleuropericarditis; Rheumatoid Arthritis; Synovitis; Vitamin D Deficiency	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	10 G, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Ginger			C	Oral	500 Mg, Unk (Takes On Occasion)		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13920960	NON-EXPEDITED			US-PFIZER INC-2017371913		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Lyrica				S		Unk			Pfizer
	Hcq				S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13927427	NON-EXPEDITED			US-AMGEN-USASP2017130082			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13945522	NON-EXPEDITED			US-PFIZER INC-2017383043		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13947747	EXPEDITED (15-DAY)		OT	CA-ROCHE-1988365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Humira			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966941	EXPEDITED (15-DAY)		DS	NO-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005113		24 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Visual Impairment	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966942	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005131		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Vision Blurred; Visual Impairment	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966943	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005133		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Plaquenil Tablet			S				Concordia
	Orencia			C				Not Reported
	Arava			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13966975	EXPEDITED (15-DAY)		OT	CA-ROCHE-1991498		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra	S	Unknown	Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967090	NON-EXPEDITED			US-AMGEN-USASP2017138277		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967234	NON-EXPEDITED			US-AMGEN-USASP2017138474		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphadenopathy; Rash	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967326	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Polyneuropathy; Rash	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Unknown			Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967435	NON-EXPEDITED			US-PFIZER INC-2017393280			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection; Nausea	Xeljanz			S		5 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967659	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010640		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dermatomyositis; Diarrhoea; Drug Ineffective; Foot Fracture; Hypertension; Infusion Related Reaction; Migraine; Off Label Use; Pain In Extremity; Poor Venous Access; Post-Traumatic Neck Syndrome; Rhinorrhoea; Road Traffic Accident; Thrombophlebitis	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	On Day 1 And Day 15		Not Reported
	Zoplicone			C				Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Diflucan			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Euro-D			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Methylprednisolone			C				Not Reported
	Prednisone			C				Not Reported

	Sulfatrim	C		Not Reported
	Vitamin B12	C		Not Reported
	Cholecalciferol	C		Not Reported
	Sumatriptan	C		Not Reported
	Bactrim	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967718	EXPEDITED (15-DAY)		OT	FR-BAYER-2017-171856		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Jaydess			S	Intra-uterine	14 Mcg/24hr, Cont		Bayer
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13968062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017868		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intracranial Pressure Increased; Meningitis; Meningitis Aseptic	Apo-Hydroxyquine			S	Unknown			Apotex
	Cimzia			S	Unknown			Not Reported
	Salazopyrin			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13972947	EXPEDITED (15-DAY)		DS	CA-SA-2017SA166551		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)		
	Humira	S	Subcutaneous	Doaage Form For Suspect Drug Humira : Solution Subcutaneous.	Not Reported
	Humira	S	Subcutaneous	Doaage Form For Suspect Drug Humira : Solution Subcutaneous.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Percocet	C	Unknown		Not Reported
	Ramipril	C			Not Reported
	Paracetamol/Oxycodone Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13099718	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Treatment Failure; Vomiting	Orencia	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Estradiol	C			Not Reported
	Furosemide	C			Not Reported
	Valsartan	C			Not Reported
	Xalatan	C			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C			Not Reported
	Atasol (Acetaminophen/Caffeine Citrate/Codeine Phosphate)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13973978	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003575		63 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Burning Sensation; Erythema; Leukocytosis; Neutrophil Count Increased; Oedema; Pruritus; Pyrexia; Rash Pustular; Rebound Effect; Red Blood Cell Sedimentation Rate Increased; Skin Exfoliation; Skin Exfoliation	Plaquenil Tablet			S				Concordia
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13973985	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005149		21 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Intentional Overdose; Tachycardia; Tinnitus	Plaquenil 200 Mg Tablet	S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13974795	NON-EXPEDITED		OT	US-AMGEN-USASP2017138442		95 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pancytopenia	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13975721	NON-EXPEDITED			US-PFIZER INC-2017397150		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Etodolac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13976248	NON-EXPEDITED			US-AMGEN-USASP2017139241		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13976469	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166684		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13976590	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166708		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate Sodium	S	Oral			Not Reported
	Methotrexate Sodium	S	Oral			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Prednisone	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13977103	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005265		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Spinal Column Injury; Treatment Failure	Plaquenil			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13977676	DIRECT					55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Substitution Issue; Therapy Non-Responder	Hydroxychloroquine	S	Oral	Quantity:1 Tablet(S);		Ranbaxy
	Cozaar	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	13978281	EXPEDITED (15-DAY)		OT	PHHY2017AU133992		77 YR	Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate			S	Unknown			Novartis
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	10-20 Mg, Unk		Not Reported
	Prolia			C	Unknown			Not Reported
	Piroxicam			C	Unknown	10 Mg, Prn		Not Reported
	Tramadol			C	Unknown	50 Mg, Bid		Not Reported
	Doxycycline			C	Unknown	50 Mg, Qd		Not Reported
	Gold			C	Unknown			Not Reported
	Plavix			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	10405636	EXPEDITED (15-DAY)		HO	US-H14001-14-00388		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Drug Interaction	Hydroxychloroquine			S	Unknown			Hikma
	Hydroxychloroquine			S	Unknown			Hikma
	Ciprofloxacin			S	Unknown			Hikma
	Rifampin			S	Unknown			Not Reported
	Rifampin			S	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13855796	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1046329		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Erythema	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13858096	EXPEDITED (15-DAY)		OT	US-UCBSA-2017031303			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Pain; Drug Ineffective; Dyspepsia; Headache; Increased Tendency To Bruise; Insomnia; Myalgia; Rheumatoid Arthritis	Cimzia			S		Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S	Oral	Higher Than 15 Mg Every Week		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tofacitinib Citrate			C				Not Reported
	Orencia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13885705	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017122984		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Autoimmune Thyroiditis; Conjunctivitis; Cough; Depression; Dry Eye; Fatigue; Fear Of Injection; Fibromyalgia; Hypoaesthesia; Insomnia; Lacrimation Decreased;	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd (200 Mg 2 Tablets)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported

Ocular Hyperaemia; Paraesthesia; Rash; Rheumatoid Arthritis; Therapeutic Response Decreased; Tinnitus; Weight Increased	Methotrexate	S	Unknown	25 Mg, Qwk (2.5 Mg 10 Tablets)	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qwk (2.5 Mg 10 Tablets)	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Rheumate	C	Oral	500 Mg, Qd	Not Reported
	Rheumate	C	Oral	500 Mg, Qd	Not Reported
	Synthroid	C	Oral	75 Mug, Qd	Not Reported
	Restasis	C	Ophthalmic	0.05 % 1 Instill Drop, Q12h	Not Reported
	Restasis	C	Ophthalmic	0.05 % 1 Instill Drop, Q12h	Not Reported
	Meloxicam	C		15 Mg, Qod	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	100 Mg, Qwk	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd (200 Mg 2 Tablets)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13962753	EXPEDITED (15-DAY)		OT	CA-ROCHE-1991479		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980443	EXPEDITED (15-DAY)		CA, HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005152			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Oesophageal Atresia	Plaquenil 200 Mg Tablet			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980444	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005227		39 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epiglottitis	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980445	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005228		31 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980446	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005229		74 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980448	EXPEDITED (15-DAY)		OT	SK-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005268		10 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Calcinosis; Dermatomyositis; Disease Progression; Drug Ineffective; Lipoatrophy; Off Label Use; Weight Decreased	Plaquenil			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Cyclosporin A			S	Unknown			Not Reported
	Immunoglobulin Iv			S	Unknown	High Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13980475	NON-EXPEDITED			US-AMGEN-USASP2017139363		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Sulindac			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13981155	EXPEDITED (15-DAY)		DE, OT	FR-ROCHE-1989744			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Bacterial Infection; Fungal Infection; Infection; Injection Related Reaction; Parvovirus B19 Infection Reactivation;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Rituximab			S				Not Reported

Pneumonia; Skin Bacterial Infection; Urinary Tract Infection Bacterial	Rituximab	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S			Not Reported
	Tocilizumab	S			Not Reported
	Tocilizumab	S			Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Infliximab	S	Unknown	Median Dose Of 5 Mg/Kg At Weeks 0, 2, 6 And Every 6 Weeksin	Not Reported
	Infliximab	S			Not Reported
	Infliximab	S			Not Reported
	Infliximab	S			Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S			Not Reported
	Etanercept	S			Not Reported
	Etanercept	S			Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S			Not Reported
	Adalimumab	S			Not Reported
	Adalimumab	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Anakinra	S			Not Reported
	Anakinra	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Cyclophosphamide	S	Unknown		Not Reported
	Cyclophosphamide	S			Not Reported
	Cyclophosphamide	S			Not Reported
	Cyclophosphamide	S			Not Reported
	Cyclosporine	S	Unknown		Not Reported
	Cyclosporine	S			Not Reported

	Cyclosporine			S					Not Reported
	Cyclosporine			S					Not Reported
	Azathioprine			S	Unknown				Not Reported
	Azathioprine			S					Not Reported
	Azathioprine			S					Not Reported
	Azathioprine			S					Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine			S					Not Reported
	Hydroxychloroquine			S					Not Reported
	Hydroxychloroquine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13981309	NON-EXPEDITED			US-PFIZER INC-2017397630			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13981412	NON-EXPEDITED			US-PFIZER INC-2017397925			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13982358	NON-EXPEDITED			US-PFIZER INC-2017399679			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Methotrexate Sodium				S		Unk			Pfizer
	Plaquenil				S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13982373	NON-EXPEDITED			US-PFIZER INC-2017397490		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13982666	NON-EXPEDITED			US-AMGEN-USASP2017140165			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13984762	NON-EXPEDITED			US-AMGEN-USASP2017140551		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2017	13984929	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	12934197	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2015SA079200		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Nausea; Pain In Extremity; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased; Staphylococcal Infection; Therapeutic Product Effect Incomplete; Vomiting	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Flagyl			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous.		Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13966937	EXPEDITED (15-DAY)		OT	NO-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005104			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinal Atrophy; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13985088	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005360			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Lethargy; Malaise; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13985265	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported

Decreased	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	Unk		Not Reported
	Coversyl /00790702/	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Leucovorin /00566701/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13985993	NON-EXPEDITED			US-PFIZER INC-2017401796		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13987940	NON-EXPEDITED			US-PFIZER INC-2017401751		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Verapamil Hcl			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Tramadol Hcl			S		Unk		Pfizer
	Oxycodone Hydrochloride			S		Unk		Pfizer
	Citalopram Hbr			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2017	13988476	EXPEDITED (15-DAY)		OT	CA-SA-2017SA134294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Retinopathy	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Tramadol			C	Unknown			Not Reported
	Pennsaid			C		Dose:5drops Route; Topical		Not Reported
	Acetaminophen			C	Unknown	Frequency: Prn Od		Not Reported
	Acetaminophen			C	Unknown	Frequency: Prn Od		Not Reported
	Caffeine			C	Unknown	Frequency: Prn Od		Not Reported
	Esomeprazole/Naproxen			C	Oral	Frequency: Prn Od		Not Reported
	Zantac			C	Oral	Frequency: Bid Prn		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Abatacept			C	Unknown			Not Reported
	Demerol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	12946805	EXPEDITED (15-DAY)		DS, HO, OT	CA-VALIDUS PHARMACEUTICALS		60 YR	Female	CAN

LLC-CA-2016VAL002986

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Nausea; Pain In Extremity; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased; Staphylococcal Infection; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Arava			S	Oral	400 Mg, Unk		Not Reported
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Flagyl /00012501/			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram(S);Daily		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Intracardiac	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Misoprostol			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13264798	EXPEDITED (15-DAY)		OT	CA-SA-2017SA029915		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bladder Disorder; Diarrhoea; Drug	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Ineffective; Drug Intolerance; Hypersensitivity; Liver Function Test Increased; Nausea; Rash; Treatment Failure; Urinary Retention; Vomiting	Methotrexate Sodium	S	Oral		Not Reported
	Losec	C	Unknown		Not Reported
	Oxycocet	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13726080	EXPEDITED (15-DAY)		OT	US-SA-2017SA118485		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Humira			S	Subcutaneous	Form Solution		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13882867	NON-EXPEDITED			US-PFIZER INC-2017334953		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Xeljanz Xr			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 Mg, Weekly		Unknown
	Plaquenil			S		Unk		Not Reported
	Ambien Cr			C		12.5 Mg, 1x/Day(1 Every Bedtime)		Not Reported
	Calcium			C		500 Mg, 1x/Day		Not Reported
	Gabapentin			C	Oral	100 Mg, 1x/Day (1 Po Qhs)		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	200 Mg, 2x/Day		Not Reported
	Omeprazole			C		40 Mg, 1x/Day		Not Reported
	Wellbutrin Sr			C		150 Mg, 2x/Day		Not Reported
	Insulin Human			C		Unk, Weekly (29g X 1/2 1ml)		Not Reported
	Omega 3			C		1000 Mg, 1x/Day		Not Reported
	Vitamin B			C		12.75 Ml, Unk (2x A Month)		Not Reported
	Folic Acid			C		2 Mg, 1x/Day		Not Reported
	Iron			C	Intravenous (not otherwise specified)	Unk Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13904904	EXPEDITED (15-DAY)		OT	US-ROCHE-1982363		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Herpes Zoster; Liver Function Test Increased; Mechanical Ventilation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

		Sulfasalazine			S	Unknown					Not Reported
		Plaquenil			S	Unknown					Not Reported
		Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13966938	EXPEDITED (15-DAY)		OT	NO-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005105			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Ischaemia; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13989248	EXPEDITED (15-DAY)		HO	US-ABBVIE-17K-163-2105463-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Appendicectomy; Constipation; Depressed Mood; Diarrhoea; Finger Deformity; Finger Deformity; Headache; Hysterectomy; Influenza Like Illness; Mononeuropathy Multiplex; Musculoskeletal Discomfort; Nausea; Pleuropericarditis; Rheumatoid Arthritis; Supraventricular Tachycardia; Synovitis; Vitamin D Deficiency	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Ginger			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13989275	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS		59 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13989281	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005278		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Infliximab		S	Intravenous (not otherwise specified)		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Oxycodone Hydrochloride/Paracetamol		C			Not Reported
					Oxycodone Terephthalate		C			Not Reported
					Percocet		C			Not Reported
					Ramipril		C			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
20-Sep-2017	13989284	EXPEDITED (15-DAY)		OT		CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005359		64 YR	Female	CAN
Preferred Term	**Product**		**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Plaquenil Tablet				S	Oral				Concordia
	Arava				S	Oral				Not Reported
	Actemra				S	Unknown				Not Reported
	Enbrel				S	Subcutaneous				Not Reported
	Methotrexate Sodium				S	Unknown				Not Reported
	Orencia				S	Unknown				Not Reported
	Simponi				S	Subcutaneous				Not Reported
	Cyclobenzaprine				C					Not Reported
	Desoximetasone				C					Not Reported
	Hydroxychloroquine				C					Not Reported
	Leflunomide				C					Not Reported
	Prednisone				C					Not Reported
	Prednisone Acetate				C					Not Reported
	Tylenol				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13989425	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005379		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Arthroplasty; Knee Arthroplasty; Mobility Decreased; Pain; Swelling	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Ramipril			C				Not Reported
	Acetaminophen Oxycodone Hydrochloride			C				Not Reported
	Acetaminophen Oxycodonehydrochloride Oxycodone Terephthalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13989429	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005391		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Xeljanz			S	Oral					Not Reported
	Folic Acid			C						Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990261	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2105311-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Ineffective; Drug Ineffective; Wound Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990528	NON-EXPEDITED			US-PFIZER INC-2017406775		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990652	NON-EXPEDITED			US-PFIZER INC-2017403235		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990668	NON-EXPEDITED			US-PFIZER INC-2017401123		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Mycophenolate			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990688	NON-EXPEDITED			US-PFIZER INC-2017403181		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990733	NON-EXPEDITED			US-PFIZER INC-2017405810		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2017	13990987	NON-EXPEDITED			US-PFIZER INC-2017403597		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

Diclofenac Sodium	S	Unk	Pfizer
Arava	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported
Meloxicam	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	12945874	EXPEDITED (15-DAY)		DS, HO, OT	CA-BAUSCH-BL-2016-027688		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Nausea; Pain In Extremity; Platelet Count Increased; Staphylococcal Infection; Therapeutic Product Effect Incomplete; Vomiting	Erythromycin Estolate			S	Unknown			Bausch And Lomb
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Flagyl			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg Weekly		Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	20 Mg Weekly		Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Misoprostol			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Arthrotec			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13762055	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004012		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13767935	NON-EXPEDITED			US-PFIZER INC-2017308579		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13915112	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004864			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil Tablet			S	Oral	1 Tablet Daily And 2 Tablets Daily Alternately		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13919918	NON-EXPEDITED			US-PFIZER INC-2017367479		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13963025	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005102		49 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neuropsychiatric Lupus; Off Label Use; Psychotic Disorder; Rash; Subacute Cutaneous Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Risperidone			C				Not Reported
	Olanzapine			C				Not Reported
	Chlorprothixene			C				Not Reported
	Valproate Sodium			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13973158	NON-EXPEDITED			US-AMGEN-USASP2017138281		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Xeljanz	C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13985850	NON-EXPEDITED			US-PFIZER INC-2017401322		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13994713	EXPEDITED (15-DAY)		OT	CA-ROCHE-1994430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13994755	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		71 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13994756	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005387			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Urticaria	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arthrotec			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate Sodium	S	Intramuscular		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Mefenamic Acid	C			Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13994763	NON-EXPEDITED			US-AMGEN-USASP2017142216		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13995032	NON-EXPEDITED			US-ORION CORPORATION ORION PHARMA-TREX2017-1757			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported

	Mycophenolate Mofetil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13995596	NON-EXPEDITED			US-PFIZER INC-2017404123		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Weight Increased	Methotrexate Sodium			S	Oral	15 Mg, Weekly (6 Tabs Po Weekly)		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day (1 Po Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13996204	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005395		19 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Peritonitis Lupus	Plaquenil			S	Oral			Concordia
	Predonine			C				Not Reported
	Predonine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2017	13996207	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005401		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	12144337	NON-EXPEDITED			US-AMGEN-USASP2016024349		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13767550	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017107208		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Back Pain; Chills; Diarrhoea; Diverticulitis; Dyspepsia; Ear Congestion; Fatigue; Gait Disturbance; Gallbladder Operation; Malaise; Neuritis; Pain; Rheumatoid Arthritis; Sinus Congestion; Skin Disorder; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Calcium			C		500 Mg, Bid		Not Reported
	Fish Oil			C		1000-1200mg, Qd		Not Reported
	One A Day			C		Unk Unk, Qd		Not Reported
	Vitamin C			C	Oral	1000-1200mg, Qd		Not Reported
	Vitamin D2			C		1000 Units, Qd		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13781408	NON-EXPEDITED		OT	US-AMGEN-USASP2017107622		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Atrophic Vulvovaginitis; Carotid Artery Disease; Carotid Artery Occlusion; Chronic Kidney Disease; Clostridium Difficile Infection; Cognitive Disorder; Cough; Deafness; Decreased Appetite; Depression; Diabetes Mellitus; Diabetic Ketoacidosis; Diabetic Neuropathy; Diarrhoea; Dizziness; Drug Dependence; Dry Eye; Dysphagia; Essential Hypertension; Extrapyramidal Disorder; Fall; Fatigue; Gait Disturbance; Haemorrhagic Disorder; Hepatic Enzyme Increased; Hyperlipidaemia; Hypersensitivity Vasculitis; Hypoaesthesia; Impaired Gastric Emptying; Infection; Iron Deficiency Anaemia; Joint Arthroplasty; Joint Range Of Motion Decreased; Malaise; Myopia; Nasal Congestion; Nausea; Neck Pain; Orthostatic Hypotension;	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk Unk, Qwk (2.5 Mg Tablet 6 Tablets By Mouth 1 Time A Week)		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Cefaclor			C	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported
	Buspar			C	Oral	15 Mg, Tid		Not Reported
	Neostigmine Bromide			C	Unknown	Unk		Not Reported
	Tresiba			C	Subcutaneous	45 Unit, Qd		Not Reported
	Pseudoephedrine			C	Unknown	Unk		Not Reported
	Minocycline Hcl			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Reglan			C	Unknown	Unk		Not Reported
	Robinul			C	Unknown	Unk		Not Reported
	Claritin			C	Oral	10 Mg, Qd (1 Time A Day As Needed)		Not Reported
	Neurontin			C	Oral	600 Mg, Bid		Not Reported
	Bentyl			C	Oral	10 Mg, Qd		Not Reported

Osteoarthritis; Osteopenia; Palpitations; Paraesthesia; Presbyopia; Purpura; Pyrexia; Radiculopathy; Rash; Restless Legs Syndrome; Retinal Degeneration; Rheumatoid Arthritis; Rotator Cuff Syndrome; Spinal Osteoarthritis; Stomatitis; Syncope; Systemic Lupus Erythematosus; Toothache; Treatment Failure; Urinary Hesitation	Lasix	C	Oral	20 Mg, Qd	Not Reported
	Benadryl	C		25 Mg, As Necessary	Not Reported
	Desyrel	C	Oral	150 Mg, Qd (1 Tablet (150 Mg) By Mouth Every Night At Bedtime)	Not Reported
	Novolog	C	Subcutaneous	Unk (6 Units Breakfast, 10 Units Lunch, 9 Units Supper)	Not Reported
	Seroquel	C	Oral	50 Mg, Qd (Take 1 Tablet (50 Mg Total) By Mouth Every Night At Bedtime)	Not Reported
	Lexapro	C	Oral	40 Mg, Qd (Take 2 Tablets (40 Mg Total) By Mouth 1 Time Per Day)	Not Reported
	Ativan	C	Oral	0.5 Mg, Unk (1 Tablet Bid And 1 Tablet At Hs, Do Not Exceed 3 Tablets In 24)	Not Reported
	Aquaphor	C		Unk (Apply 1 Application To Affected Area Every Night At Bedtime Apply To Feet)	Not Reported
	Florastor	C	Oral	250 Mg, Bid	Not Reported
	Levothyroxine	C	Oral	50 Mug, Qd	Not Reported
	Zantac	C	Unknown	150 Mg, Tid	Not Reported
	Aspirin	C	Oral	81 Mg, Qd	Not Reported
	Calcium Carbonate	C	Oral	600 Mg, Bid	Not Reported
	Prilosec	C	Oral	20 Mg, Bid (Take 1 Capsule By Mouth 2 Times A Day Befbre Meals)	Not Reported
	Vitamin D3	C	Oral	1000 Unit, Bid	Not Reported
	Glucagen	C	Unknown	1 Mg, Unk (1 Mg Injection Kit)	Not Reported
	Pravachol	C	Oral	40 Mg, Qd	Not Reported

	Lopressor	C	Oral	25 Mg, Bid		Not Reported
	Colchicine	C	Oral	0.6 Mg, Qd		Not Reported
	Tucks Hemorrhoidal	C	Topical	Unk Unk, Qd		Not Reported
	Melatonin	C	Oral	3 Mg, Qd		Not Reported
	Anusol	C	Topical	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13844128	NON-EXPEDITED			US-PFIZER INC-2017339284		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13863450	NON-EXPEDITED			US-PFIZER INC-2017348113			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Celebrex			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13999379	EXPEDITED (15-DAY)		OT	CA-ROCHE-1966966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Stopped Due To Problems With Lungs		Not Reported

	Cimzia	S	Unknown			Not Reported
	Orencia	S	Unknown	4-6 Months Duration		Not Reported
	Humira	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Xeljanz	C	Oral	5mg/Bid (2x/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	13999555	NON-EXPEDITED			US-AMGEN-USASP2017143660		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14001915	EXPEDITED (15-DAY)			CA-APOTEX-2017AP017221		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Celebrex			S	Oral			Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14002633	NON-EXPEDITED			US-AMGEN-USASP2017143271		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14004715	EXPEDITED (15-DAY)		OT	CA-ROCHE-1993177		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 1 Year		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 2 Months, Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 1 Month		Not Reported
	Kineret			S	Subcutaneous	Therapy Duration: 2 Years, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes; Solut		Not Reported
	Leflunomide			S	Oral	Therapy Duration: 7 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14004787	NON-EXPEDITED			US-PFIZER INC-2017407312		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14004849	NON-EXPEDITED			US-PFIZER INC-2017407567		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2017	14004919	NON-EXPEDITED			US-PFIZER INC-2017408307		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2017	13891818	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP016759		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Nasopharyngitis;	Apo-Meloxicam			S	Unknown			Apotex
	Methotrexate			S	Unknown	0.6 Ml, Q.Wk.		Not Reported

Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	0.4 Ml, Unk		Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	12124095	NON-EXPEDITED			US-PFIZER INC-2016119829		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Celebrex			S		200 Mg, Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Naproxen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13297067	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001415		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bladder Disorder; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Liver Function Test Increased; Nausea; Rash; Treatment Failure; Urinary Retention; Vomiting	Hydroxychloroquine Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Losec			C				Not Reported
	Oxycocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13443879	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2017055773		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Stevens-Johnson Syndrome; Visual Acuity Reduced	Repatha			S	Unknown	140 Mg, Q2wk		Amgen
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13946748	EXPEDITED (15-DAY)		HO, OT	PHHO2017US012448		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hypoglycaemia	Gsk2118436			S	Oral	100 Mg, Bid		Novartis
	Gsk1120212			S	Oral	1.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	600mg/400mgunk		Not Reported
	Glimepiride			S	Oral	2 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13948312	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004701		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash	Plaquenil			S	Oral			Concordia
	Prednisolone			C	Oral			Not Reported
	Prograf			C	Oral			Not Reported
	Alfacalcidol			C	Oral			Not Reported
	Beraprost			C	Oral			Not Reported
	Sennoside			C	Oral			Not Reported
	Hirudoid			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	13981104	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS			Unknown	JPN

INC.-GSH201709-005253

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006446	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005427			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Wound Infection	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported
	Penicillin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006447	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005436			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicectomy; Cardiac Ablation; Depressed Mood; Finger Deformity; Gastrointestinal Disorder; Headache; Hysterectomy; Influenza Like Illness; Limb Discomfort; Nausea;	Plaquenil			S	Unknown			Concordia
	Methorexate			S	Unknown			Not Reported
	Methorexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Pleuropericarditis; Rheumatoid Arthritis; Synovitis; Vitamin D Deficiency	Humira		S	Unknown		Not Reported
	Prednisone		C			Not Reported
	Xeljanz		C			Not Reported
	Ginger		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006709	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005439		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Plaquenil			S	Oral			Concordia
	Lansoprazole			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Cortancyl			S	Oral	Dose Reduced		Not Reported
	Paracetamol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006829	NON-EXPEDITED			US-PFIZER INC-2017409848			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006844	NON-EXPEDITED			US-PFIZER INC-2017408765		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006852	NON-EXPEDITED			US-PFIZER INC-2017410046		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006894	NON-EXPEDITED			US-PFIZER INC-2017411579			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006918	NON-EXPEDITED			US-PFIZER INC-2017408961		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14006961	NON-EXPEDITED			US-PFIZER INC-2017411423		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Humira	S	Unk		Not Reported
	Simponi	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14007513	NON-EXPEDITED			US-PFIZER INC-2017411522		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14008061	NON-EXPEDITED			US-PFIZER INC-2017410091			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14008530	EXPEDITED (15-DAY)		OT	PHHY2017CA138366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Sodium Aurothiomalate Injection Bp			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Novartis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Q2w		Not Reported

Humira	S	Subcutaneous	200 Mg, 2 In Every 1 Day	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, 2 Every 1 Day	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Dexamethasone	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Anakinra	C	Unknown		Not Reported
Ativan	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Diphenhydramine	C	Unknown		Not Reported
Kenalog	C	Intra-articular		Not Reported
Lasix	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Metered Dose	Not Reported
Oxyneo	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown		Not Reported

	Vagifem			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14008534	EXPEDITED (15-DAY)		OT	PHHY2017CA138341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Sodium Aurothiomalate Injection Bp			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Novartis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Remicade			S	Unknown	200 Mg, Unk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown	200 Mg, Bid		Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Dyclone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Enablex			C	Unknown			Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog			C	Unknown			Not Reported

	Kineret	C	Unknown	Not Reported
	Lasix	C	Unknown	Not Reported
	Loperamide	C	Unknown	Not Reported
	Norflex	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Rituxan	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14008535	EXPEDITED (15-DAY)		OT	PHHY2017CA138351		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Mg, Qd		Novartis
	Gold Sodium Thiomalate			S	Intramuscular			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Unknown	300 Mg, Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Codeine Phosphate			C	Unknown			Not Reported

	Hydromorphone	C	Unknown		Not Reported
	Pantoprazole Sodium	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown		Not Reported
	Enablex	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Kenalog	C	Intra-articular	40 Mg, Unk	Not Reported
	Kineret	C	Unknown	100 Mg, Unk	Not Reported
	Lasix	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Synthroid	C	Unknown		Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown	200 Mg, Unk	Not Reported
	Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2017	14009654	EXPEDITED (15-DAY)		OT	CA-SA-2017SA170505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Hydroxychloroquine			S	Oral			Not Reported

Administered; Drug Intolerance; Macular Degeneration	Leflunomide		S	Oral	Not Reported
	Methotrexate		C	Subcutaneous	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	13929382	NON-EXPEDITED			US-AMGEN-USASP2017131097		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear Of Injection; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	13943505	NON-EXPEDITED			US-AMGEN-USASP2017133718		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Incorrect Route Of Product Administration; Musculoskeletal Pain; Pain In Extremity; Treatment Failure	Enbrel			S	Intramuscular	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	2.5 Mg, 8 Tablets Weekly		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	13945396	NON-EXPEDITED			US-PFIZER INC-2017380627		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14010203	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005437			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiac Failure; Cardiomegaly; Cardiomyopathy; Dyspnoea; Myocarditis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14010293	NON-EXPEDITED			US-AMGEN-USASP2017144629			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14010415	EXPEDITED (15-DAY)		OT	CA-ROCHE-1995155		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14010901	NON-EXPEDITED			US-PFIZER INC-2017412849		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14012408	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017411764		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14012440	NON-EXPEDITED			US-AMGEN-USASP2017142470		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14012850	EXPEDITED (15-DAY)		HO	CA-BAYER-2017-177628		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue; Femur Fracture;	Aleve			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported

Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C		Unk		Not Reported
	Methotrexate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14013001	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2017GSK148226		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Leukopenia; Live Birth	Belimumab			S		10 Mg/Kg, Unk		Glaxosmithkline
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Prednisone			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14013041	NON-EXPEDITED			US-PFIZER INC-2017413714		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Proair			S		Unk		Not Reported

	Triamterene			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2017	14013184	NON-EXPEDITED			US-AMGEN-USASP2017144864			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	13973981	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005095		35 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral	1 Tablet Daily And 2 Tablets Daily On Alternate Days		Concordia
	Rinderon [Betamethasone]			C				Not Reported
	Prograf			C				Not Reported
	Cellcept			C				Not Reported
	Pariet			C				Not Reported
	Bayaspirin			C				Not Reported
	Bonoteo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	13990752	NON-EXPEDITED			US-PFIZER INC-2017405247		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Enbrel	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14014223	NON-EXPEDITED			US-AMGEN-USASP2017145326			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14014625	EXPEDITED (15-DAY)		OT	CA-ROCHE-1997238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015418	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015419	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005449		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Auditory	Plaquenil			S	Oral			Concordia
	Nebivolol			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Simvastatin			C				Not Reported
	Paracetamol			C				Not Reported
	Nefopam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14015480	EXPEDITED (15-DAY)		HO	CA-BAYER-2017-178371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis;	Aspirin			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Vomiting; Weight Decreased	Humira	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14017542	EXPEDITED (15-DAY)		OT	US-TEVA-811071USA		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive	Hydroxychloroquine			S	Unknown	From 15 Years		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2017	14017805	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1059870		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive	Hydroxychloroquine			S	Unknown	From 15 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	13868248	NON-EXPEDITED			US-AMGEN-USASP2017121715		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Disorder	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	13945308	NON-EXPEDITED			US-PFIZER INC-2017381245		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Product Use Issue	Enbrel			S	Intramuscular	50 Mg, Qwk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	2.5 Mg, 8 Tablets Weekly		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	13973895	NON-EXPEDITED			US-AMGEN-USASP2017138363		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C		11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14018831	NON-EXPEDITED			US-PFIZER INC-2017417379		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2017	14022329	EXPEDITED (15-DAY)		LT	PHHY2017US141697		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	12492857	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016308056		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Fall; Limb Injury; Pelvic Fracture; Staphylococcal Infection; Wound	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		3 Doses A Week-7pills		Pfizer
	Methotrexate Sodium			S		12.5 Mg, Weekly (5 Per Week)		Pfizer
	Leucovorin			S		5 Mg, 1x/Day		Pfizer
	Meloxicam			S		7.5 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Protonix			C		40 Mg, 2x/Day		Not Reported
	Montelukast			C		1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	13044915	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-124430		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Long Qt Syndrome; Toxicity To Various Agents	Quinine			S	Unknown	Unk		Sun
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	13903602	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP016922		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Apo-Diclofenac			S	Unknown			Apotex
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	13996200	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005367		9 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Aspirin			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14025212	NON-EXPEDITED			US-AMGEN-USASP2017146780		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14027638	NON-EXPEDITED			US-PFIZER INC-2017419945		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2017	14027697	NON-EXPEDITED			US-PFIZER INC-2017420112		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2017	13932345	NON-EXPEDITED			US-AMGEN-USASP2017132768		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Rituxan			S	Unknown	Unk			Not Reported
	Humira			S	Unknown	Unk			Not Reported
	Cimzia			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2017	14030236	NON-EXPEDITED			US-AMGEN-USASP2017146813		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	12217808	EXPEDITED (15-DAY)		OT	CA-ROCHE-1330299		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthralgia; Arthritis; Blood Pressure Increased; Bronchitis; Bronchospasm; Chest Pain; Cough; Dizziness; Fall; Fatigue; Gastroenteritis; Headache; Headache; Hepatic Enzyme Increased; Hepatic Enzyme Increased; Hepatic Steatosis; Hot Flush; Influenza; Infusion Related Reaction; Joint Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Medication Error; Mobility Decreased; Muscle Strain; Musculoskeletal Discomfort; Musculoskeletal Pain; Nasal Congestion; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Oropharyngeal Pain; Oropharyngeal Pain; Pain In Extremity; Painful Respiration; Plantar Fasciitis; Poor Venous Access; Pruritus; Pyrexia; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis; Tendon Pain; Tracheitis; Vaginal Haemorrhage; Vomiting; Weight Increased	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Prometrium (Canada)	S	Oral			Not Reported
	Estradot	S	Unknown	Patch		Not Reported
	Methotrexate	C				Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	13999104	NON-EXPEDITED			US-AMGEN-USASL2017142341		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Hyperhidrosis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14032318	NON-EXPEDITED			US-PFIZER INC-2017422493		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk		Pfizer
	Hydroxychloroquine	S	Unk		Not Reported
	Humira	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2017	14032493	NON-EXPEDITED			US-PFIZER INC-2017422161			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	12440783	EXPEDITED (15-DAY)		DS	CA-ABBVIE-16K-028-1641589-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Chronic Sinusitis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Resistance; Dry Eye; Fibromyalgia; Impaired Work Ability; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Sjogren'S Syndrome; Spinal Pain; Therapeutic Product Effect Incomplete; Upper-Airway Cough Syndrome; Weight	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported
	Effexor			C				Not Reported
	Imuran			C				Not Reported
	Atorvastatin			C				Not Reported
	Alendronate			C				Not Reported
	Amitriptyline			C		10mg Bedtime		Not Reported
	Azathioprine			C		500 Mg Qd		Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	13930465	NON-EXPEDITED			US-PFIZER INC-2017378708		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Solganal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	13963147	NON-EXPEDITED			US-PFIZER INC-2017394966		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	13981577	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017138576		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14010206	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005453		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Restrictive Cardiomyopathy	Hydroxychloroquine			S				Concordia
	Prednisone			C		5 Mg Daily		Not Reported
	Naproxen			C				Not Reported
	Atenolol			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Benazepril			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Dexlansoprazole			C	Oral	30 To 60 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14018788	NON-EXPEDITED			US-PFIZER INC-2017417691		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14031986	NON-EXPEDITED			US-AMGEN-USASP2017148430			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2017	14033000	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-03		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Lesion	Methotrexate			S	Unknown			Westward
	Prednisone			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	13667337	EXPEDITED (15-DAY)		HO, LT, OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00008106		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Gestational Diabetes; Glucose Tolerance Impaired; Sepsis; Staphylococcal Sepsis	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia

					Prednisolone		S	Oral	Concordia
					Prednisolone		S	Oral	Concordia
					Hydroxychloroquine		S		Concordia
					Tacrolimus		S		Not Reported
					Tacrolimus		S		Not Reported
					Azathioprine		S		Not Reported
					Azathioprine		S		Not Reported
					Mycophenolate Mofetil		S		Not Reported
					Mycophenolate Mofetil		S		Not Reported
					Mycophenolate Mofetil		S		Not Reported
					Mycophenolate Mofetil		S		Not Reported
					Rituximab		S		Not Reported
					Methylprednisolone		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14009374	EXPEDITED (15-DAY)		OT	CA-SA-2017SA172274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Contusion; Epistaxis; Haemorrhage; Nausea; Throat Cancer; Thrombocytopenia; Treatment Failure	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Frequency: Q4 Weeks		Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			C	Subcutaneous			Not Reported
	Methotrexate Sodium			C	Subcutaneous			Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14025308	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005459			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Contusion; Epistaxis; Haemorrhage;	Plaquenil			S	Oral			Concordia

Nausea; Throat Cancer; Thrombocytopenia; Treatment Failure	Arava Tablet			S	Oral				Not Reported
	Arava Tablet			S	Oral				Not Reported
	Sodium Aurothiomalate			S	Intramuscular				Not Reported
	Methotrexate Sodium			C					Not Reported
	Folic Acid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14037296	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2998		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Intolerance; Inflammation; Mouth Ulceration; Rheumatoid Arthritis; Rotator Cuff Syndrome; Tooth Infection; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Indocin			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14037633	NON-EXPEDITED			US-PFIZER INC-2017424167		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Heparin Sodium			S		Unk		Unknown

	Benadryl	S	Unk		Not Reported
	Aspirin	S	Unk		Not Reported
	Darvocet	S	Unk		Not Reported
	Toradol	S	Unk		Not Reported
	Levaquin	S	Unk		Not Reported
	Plaquenil	S			Not Reported
	Relafen	S	Unk		Not Reported
	Prolia	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14037648	NON-EXPEDITED			US-PFIZER INC-2017424973			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Azulfidine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14037683	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005552		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Unknown	Every Other Week		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisolon			C				Not Reported
	L-Thyroxin			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14037731	NON-EXPEDITED			US-PFIZER INC-2017424724		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14038490	NON-EXPEDITED			US-AMGEN-USASP2017147706		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Rash; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2017	14038702	NON-EXPEDITED		OT	US-APOTEX-2017AP019077		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Resistance	Clarithromycin			S	Unknown	Unk		Apotex
	Clarithromycin			S				Apotex
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rifampin			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Ethambutol			S	Unknown			Not Reported
	Moxifloxacin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13944778	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2090968-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Anxiety; Arthralgia; Arthritis; Autoimmune Thyroiditis; Conjunctivitis; Cough; Depression; Dry Eye; Fatigue; Fear Of Injection; Fibromyalgia; Hypoaesthesia; Injection Site Pain; Injection Site Swelling; Insomnia; Joint Stiffness; Joint Swelling; Lacrimation Decreased; Ocular Hyperaemia; Paraesthesia; Rash; Therapeutic Product Effect Decreased; Tinnitus; Weight Increased	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Rheumate	C				Not Reported
	Rheumate	C				Not Reported
	Synthroid	C				Not Reported
	Restasis	C		Eye Drops		Not Reported
	Restasis	C		Eye Drops		Not Reported
	Meloxicam	C				Not Reported
	Hydroxychloroquine	C				Not Reported
	Remicade	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13966934	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005087		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Off Label Use	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13966935	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005090		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Off Label Use	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13966936	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005094		37 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Off Label Use	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	13968985	EXPEDITED (15-DAY)		OT	US-ABBVIE-17P-163-2096677-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Exposure During Pregnancy; Normal Newborn; Uterine Leiomyoma; White Blood Cell Count Decreased	Lupron Depot			S	Intramuscular			Not Reported
	Lupron Depot			S	Intramuscular			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tamoxifen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14010487	EXPEDITED (15-DAY)		DS, HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005450		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bone Density Decreased; Bone Pain; Bone Swelling; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Nail Dystrophy; Nail Pitting; Off Label Use; Psoriasis; Psoriatic Arthropathy; Psoriatic Arthropathy; Pyrexia; Skin Exfoliation; Underweight	Hydroxychloroquine	S	Unknown			Concordia
	Prednisone	S	Unknown			Not Reported
	Prednisone	S		Low-Dose Prednisone		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Minocycline Hydrochloride	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14016685	NON-EXPEDITED			US-PFIZER INC-2017417727		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14032562	EXPEDITED (15-DAY)		OT	CA-ROCHE-1702399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Humira				S	Subcutaneous				Not Reported
	Lipitor				C	Oral				Not Reported
	Xeljanz				C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14037682	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005515		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Ejection Fraction Decreased; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14044962	NON-EXPEDITED			US-AMGEN-USASP2017149537		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14045069	EXPEDITED (15-DAY)		LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005631		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Candida Infection; Chest	Hydroxychloroquine			S				Concordia
	Carvedilol			S				Not Reported

Discomfort; Diabetes Mellitus; Haemorrhage; Hand Deformity; Headache; Hypoglycaemia; Inflammation; Malaise; Nodule; Rheumatoid Arthritis; Sinonasal Obstruction	Omalizumab		S	Subcutaneous		Not Reported
	Omalizumab		S			Not Reported
	Omalizumab		S			Not Reported
	Omalizumab		S			Not Reported
	Prednisone		S			Not Reported
	Prednisone		S			Not Reported
	Naproxen		C			Not Reported
	Cortisone		C			Not Reported
	Leflunomide		C			Not Reported
	Tiotropium Bromide		C			Not Reported
	Diflucan		C			Not Reported
	Levothyroxine		C			Not Reported
	Prilosec		C			Not Reported
	Lexapro		C			Not Reported
	Albuterol		C			Not Reported
	Ventolin		C			Not Reported
	Xanax		C			Not Reported
	Vitamin D Nos		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14045467	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005556		72 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hallucination	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14045471	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005678			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pancytopenia	Plaquenil			S				Concordia
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported
	Remicade			S				Not Reported
	Xeljanz			S				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14045757	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2116713-00		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaphylactic Reaction; Anxiety Disorder; Appetite Disorder; Arthralgia; Arthritis; Atrophic Vulvovaginitis; Back Pain; Carotid Artery Disease; Carotid Artery Occlusion; Chronic Kidney Disease; Clostridium Difficile Infection; Cognitive Disorder; Cough; Deafness; Depression; Diabetes Mellitus; Diabetic Ketoacidosis; Diabetic Neuropathy; Dizziness; Drug Dependence; Drug Ineffective; Dry Eye; Dysphagia; Essential Hypertension; Extrapyramidal Disorder; Fall; Fatigue; Fibromyalgia; Gait Disturbance; Haemorrhagic Disorder; Hepatic Enzyme Increased; Hyperlipidaemia; Hypersensitivity Vasculitis; Hypoaesthesia; Impaired Gastric Emptying; Infection; Iron Deficiency Anaemia; Joint Arthroplasty; Joint Range Of Motion Decreased; Joint Swelling; Malaise;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Minocycline Hcl			S	Unknown			Not Reported
	Buspar			C				Not Reported
	Neostigmine Bromide			C				Not Reported
	Tresiba			C				Not Reported
	Pseudoephedrine			C				Not Reported
	Lyrica			C				Not Reported
	Reglan			C				Not Reported
	Robinul			C				Not Reported
	Claritin			C				Not Reported
	Neurontin			C				Not Reported
	Bentyl			C				Not Reported
	Lasix			C				Not Reported
	Benadryl			C				Not Reported
	Desyrel			C				Not Reported
	Novolog			C				Not Reported
	Seroquel			C				Not Reported
	Lexapro			C				Not Reported
	Ativan			C				Not Reported
	Aquaphor			C				Not Reported
	Florastor			C				Not Reported
	Levothyroxine			C				Not Reported

Myalgia; Myopia; Nasal Congestion; Nausea; Neck Pain; Orthostatic Hypotension; Osteoarthritis; Osteopenia; Pain; Palpitations; Paraesthesia; Presbyopia; Purpura Non-Thrombocytopenic; Pyrexia; Radiculopathy; Rash; Restless Legs Syndrome; Retinal Degeneration; Rotator Cuff Syndrome; Spinal Osteoarthritis; Spinal Osteoarthritis; Stomatitis; Syncope; Synovitis; Systemic Lupus Erythematosus; Toothache; Urinary Hesitation	Zantac	C			Not Reported
	Aspirin	C			Not Reported
	Calcium Carbonate	C			Not Reported
	Prilosec	C			Not Reported
	Vitamin D3	C			Not Reported
	Glucagen	C			Not Reported
	Pravachol	C			Not Reported
	Lopressor	C			Not Reported
	Colchicine	C			Not Reported
	Tucks Hemorrhoidal	C		1-12.5%	Not Reported
	Melatonin	C			Not Reported
	Anusol	C		1-12.5	Not Reported
	Cefaclor	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2017	14050045	EXPEDITED (15-DAY)		OT	US-TEVA-812811USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Cancer	Gabapentin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	12914285	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092000		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Orencia			S	Intravenous (not			Bristol Myers Squibb

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis			otherwise specified)		
	Remicade	S	Unknown	200 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Enbrel	S	Unknown	2	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Benadryl /00000402/	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Enablex /01760401/	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Kenalog /00031902/	C	Intra-articular		Not Reported
	Kineret	C	Unknown		Not Reported
	Lasix /00032601/	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex /00018303/	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoloc /01263204/	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported

	Rituxan	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Trimethoprim	C	Unknown			Not Reported
	Urispas	C	Unknown	200 Mg, Unk		Not Reported
	Vagifem	C	Unknown			Not Reported
	Anakinra	C	Subcutaneous			Not Reported
	Enablex /01760401/	C	Unknown			Not Reported
	Gold	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	13385903	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002044		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Joint Instability; Pain	Hydroxychloroquine			S	Unknown			Concordia
	Naproxen			S	Unknown			Not Reported
	Leflunomide			S	Oral	Every Other Day		Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Actemra			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	13386929	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002043		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Anxiety; Condition Aggravated; Dyspnoea; Hepatic Enzyme	Hydroxychloroquine			S	Oral			Concordia
	Tracleer			S	Oral			Not Reported
	Vitamin D Nos			C				Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	13388778	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002048		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Apo-Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	13395047	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002026		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actmera			S	Unknown			Not Reported
	Cetrizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

Arthritis; Swelling; Systemic Lupus Erythematosus; Unevaluable Event; Wound	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	13948009	NON-EXPEDITED			US-PFIZER INC-2017386605			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Cellcept			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Myfortic			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14051560	EXPEDITED (15-DAY)		HO, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005680		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture; Impaired Healing	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Lodotra			C				Not Reported
	Ibuprofen			C				Not Reported
	Novaminsulfon			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisolone			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14052025	NON-EXPEDITED			US-PFIZER INC-2017428577		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Abilify			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14053867	EXPEDITED (15-DAY)		HO	US-APOTEX-2017AP019233		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose	Meloxicam			S	Oral	450 Mg Total		Apotex
	Tramadol Hydrochloride			S	Oral	1.5 G, Total		Apotex
	Hydroxychloroquine			S	Oral	6 G Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Oct-2017	14057513	EXPEDITED (15-DAY)		HO, OT	US-TEVA-812741USA		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Restrictive Cardiomyopathy; Sinus Node Dysfunction	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown	5 Mg Daily As Needed		Not Reported
	Naproxen			C	Unknown	As Needed		Not Reported
	Atenolol			C	Oral	100 Mg Daily		Not Reported
	Amlodipine, Benazepril			C	Oral	10mg/20mg Daily		Not Reported
	Simvastatin			C	Oral	10 Mg Daily		Not Reported
	Dexlansoprazole			C	Oral	30 To 60 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2017	14060653	EXPEDITED (15-DAY)		OT	CA-ROCHE-1999440			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown	Last Injection On 04/Sep/2017		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	13884330	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2563		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction;	Methotrexate (Trade Name			S	Oral			Not Reported

Interstitial Lung Disease; Rheumatoid Lung	Unknown) Hydroxychloroquine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	13984928	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Off Label Use; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	13985379	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	13989008	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Drug Ineffective; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	2.05 Mci, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported
	Prednisone			C	Unknown	20.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14028123	NON-EXPEDITED			US-AMGEN-USASP2017146614		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14060785	EXPEDITED (15-DAY)		OT	CA-ROCHE-1998866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061434	NON-EXPEDITED			US-AMGEN-USASP2017150727		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061603	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005708		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Hydroxychloroquine			S	Unknown			Concordia

Rheumatoid Arthritis	Leflunomide			S	Unknown		Not Reported
	Anakinra			S	Unknown		Not Reported
	Enbrel			S	Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)		Not Reported
	Imuran			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061607	EXPEDITED (15-DAY)		DE	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005658		42 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Drug Level Increased	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061608	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005659		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Eltroxin			C				Not Reported
	Lorazepam			C				Not Reported
	Symbicort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061610	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005684		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061611	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005697		80 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiocentric Lymphoma; Pain Of Skin; Skin Lesion; Skin Odour Abnormal	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Atenolol			C				Not Reported
	Prazosin			C				Not Reported
	Ramipril			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14061668	EXPEDITED (15-DAY)		OT	GB-VISTAPHARM, INC.-VER201709-000776		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Lethargy; Leukopenia; Treatment Failure	Prednisolone			S				Vistapharm
	Prednisolone			S				Vistapharm
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

	Dapsone	S	Not Reported
	Dapsone	S	Not Reported
	Colchicine	S	Not Reported
	Colchicine	S	Not Reported
	Azathioprine	S	Not Reported
	Azathioprine	S	Not Reported
	Rituximab	S	Not Reported
	Rituximab	S	Not Reported
	Mycophenolate Mofetil	S	Not Reported
	Mycophenolate Mofetil	S	Not Reported
	Methotrexate	S	Not Reported
	Methotrexate	S	Not Reported
	Omalizumab	C	Not Reported
	Omalizumab	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14062101	NON-EXPEDITED			US-PFIZER INC-2017431466			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14062472	NON-EXPEDITED			US-PFIZER INC-2017428463		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14063302	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1062357		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Fibrillation; Cardiac Failure; Restrictive Cardiomyopathy; Sinus Node Dysfunction	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	C	Unknown	5 Mg Daily As Needed		Mylan
	Naproxen	C	Unknown	As Needed		Mylan
	Atenolol	C	Oral	100 Mg Daily		Mylan
	Amlodipine W/Benazepril	C	Oral	10mg/20mg Daily		Mylan
	Simvastatin	C	Oral	10 Mg Daily		Mylan
	Dexlansoprazole	C	Oral	30 To 60 Mg Daily		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14064231	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017430448			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Cancer	Celebrex			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14065055	EXPEDITED (15-DAY)		OT	CA-SA-2017SA188095		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Kidney Infection	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2017	14068263	DIRECT	Y	LT			62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Product Dispensing Error; Urticaria; Wrong Product Administered	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	13903472	NON-EXPEDITED			US-PFIZER INC-2017363370		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14045469	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005656		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Autoimmune Thyroiditis; Conjunctivitis; Cough; Depression; Dry Eye; Fatigue; Fear Of Injection; Fibromyalgia; Hypoaesthesia; Insomnia; Lacrimation Decreased; Ocular Hyperaemia; Paraesthesia; Rash; Rheumatoid Arthritis; Therapeutic Response Decreased; Tinnitus; Weight Increased	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	2.5 Mg 10 Tablets		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Rheumate			C				Not Reported
	Rheumate			C				Not Reported
	Synthroid			C				Not Reported
	Restasis			C				Not Reported
	Restasis			C				Not Reported
	Meloxicam			C				Not Reported
	Remicade			C				Not Reported

	Hydroxychloroquine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14051953	NON-EXPEDITED			US-PFIZER INC-2017428582		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14065327	EXPEDITED (15-DAY)		LT, OT	US-SA-2017SA191487		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Candida Infection; Chest Discomfort; Diabetes Mellitus; Haemorrhage; Hand Deformity; Headache; Hunger; Hypoglycaemia; Inflammation; Malaise; Nodule; Product Use Issue; Rheumatoid Arthritis; Sinonasal Obstruction	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Carvedilol			S	Unknown			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous	Start Date: 07-Jan-2016		Not Reported
	Omalizumab			S	Subcutaneous	Start Date: 07-Jan-2016		Not Reported
	Omalizumab			S	Subcutaneous	Start Date: 07-Jan-2016		Not Reported
	Omalizumab			S	Subcutaneous	Start Date: 07-Jan-2016		Not Reported
	Omalizumab			S	Subcutaneous	Start Date: 07-Jan-2016		Not Reported
	Omalizumab			S	Subcutaneous	300 Mg,1 In 2 Wk		Not Reported
	Omalizumab			S	Subcutaneous	300 Mg,1 In 2 Wk		Not Reported
	Omalizumab			S	Subcutaneous	300 Mg,1 In 2 Wk		Not Reported
	Omalizumab			S	Subcutaneous	300 Mg,1 In 2 Wk		Not Reported

Omalizumab	S	Subcutaneous	300 Mg,1 In 2 Wk		Not Reported
Omalizumab	S	Subcutaneous			Not Reported
Omalizumab	S	Subcutaneous			Not Reported
Omalizumab	S	Subcutaneous			Not Reported
Omalizumab	S	Subcutaneous			Not Reported
Omalizumab	S	Subcutaneous			Not Reported
Prednisone	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Naproxen	C				Not Reported
Cortisone	C				Not Reported
Leflunomide	C				Not Reported
Hydroxychloroquine	C				Not Reported
Tiotropium Bromide	C				Not Reported
Diflucan	C				Not Reported
Levothyroxine	C				Not Reported
Prilosec	C				Not Reported
Lexapro	C				Not Reported
Salbutamol	C				Not Reported
Ventolin	C				Not Reported
Xanax	C				Not Reported
Vitamin D2	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14067010	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005652		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Diastolic Decreased; Decreased Appetite; Heart Rate Increased; Hypotension; Pyrexia; Viral Upper Respiratory Tract Infection; Weight Decreased	Hydroxychloroquine			S	Oral			Concordia
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

	Naproxen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14067021	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005700			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tooth Abscess; Tooth Infection	Plaquenil			S	Unknown			Concordia
	Xeljanz			S	Unknown			Not Reported
	Methotrexale Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14067462	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017151890		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Amgen
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14067566	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005707		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Drug Intolerance; Faeces Soft; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14067862	NON-EXPEDITED			US-AMGEN-USASP2017150093			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14068285	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005725		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthropathy; Diarrhoea; Disease Progression; Drug Ineffective; Dry Mouth; Fall; Fatigue; Haematuria; Hand Deformity; Hypoaesthesia; Ill-Defined Disorder; Joint Range Of Motion Decreased; Musculoskeletal Disorder; Musculoskeletal Stiffness; Osteoarthritis; Pain In Extremity; Paraesthesia; Peripheral Swelling; Pleural Effusion; Pneumonia; Rheumatoid Arthritis; Sinusitis; Sleep Disorder; Synovitis;	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aspirin			C				Not Reported
	Atenolol			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported
	Docusate Sodium			C				Not Reported
	Escitalopram Oxalate			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrochlorothiazide/Irbesartan			C				Not Reported
	Imovane			C				Not Reported
	Irbesartan			C				Not Reported
	Lipitor			C				Not Reported
	Loratadine			C				Not Reported

Temperature Intolerance;	Myrbetriq	C	Not Reported
Tenderness; Urinary Tract	Nitroglycerin	C	Not Reported
Infection; Viith Nerve	Omnaris	C	Not Reported
Injury; Viral Upper	Venlafaxine Hydrochloride	C	Not Reported
Respiratory Tract	Vesicare	C	Not Reported
Infection; Weight	Vitamin B12	C	Not Reported
Increased	Cipralex	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14068701	NON-EXPEDITED			US-PFIZER INC-2017433498		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14068736	NON-EXPEDITED			US-PFIZER INC-2017434579			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14069011	EXPEDITED (15-DAY)		OT	US-TEVA-813614USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Skin Discolouration; Skin Tightness	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14069413	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005728		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Deposits	Plaquenil			S	Unknown			Concordia
	Deflan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14069414	EXPEDITED (15-DAY)		LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005751			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Pain; Candida Infection; Chest Discomfort; Diabetes Mellitus; Haemorrhage; Hand Deformity; Headache; Hunger; Hypoglycaemia; Inflammation; Malaise; Nasal Congestion; Nodule; Product Use Issue; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Naproxen			C				Not Reported
	Cortisone			C				Not Reported
	Leflunomide			C				Not Reported
	Tiotropium Bromide			C				Not Reported
	Diflucan			C				Not Reported
	Levothyroxine			C				Not Reported
	Prilosec			C				Not Reported
	Lexapro			C				Not Reported
	Salbutamol			C				Not Reported
	Ventolin			C				Not Reported
	Xanax			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Carvedilol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2017	14075272	EXPEDITED (15-DAY)			US-MYLANLABS-2016M1035425			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy	Hydroxychloroquine	S	Oral	200 Mg, Bid		Not Reported
	Nuvaring	C				Mylan
	Adderall	C				Mylan
	Glumetza	C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	11191895	EXPEDITED (15-DAY)		DS, OT	CA-SA-2015SA080766		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Unknown	5-20 Mg, As Necessary		Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13957945	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017756		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased;	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Arava		S	Unknown	Unk	Not Reported
	Advil /00044201/		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Ketorolac		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Methotrexate		C	Unknown	20 Mg, Q.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13958227	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017824		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Apo-Hydroxyquine			S	Oral	Unk, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	Unk, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13959560	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017761		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Ineffective; Drug Intolerance; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Naprosyn /00256201/		C	Unknown	Unk			Not Reported
	Sulfasalazine		C	Unknown	500 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13962817	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017788		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diverticulitis; Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Injection Site Reaction; Liver Function Test Increased; Rash; Urticaria	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Every One Day		Apotex
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13962939	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017773		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Joint Fluid Drainage; Large Intestinal Obstruction; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13963002	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Drug Ineffective; Encephalitis; Hypoaesthesia	Apo-Hydroxyquine		S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide		S	Unknown	20 Mg, Qd		Apotex
	Adalimumab		S	Unknown			Not Reported
	Etanercept		S	Unknown			Not Reported
	Methotrexate		S	Unknown	20 Mg, Qd		Not Reported
	Orencia		S	Unknown			Not Reported
	Acetaminophen		C	Unknown			Not Reported
	Pregabalin		C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13963370	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017873		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Bid		Not Reported
	Naprosyn /00256201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13967555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017891		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported

					Enbrel	S	Unknown	Unk	Not Reported
					Gold	S	Unknown	50 Mg, Unk	Not Reported
					Humira	S	Unknown	Unk	Not Reported
					Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
					Orencia	S	Unknown	750 Mg, Unk	Not Reported
					Remicade	S	Unknown	Unk	Not Reported
					Sulfasalazine	C	Unknown	Unk	Not Reported
					Meloxicam	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13970520	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018065		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	13974929	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP018008			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Hydroxyquine			S				Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Leflunomide			S				Apotex
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Enbrel	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S			Not Reported
Ilaris	S	Unknown		Not Reported
Ilaris	S			Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S			Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14010204	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005442		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Off Label Use; Pancytopenia; Porphyria Non-Acute; Serum Ferritin Increased; Treatment Failure; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Ribavirin			S	Unknown			Not Reported
	Ribavirin			S	Unknown			Not Reported
	Ribavirin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14010205	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005452		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Blister;	Hydroxychloroquine			S	Unknown			Concordia

Decreased Appetite; Disease Recurrence; Dizziness; Dyspnoea; Fatigue; Headache; Insomnia; Off Label Use; Pancytopenia; Porphyria Non-Acute	Ribavirin	S	Unknown	Not Reported
	Telaprevir	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14012254	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005514		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Disease Recurrence; Off Label Use; Porphyria Non-Acute; Porphyrins Urine Increased	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Ribavirin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14071326	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dental Care; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete; Vomiting; Weight Decreased	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Magnesium			C				Not Reported
	Naprosyn			C				Not Reported

	Pantoprazole Sodium			C							Not Reported
	Potassium			C							Not Reported
	Tramadol			C							Not Reported
	Vitamin D2			C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14071820	NON-EXPEDITED			US-PFIZER INC-2017434473		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14072053	NON-EXPEDITED			US-PFIZER INC-2017437327		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14072957	EXPEDITED (15-DAY)		OT	PHEH2017US032111			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Condition Aggravated	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Bid		Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14075139	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1062261			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Hydroxychloroquine			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14075627	NON-EXPEDITED			US-PFIZER INC-2017434873			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hepatic Enzyme Increased	Ciprofloxacin			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Fluticasone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2017	14075740	NON-EXPEDITED			US-PFIZER INC-2017430439			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	12179502	EXPEDITED (15-DAY)		OT	CA-SA-2016SA032722			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diabetic Neuropathy; Drug Ineffective; Finger Amputation; Pain; Pain	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Simponi			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Alendronate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13090326	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016144186		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Product Use Issue; Rheumatoid Arthritis; Sepsis	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S		17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S		10 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Vit B12			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13914396	NON-EXPEDITED			US-PFIZER INC-2017372083		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13937027	EXPEDITED (15-DAY)		OT	SK-TEVA-801286ROM		19 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hepatic Enzyme Increased; Leukopenia	Isotretinoin			S				Barr
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13939116	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017414		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; No Adverse Event	Apo-Leflunomide	S	Unknown			Apotex
	Apo-Hydroxyquine	S	Unknown			Apotex
	Apo-Azathioprine	S	Unknown			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous	25 Mg, 2 Every 1 Week		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13939230	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017490		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Prolia			S	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13948315	NON-EXPEDITED			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005138			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13960284	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13966940	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005108		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cardiac Failure; Cytopenia; Generalised Oedema; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Synovitis	Plaquenil			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13968386	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13968605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018031		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Neutrophil Count Decreased; Pain; Pruritus; Therapeutic Response Decreased	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			C	Oral	Unk, Q.Wk.		Not Reported
	Salazopyrin			C	Unknown	2 G, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13968716	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018032		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gastrointestinal Disorder	Apo-Hydroxyquine	S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide	S	Oral	25 Mg, Qd		Apotex
	Hydrochlorothiazide	C	Unknown	Unk		Not Reported
	Leucovorin /00566701/	C	Oral	5 Mg, Unk		Not Reported
	Quinapril	C	Unknown	Unk		Not Reported
	Rosuvastatin	C	Unknown	Unk		Not Reported
	Enbrel	C	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium	C	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine	C	Oral	1 G, Bid		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Oxycodone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13968916	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP017987			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S				Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Ilaris			S	Unknown	Unk		Not Reported
	Ilaris			S				Not Reported

	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S					Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Remicade			S					Not Reported
	Rituxan			S	Unknown	Unk			Not Reported
	Rituxan			S					Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Sulfasalazine			S					Not Reported
	Methotrexate Sodium			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13974693	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018004			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Retinitis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Q.Wk.		Apotex
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	13996206	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005400		59 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Myositis; Psoriasis	Plaquenil	S	Oral			Concordia
	Plaquenil	S	Oral	Increased To 200 Mg Once A Day And 400 Mg Per Day		Concordia
	Predonine	C	Unknown			Not Reported
	Predonine	C	Unknown			Not Reported
	Predonine	C	Unknown	Decreased To An Unspecified Dose		Not Reported
	Predonine	C	Unknown			Not Reported
	Mycophenolate Mofetil	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14032949	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005620		43 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Resistance	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Oral			Not Reported
	Prednisone			S		Low-Dose, 10 ? 20 Mg		Not Reported
	Cladribine			C	Subcutaneous			Not Reported
	Rituximab			C		Four Doses Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14076749	EXPEDITED (15-DAY)		OT	US-BIOTEST PHARMACEUTICALS CORPORATION-US-2017ADM0			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercalcaemia	Human Immunoglobulin G			S		Unk		Biotest
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14078303	NON-EXPEDITED			US-PFIZER INC-2017434702			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14078427	NON-EXPEDITED			US-PFIZER INC-2017439020			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Plaquenil			S		200 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14078485	NON-EXPEDITED			US-PFIZER INC-2017439463		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14079676	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-17P-028-2128454-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Synthroid			S	Unknown	Unk	Not Reported
	Diclofenac			S	Oral	75 Mg, Unk	Not Reported
	Folic Acid			S	Unknown	Unk	Not Reported
	Lisinopril Dihydrate			S	Unknown	Unk	Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qw	Not Reported
	Plaquenil			S	Oral	200 Mg, Qd	Not Reported
	Sulfasalazine			S	Oral	1 G, Bid	Not Reported
	Tecta			S	Oral	Unk	Not Reported
	Xeljanz			S	Oral	5 Mg, Bid	Not Reported
	Gold			C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14079949	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-2128458-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Synthroid			S	Unknown	Unk		Not Reported
	Pantoprazole Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Apo-Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14080706	EXPEDITED (15-DAY)			US-MYLANLABS-2017M1038990			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14081492	NON-EXPEDITED		OT	US-PFIZER INC-2017434559		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2017	14083147	NON-EXPEDITED			US-AMGEN-USASP2017153551		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Headache; Nausea; Treatment Failure; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	13625340	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003383		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

Mass	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	13895748	NON-EXPEDITED			US-PFIZER INC-2017360967		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Influenza Like Illness	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	13995714	NON-EXPEDITED			US-PFIZER INC-2017405668		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14032839	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015280372		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Retinal Disorder; Rheumatoid Arthritis	Methotrexate Sodium	S	Subcutaneous	Unk		Unknown
	Plaquenil	S		Unk		Not Reported
	Cimzia	S		Unk		Not Reported
	Humira	S		Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14057375	NON-EXPEDITED			US-PFIZER INC-2017428679		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Otezla			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Stelara			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14081448	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP020137		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Pentoxifylline			S	Unknown			Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 Df, Unk		Not Reported

	Acitretin			S	Unknown	Unk				Not Reported
	Ustekinumab			S	Other	1 Df, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14082076	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005726		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Treatment Failure	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14082078	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005729		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Kidney Infection	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14082081	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010610			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diabetes Mellitus; Diabetic Neuropathy; Drug Ineffective; Finger Amputation; Pain; Pain	Plaquenil	S	Oral		Concordia
	Arava	S	Oral		Not Reported
	Simponi	C			Not Reported
	Methotrexate	C			Not Reported
	Alendronate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14084070	NON-EXPEDITED			US-AMGEN-USASP2017153882		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14084080	EXPEDITED (15-DAY)		OT	RO-IPCA LABORATORIES LIMITED-IPC-2017-RO-003250		27 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine			S				Ipca
	Azathioprine			S				Not Reported
	Fraxyparine			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Prednisone			S				Not Reported
	Albumin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14085351	NON-EXPEDITED			US-PFIZER INC-2017441726		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Rituxan	S	Unk		Not Reported
	Remicade	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Imuran	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14085397	NON-EXPEDITED			US-PFIZER INC-2017441415		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2017	14091722	DIRECT	Y	HO, LT			75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Left Ventricular Failure; Cardiomyopathy; Dilatation Atrial; Ejection Fraction; Left Ventricular Dysfunction; Myocarditis; Ventricular Hypokinesia	Hydroxychloroquine			S	Oral			Prasco
	Metoprolol			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2017	13995454	NON-EXPEDITED			US-AMGEN-USASP2017142507			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Plaquenil	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	10611372	NON-EXPEDITED			US-PFIZER INC-2014323224		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Fluconazole			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Gabapentin			S				Pfizer
	Erythrocin			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Hydrocodone Bitartrate			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Indocin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	13063422	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2765		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Infection; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Ergocalciferol			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Vitamin B12			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	13287791	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001374		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemic Coma	Plaquenil Tablet			S	Oral			Concordia
	Metformin			S	Oral			Not Reported
	Abasaglar			S	Subcutaneous			Not Reported
	Kwikpen			C				Not Reported
	Omeprazole			C				Not Reported
	Irbesartan			C				Not Reported
	Clopidogrel			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	13929469	NON-EXPEDITED			US-AMGEN-USASP2017132242		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14032944	EXPEDITED (15-DAY)		LT, OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005583		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy; Retinopathy	Hydroxychloroquine			S		100-200 Mg		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			C		<10 Mg/D		Not Reported
	Prednisone			C				Not Reported
	Furosemide			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14032945	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005585		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy	Hydroxychloroquine			S				Concordia
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14032946	EXPEDITED (15-DAY)		HO, LT, OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005586		52 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Sinus Node Dysfunction	Hydroxychloroquine			S		Total Dose, 1,898 Grams		Concordia
	Prednisone			C		Low Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14036788	EXPEDITED (15-DAY)		DE	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-		66 YR	Female	USA

005588

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S				Concordia
	Prednisone			C		<5 Mg/D		Not Reported
	Azathioprine			C				Not Reported
	Hydralazine			C				Not Reported
	Carvedilol			C				Not Reported
	Isordil			C				Not Reported
	Torsemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14036790	EXPEDITED (15-DAY)		DE	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005590		52 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Restrictive Cardiomyopathy; Ventricular Arrhythmia	Hydroxychloroquine			S				Concordia
	Prednisolone			C	Oral	5?10 Mg		Not Reported
	Bisoprolol			C				Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14062046	NON-EXPEDITED			US-PFIZER INC-2017426376		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14078379	NON-EXPEDITED			US-PFIZER INC-2017436975		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091023	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Plaquenil			S	Oral			Concordia
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Rituxan			C				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091350	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2017SP013407			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy; Toxicity To Various Agents; Vision Blurred; Visual Field Defect	Ibuprofen			S	Unknown	Unk, Prn		Svads Holdings
	Hydroxychloroquine			S	Unknown	400 Mg, Per Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14091956	NON-EXPEDITED			US-PFIZER INC-2017442014		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium		S	Unk		Pfizer
	Sulfasalazine		S	Unk		Pfizer
	Arava		S	Unk		Not Reported
	Plaquenil		S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092068	NON-EXPEDITED			US-PFIZER INC-2017443602			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Clemastine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092175	NON-EXPEDITED			US-PFIZER INC-2017444709		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092182	NON-EXPEDITED			US-PFIZER INC-2017445830			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092583	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017438484		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Eye Disorder; General Physical Health Deterioration; Gluten Sensitivity	Methotrexate Sodium			S				Pfizer
	Celebrex			S		Unk		Pfizer
	Plaquenil /00072603/			S				Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092929	EXPEDITED (15-DAY)		OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004635		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Visual Field Defect	Hydroxychloroquine			S	Unknown	Average Daily Dose: 5.7 Mg/Kg, Real Body Weight; 6.1 Mg/Kg Lean Body Weight		Concordia
	Anastrozole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14092932	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005861			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Urticaria; Vocal Cord Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14093393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-2131236-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Synthroid		S	Unknown	Unk		Not Reported
	Lisinopril		S	Unknown	Unk		Not Reported
	Methotrexate Sodium		S	Subcutaneous	20 Mg, Qw		Not Reported
	Pantoprazole Magnesium		S	Unknown	Unk		Not Reported
	Plaquenil		S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine		S	Oral	1 G, Bid		Not Reported
	Diclofenac		S	Oral	75 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2017	14094561	EXPEDITED (15-DAY)		HO, OT	PHHY2017PT151348			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Atrioventricular Block Complete; Foetal Exposure During Pregnancy; Hepatomegaly; Lupus Pneumonitis; Neonatal Lupus Erythematosus; Premature Baby; Rash; Sepsis Neonatal; Thrombocytopenia Neonatal	Hydroxychloroquine			S	Transplacental			Novartis
	Salbutamol			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Dexamethasone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13974714	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel	S	Unknown	50 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Imuran /00001501/	S	Unknown			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	13975158	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Q.Wk.		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14006930	NON-EXPEDITED			US-PFIZER INC-2017411617		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk	Pfizer
	Enbrel	S	Unk	Pfizer
	Orencia	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14057596	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-088328		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthropathy; Atrophic Vulvovaginitis; Carotid Artery Disease; Carotid Artery Occlusion; Chronic Kidney Disease; Clostridium Difficile Infection; Cognitive Disorder; Cough; Deafness; Decreased Appetite; Depression; Diabetes Mellitus; Diabetic Ketoacidosis; Diabetic Neuropathy; Diarrhoea; Dizziness; Drug Use Disorder; Dry Eye; Dysphagia; Essential Hypertension; Extrapyramidal Disorder; Fall; Fatigue; Gait Disturbance; Haemorrhagic Disorder; Hepatic Enzyme Increased; Hyperlipidaemia; Hypersensitivity Vasculitis; Hypoaesthesia; Impaired Gastric Emptying; Infection; Iron Deficiency	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Minocycline Hcl			S	Unknown	Unk		Not Reported
	Cefaclor			C	Unknown			Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Buspar			C	Unknown	Unk		Not Reported
	Neostigmine Bromide			C	Unknown			Not Reported
	Tresiba			C	Unknown	Unk		Not Reported
	Pseudoephedrine			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Reglan /00041901/			C	Unknown			Not Reported
	Robinul			C	Unknown			Not Reported

Anaemia; Joint Range Of Motion Decreased; Malaise; Myopia; Nasal Congestion; Nausea; Neck Pain; Off Label Use; Orthostatic Hypotension; Osteoarthritis; Osteopenia; Palpitations; Paraesthesia; Presbyopia; Purpura; Pyrexia; Radiculopathy; Rash; Restless Legs Syndrome; Retinal Degeneration; Rheumatoid Arthritis; Rotator Cuff Syndrome; Spinal Osteoarthritis; Stomatitis; Syncope; Systemic Lupus Erythematosus; Toothache; Treatment Failure; Urinary Hesitation	Claritin /00413701/	C	Unknown	Unk		Not Reported
	Neurontin	C	Unknown	Unk		Not Reported
	Bentyl	C	Unknown	Unk		Not Reported
	Lasix /00032601/	C	Unknown	Unk		Not Reported
	Benadryl /00000402/	C	Unknown			Not Reported
	Desyrel	C	Unknown	Unk		Not Reported
	Novolog	C	Unknown	Unk		Not Reported
	Seroquel	C	Unknown	Unk		Not Reported
	Lexapro	C	Unknown	Unk		Not Reported
	Ativan	C	Unknown	Unk		Not Reported
	Aquaphor /00298701/	C	Unknown	Unk		Not Reported
	Florastor	C	Unknown	Unk		Not Reported
	Levothyroxine	C	Unknown	Unk		Not Reported
	Zantac	C	Unknown	Unk		Not Reported
	Aspirin /00002701/	C	Unknown	Unk		Not Reported
	Calcium Carbonate	C	Unknown	Unk		Not Reported
	Prilosec /00661201/	C	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported
	Glucagen /00157801/	C	Unknown	Unk		Not Reported
	Pravachol	C	Unknown	Unk		Bristol Myers Squibb
	Lopressor	C	Unknown	Unk		Not Reported
	Colchicine	C	Unknown	Unk		Not Reported
	Tucks /00343801/	C	Unknown	Unk		Not Reported
	Melatonin	C	Unknown			Not Reported
	Anusol /00117301/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14095608	NON-EXPEDITED			US-AMGEN-USASP2017155297		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contusion; Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Tofacitinib	C		Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14095609	NON-EXPEDITED			US-AMGEN-USASP2017155323		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14096317	NON-EXPEDITED			US-AMGEN-USASP2017155924		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14096363	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3141		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Eye Disorder; General Physical Health Deterioration; Gluten Sensitivity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14096655	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Retinopathy	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Orencia			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Caffeine/Codeine/Paracetamol			C				Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported
	Salazopyrin			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Apo-Amoxi Clav			C				Not Reported
	Nasonex			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14097038	NON-EXPEDITED			US-PFIZER INC-2017445728		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14099926	EXPEDITED (15-DAY)		OT	IE-FRESENIUS KABI-FK201708683		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Anastrozole (Manufacturer Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2017	14100624	EXPEDITED (15-DAY)		OT	PHHY2017CA150860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac			S	Unknown	75 Mg, Bid		Novartis
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Unknown	500 Mg, Bid		Not Reported
	Piroxicam			C	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10-20 Mg Qd Prn		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	13996205	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-		15 YR	Female	JPN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Scleritis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14036789	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005589		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy; Torsade De Pointes	Hydroxychloroquine			S		400-600 Mg		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			C				Not Reported
	Naproxen			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Simvastatin			C				Not Reported
	Amlodipine			C				Not Reported
	Fluticasone?Salmeterol And Albuterol			C				Not Reported
	Calcitriol			C				Not Reported
	Calcium			C				Not Reported
	Temazepam			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14072037	NON-EXPEDITED			US-PFIZER INC-2017437491		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14078308	NON-EXPEDITED			US-PFIZER INC-2017437466		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14100695	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005862			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Pain In Extremity; Rheumatoid Lung; Therapeutic Response Decreased	Plaquenil			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported
	Lipitor			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14101509	NON-EXPEDITED			US-PFIZER INC-2017448234		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14101590	NON-EXPEDITED			US-PFIZER INC-2017446188		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Gabapentin			S		Unk		Pfizer
	Xeljanz			S		5 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14101676	NON-EXPEDITED			US-AMGEN-USASP2017155841			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14102982	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017156178		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Chest Discomfort; Extra Dose Administered; Headache; Insomnia; Migraine; Migraine With Aura; Overdose; Vertigo; Vision Blurred	Benlysta Powder For Infusion			S	Intravenous (not otherwise specified)	10 Mg/Kg, Cyc Every 4 Weeks		Glaxosmithkline
	Plaquenil			S				Not Reported
	Fioricet			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14103966	EXPEDITED (15-DAY)		OT	AU-ASTRAZENECA-2017SF04580		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epiglottitis; Toxic Epidermal Necrolysis	Omeprazole			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Augmentin-Duo			C				Not Reported
	Doxycycline			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2017	14103986	EXPEDITED (15-DAY)		HO, LT, OT	CA-MYLANLABS-2017M1046581			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S		Unk		Mylan
	Actemra			S				Mylan
	Anakinra			S		Unk		Mylan
	Anakinra			S				Mylan
	Enbrel			S		Unk		Mylan
	Enbrel			S				Mylan
	Gold			S		Unk		Mylan
	Humira			S		Unk		Mylan
	Humira			S				Mylan
	Humira			S	Subcutaneous	Unk		Mylan
	Humira			S				Mylan
	Hydroxychloroquine Sulfate			S		Unk		Mylan
	Hydroxychloroquine Sulfate			S				Mylan
	Ilaris			S		Unk		Mylan
	Ilaris			S				Mylan

	Ilaris			S	Subcutaneous	Unk		Mylan
	Ilaris			S				Mylan
	Leflunomide			S		Unk		Mylan
	Leflunomide			S				Mylan
	Orencia			S	Intravenous (not otherwise specified)	Unk		Mylan
	Orencia			S				Mylan
	Plaquenil /00072602/			S		Unk		Mylan
	Plaquenil /00072602/			S				Mylan
	Remicade			S		Unk		Mylan
	Remicade			S				Mylan
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Mylan
	Rituxan			S				Mylan
	Rituxan			S		Unk		Mylan
	Rituxan			S				Mylan
	Sulfasalazine			S		Unk		Mylan
	Sulfasalazine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	12809315	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Nausea; Retinal Disorder; Rheumatoid Arthritis; Vomiting	Cimzia			S	Subcutaneous	Unk		Ucb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Isoniazid W/Vitamin B6			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	13583474	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201705-		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Maculo-Papular	Plaquenil			S	Oral			Concordia
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	13778604	EXPEDITED (15-DAY)		DS, OT	NO-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011557		46 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Headache; Hypoacusis; Migraine; Sleep Disorder; Tinnitus	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Metex (Methotrexate Sodium)			C				Not Reported
	Nexium			C				Not Reported
	Provera			C				Not Reported
	Selo-Zok			C				Not Reported
	Neurontin			C				Not Reported
	Lisinopril			C				Not Reported
	Imigran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	13868747	NON-EXPEDITED			US-PFIZER INC-2017349561		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	13967624	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017900		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	13990027	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018204		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Pain; Pneumonitis; Polyneuropathy; Rash; Sepsis	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14108061	EXPEDITED (15-DAY)		HO, LT, OT	CA-MYLANLABS-2017M1046591			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis;	Methotrexate			S	Intra-arterial	Unk		Not Reported

Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S		Unk	Mylan
	Actemra	S			Mylan
	Anakinra	S		Unk	Mylan
	Anakinra	S			Mylan
	Enbrel	S		Unk	Mylan
	Enbrel	S			Mylan
	Gold	S		Unk	Mylan
	Humira	S	Subcutaneous	Unk	Mylan
	Humira	S			Mylan
	Hydroxychloroquine Sulfate	S		Unk	Mylan
	Hydroxychloroquine Sulfate	S			Mylan
	Ilaris	S	Subcutaneous	Unk	Mylan
	Ilaris	S			Mylan
	Ilaris	S	Subcutaneous	Unk	Mylan
	Ilaris	S			Mylan
	Leflunomide	S		Unk	Mylan
	Leflunomide	S			Mylan
	Orencia	S		Unk	Mylan
	Orencia	S			Mylan
	Orencia	S	Intravenous (not otherwise specified)	Unk	Mylan
	Orencia	S			Mylan
	Plaquenil	S		Unk	Mylan
	Plaquenil	S			Mylan
	Remicade	S	Intravenous (not otherwise specified)	Unk	Mylan
	Remicade	S			Mylan
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
	Rituxan	S			Mylan
	Rituxan	S		Unk	Mylan
	Rituxan	S			Mylan
	Sulfasalazine	S		Unk	Mylan
	Sulfasalazine	S			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14108426	EXPEDITED (15-DAY)		OT	CA-SA-2017SA185909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Pain	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Demerol			C	Unknown			Not Reported
	Fosavance			C	Unknown	70/5600 Q		Not Reported
	Palafer			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2017	14108470	EXPEDITED (15-DAY)		OT	IE-MYLANLABS-2017M1064889		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	5.7mg/Kg Real Body Weight; Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	11923201	NON-EXPEDITED		OT	US-AMGEN-USASL2016002560		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

	Humira			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Hcq			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	12629635	EXPEDITED (15-DAY)		DE, OT	FR-GLAXOSMITHKLINE-FR2016GSK113369			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Sepsis	Prednisone			S		20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S		2 G, Qd		Glaxosmithkline
	Hydroxychloroquine			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14025747	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005516		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Drug Intolerance; Headache; Insomnia; Off Label Use; Psychiatric Symptom; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14096805	NON-EXPEDITED			US-PFIZER INC-2017443932		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Arava			S		Unk		Not Reported

	Plaquenil	S	Unk	Not Reported
	Humira	S	Unk	Not Reported
	Cimzia	S	Unk	Not Reported
	Actemra	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14109709	NON-EXPEDITED			US-TEVA-791202USA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Peripheral Swelling	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Centrum Silver			C				Not Reported
	Biotin			C		5000 Microgram Daily;		Not Reported
	Vitamin D3			C	Oral	5000 Iu (International Unit) Daily;		Not Reported
	Fluticasone Propionate			C	Nasal	Per Nostril		Not Reported
	Amoxicillin			C	Oral	2000 Milligram Daily;		Not Reported
	Lisinopril W/Hydrochlorothiazide			C	Oral	20-12.5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14109710	NON-EXPEDITED			US-TEVA-780244ACC			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14109711	NON-EXPEDITED			US-TEVA-799045ACC			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Urticaria; Urticaria	Hydroxychloroquine	S	400 Milligram Daily; 200mg Tablet Twice A Day By Mouth	Teva		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14109712	NON-EXPEDITED			US-TEVA-791353ACC			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bowel Movement Irregularity; Condition Aggravated; Drug Ineffective; Reaction To Excipient	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14110067	NON-EXPEDITED			US-AMGEN-USASP2017156746		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14110510	NON-EXPEDITED			US-PFIZER INC-2017451060		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

	Plaquenil			S		Unk				Not Reported
	Orencia			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14111208	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK159969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac			S	Unknown	75 Mg, Bid		Glaxosmithkline
	Methotrexate			S	Unknown	25 Mg, We		Glaxosmithkline
	Naproxen			S	Unknown	500 Mg, Bid		Glaxosmithkline
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Piroxicam			C		Unk		Glaxosmithkline
	Hydroxychloroquine			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14111564	EXPEDITED (15-DAY)		OT	US-ANIPHARMA-2017-US-012217		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy	Ibuprofen (Non-Specific)			S				Ani
	Hydroxychloroquine			S		200 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14112446	EXPEDITED (15-DAY)		HO, OT	AU-IMPAX LABORATORIES, INC-2017-IPXL-02928		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epiglottitis; Toxic Epidermal Necrolysis	Omeprazole Delayed Release			S	Unknown	Unk		Impax

	Doxycycline			S	Unknown	Unk				Impax
	Hydroxychloroquine			S	Unknown	400 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2017	14112560	NON-EXPEDITED			US-AMGEN-USASP2017157606		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Ageusia; Rash; Red Blood Cell Sedimentation Rate Increased; Swelling; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2017	14112763	EXPEDITED (15-DAY)		OT	GB-EDENBRIDGE PHARMACEUTICALS, LLC-GB-2017EDE00017		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Lethargy; Leukopenia; Therapy Non-Responder; Toxicity To Various Agents	Prednisolone Sodium Phosphate			S		Unk		Edenbridge Pharmaceuticals
	Hydroxychloroquine			S		Unk		Not Reported
	Dapsone			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	13771675	NON-EXPEDITED			US-PFIZER INC-2017309873		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Medrol	S	Unk		Pfizer
	Lopid	S	Unk		Pfizer
	Rituxan	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported
	Hcq	S	Unk		Not Reported
	Dolobid	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	13880684	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017122889			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	14113675	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Pain In Extremity; Rheumatoid Nodule	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	14117512	NON-EXPEDITED			US-AMGEN-		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection; Injection Site Reaction; Malaise; Photosensitivity Reaction; Skin Discolouration	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Minocin			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2017	14119081	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Retention	Cosentyx 150mg/Ml Novartis			S	Subcutaneous	Frequency - Q 4 W		Novartis
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	13233910	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001095		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Eye Disorder; Nausea; Retinal Disorder; Rheumatoid Arthritis; Vomiting	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported
	Isoniazid	C		Not Reported
	Vitamin B6	C		Not Reported
	Hydroxychloroquine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	13539281	NON-EXPEDITED			US-PFIZER INC-2017193320		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S	Oral	500 Mg, 2x/Day For 1 Week		Pfizer
	Sulfasalazine			S	Oral	1500 Mg, Daily (2 Tabs Po Qam For 1 Week And 1 Tab Po Qpm For 1 Week)		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		500 Mg, 2x/Day		Pfizer
	Enbrel			S		50 Mg/Ml, Weekly (1 X Wk)		Unknown
	Cimzia			S		200 Mg/Ml, Weekly (1 X Wk)		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk (2 Or 3 X Day)		Not Reported
	Humira Pen			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira Pen			S		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, 1x/Day		Not Reported
	Acetaminophen W/Hydrocodone			C	Oral	1 Df, 4x/Day [Acetaminophen: 325mg]-[Hydrocodone: 10mg]		Not Reported
	Aspirin			C	Oral	81 Mg, 1x/Day		Not Reported
	Aspirin			C		Unk		Not Reported

Atenolol	C	Oral	25 Mg, 1x/Day	Not Reported
Atenolol	C		Unk	Not Reported
Calcium	C	Oral	1200 Iu, 1x/Day	Not Reported
Celebrex	C	Oral	200 Mg, 2x/Day	Not Reported
Crestor	C	Oral	20 Mg, 1x/Day (At Bedtime)	Not Reported
Crestor	C		Unk	Not Reported
Folic Acid	C	Oral	1 Mg, 1x/Day	Not Reported
Folic Acid	C		Unk	Not Reported
Leucovorin	C	Oral	15 Mg, Weekly(3 Tabs(S) Orally Once A Week)	Not Reported
Leucovorin	C		Unk	Not Reported
Lidocaine	C	Topical	Unk, 2x/Day	Not Reported
Methotrexate	C	Oral	25 Mg, Weekly(10 Tablets Orally Once A Week)	Not Reported
Methotrexate	C		Unk	Not Reported
Prednisone	C	Oral	4 Tabs Daily For 4 Days, 3 Tabs Daily For 4 Days, 2 Tabs Daily For 4 Days, 1 Tab Daily For 4 Days	Not Reported
Prozac	C	Oral	40 Mg, 1x/Day	Not Reported
Prozac	C		Unk	Not Reported
Ritalin	C	Oral	10 Mg, 1x/Day	Not Reported
Ritalin	C		Unk	Not Reported
Vitamin D2	C	Oral	1000 Iu, 1x/Day	Not Reported
Vitamin D	C		Unk	Not Reported
Xanax	C	Oral	0.50 Mg, 1x/Day (2 Tab(S) Orally Once A Day)	Not Reported
Xanax	C		Unk	Not Reported
Zetia	C	Oral	10 Mg, 1x/Day	Not Reported
Norco	C		Unk Only Occasionally	Not Reported

	Xeljanz			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	13725350	NON-EXPEDITED			US-PFIZER INC-2017288161			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Field Defect; Visual Impairment	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14100694	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005790		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14118078	EXPEDITED (15-DAY)		HO	US-ABBVIE-17K-163-2135353-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Drug Ineffective; Fluid Overload; Heart Rate Increased; Infection; Pyrexia	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14118125	NON-EXPEDITED			US-AMGEN-USASP2017158575		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14118265	EXPEDITED (15-DAY)		DE	NZ-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005924		67 YR	Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Respiratory Failure	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14118862	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-152943		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy; Toxicity To Various Agents	Ibuprofen		Y	S	Unknown	Unk, Prn		Ranbaxy
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119308	NON-EXPEDITED			US-PFIZER INC-2017455521		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119317	NON-EXPEDITED			US-PFIZER INC-2017448551		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119387	NON-EXPEDITED			US-PFIZER INC-2017457411			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119465	NON-EXPEDITED			US-PFIZER INC-2017457170		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119470	NON-EXPEDITED			US-PFIZER INC-2017456762		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119689	EXPEDITED (15-DAY)		OT	IE-ACCORD-060134		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Anastrozole			S				Accord
	Hydroxychloroquine			S		5.7 Mg/Kg Real Body Weight (6.1 Mg/Kg Lean Body Weight)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14119788	NON-EXPEDITED			US-PFIZER INC-2017454698			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14120372	NON-EXPEDITED			US-PFIZER INC-2017456540		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cleocin			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Dextromethorphan Hbr		Y	S		Unk		Unknown

	Cipro	S	Unk	Not Reported
	Rifampin	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Clinoril	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14120480	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1065812		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg/Day And After One Week Decreased To 200 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Decreased To 200 Mg/Day		Not Reported
	Ibuprofen			S	Unknown	Taken As Needed Prior To Hydroxychloroquine Therapy And Later Taken Throughout		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14121310	EXPEDITED (15-DAY)		OT	GB-TEVA-817988ROM		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Lethargy; Leukopenia	Azathioprine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14121813	EXPEDITED (15-DAY)		OT	CA-SA-2017SA167147		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Surgery	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Indocid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Stopped In 2015/2016		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14122023	NON-EXPEDITED		OT	US-SA-2017SA054966		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lodine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Seroquel			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14122026	NON-EXPEDITED		OT	US-SA-2017SA081307		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Back Pain; Bursitis; Crepitations; Drug Ineffective; Enthesopathy; Eye Disorder; Pain; Rheumatoid Arthritis; Scar	Arava		S	Oral	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Hydrochlorothiazide/Triamterene		C	Unknown	Not Reported
	Hydrochlorothiazide/Triamterene		C	Unknown	Not Reported
	Hydrochlorothiazide/Triamterene		C	Unknown	Not Reported
	Flexeril		C	Unknown	Not Reported
	Flexeril		C	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported
	Gold Sodium Thiomalate		C	Unknown	Not Reported
	Remicade		C	Unknown	Not Reported
	Medrol		C	Unknown	Not Reported
	Ansaid		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14122033	NON-EXPEDITED			US-SA-2017SA118011			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Infection; Insomnia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Product Dose Omission; Therapeutic Response Decreased	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14122034	NON-EXPEDITED		OT	US-SA-2017SA118046		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14122046	NON-EXPEDITED		OT	US-SA-2017SA169457		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash; Treatment Failure	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2017	14122774	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

INC.-GSH201710-005976

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Pain	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Vitamin D2			C				Not Reported
	Orencia			C				Not Reported
	Demerol			C				Not Reported
	Fosavance			C				Not Reported
	Palafer			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14109723	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/17/0094063		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy; Toxicity To Various Agents; Visual Field Defect	Ibuprofen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14110927	NON-EXPEDITED			US-PFIZER INC-2017453077		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14123496	EXPEDITED (15-DAY)		OT	IE-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-152900		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	5.7 Mg/Kg, Daily		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14124410	NON-EXPEDITED			US-PFIZER INC-2017457067		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14125054	EXPEDITED (15-DAY)		OT	IE-TEVA-818022ROM		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown	5.7mg/Kg Real Body Weight; Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2017	14125933	EXPEDITED (15-DAY)		OT	US-TEVA-819485USA		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram Daily; One Week Decreased To 200 Mg/Day		Teva

	Hydroxychloroquine	S	Unknown	Decreased To 200 Mg/Day		Teva
	Ibuprofen	S	Unknown	Taken As Needed Prior To Hydroxychloroquine Therapy And Later Taken Throughout		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	13457897	EXPEDITED (15-DAY)		OT	PT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138627		35 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Dexamethasone			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisolone			S	Unknown	Unk		Taro
	Salbutamol			S	Unknown	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	13457994	EXPEDITED (15-DAY)		LT, OT	PT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-138631			Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Foetal Exposure During Pregnancy; Neonatal Lupus Erythematosus; Pneumonitis; Premature Baby; Respiratory Failure; Sepsis Neonatal	Dexamethasone			S	Transplacental	Unk		Sun
	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Prednisolone			S	Transplacental	Unk		Taro
	Salbutamol			S	Transplacental	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	13945554	NON-EXPEDITED			US-PFIZER INC-2017386997		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Nausea	Methotrexate Sodium	S		Unk		Pfizer
	Sulfasalazine	S		Unk		Pfizer
	Plaquenil	S	Oral	400 G, Daily		Not Reported
	Plaquenil	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14112137	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017445051		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine /00072603/			S				Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14126953	NON-EXPEDITED			US-AMGEN-USASP2017161015			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14127088	EXPEDITED (15-DAY)		OT	IE-CIPLA LTD.-2017IE18795			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To	Anastrozole			S	Unknown	Unk		Cipla

Various Agents	Hydroxychloroquine	S	Unknown	5.7 Mg/Kg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14127112	EXPEDITED (15-DAY)		CA, DE, OT	FR-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011432			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arteriosclerosis; Foetal Exposure During Pregnancy; Heart Valve Calcification; Hydrops Foetalis; Pericardial Effusion	Plaquenil 200 Mg Tablet			S	Transplacental			Concordia
	Speciafoldine			C				Not Reported
	Aspegic [Acetylsalicylate Lysine]			C				Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			C				Not Reported
	Estreva			C				Not Reported
	Estima (Progesterone)			C				Not Reported
	Innovair			C				Not Reported
	Ventoline			C				Not Reported
	Gonal-F			C				Not Reported
	Cetrotide			C				Not Reported
	Luveris			C				Not Reported
	Ovitrelle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14127313	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005926		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Oedema Mucosal	Plaquenil Tablet			S	Unknown	1 Tablet Daily And 2 Tablets Daily Alternatively		Concordia
	Plaquenil Tablet			S	Unknown	1 Tablet Daily And 2 Tablets Daily Alternatively		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14129058	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020174		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Hospitalisation	Apo-Leflunomide		S	Oral	10 Mg, Unk	Apotex
	Enbrel		S	Unknown	Unk	Not Reported
	Methotrexate		S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Plaquenil /00072602/		S	Unknown	200 Mg, Bid	Not Reported
	Arava		C	Unknown	Unk	Not Reported
	Cimzia		C	Unknown	Unk	Not Reported
	Humira		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Remicade		C	Unknown	Unk	Not Reported
	Rituxan		C	Unknown	Unk	Not Reported
	Viread		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2017	14133155	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1572853-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapy Non-Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	0.8mg/Kg,		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Ada (Benzalkonium Chloride\Diphenhydramine Hydrochloride\Phenylephrine Hydrochloride)			S	Unknown			Not Reported

	Celebrex	C	Not Reported
	Ibuprofen	C	Not Reported
	Xeljanz	C	Not Reported
	Lipitor	C	Not Reported
	Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	13625290	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017084644		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Asthenia; Chest Pain; Constipation; Drug Ineffective; Dysphagia; Dyspnoea; Feeling Abnormal; Gastrointestinal Disorder; Headache; Rash; Rheumatoid Arthritis; Sleep Disorder; Vision Blurred; Weight Increased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	15 Mg, Qwk (2.5 Mg (6 Tablets By Mouth Once Weekly)		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported
	Tramadol Hcl			C	Oral	50 Mg, Q8h		Not Reported
	Prednisone			C	Oral	5 Mg, Bid		Not Reported
	Neurontin			C	Oral	400 Mg, Bid		Not Reported
	Arava			C	Oral	20 Mg, Qd		Not Reported
	Fosamax			C	Oral	70 Mg, Qwk		Not Reported
	Estradiol			C	Oral	2 Mg, Qd		Not Reported
	Levocetirizine Dihydrochloride			C	Oral	5 Mg, Qd		Not Reported
	Norco			C	Oral	Unk Unk, Q6h (10-325 Mg)		Not Reported
	Movantik			C	Oral	36 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	13852910	NON-EXPEDITED			US-AMGEN-USASP2017118329		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective	Enbrel		S	Unknown	50 Mg, Qwk		Amgen
	Enbrel		S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate		S	Unknown	Unk		Not Reported
	Humira		S	Unknown	Unk		Not Reported
	Arava		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Xeljanz Xr		C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	13965966	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166433		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Blood Test Abnormal; Hepatotoxicity; Injection Site Pain	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Frequency: Total		Not Reported
	Xeljanz			C	Oral			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	13995448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Apo-Cetirizine 10mg Tabs			S	Unknown	Unk		Apotex
	Apo Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Rituxan			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

	Phthalylsulfathiazole			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Humira			S	Unknown	Unk			Not Reported
	Fosamax			S	Unknown	Unk			Not Reported
	Enbrel			S	Unknown	Unk			Not Reported
	Cortisone Acetate			S	Unknown	Unk			Not Reported
	Cimzia			S	Unknown	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14027635	NON-EXPEDITED			US-PFIZER INC-2017419880		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14061514	NON-EXPEDITED			US-AMGEN-USASP2017150882		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			C		Unk		Not Reported

	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported
	Mtx			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14128935	EXPEDITED (15-DAY)		OT	SK-GLAXOSMITHKLINE-SK2017GSK154005		45 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus	Benlysta			S		Unk		Glaxosmithkline
	Prednisolon			S		Unk		Glaxosmithkline
	Azathioprine			S		Unk		Glaxosmithkline
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14128936	EXPEDITED (15-DAY)		OT	SK-GLAXOSMITHKLINE-SK2017GSK154011		45 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoporotic Fracture	Benlysta			S				Glaxosmithkline
	Prednisolone			S				Glaxosmithkline
	Cyclosporin			S				Glaxosmithkline
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14133002	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-096811		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14133486	EXPEDITED (15-DAY)		OT	CA-ABBVIE-12P-028-0978513-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14133523	EXPEDITED (15-DAY)		HO, OT	AU-IPCA LABORATORIES LIMITED-IPC-2017-AU-003396		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Ipca
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown			Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14135195	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017161793			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Basal Cell Carcinoma; Rheumatoid Arthritis	Enbrel		S	Unknown	Unk	Amgen
	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14137622	EXPEDITED (15-DAY)		HO, LT, OT	AU-GLENMARK PHARMACEUTICALS-2017GMK029326		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Toxic Epidermal Necrolysis	Omeprazole			S	Unknown	Unk		Glenmark
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Prednisolone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14138218	EXPEDITED (15-DAY)		HO, OT	IN-SA-2017SA199478		61 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Arthritis Infective; Aspartate Aminotransferase Increased; Drug-Induced Liver Injury; Hepatitis; Joint Swelling; Tuberculosis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Isoniazid			S				Not Reported
	Isoniazid			S				Not Reported
	Rifampicin			S	Unknown			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Ethambutol			S	Unknown			Not Reported
	Ethambutol			S	Unknown			Not Reported

	Wysolone		S	Unknown		Not Reported
	Wysolone		S	Unknown		Not Reported
	Wysolone		S	Unknown	Tapered Upto 2.5 Mg And Stopped	Not Reported
	Wysolone		S	Unknown	Tapered Upto 2.5 Mg And Stopped	Not Reported
	Wysolone		S	Unknown		Not Reported
	Wysolone		S	Unknown		Not Reported
	Azoran (Azathioprine)		S	Unknown		Not Reported
	Azoran (Azathioprine)		S	Unknown		Not Reported
	Azoran (Azathioprine)		S	Unknown	Half A Tablet Of 50 Mg Azoran	Not Reported
	Azoran (Azathioprine)		S	Unknown	Half A Tablet Of 50 Mg Azoran	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Oct-2017	14138577	EXPEDITED (15-DAY)		OT	CA-SA-2017SA208550		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Haemoptysis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Pneumonia; Productive Cough; Seizure	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2017	13186194	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1857380-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Enbrel	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2017	14139654	EXPEDITED (15-DAY)		HO, OT	PHHY2017IN156499		61 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Tuberculosis; Joint Swelling; Movement Disorder; Product Use In Unapproved Indication	Hydrochlorothiazide			S	Unknown	200 Mg, Od		Novartis
	Hydrochlorothiazide			S				Novartis
	Hydroxychloroquine			S	Unknown	200 Mg,Od		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Unknown	20 Mg, Od		Not Reported
	Leflunomide			S				Not Reported
	Azoran (Azathioprine)			S	Unknown	50 Mg, Od		Not Reported
	Azoran (Azathioprine)			S	Unknown	Half Tablet Of 50 Mg		Not Reported
	Wysolone			S	Unknown	20 Mg, Qd		Not Reported
	Wysolone			S	Unknown	2.5 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	12573530	NON-EXPEDITED			US-PFIZER INC-2016316219		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Celebrex		S	Unk		Pfizer
	Sulfasalazine		S	Unk		Pfizer
	Cymbalta		S	Unk		Not Reported
	Plaquenil		S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	13985878	NON-EXPEDITED			US-PFIZER INC-2017401319		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14119743	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3183		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14139954	NON-EXPEDITED			US-AMGEN-USASP2017163250		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Wellbutrin			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	50 Mg, Unk		Not Reported

					Clindamycin	S	Unknown	300 Mg, Unk	Not Reported
					Gabapentin	S	Unknown	100 Mg, Unk	Not Reported
					Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
					Ibuprofen	S	Unknown	800 Mg, Unk	Not Reported
					Omeprazole	S	Unknown	20 Mg, Unk	Not Reported
					Oxycodone With Apap	S	Unknown	Unk	Not Reported
					Proventil Hfa	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140609	NON-EXPEDITED			US-PFIZER INC-2017463255		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Minocycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140626	NON-EXPEDITED			US-PFIZER INC-2017465960			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Clinoril			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2017	14140782	NON-EXPEDITED			US-AMGEN-USASP2017162491			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	13987818	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017371060		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil /00072602/			S		200 Mg, 2x/Day		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Orencia			S		125 Mg, Weekly		Not Reported
	Humira			S		40 Mg, Per 2 Weeks		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14043093	NON-EXPEDITED			US-PFIZER INC-2017419836		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14112697	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-41956		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy; Toxicity To Various Agents	Ibuprofen			S		Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14122772	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005925		1 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Disease Recurrence; Drug Ineffective; Haemoglobin Decreased; Hepatomegaly; Mean Cell Volume Decreased; Plasmodium Malariae Infection; Pyrexia; Refractory Cytopenia With Unilineage Dysplasia; Splenomegaly; Transferrin Saturation Decreased	Hydroxychloroquine			S	Oral	10 Mg Base/Kg Followed By 6, 24 And 48 H		Concordia
	Artemether Lumefantrine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14144319	NON-EXPEDITED			US-PFIZER INC-2017465747		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported
	Remicade	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14144324	NON-EXPEDITED			US-PFIZER INC-2017465633		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14144338	NON-EXPEDITED			US-PFIZER INC-2017467832		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mental Status Changes	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Gabapentin			S	Unknown	100 Mg, Unk		Pfizer
	Ibuprofen			S	Unknown	800 Mg, Unk		Pfizer
	Clindamycin Hcl			S	Unknown	300 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	50 Mg, Unk		Not Reported
	Omeprazole			S	Unknown	20 Mg, Unk		Not Reported
	Oxycodone With Apap			S	Unknown	Unk		Not Reported

	Proventil Hfa /00139501/			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14144361	NON-EXPEDITED			US-PFIZER INC-2017465641		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14144366	NON-EXPEDITED			US-PFIZER INC-2017465908		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14144726	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006062		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Surgery	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Indocid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14145035	EXPEDITED (15-DAY)		LT, OT	PHHY2017AU154999		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Genital Lesion; Oral Disorder; Toxic Epidermal Necrolysis	Omeprazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Novartis
	Prednisolone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2017	14146967	EXPEDITED (15-DAY)		HO	AU-MYLANLABS-2017M1067428		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Toxic Epidermal Necrolysis	Omeprazole			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400mg		Not Reported
	Prednisolone			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	13742637	EXPEDITED (15-DAY)		DE, OT	PHHY2017CN098310		24 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Coma; Drug Dependence; Drug Ineffective; Headache; Musculoskeletal Stiffness; Pseudomonas Infection; Pyrexia; Type 2 Lepra Reaction; Vomiting Projectile	Clofazimine			S	Unknown	300 Mg, Qmo		Not Reported
	Clofazimine			S	Unknown	50 Mg, Qd		Not Reported
	Clofazimine			S	Unknown	200 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	60 Mg, Qd		Novartis
	Methylprednisolone			S	Oral	30 Mg, Qd		Novartis
	Methylprednisolone			S	Oral	60-80 Mg Qd		Novartis
	Methylprednisolone			S	Oral	25 Mg, Qd		Novartis
	Methylprednisolone			S	Oral	20 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Dapsone			S	Unknown	100 Mg, Unk		Not Reported
	Thalidomide			S	Unknown	300 Mg, Qd		Not Reported

	Rifampin			S	Unknown	600 Mg, Unk				Not Reported
	Cyclophosphamide			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14148235	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Lyrica			C				Not Reported
	Oxycodone			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14148236	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006121			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Toxicity To Various Agents	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14148237	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006128		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Haemoptysis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Pneumonia; Productive	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Cough; Seizure	Methotrexate	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14148239	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006133		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intra-articular			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2017	14149562	NON-EXPEDITED			US-AMGEN-USASP2017164313		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicaide			S	Unknown	Unk		Not Reported

	Hcq			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	13057412	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015703		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	13696675	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003825		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Limb Discomfort; Osteomyelitis; Pain	Plaquenil			S	Oral			Concordia
	Meloxicam			C				Not Reported
	Tylenol			C				Not Reported
	Prednisone			C				Not Reported

	Sulfasalazine	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	13900249	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK128773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Cyst; Dizziness; Drug Ineffective; Fatigue; Joint Swelling; Pain; Product Dose Omission; Somnolence; Systemic Lupus Erythematosus	Benlysta			S	Intravenous (not otherwise specified)	950 Mg, Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	13950460	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2017382232		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Drug Ineffective; Dyspnoea; Fatigue; Lower Respiratory Tract Infection	Methotrexate Sodium			S	Oral	12.5 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 1x/Day (Am)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Oral	2 G, Daily		Pfizer
	Plaquenil			S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	13994889	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2693		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14102596	NON-EXPEDITED			US-PFIZER INC-2017448582		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14120576	NON-EXPEDITED			US-AMGEN-USASP2017159279		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Meloxicam			C				Not Reported

	Methotrexate			C						Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk				Not Reported
	Prednisone			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14150828	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14150831	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006164		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Local Reaction; Psoriasis; Sinusitis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14150832	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00012314		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysstasia; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Mobility Decreased; Nausea; Rheumatoid Arthritis; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Advil			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151006	NON-EXPEDITED			US-AMGEN-USASP2017164630		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity; Dry Mouth; Oropharyngeal Pain	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151149	NON-EXPEDITED			US-AMGEN-USASP2017164652		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151248	EXPEDITED (15-DAY)		HO, OT	IT-IPCA LABORATORIES LIMITED-IPC201305-000203		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Decreased; Condition Aggravated; Exposure During Pregnancy; Myopathy; Toxicity To Various Agents	Hydroxychloroquine Sulfate Tablets, Usp			S		200 Mg, Bid		Ipca
	Methylprednisolone			S		200 Mg Twice A Day25 Mg/Day,Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	200 Mg Twice A Day25 Mg/Day60 Mg/Day,Unk		Not Reported
	Methylprednisolone			S		200 Mg Twice A Day25 Mg/Day60 Mg/Day8 Mg/Day,Unk		Not Reported
	Aspirin			S		200 Mg Twice A Day25 Mg/Day60 Mg/Day8 Mg/Day100 Mg/Day,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151525	NON-EXPEDITED			US-PFIZER INC-2017470069		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Pregabalin			S		Unk		Pfizer
	Nystatin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151621	NON-EXPEDITED			US-PFIZER INC-2017467494		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer

	Hydroxychloroquine			S		200 Mg, 2x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14151774	NON-EXPEDITED			US-PFIZER INC-2017468116		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2017	14153166	EXPEDITED (15-DAY)		OT	PHHY2017CA161036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Estradot			S	Transdermal	Unk Unk, Qw		Novartis
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	15 To 20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	11912449	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016002218		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk (Six Weeks)		Amgen
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	1 Ml, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	1 Ml, Qwk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Unk		Not Reported

		Hydroxychloroquine			C	Unknown	200 Mg, Bid (One Year)			Not Reported
		Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	13033062	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSL2016175283		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Urine Present; Cystitis; Drug Ineffective; Drug Intolerance; Genital Pain; Hysterectomy; Nephrolithiasis; Unevaluable Event; Uterine Leiomyoma	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Protol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	13894399	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2076253-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Joint Stiffness; Joint Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	13989276	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005269		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Blood Test Abnormal; Hepatotoxicity; Injection Site Pain	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Total		Not Reported
	Enbrel			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14051558	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005654			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Methorexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155231	NON-EXPEDITED			US-AMGEN-USASP2007000227		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155705	EXPEDITED (15-DAY)		HO, OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-153907		61 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Hepatitis; Tuberculosis	Hydrochlorothiazide			S	Unknown	200 Mg, Qd		Sun
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Ipca
	Sulfasalazine			S	Unknown			Sun
	Azoran (Azathioprine)			S	Unknown	50 Mg, Bid		Not Reported
	Azoran (Azathioprine)			S	Unknown	Half Tablet Of 50mg Azoran		Not Reported
	Azoran (Azathioprine)			S				Not Reported
	Lefno			S	Unknown	20 Mg, Qd		Not Reported
	Wysolone			S	Unknown	Unk		Not Reported
	Wysolone			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155717	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006187		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156090	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	50 Mg, Q2wk		Amgen
	Arava	S	Unknown	20 Mg, Qd		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Q2wk Solution Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Q2wk Solution Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate Sodium	S	Oral	17.5 Mg, Qwk		Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Qwk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	Unk		Not Reported
	Coversyl	C		Unk		Not Reported
	Ergocalciferol	C		Unk		Not Reported
	Ergocalciferol	C		Unk		Not Reported
	Leucovorin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156222	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165291		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156355	NON-EXPEDITED			US-PFIZER INC-2017472116		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156363	NON-EXPEDITED			US-PFIZER INC-2017471316		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156519	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2017-030678			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Necrotising	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14157024	DIRECT		HO			73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Angina Pectoris; Back Pain; Nausea; Tremor	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2017	14157777	NON-EXPEDITED			US-AMGEN-USASP2017165321		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Hcq	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2017	14157900	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006237		51 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Plaquenil			S	Oral			Concordia
	Previscan (Fluindione)			C				Not Reported
	Seresta			C				Not Reported
	Xanax			C				Not Reported
	Zopiclone			C				Not Reported
	Venlafaxine			C				Not Reported
	Lumirelax (Methocarbamol\Methyl Nicotinate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	9472769	NON-EXPEDITED			US-PFIZER INC-2013243887		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Fentanyl Citrate			S		Unk		Unknown
	Hydromorphone Hydrochloride			S		Unk		Unknown
	Cymbalta			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	13250262	NON-EXPEDITED			PHEH2017US003792			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Device Issue; Hypertension; Incorrect Dose Administered	Cosentyx			S	Subcutaneous	300 Mg, Qw		Not Reported
	Cosentyx			S	Subcutaneous	30 Mg, Qmo		Not Reported
	Nabumetone Tablets			S	Unknown			Novartis
	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Toprol			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Erolin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	13930055	NON-EXPEDITED			US-AMGEN-USASP2017131185			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Maternal Exposure During Pregnancy	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14127339	NON-EXPEDITED			US-AMGEN-USASP2017160342		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	30 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14158530	EXPEDITED (15-DAY)		HO, LT, OT	AU-DEXPHARM-20171544		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Omeprazole			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14160714	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006260		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Cranial Nerve Injury; Drug Hypersensitivity; Herpes Zoster; Nodule; Pain In Extremity; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14160718	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006266		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapy Non-Responder	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Weekly		Not Reported
	Desoximetasone			C				Not Reported
	Morphine			C				Not Reported
	Rituxan			C				Not Reported
	Acetaminophen			C				Not Reported
	Acetylsalicylic Acid/Caffeine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14161958	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE JAPAN K.K.-2017CA015058			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Unk		Celltrion
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S		640 Mg, Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported

	Humira			S	Subcutaneous	40 Mg, Unk			Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Imuran /00001501/			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14162131	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1068655		56 YR	Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhegmatogenous Retinal Detachment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2017	14162325	NON-EXPEDITED			US-PFIZER INC-2017475547		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	13152009	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017021602		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Femur Fracture	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil /00072602/			S		400 Mg, Daily		Not Reported
	Arava			C		20 Mg, 1x/Day		Not Reported
	Metformin			C	Oral	500 Mg, 3x/Day		Not Reported
	Ramipril			C		10 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	13153642	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017010739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Constipation; Drug Ineffective; Fall; Femur Fracture; Fibula Fracture; Gastric Disorder; Hand Deformity; Hypertension; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tibia Fracture; Type 2 Diabetes Mellitus	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Alendronate			S	Unknown	Unk		Not Reported
	Arava			C		20 Mg, Qd		Not Reported
	Metformin			C	Oral	500 Mg, Tid		Not Reported
	Ramipril			C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	13985509	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2017-2805		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cough; Dyspnoea; Fatigue; Lower Respiratory Tract Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown	Am		Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14124577	NON-EXPEDITED			US-PFIZER INC-2017459040		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Methotrexate Sodium	S	Unk		Pfizer
	Acetaminophen	S	Unk		Not Reported
	Oxycodone	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14140770	EXPEDITED (15-DAY)		HO, OT	IN-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006072		61 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Infective; Aspartate Aminotransferase Increased; Drug Ineffective; Drug-Induced Liver Injury; Hepatitis; Joint Swelling; Tuberculosis	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Gradually Tapered Up To 2.5mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lefno			S	Unknown			Not Reported
	Lefno			S				Not Reported
	Isoniazid			S	Unknown			Not Reported
	Isoniazid			S				Not Reported
	Rifampicin			S	Unknown			Not Reported
	Rifampicin			S				Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Pyrazinamide			S				Not Reported
	Ethambutol			S	Unknown			Not Reported
	Ethambutol			S				Not Reported
	Azoran (Azathioprine)			S	Unknown			Not Reported
	Azoran (Azathioprine)			S		Taking Half Tablet Of 50 Mg Azoran		Not Reported
	Azoran (Azathioprine)			S				Not Reported
	Azoran (Azathioprine)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14164177	NON-EXPEDITED			US-AMGEN-USASP2017166653			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14164316	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14164622	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017478070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Pfizer

Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Sulfasalazine	S	Oral	Unk		Pfizer
	Arava	S	Unknown	20 Mg, Qd		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Q2wk Solution Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Q2wk Solution Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Coversyl	C		Unk		Not Reported
	Ergocalciferol	C		Unk		Not Reported
	Ergocalciferol	C		Unk		Not Reported
	Leucovorin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14164662	NON-EXPEDITED			US-PFIZER INC-2017475518		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14164693	NON-EXPEDITED			US-PFIZER INC-2017476168		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		200 Mg, Unk		Not Reported
	Ramadol			S		50 Mg, Unk		Not Reported

	Actemra			S		162 Mg/Ml				Not Reported
	Naproxen			S		500 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14164711	NON-EXPEDITED			US-PFIZER INC-2017476289		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14165948	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210556		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Cirrhosis	Arava			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution, Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14165980	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210575		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Cataract; Dizziness; Drug Ineffective; Headache; Hypersensitivity; Nausea; Peripheral Swelling;	Arava			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Therapeutic Response Unexpected; Viral Infection; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166039	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210592			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form- Solution Subcuteneous		Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form- Solution Intravenous		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166100	EXPEDITED (15-DAY)		OT	CA-HIKMA PHARMACEUTICALS CO. LTD-2017CA015156			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Inflectra			S	Unknown			Celltrion
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166182	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017167348			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mouth Ulceration; Retinopathy	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166362	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE JAPAN K.K.-2017CA015129			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Qwk		Celltrion
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown	640 Mg,Qwk		Not Reported

	Arava	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Imuran /00001501/	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166363	EXPEDITED (15-DAY)		OT	CA-HIKMA PHARMACEUTICALS CO. LTD-2017CA015139			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Infliximab Hospira			S	Unknown			Celltrion
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Unk, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qid		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166605	NON-EXPEDITED			US-AMGEN-USASP2017166675		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14166716	EXPEDITED (15-DAY)		DE, HO, LT, OT	CN-CIPLA LTD.-2017CN19217			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Drug Dependence; Drug Ineffective; Type 2 Lepra Reaction	Methylprednisolone			S	Oral	60 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	30 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	60-80 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	25 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	20 Mg, Unk		Not Reported
	Meropenem			S	Unknown	6 G, Qd		Not Reported
	Ceftriaxone			S	Unknown	4 G, Qd		Not Reported
	Levofloxacin			S	Unknown	400 G, Qd		Cipla
	Cyclophosphamide			S	Unknown	Unk		Cipla
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Cipla
	Rifampin			C	Unknown	600 Mg, Unk		Not Reported
	Clofazimine			C	Unknown	300 Mg, Unk		Not Reported
	Clofazimine			C	Unknown	50 Mg, Qd		Not Reported
	Clofazimine			C		200 Mg, Qd		Not Reported
	Dapsone			C	Unknown	100 Mg, Qd		Not Reported
	Thalidomide			C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14167146	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1068396			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azathioprine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

	Methotrexate	S	Unk		Mylan
	Sulfasalazine	S	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2017	14167431	EXPEDITED (15-DAY)		CA, OT	US-MYLANLABS-2017M1069683			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Block Congenital	Hydroxychloroquine			S	Transplacental	200mg Daily		Not Reported
	Hydroxychloroquine			S	Unknown	400mg Daily		Not Reported
	Dexamethasone			S	Transplacental	8 Mg		Not Reported
	Immune Globulin Nos			S	Transplacental	1g/Kg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	13963850	NON-EXPEDITED			US-AMGEN-USASP2017136633		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chills; Diarrhoea; Gastrointestinal Inflammation; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qwk		Not Reported
	Otrexup			C		Unk, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14127813	NON-EXPEDITED			US-PFIZER INC-2017454836		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported

	Orencia	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Simponi	S	Unk	Not Reported
	Actemra	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Arava	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14156371	NON-EXPEDITED			US-PFIZER INC-2017469990		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14166963	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2017M1069231		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	200mg Daily		Not Reported
	Hydroxychloroquine			S	Unknown	400mg Daily		Not Reported
	Dexamethasone			S	Unknown	8 Mg		Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)	1g/Kg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167192	NON-EXPEDITED			US-ZYDUS-015401			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Dysphagia; Dyspnoea	Hydroxychloroquine			S				Zydus Pharm
	Doxycycline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167203	NON-EXPEDITED			US-ZYDUS-016011			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S				Zydus Pharm
	Metoprolol			C				Not Reported
	Prednisone			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167204	NON-EXPEDITED			US-ZYDUS-012876			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167206	NON-EXPEDITED			US-ZYDUS-015695			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutrophil Count Decreased	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167207	NON-EXPEDITED			US-ZYDUS-012250		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Discolouration; Weight Increased	Hydroxychloroquine			S	Oral			Zydus Pharm
	Hydralazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167208	NON-EXPEDITED			US-ZYDUS-015843		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Urticaria	Hydroxychloroquine			S				Zydus Pharm
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167209	NON-EXPEDITED			US-ZYDUS-015775			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167210	NON-EXPEDITED			US-ZYDUS-012621		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Diarrhoea; Halo Vision; Muscular Weakness; Myalgia	Hydroxychloroquine			S	Oral			Zydus Pharm
	Azathioprine			C				Not Reported
	Steroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167696	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006268		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	Daily		Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	Weekly		Not Reported
	Methotrexate Sodium			S	Oral	Weekly		Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167699	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006270			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167702	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006272		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Altace	C		Not Reported
Atorvastatin	C		Not Reported
Cipralex	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Cymbalta	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Hydromorphone Hydrochloride	C		Not Reported
Prednisone	C		Not Reported
Tapentadol Hydrochloride	C		Not Reported
Taro Mupirocin	C		Not Reported
Tramacet	C		Not Reported
Tramadol Hydrochloride	C		Not Reported
Shark Liver Oil	C		Not Reported
Conjugated Estrogens	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167704	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006281		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

	Prednisone			C						Not Reported
	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167705	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14167922	NON-EXPEDITED			US-AMGEN-USASP2017167336		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Ophthalmological Examination Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Naproxen			S	Unknown	375 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14168876	NON-EXPEDITED			US-PFIZER INC-2017478178			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium			S		Unk				Pfizer
	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14168931	NON-EXPEDITED			US-PFIZER INC-2017475870		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14169484	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14170434	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE JAPAN K.K.-2017CA015236			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Unk		Celltrion
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	640 Mg, Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Ciclosporin	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Imuran /00001501/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14171506	EXPEDITED (15-DAY)		OT	CA-SA-2017SA212192		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Orencia			C	Unknown			Not Reported
	Humira			C	Unknown	Frequency: Per 2 Weeks		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2017	14171509	EXPEDITED (15-DAY)		OT	CH-SA-2017SA214728		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Mabthera			S	Intravenous drip			Not Reported

	Prednisone		S	Oral	Not Reported
	Cipralex		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	12809289	EXPEDITED (15-DAY)		OT	CA-ROCHE-1837444		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil			C				Not Reported
	Folic Acid			C				Not Reported
	Ketorolac			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	13147908	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0289		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Urine Present; Cystitis; Drug Ineffective; Drug Intolerance; Genital Pain; Hysterectomy;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Nephrolithiasis; Treatment Failure; Unevaluable Event; Uterine Leiomyoma	Arava		S	Unknown		Not Reported
	Ibuprofen		C	Unknown		Not Reported
	Protol		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	13162431	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0249		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Toe Amputation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	13654630	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170608340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Cancer; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	13968429	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Salazopyrin			C				Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Maxeran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14066602	NON-EXPEDITED			US-AMGEN-USASP2017149525		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14150829	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006107		56 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Detachment; Maculopathy; Retinal Injury; Retinal Tear; Rhegmatogenous Retinal Detachment; Toxicity To Various Agents; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14164619	NON-EXPEDITED			US-PFIZER INC-2017476073		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14172422	NON-EXPEDITED			US-AMGEN-USASP2017168549			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk (3 Months)		Amgen
	Methotrexate			S	Unknown	Unk (3 Months)		Not Reported
	Humira			S	Unknown	Unk (3 Months)		Not Reported

	Actemra	S	Unknown	Unk (3 Months)		Not Reported
	Plaquenil	S	Unknown	Unk (3 Month)		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14172666	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006328		73 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14173087	EXPEDITED (15-DAY)		OT	CH-ROCHE-2019359		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Mabthera			S	Intravenous drip			Not Reported
	Mabthera			S	Intravenous drip			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported
	Stilnox			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14173839	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Coversyl	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Leucovorin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14173939	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3421		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

Rheumatoid Arthritis;
Synovitis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14174080	NON-EXPEDITED			US-AMGEN-USASP2017167773		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14174135	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lichen Planus; Rheumatoid Arthritis; Rosacea; Spinal Stenosis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Salazopyrin			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14174864	EXPEDITED (15-DAY)		HO	AU-TEVA-822359ROM		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Toxic Epidermal Necrolysis	Omeprazole	S	Unknown			Actavis
	Hydroxychloroquine	S	Unknown	400mg		Not Reported
	Prednisolone	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14175957	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210804		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Cranial Nerve Injury; Drug Hypersensitivity; Herpes Zoster; Nodule; Pain In Extremity; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2017	14176028	EXPEDITED (15-DAY)		OT	CO-MYLANLABS-2017M1070170		51 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Virus Infection; Iridocyclitis	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisolone			S	Unknown	1%		Not Reported
	Belimumab			S	Unknown			Mylan
	Aciclovir			C	Intravenous (not otherwise specified)			Mylan
	Atropine			C	Unknown			Mylan
	Brimonidine			C	Unknown			Mylan
	Dorzolamide			C	Unknown			Mylan
	Acetazolamide			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	13889819	NON-EXPEDITED			US-AMGEN-USASP2017124291		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain In Extremity	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold Salt			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Celebrex			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	13915687	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017127008		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Injection Site Reaction; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14107903	EXPEDITED (15-DAY)		HO, OT	DE-GLAXOSMITHKLINE-DE2017GSK154274		63 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adenocarcinoma Of Colon	Hydroxychloroquine	S	400 Mg, Qd	Not Reported
	Azathioprine	S	Unk	Glaxosmithkline
	Azathioprine	S	100 Mg	Glaxosmithkline
	Azathioprine	S	50 Mg	Glaxosmithkline
	Azathioprine	S	150 Mg	Glaxosmithkline
	Azathioprine	S	200 Mg	Glaxosmithkline
	Azathioprine	S	150 Mg	Glaxosmithkline
	Azathioprine	S	100 Mg	Glaxosmithkline
	Azathioprine	S	50 Mg	Glaxosmithkline
	Prednisone	S	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14118380	NON-EXPEDITED			US-AMGEN-USASP2017158529		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14119472	NON-EXPEDITED			US-PFIZER INC-2017456731		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer

	Methotrexate Sodium	S		Unk	Pfizer
	Actemra	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Leflunomide	S		30 Mg, Qd	Not Reported
	Humira	S		Unk	Not Reported
	Plaquenil /00072603/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14176952	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006292		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective	Plaquenil			S	Oral	Twice A Day		Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			C				Not Reported
	Sulfasalazine			C				Not Reported
	Orencia			C				Not Reported
	Humira			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14177622	EXPEDITED (15-DAY)		OT	PHHY2017MY162541			Unknown	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Hydroxychloroquine			S	Transplacental	Unk		Novartis
	Methotrexate			S	Transplacental	Unk		Not Reported
	Tocilizumab			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14179332	EXPEDITED (15-DAY)		OT	CO-FRESENIUS KABI-FK201709572		51 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Iridocyclitis	Methotrexate (Manufacturer Unknown)	S	Unknown			Fresenius Medical Care
	Hydroxychloroquine Sulfate	S				Not Reported
	Belimumab	S				Not Reported
	Prednisone	S				Not Reported
	Atropine	C				Not Reported
	Brimonidine Tartrate	C				Not Reported
	Dorzolamide	C				Not Reported
	Acetazolamide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2017	14180007	EXPEDITED (15-DAY)		HO	TR-EDENBRIDGE PHARMACEUTICALS, LLC-TR-2017EDE00019		72 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Female Genital Tract Fistula	Prednisolone Sodium Phosphate			S		7.5 Mg, Qd		Edenbridge Pharmaceuticals
	Prednisolone Sodium Phosphate			S		2.5 Mg, Qd		Edenbridge Pharmaceuticals
	Tofacitinib			S		5 Mg, Bid		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2017	14178805	EXPEDITED (15-DAY)		OT	CA-ROCHE-2019329			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2017	14180480	EXPEDITED (15-DAY)		OT	CO-TEVA-825473ROM		51 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Virus Infection; Iridocyclitis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Prednisolone Acetate			S	Unknown	1%		Not Reported
	Prednisone			S	Oral			Not Reported
	Aciclovir			C	Intravenous (not otherwise specified)			Not Reported
	Atropine			C	Unknown			Not Reported
	Brimonidine			C	Unknown			Not Reported
	Dorzolamide			C	Unknown			Not Reported
	Acetazolamide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2017	14185128	DIRECT					68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Flushing; Headache; Nausea; Palpitations; Therapy Change	Hydroxychloroquine			S	Oral	Quantity:30 Tablet(S);Other Frequency:1x Per Day;		Northstar
	Ursodiol			C				Not Reported
	Anastrole			C				Not Reported
	Flovent			C				Not Reported
	Xopenex			C				Not Reported
	Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	13943488	NON-EXPEDITED			US-AMGEN-USASP2017135283		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	14045465	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005537		69 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Oedema; Pruritus	Plaquenil Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Predonine			C		Increased Dose		Not Reported
	Antebate			C				Not Reported
	Maintate			C				Not Reported
	Salagen			C				Not Reported
	Pariet			C				Not Reported
	Bonoteo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	14155716	EXPEDITED (15-DAY)		OT	IL-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006165		46 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Dyspnoea; Hypersensitivity; Treatment Failure; Urticaria	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown	Re-Challenge Of Hydroxychloroquine		Concordia
	Plaquenil			S	Unknown	1ml Of 0.1mg/Ml On Day 1		Concordia
	Plaquenil			S	Unknown	2 Ml Of 0.1mg/Ml Hydroxychloroquine Sulfate On Day 2		Concordia

Plaquenil	S	Unknown	4 Ml Of 0.1mg/Ml Hydroxychloroquine On Day 3	Concordia
Plaquenil	S	Unknown	8 Ml Of 0.1mg/Ml Hydroxychloroquine On Day 4	Concordia
Plaquenil	S	Unknown	10 Ml Of 0.1mg/Ml Hydroxychloroquine (1mg Per Day)-On Day 5 To 11-15	Concordia
Plaquenil	S	Unknown	1 Ml Of 2 Mg/Ml Hydroxychloroquine (2 Mg Per Day)-On Day 1 For Stage 2	Concordia
Plaquenil	S	Unknown	2 Ml Of 2 Mg/Ml Hydroxychloroquine (4 Mg Per Day)-On Day 2 For Stage 2	Concordia
Plaquenil	S	Unknown	3 Ml Of 2 Mg/Ml Hydroxychloroquine (6 Mg Per Day)-On Day 3 For Stage 2	Concordia
Plaquenil	S	Unknown	4 Ml Of 2 Mg/Ml Hydroxychloroquine (8 Mg Per Day)-On Day 4 For Stage 2	Concordia
Plaquenil	S	Unknown	5 Ml Of 2 Mg/Ml Hydroxychloroquine (10 Mg Per Day)-On Day 5-11 For Stage 2	Concordia
Plaquenil	S	Unknown	10 Ml Of 2 Mg/Ml Hydroxychloroquine (20 Mg Per Day)-On Day 12 For Stage 2	Concordia
Plaquenil	S	Unknown	20 Ml Of 2 Mg/Ml Hydroxychloroquine (40 Mg Per Day)-On Day 13 For Stage 2	Concordia

	Plaquenil	S	Unknown	40 Ml Of 2 Mg/Ml Hydroxychloroquine (80 Mg Per Day)-On Day 14 For Stage 2	Concordia
	Plaquenil	S	Unknown	100 Mg Hydroxychloroquine 0.5 Tablet (100 Mg Per Day)-On Day 15-21 For Stage 2	Concordia
	Plaquenil	S	Unknown	200 Mg Hydroxychloroquine 1 Tablet (200 Mg Per Day)-On Day 22-26 For Stage 2	Concordia
	Plaquenil	S	Unknown	200?400 Mg; According To Physician Recommendation	Concordia
	Prednisone	C		Prednisone At Doses Of 5 Mg Or Less	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	14181394	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006349			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Tetanus Toxoid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2017	14181395	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006350		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Pain; Upper Limb Fracture	Plaquenil			S	Unknown			Concordia
	Xeljanz Xr			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	12727339	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP011016		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Apo-Esomeprazole			S	Oral	40 Mg, Qd		Apotex
	Apo Folic Acid			S	Unknown	1 Df, Twice Weekly		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Gabapentin			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	5 Mg, Qd		Apotex
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	13963073	NON-EXPEDITED			US-PFIZER INC-2017390382		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			C		20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	13981432	NON-EXPEDITED			US-PFIZER INC-2017399999			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Intolerance	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Hcq	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14170430	EXPEDITED (15-DAY)		OT	CA-CELLTRION HEALTHCARE HUNGARY KFT-2017CA015260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg, Qwk		Celltrion
	Infliximab Hospira			S	Unknown	5 Mg, Unk		Celltrion
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Enbrel			S	Unknown	12.5 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Not Reported
	Immunoglobulin /07494701/			S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14174521	NON-EXPEDITED			US-PFIZER INC-2017481764		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181744	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003658		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine Besilate			S	Oral			Unknown
	Tranylcypromine Sulfate			S	Oral			Unknown
	Olanzapine			S	Oral			Unknown
	Lisinopril			S	Oral			Unknown
	Sertraline Hydrochloride			S	Oral			Unknown
	Hydroxychloroquine Sulfate			S	Oral			Unknown
	Buspirone Hydrochloride			S	Oral			Unknown
	Levothyroxine Sodium			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14181747	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-TREX2017-3420		73 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14182260	NON-EXPEDITED			US-AMGEN-USASP2017169208		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14182593	NON-EXPEDITED			US-PFIZER INC-2017486453		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk, 2x/Day (1500 Bid)		Pfizer
	Prednisone			S		10 Mg, Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk 1x/Day (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14182603	NON-EXPEDITED			US-PFIZER INC-2017486665			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14183164	NON-EXPEDITED			US-PFIZER INC-2017484604		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14183510	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2017481159		73 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2017	14185463	NON-EXPEDITED			US-AMGEN-USASP2017170330		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14091048	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017154538		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14184851	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2160379-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186330	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-003559			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186393	EXPEDITED (15-DAY)		HO	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006352		57 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Chest	Plaquenil 200 Mg Tablet			S	Oral			Concordia

Discomfort; Dyspnoea	Plaquenil 200 Mg Tablet			S						Concordia
	Brufen			C						Not Reported
	Omeprazole			C						Not Reported
	Behepan [Cyanocobalamin]			C						Not Reported
	Folacin (Calcium Phosphate\Folic Acid)			C						Not Reported
	Indivina			C						Not Reported
	Metotab			C						Not Reported
	Tradolan			C						Not Reported
	Alvedon			C						Not Reported
	Cymbalta			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186397	EXPEDITED (15-DAY)		HO	RU-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006355		21 YR	Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Tachycardia	Plaquenil			S	Oral	Once		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186398	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006359		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S	Oral			Concordia
	Stilnox			S	Oral			Not Reported
	Mabthera			S	Intravenous drip			Not Reported
	Prednisone			S	Oral			Not Reported
	Cipralex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186426	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP020965		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Alopecia; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Mycophenolate Mofetil	S	Unknown	2 G, Qd		Apotex
	Mycophenolate Mofetil	S				Apotex
	Mycophenolate Mofetil	S				Apotex
	Leflunomide	S	Oral	10 Mg, Qd		Apotex
	Leflunomide	S				Apotex
	Leflunomide	S				Apotex
	Hydroxychloroquine	S	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine	S				Not Reported
	Octreotide	C	Unknown	Unk		Not Reported
	Nadolol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14186987	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1765143US		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Pregnancy	Escitalopram Oxalate - Bp			S	Unknown	20 Mg, Qd		Allergan
	Plaquenil			S	Unknown	200 Mg, Q12h		Not Reported
	Mabthera			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Stilnox			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14187361	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2035891-00		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Barrett'S Oesophagus; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Feeling Abnormal; Impaired Gastric Emptying; Malaise;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Pelvic Mass; Pharyngeal Swelling; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14187462	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017170105			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2017	14188605	EXPEDITED (15-DAY)		HO	US-ACTELION-A-US2017-162303		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Colitis; Dehydration; Diarrhoea; Gastroenteritis Viral; Orthostatic Hypotension; Vomiting	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Cellcept			S	Unknown	250 Mg, Bid		Not Reported
	Percocet			S	Unknown	10-325 Mg, Qpm		Not Reported
	Protonix			S	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	13560146	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086228		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased;	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Sleep Disorder	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Form: Solution Intravenous	Not Reported
	Simponi		S	Unknown	Form: Solution Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	13560269	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086258			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	13560302	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086368		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Adalimumab		S	Subcutaneous		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Minocycline		S	Unknown		Not Reported
	Rituxan		S	Unknown	Form: Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	13569543	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA086267		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Disability; Drug Ineffective; Drug Intolerance; Joint Stiffness; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naprosyn			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	13569700	EXPEDITED (15-DAY)		OT	CA-SA-2017SA085968		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Emphysema; Hand Deformity; Joint Swelling; Nausea; No Adverse Event; Rheumatoid Arthritis	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			C	Unknown	Powder For Suspension Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	13574117	EXPEDITED (15-DAY)		OT	CA-SA-2017SA085889		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14182556	NON-EXPEDITED			US-PFIZER INC-2017486777		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Enbrel	S	Unk		Pfizer
	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14189986	NON-EXPEDITED			US-AMGEN-USASP2017170314		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14191390	EXPEDITED (15-DAY)		HO, OT	IN-ALEMBIC PHARMACUETICALS LIMITED-2017SCAL000904			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Product Use In Unapproved Indication; Tuberculosis	Hydrochlorothiazide			S		200 Mg, Od		Alembic
	Azoran /00001501/			S		50 Mg, Bid		Not Reported
	Azoran /00001501/			S		Half Tablet Of 50 Mg		Not Reported
	Azoran /00001501/			S				Not Reported
	Lefno			S		20 Mg, Od		Not Reported
	Wysolone			S		20 Mg, Od		Not Reported
	Wysolone			S		2.5 Mg, Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

	Hydroxychloroquine				S		200 Mg, Od			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14191853	NON-EXPEDITED		OT	US-AMGEN-USASP2017170287		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2017	14193816	NON-EXPEDITED			US-AMGEN-USASP2017171055		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Injection Site Pain; Paraesthesia	Enbrel			S	Unknown	50 Mg, Qwk (On Mondays)		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	13560196	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086234		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury;	Arava			S	Oral			Not Reported

Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Plaquenil	S	Oral			Not Reported
	Humira	S	Subcutaneous	Dosage Form- Solution Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram ,1 Every 1 (Week(S)		Not Reported
	Orencia	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form-Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Doasage Form-Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	13568999	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Drug Hypersensitivity; Drug Ineffective; Furuncle; Hand Deformity; Ovarian Neoplasm; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Unknown	Form: Solution Intravenous		Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	13569640	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA085943			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Arava	S	Oral			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Celebrex	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Remicade	S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Rituxan	S	Unknown	Form: Solution Intravenous		Not Reported
	Prednisone	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	13658735	EXPEDITED (15-DAY)		OT	CA-ROCHE-1949445		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Xeljanz			S	Unknown				Not Reported
		Hydroxychloroquine			C					Not Reported
		Leflunomide			C					Not Reported
		Amoxil			C					Not Reported
		Clavulin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	13742316	EXPEDITED (15-DAY)		OT	CA-SA-2017SA122077		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Insomnia; Multiple Sclerosis	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutenous		Not Reported
	Imuran			S	Unknown	100mg Every Morning And 50 Mgevery Evening		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14194273	NON-EXPEDITED			US-PFIZER INC-2017489891		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14194290	NON-EXPEDITED			US-PFIZER INC-2017488710		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Methotrexate Sodium		S	Unk	Pfizer
	Sulfasalazine		S	Unk	Pfizer
	Plaquenil		S	Unk	Not Reported
	Leflunomide		S	Unk	Not Reported
	Rituxan		S	Unk	Not Reported
	Minocycline		S	Unk	Not Reported
	Actemra		S	Unk	Not Reported
	Orencia		S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14194296	NON-EXPEDITED			US-PFIZER INC-2017488821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Actonel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14194393	NON-EXPEDITED			US-PFIZER INC-2017489044		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14195896	EXPEDITED (15-DAY)		OT	CA-SA-2017SA122044		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown	Form: Solution Subcutenous		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14196059	EXPEDITED (15-DAY)		OT	CA-SA-2017SA097945		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Drug Tolerance Decreased; Lymphoma	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Voltaren			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Zostavax			C		Powder For Suspension Subcutaneous			Not Reported
	Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14196518	EXPEDITED (15-DAY)		OT	CA-HIKMA PHARMACEUTICALS CO. LTD-2017CA015727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Qwk		Celltrion
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Qwk		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2017	14197196	EXPEDITED (15-DAY)		OT	PHHY2017PT168675		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Hepatic Enzyme Increased; Hepatic Pain; Hepatitis Toxic; Hepatomegaly; Leukopenia; Polymerase	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Methylprednisolone			S	Unknown			Not Reported

Chain Reaction Positive; Product Use In Unapproved Indication; Pyrexia; Therapy Non-Responder; Thrombocytopenia	Prednisolone		C	Unknown			Not Reported
	Prednisolone		C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14198266	EXPEDITED (15-DAY)		OT	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-154933			Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis	Bortezomib			S	Unknown	Cyclical (2 Cycles)		Not Reported
	Dexamethasone			S	Unknown	Cyclical (2 Cycles)		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Ipca
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Ipca
	Mycophenolate			S	Unknown	2000 Mg, Daily		Not Reported
	Prednisolone			S	Unknown	5 Mg, Daily		Taro
	Belimumab			S	Unknown	Unk, Daily		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	800 Mg, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14198750	NON-EXPEDITED			US-PFIZER INC-2017488651		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199036	EXPEDITED (15-DAY)		DE	US-TORRENT-00004124		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Trazodone Hydrochloride			S		Ingestion Plus Unknown		Unknown
	Morphine Sulfate			S		Ingestion Plus Unknown		Unknown
	Amitriptyline			S		Ingestion Plus Unknown		Unknown
	Sertraline Hydrochloride			S		Ingestion Plus Unknown		Unknown
	Cyclobenzaprine Hydrochloride			S		Ingestion Plus Unknown		Unknown
	Hydroxychloroquine Sulfate			S		Ingestion Plus Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14199197	EXPEDITED (15-DAY)		OT	PHHY2017PT168435		16 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Product Use In Unapproved Indication; Skin Toxicity	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	375 Mg/M2, (1 Day, First Cycle Dose)		Not Reported
	Cyclophosphamide			S	Unknown	750 Mg/M2, (0d ;15 D, 2nd Cycle)		Not Reported
	Prednisolone			S	Unknown	20 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14200006	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004104		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest;	Hydroxychloroquine			S	Oral			Unknown

Completed Suicide; Toxicity To Various Agents	Bupropion Hydrochloride		S	Oral	Unknown
	Zolpidem		S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2017	14201772	NON-EXPEDITED			US-AMGEN-USASP2017171943		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hidradenitis; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2017	13704410	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955888			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

Ilaris	S	Intravenous (not otherwise specified)	Not Reported
Ilaris	S		Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2017	14204804	DIRECT					35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Crying; Diarrhoea; Dizziness; Eye Pain; Feeling Cold; Headache; Hot Flush; Nausea; Tremor; Vomiting	Plaquinil, Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2017	14200199	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006402		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2017	14202804	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006408			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13058523	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015797		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13058898	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015803		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Insomnia; Multiple Sclerosis; Therapeutic Product Effect	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Azathioprine Tablets			S	Unknown	Unk, Bid		Not Reported

Incomplete	Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.		Not Reported
	Imuran /00001501/	S	Unknown	150 Mg, Every 1 Day		Not Reported
	Sulfasalazine	S	Oral	1500 Mg, Bid		Not Reported
	Naprosyn /00256201/	C	Unknown	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13059919	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Retinitis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Sulfasalazie			S	Oral	1 G, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown			Apotex
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13093057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013469		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diarrhoea; Drug Intolerance; Influenza; Musculoskeletal Pain; Rash Macular; Treatment Failure; Vomiting	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Once Every 2 Days		Apotex
	Methotrexate Sodium			S	Subcutaneous	1 Ml, Q.Wk.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Acetaminophen			C		Unk, Prn				Not Reported
	Methotrexate			C	Subcutaneous	1.0 Ml				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13571184	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003052		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Plaquenil			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13571303	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003049		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Minocycline		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13571957	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003145		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Emphysema; Hand Deformity; Joint Swelling; Nausea; No Adverse Event; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13571973	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003143		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Disability; Drug Ineffective; Drug Intolerance; Joint Stiffness; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Product Effect Incomplete	Orencia				S	Unknown				Not Reported
	Rituximab				S	Unknown				Not Reported
	Leflunomide				C					Not Reported
	Naprosyn				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13571994	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13575339	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003055		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Totalis; Alopecia Universalis; Drug Ineffective; Herpes Zoster	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

		Methotrexate Sodium			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Mefenamic Acid			C					Not Reported
		Naproxen			C					Not Reported
		Advil			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13575367	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003054			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13575378	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003056		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia Totalis; Alopecia Universalis; Condition Aggravated; Drug Ineffective; Ear Infection; Herpes Zoster; Pain; Sinusitis; Therapeutic Product Effect Decreased	Plaquenil Tablet		S	Unknown	Concordia
	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Mefenamic Acid		C		Not Reported
	Naproxen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13575385	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Drug Hypersensitivity; Drug Ineffective; Furuncle; Hand Deformity; Ovarian Neoplasm; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13579320	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003178		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling;	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete	Enbrel		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Methotrexate Sodium		S			Not Reported
	Orencia		S	Unknown		Not Reported
	Rituxan		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13640910	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003408		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Drug Tolerance Decreased; Lymphoma	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			C				Not Reported
	Xeljanz			C				Not Reported
	Desoximetasone			C				Not Reported
	Voltaren			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13742320	EXPEDITED (15-DAY)		OT	CA-SA-2017SA122076		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug	Plaquenil			S	Oral			Not Reported

Ineffective; Liver Injury; Liver Injury; Nausea; Toxicity To Various Agents	Arava	S	Oral			Not Reported
	Imuran	S	Unknown			Not Reported
	Simponi	S	Unknown	Form:Solution Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown	Dose- 7.5 To 12.5 Mg		Not Reported
	Methotrexate Sodium	S	Unknown	Dose- 7.5 To 12.5 Mg		Not Reported
	Sulfasalazine	C				Not Reported
	Xeljanz	C	Oral			Not Reported
	Enbrel	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13759359	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004079		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cymbalta			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Leflunomide			C				Not Reported
	Pregabalin			C				Not Reported
	Duloxetine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	13949889	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-079329			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Rheumatoid	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Arthritis	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203158	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2162791-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203235	NON-EXPEDITED			US-AMGEN-USASP2017173070		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Imitrex			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

	Humira			C	Unknown	Unk			Not Reported
	Cosentyx			C	Unknown	Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203449	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-003569			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	200-400 Mg/Day		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203450	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-003567			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	200-400 Mg/Day		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203451	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-003566			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	200-400 Mg/Day		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203452	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2017-US-003568			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Rash; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	200-400 Mg/Day		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14203721	NON-EXPEDITED			US-PFIZER INC-2017493421		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Minocin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14204552	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017496635		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Large Intestine Polyp	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14204650	NON-EXPEDITED			US-PFIZER INC-2017495878		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14205421	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006423		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Toxic Skin Eruption	Plaquenil			S	Oral			Concordia
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14206623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025500		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoarthritis; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2017	14208103	DIRECT	Y				68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13759352	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004056		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Gastric Disorder; Interstitial Lung Disease; Lung Disorder; Pneumonitis; Polyarthritis; Rheumatoid Arthritis; Treatment Failure; Unevaluable Event	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13759363	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004035		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13759364	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004037		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Insomnia; Multiple Sclerosis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Imuran			S	Unknown	100 Mg Every Morning And 50 Mg Every Evening		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Naprosyn			C				Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13759366	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004052		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13762056	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		43 YR	Female	CAN

INC.-GSH201707-004036

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Neck Injury; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13762060	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004070		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Rash	Plaquenil Tablet			S	Oral			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13762064	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004084		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site	Hydroxychloroquine			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naproxen Sodium	C		Not Reported
	Plaquenil	C		Not Reported
	Venlafaxine Hydrochloride	C		Not Reported
	Benadryl	C		Not Reported
	Gold	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13905926	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004854		28 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enterocolitis; Erythema Multiforme	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Bayaspirin			C				Not Reported
	Bredinin			C				Not Reported
	Imuran			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13915396	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982906		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis;	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Enbrel		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Potassium Chloride		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	13989291	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005364		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaphylactic Reaction; Blister; Drug Ineffective; Urticaria	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Ibuprofen			C				Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14190008	NON-EXPEDITED			US-PFIZER INC-2017486641		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Hcq			S				Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14197747	NON-EXPEDITED			US-AMGEN-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Synovitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14202803	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006404		60 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Off Label Use; Retinal Degeneration; Retinal Fovea Disorder; Retinal Toxicity; Retinopathy; Vision Blurred; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown			Concordia
	Acetazolamide			S	Oral			Not Reported
	Acetazolamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14205598	NON-EXPEDITED			US-PFIZER INC-2017492914		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Upper Respiratory Tract Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14206783	EXPEDITED (15-DAY)		OT	KR-IPCA LABORATORIES LIMITED-IPC-2017-KR-003618		62 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Retinal Toxicity; Retinopathy; Visual Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14206792	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3748		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Losec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14208634	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2166093-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event;	Humira			S	Subcutaneous			Not Reported

Arthropathy; Back Pain; Drug Intolerance; Eye Disorder; Impaired Healing; Localised Infection; Mobility Decreased; Musculoskeletal Disorder; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Twinrix Vaccine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14208636	NON-EXPEDITED			US-AMGEN-USASP2017173295			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Pain; Malaise; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14209842	NON-EXPEDITED			US-PFIZER INC-2017497932			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14210193	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017493066		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14212745	NON-EXPEDITED			US-AMGEN-USASP2017173392		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Kineret			S	Unknown	Unk		Not Reported
	Kineret			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Methotrexate			C				Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Remicade			C				Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Arava			C				Not Reported
	Rituxan			C	Unknown	Unk		Not Reported
	Rituxan			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13348697	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017038574		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Gastrooesophageal Reflux Disease; Infection; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Celebrex			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13759320	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004051		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use Issue; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	M-Eslon			C				Not Reported
	Morphine			C				Not Reported
	Statex (Morphine Sulfate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13759324	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004074			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Septic Shock	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13759325	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004075		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Transaminases Increased	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13759357	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004068		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Liver Injury; Liver Injury; Nausea; Toxicity To Various Agents	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported

	Imuran	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Sulfasalazine	C				Not Reported
	Xeljanz	C				Not Reported
	Enbrel	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13762062	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004077		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapy Non-Responder; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Rho(D) Immune Globulin Human			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Ibuprofen			C				Not Reported
	Lipitor			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13762070	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004147		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Hydroxychloroquine		S	Oral	Concordia
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Anakinra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Warfarin		C		Not Reported
	Cortisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13767763	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004179		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous	7.5-12.5 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Myochrysine	S	Intramuscular	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Oxycontin	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Acetaminophen W/Oxycodone	C		Not Reported
Aclasta	C		Not Reported
Actonel	C		Not Reported
Calcium	C		Not Reported
Diphenoxylate Hydrochloride	C		Not Reported
Ergocalciferol	C		Not Reported
Esomeprazole	C		Not Reported
Ferrous Gluconate	C		Not Reported
Loperamide Hydrochloride	C		Not Reported
Nasonex	C		Not Reported
Nortriptyline Hydrochloride/Perphenazine	C		Not Reported
Pantoprazole	C		Not Reported
Prednisone	C		Not Reported
Trazodone Hydrochloride	C		Not Reported
Tylenol	C		Not Reported
Vitamin D2	C		Not Reported
Biotin/Calcium D-Pantothenate/D-Alphatocopherylacetate/Nicotinamide/Pyridoxine/Hydrochloride/Retinol	C		Not Reported
D-Alpha Tocopherol/ Fish Oil	C		Not Reported
Pantoprazole Magnesium	C		Not Reported
Calcium Dpantothenate/Ergocalciferol/Nicotinamide/Pyridoxine Hydrochloride/Riboflavin/Thiamine Hydro	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13891710	NON-EXPEDITED			US-PFIZER INC-2017359153			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Diclofenac Sodium			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13990631	NON-EXPEDITED			US-PFIZER INC-2017403528		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14119590	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020045		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cefazolin For Injection			S	Unknown			Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Naproxen	C	Unknown	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14128701	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020160			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Urticaria	Apo-Leflunomide			S	Unknown			Apotex
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Simponi			S	Subcutaneous	50 Mg, 1 Every 3 Weeks		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Intramuscular	25 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Week		Not Reported
	Gold			S	Other			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Arthrotec			S	Oral	50 Mg, Bid		Not Reported
	Mefenamic Acid			C	Unknown	200 Mg, Unk		Not Reported
	Tylenol /00020001/			C	Unknown	650 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14198901	NON-EXPEDITED			US-PFIZER INC-2017493360		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14212335	EXPEDITED (15-DAY)		OT	PHHY2017KR170696		60 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Retinal Degeneration; Retinopathy; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14213305	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3759		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyp	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14213588	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017174356		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Chills; Dizziness; Headache; Infection; Nausea; Palpitations; Pharyngitis; Pruritus; Rash; Rectal Haemorrhage; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	11915544	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-16K-028-1537207-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Decreased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Sulfasalazine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	12431174	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1639869-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13759358	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Muscle Spasms; Pyelonephritis	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Remeron			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13762057	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004065		85 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Body Temperature Increased; Diarrhoea; Drug Ineffective; Dry Skin; Gastrointestinal Disorder; Headache; Nausea; Pharyngeal Oedema; Pruritus; Pustule; Rheumatoid Arthritis; Visual Impairment	Hydroxychloroquine			S	Oral			Concordia
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13762059	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004067		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Foot Deformity; Grip Strength Decreased; Hip Arthroplasty; Hypoaesthesia; Hypoaesthesia; Joint Swelling; Knee Arthroplasty; Musculoskeletal Disorder; Pain In Extremity; Red Blood Cell Sedimentation Rate Abnormal; Treatment Noncompliance	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Every Other Week		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Pantoprazole			C				Not Reported
	Perindopril			C				Not Reported
	Rosuvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13762063	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-		62 YR	Female	CAN

004080

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Insomnia; Joint Swelling; Malaise; Meniere'S Disease; Pain; Peripheral Swelling	Plaquenil			S	Oral			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Omeprazole			C				Not Reported
	Tylenol 3			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13762069	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004145		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erythema; Extremity Contracture; Gastrointestinal Toxicity; Hypersensitivity Vasculitis; Hypoaesthesia; Hypoaesthesia; Joint Stiffness; Joint Swelling; Paraesthesia; Rash; Scar; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Diclofenac			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Omega-3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13762071	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004181		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported

	Methotrexate				S	Unknown				Not Reported
	Simponi				S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13767761	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004141		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Oral			Concordia
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13767762	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004156		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Depression; Drug Ineffective; Drug	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported

Intolerance; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Pain; Osteoarthritis; Pain In Extremity; Peripheral Swelling; Psoriasis; Rash; Rash; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13803313	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004428		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Asthenia; Chest Pain; Constipation; Drug Ineffective; Dysphagia; Dyspnoea; Fatigue; Feeling Abnormal; Gastritis; Gastrointestinal Disorder; Headache; Rash; Rheumatoid Arthritis; Sleep Disorder; Vision Blurred; Weight Increased	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Tablet			S	Oral	2.5 Mg (6 Tablets By Mouth Once Weekly)		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Movantik			C				Not Reported
	Xeljanz			C				Not Reported
	Tramadol Hcl			C				Not Reported
	Prednisone			C				Not Reported
	Neurontin			C				Not Reported
	Arava			C				Not Reported
	Fosamax			C				Not Reported
	Estradiol			C				Not Reported
	Levocetirizine Dihydrochloride			C				Not Reported
	Norco			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13877033	NON-EXPEDITED			US-PFIZER INC-2017353740		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported
	Reclast	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13939919	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005088		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Plaquenil Tablet			S	Oral			Concordia
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Imuran			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Codeine			C				Not Reported
	Fentanyl			C				Not Reported
	Gold			C				Not Reported
	Levofloxacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	13947859	NON-EXPEDITED			US-AMGEN-USASP2017133931			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Rituxan	S	Unknown	Unk		Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14089188	EXPEDITED (15-DAY)		OT	US-BEH-2017084319		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced	Human Immunoglobulin Iv (Inn)			S	Intravenous (not otherwise specified)	400 1g/Kg		Csl Behring
	Human Immunoglobulin Iv (Inn)			S				Csl Behring
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (At 6 Weeks Gestation)		Not Reported
	Dexamethasone			S	Unknown	8 Mg, Unk		Not Reported
	Dexamethasone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14089247	EXPEDITED (15-DAY)		OT	US-BEH-2017084346			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Block Congenital	Human Immunoglobulin Iv (Inn)			S	Intravenous (not otherwise specified)	400 1g/Kg		Csl Behring
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (From 6 Weeks Gestation)		Not Reported
	Dexamethasone			S	Unknown	8 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14128207	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020228		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Apo-Leflunomide			S	Unknown	Unk		Apotex

Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14134651	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020182		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; No Adverse Event; Peripheral Swelling; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.I.W		Not Reported
	Plaquenil /00072602/			S	Oral	600 Mg, Unk		Not Reported
	Folic Acid			C	Unknown	1 Df, Q.I.W		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14136074	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug	Apo-Leflunomide			S	Unknown	1 Every 1 Day		Apotex

Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Q.I.W	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14137094	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020197		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14144563	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Toxicity; Drug Ineffective	Apo-Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Mavik			C	Unknown	Unk		Not Reported
	Vitamin B12 /00056201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14145504	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020337		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Nausea; Pain; Pain In Extremity	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			C	Oral	200 Mg, Bid		Not Reported
	Imuran /00001501/			C	Unknown	3 Df, Qd		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported
	Sulfasalazine			C	Unknown	2 Df, Qd		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14149683	NON-EXPEDITED			US-AMGEN-USASP2017164463		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	25 Mg, Unk		Amgen
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	2.5 Mg, Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14186399	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006388		60 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cystoid Macular Oedema; Off Label Use; Retinal Degeneration; Retinal Fovea Disorder; Retinal Toxicity; Retinopathy; Vision Blurred; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine	S	Unknown	Total Cumulative Dose Was 2920 G		Concordia
	Acetazolamide	S	Oral			Not Reported
	Acetazolamide	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14209688	NON-EXPEDITED			US-PFIZER INC-2017495692		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S				Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported
	Imitrex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14217879	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Interstitial Lung Disease; Pulmonary Fibrosis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.I.W		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2017	14217959	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex

Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Apo-Mirtazapine	S	Unknown	15 Mg, Unk		Apotex
	Actemra	S	Unknown	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	11923225	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539186-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	11923638	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539505-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cystitis; Drug Ineffective; Guillain-Barre Syndrome; Micturition Disorder; Walking Aid User	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	11924440	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539316-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Fall; Feeling Hot; Joint Effusion; Liver Function Test Abnormal; Local Reaction; Weight Increased; Wrist Fracture	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	13912391	NON-EXPEDITED			US-PFIZER INC-2017368520		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14003929	NON-EXPEDITED		OT	US-JNJFOC-20170901323			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14129059	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP020172		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dysstasia; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Mobility Decreased; Nausea; Pain; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Arava			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Mg, 1 Every 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14144410	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14144455	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diverticulitis; Drug Ineffective; Fatigue; Malaise; Nausea; Poor Quality Sleep	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown	10 Mg, 1 Every 3 Week(S)		Not Reported
	Sodium Aurothiomalate			S	Unknown	50 Mg, 1 Every 3 Week(S)		Not Reported
	Methotrexate			C	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	15 Mg, Unk		Not Reported

	Sulfasalazine			C	Unknown	1.5 Mg, Bid				Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Tid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14145036	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020348		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Enbrel			C	Unknown	50 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14145041	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020352		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14148577	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP020369		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Myochrysine			S	Unknown	50 Mg, Unk		Not Reported

			Plaquenil /00072602/		S	Unknown	Unk		Not Reported
			Enbrel		C	Unknown			Not Reported
			Humira		C	Unknown			Not Reported
			Meloxicam		C	Unknown	Unk		Not Reported
			Methotrexate		C	Unknown	20 Mg, Unk		Not Reported
			Orencia		C	Unknown			Not Reported
			Remicade		C	Unknown	Unk		Not Reported
			Sulfasalazine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14156367	NON-EXPEDITED			US-PFIZER INC-2017470147		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14221233	NON-EXPEDITED			US-PFIZER INC-2017497894		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14221316	NON-EXPEDITED			US-PFIZER INC-2017503437		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metoprolol Tartrate			S		Unk		Unknown
	Atenolol			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14221394	NON-EXPEDITED			US-PFIZER INC-2017505779		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14222376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2173796-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14222450	EXPEDITED (15-DAY)		OT	US-ALEMBIC PHARMACUETICALS LIMITED-2017SCAL000931			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S		Unk		Alembic
	Humira			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Azathioprine			S		50 Die		Not Reported
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Imuran /00001501/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2017	14222936	NON-EXPEDITED		OT	US-JNJFOC-20170915896			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Albuterol			C	Unknown			Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Oral			Not Reported
	Naproxen			C	Oral			Not Reported
	Oxycontin			C	Oral			Not Reported
	Valacyclovir			C	Unknown			Not Reported
	Hydromorphone			C	Oral			Not Reported
	Norvasc			C	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2017	14223813	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005899		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Bradyarrhythmia; Brain Natriuretic Peptide Increased; Bundle Branch Block Right; Cardiac Hypertrophy; Cardiac Index Decreased; Cardiomyopathy; Chest Discomfort; Conduction Disorder; Dizziness; Dyspnoea; Hyperdynamic Left Ventricle; Palpitations; Pulmonary Hypertension; Sinus Bradycardia	Plaquenil Tablet			S	Oral			Concordia
	Synthroid			C				Not Reported
	Evista			C				Not Reported
	Teriparatide			C				Not Reported
	Boniva			C				Not Reported
	Dyazide			C				Not Reported
	An Over-The-Counter Nonsteroidal Anti-In?Ammatory			C				Not Reported
	Nutritional Supplements			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2017	14223819	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006469		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Lupus Myocarditis; Lymphocytic Infiltration	Plaquenil			S	Unknown			Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2017	14223821	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006473		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil			S	Oral	200 Mg Daily And 400 Mg Daily Alternatively		Concordia
	Plaquenil			S				Concordia
	Fosamac			C				Not Reported
	Pariet			C				Not Reported
	Onealfa			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2017	11931835	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1539512-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Lupus-Like Syndrome; Pain; Pemphigus; Rheumatoid Arthritis; Swelling	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel Kit			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Cortisone		S	Unknown		Not Reported
					Reactine (Cetirizine Hydrochloride)		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2017	12918685	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1771809-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fibromyalgia; Gait Disturbance; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown	Dosage Maintained		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2017	13692479	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-		46 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Vimovo			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2017	14223908	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006472		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy	Plaquenil Tablet			S	Oral			Concordia
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2017	14223909	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006478			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2017	14224324	NON-EXPEDITED			US-AMGEN-USASP2017176452		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	13028955	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006376		39 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Hypoglycaemia	Plaquenil			S	Oral	Dose Alternated Between 200 Mg And 400 Mg Every Day		Concordia
	Plaquenil			S				Concordia
	Metgluco			C				Not Reported
	Basen [Voglibose]			C				Not Reported
	Bydureon			C				Not Reported
	Humalog			C				Not Reported
	Predonine			C				Not Reported
	Endoxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	13668946	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA105857		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident;	Leflunomide			S	Oral			Not Reported

Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Hydroxychloroquine	S	Oral			Not Reported
	Actemra	S	Unknown			Not Reported
	Cimzia	S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Unknown	Form: Solution Intravenous		Not Reported
	Prednisone	C	Unknown			Not Reported
	Methotrexate	C				Not Reported
	Aspirin	C				Not Reported
	Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	13687633	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003769		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported
	Aspirin			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	13692739	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	13692740	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003794		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	13955955	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017387353		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Fall; Pain; Upper Limb Fracture	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14126068	EXPEDITED (15-DAY)		LT, OT	PHHY2017AU157224			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Lupus Nephritis; Product Use In Unapproved Indication; Rash; Serositis; Systemic Lupus Erythematosus	Methotrexate			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Azathioprine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclophosphamide			S	Oral	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14148090	NON-EXPEDITED			US-PFIZER INC-2017469922			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		25 Mg, Unk		Pfizer
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer

	Azulfidine	S		500 Mg, Unk		Pfizer
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil	S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14224541	EXPEDITED (15-DAY)		DE, HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005898		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Aortic Valve Incompetence; Biopsy Heart Abnormal; Blood Creatinine Increased; Cardiac Failure Congestive; Cardiac Index Decreased; Cardiomyopathy; Dilatation Atrial; Ejection Fraction Decreased; Left Ventricular Dilatation; Mitral Valve Incompetence; Myocarditis; Prohormone Brain Natriuretic Peptide Increased; Pulmonary Hypertension; Right Ventricular Systolic Pressure Increased; Tricuspid Valve Incompetence; Vascular Resistance Pulmonary Increased	Plaquenil Tablet			S	Oral			Concordia
	Aspirin			C				Not Reported
	Prednisone			C				Not Reported
	Isordil			C				Not Reported
	Isordil			C				Not Reported
	Hydralazine			C				Not Reported
	Coreg			C				Not Reported
	Cytoxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14224543	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006490		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Rash Maculo-Papular; Rash Pruritic	Plaquenil			S	Oral			Concordia
	Plaquenil			S				Concordia
	Lanzor			S	Oral			Not Reported
	Amlor			S	Oral			Not Reported
	Cortancyl			C				Not Reported
	Cortancyl			C				Not Reported
	Orocal D(3)			C				Not Reported
	Uvedose			C				Not Reported
	Doliprane			C				Not Reported
	Endotelon			C				Not Reported
	Laroxyl			C				Not Reported
	Refresh			C				Not Reported
	Diffu K			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14224544	EXPEDITED (15-DAY)		HO	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006491			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Systemic Lupus Erythematosus	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14225305	NON-EXPEDITED			US-PFIZER INC-2017476157		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Sulfasalazine			S				Pfizer

	Plaquenil	S	Unk		Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Arava	S	20 Mg, Unk		Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14225465	NON-EXPEDITED			US-PFIZER INC-2017509024		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14225482	NON-EXPEDITED			US-PFIZER INC-2017507498		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14225837	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021538			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Mycophenolate			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14226200	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017498317		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperthermia; Neutrophil Count Increased; Rash Maculo-Papular; Rash Pruritic	Amlor			S	Oral	5 Mg, Daily		Pfizer
	Plaquenil			S		200 Mg, Daily		Not Reported
	Lanzor			S	Oral	30 Mg, Daily		Not Reported
	Cortancyl			C		20 Mg, Unk		Not Reported
	Orocal D3			C		500 Mg/400ui		Not Reported
	Uvedose			C		100000 Iu		Not Reported
	Doliprane			C		Unk		Not Reported
	Endotelon			C		150 Mg, Unk		Not Reported
	Laroxyl			C		10 Gtt, Unk		Not Reported
	Refresh			C				Not Reported
	Diffu K			C		600 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14226617	NON-EXPEDITED			US-ANTARES PHARMA, INC.-2017-SPO-MX-0302		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Cough; Decreased Appetite; Hepatitis; Injection Site Haemorrhage; Injection Site Swelling; Malaise; Secretion Discharge; Skin Odour Abnormal; Urine Abnormality; White Blood Cell Count Decreased	Otrexup			S	Subcutaneous	10 Mg/0.4ml, Qwk		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Clonazepam			C		2 Mg, Unk		Not Reported
	Fluoxetin			C	Oral	20 Mg, Qd		Not Reported
	Folic Acid			C		1 Mg, Unk		Not Reported
	Multivitamins			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2017	14228119	DIRECT					79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucinations, Mixed	Hydroxychloroquine			S	Oral			Not Reported
	Allopurinol			C				Not Reported
	Isosorb Mono			C				Not Reported
	Metformin			C				Not Reported
	Metoprolol			C				Not Reported
	Simvastatin			C				Not Reported
	Spironolactone			C				Not Reported
	Warfarin			C				Not Reported
	Calcium			C				Not Reported
	Vitamin E			C				Not Reported
	Omega 3 Q Plus			C				Not Reported
	One A Day			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	12614054	NON-EXPEDITED			US-PFIZER INC-2016369363		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Biaxin			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Prenatal			S		Unk		Not Reported
	Tylenol 8 Hour			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Penicillamine			S		Unk		Not Reported
	Tylenol			S		Unk		Not Reported
	Polaramine			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Phenothrin			S		Unk		Not Reported
	Tryptan			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

	Rumex Acetosa			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	13251899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006759		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Maculopathy; Pulmonary Toxicity; Thrombocytopenia	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported
	Apixaban			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	13669045	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105891		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Surgery; Joint Swelling; Knee Arthroplasty; Pain; Therapeutic Response Decreased	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Oral			Not Reported
	Clindamycin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	13669276	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105875		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Off Label Use; Osteoporosis; Synovitis; Therapeutic Response Decreased; Treatment Failure	Arava			S	Oral	Last Period: 4.4 Years		Not Reported
	Hydroxychloroquine			S	Oral	Last Period: 4.4 Years		Not Reported
	Hydroxychloroquine			S	Oral	Last Period: 4.4 Years		Not Reported
	Hydroxychloroquine			S	Oral	Last Period: 4.4 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown	Intravenous Solution		Not Reported
	Sulfasalazine			S	Oral	Last Period: 4.4 Years		Not Reported
	Xeljanz			S	Oral	Last Period: 4.4 Years		Not Reported
	Actemra			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	13670204	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105979		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	13670244	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA105878		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Cardiovascular Disorder; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Arava			S	Oral				Not Reported
	Plaquenil			S	Oral				Not Reported
	Celebrex			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Actemra			C					Not Reported
	Dilaudid			C					Not Reported
	Furosemide			C					Not Reported
	Hydromorph Contin			C	Unknown				Not Reported
	Lyrica			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14214009	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2023197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Imuran			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14221253	NON-EXPEDITED			US-PFIZER INC-2017505702		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14221291	NON-EXPEDITED			US-PFIZER INC-2017504376		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14228591	EXPEDITED (15-DAY)		OT	US-ROCHE-2025989		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Seizure; Vomiting	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Nucynta			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Enbrel			S	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14228893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2027073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Ill-Defined Disorder; Mental Disorder; Muscle Injury; Myalgia; Pruritus; Rash	Cellcept			S	Unknown	Maximum Dose 1.5 Gm Bid (Ongoing)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14229074	NON-EXPEDITED			US-AMGEN-USASP2017177267		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14229125	NON-EXPEDITED			PHEH2017US037803			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fluid Retention; Inappropriate Schedule Of Product Administration	Cosentyx			S	Subcutaneous	300 Mg, Qmo (Q4w)		Novartis
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14229320	NON-EXPEDITED			US-PFIZER INC-2017509136		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	12127125	NON-EXPEDITED			US-PFIZER INC-2016116717		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Azulfidine			S	Oral	50 Mg, 2x/Day		Pfizer
	Azulfidine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	12893024	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013313		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Apotex
	Apo-Leflunomide			S	Oral			Apotex
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	13687632	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		65 YR	Female	CAN

INC.-GSH201706-003766

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Surgery; Joint Swelling; Knee Arthroplasty; Pain; Therapeutic Response Decreased	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C				Not Reported
	Clindamycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	13692483	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003779		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling;	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Dilaudid			C				Not Reported
	Furosemide			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C				Not Reported

Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	13758267	NON-EXPEDITED			US-PFIZER INC-2017303580		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14221018	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539333-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

Decreased	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14235002	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Apo Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14235431	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Asa 81			S	Unknown	Unk		Not Reported

Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Apo-Diclo Rapide	S	Unknown	Unk		Apotex
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14235435	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021654		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Fatigue; Nausea; Toxicity To Various Agents; Viral Upper Respiratory Tract Infection; Visual Impairment	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Allergy Liquid Gel Capsules(Diphenhydramine Hydrochloride)			S	Oral	50 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Cyclinex 2			C	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Mg, Unk		Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06852001/			C	Unknown	Unk		Not Reported
	Filgrastim			C	Unknown	Unk		Not Reported
	Melatonin			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Percocet /00446701/			C	Unknown	Unk		Not Reported
	Tecta			C	Unknown	Unk		Not Reported

	Vitamin C /00008001/			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14236014	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006507		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Plaquenil Tablet			S	Unknown			Concordia
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14236364	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3845			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14236429	NON-EXPEDITED			US-PFIZER INC-2017506051		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Daypro			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

	Humira			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14236601	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Seizure	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Methotrexate			C	Oral	25 Mg, Unk		Not Reported
	Methotrexate			C	Oral	10 Mg, Unk		Not Reported
	Sulfasalazine			C	Oral	1 G, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14236630	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021540			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Atorvastatin			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Trichlormethiazide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2017	14237699	NON-EXPEDITED			US-AMGEN-USASP2017177359			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen

	Humira	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Methotrexate	C		Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14202802	EXPEDITED (15-DAY)		HO	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006399		81 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Cryptococcosis; Cryptococcus Test Positive; Depressed Level Of Consciousness; Encephalitis; Headache; Peritonitis; Pulmonary Mass; Pulmonary Tuberculosis; Pyrexia; Rales	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14236093	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1680413-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Retinal Toxicity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14237909	NON-EXPEDITED			US-AMGEN-USASP2017177654		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Cytoxan			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238009	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006862		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Prednisone			S	Unknown	40 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	20 Mg, Qd		Apotex

Sulfasalazine	S	Oral	2 Mg, Qd		Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
Enbrel	S	Unknown	Unk, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238249	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006516		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Hydroxychloroquine			S	Oral			Concordia
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238250	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006517		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Polyneuropathy; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238253	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006519		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Cystitis; Dermal Cyst; Ear Infection; Pain In Extremity; Pleurisy; Urinary Tract Infection	Plaquenil Tablet			S	Oral			Concordia
	Ciclosporin			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238257	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006523		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Cimzia			S	Subcutaneous	Every Other Week		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238258	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006524		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			C				Not Reported

		Arava			C						Not Reported
		Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238264	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006540		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Pressure Increased; Drug Hypersensitivity; Dyspnoea; Eosinophilic Bronchitis; Influenza; Respiratory Disorder	Plaquenil Tablet			S	Oral			Concordia
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Aerius (Desloratadine)			C				Not Reported
	Alvesco			C				Not Reported
	Amlodipine Besilate			C				Not Reported
	Pulmicort			C				Not Reported
	Singulair			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238265	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006541		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238268	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006544		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Pneumonia	Hydroxychloroquine			S	Oral			Concordia
	Certolizumab Pegol			S	Subcutaneous	Every Other Week		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Every Other Week		Not Reported
	Lipitor			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14238430	NON-EXPEDITED			US-PFIZER INC-2017510940		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2017	14239442	NON-EXPEDITED			US-PFIZER INC-2017512700		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	13164232	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17P-028-1848106-00		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pneumonia; Weight Increased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	13385904	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002047		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Bladder Cancer; C-Reactive Protein Abnormal; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Every Other Week		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	13692294	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003799		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Drug Ineffective; Haemochromatosis;	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia

Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Off Label Use; Osteoporosis; Synovitis; Therapeutic Response Decreased; Treatment Failure	Arava			S	Oral	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Rituxan			S	Unknown	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Xeljanz			S	Oral	Not Reported
	Actemra			S	Unknown	Not Reported
	Infliximab			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14223910	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006480		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Bladder Cancer; C-Reactive Protein Abnormal; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			C				Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14241609	NON-EXPEDITED			US-AMGEN-USASP2017178453		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14241644	EXPEDITED (15-DAY)		HO	CA-APOTEX-2017AP021732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Viread			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14241790	EXPEDITED (15-DAY)		DE	US-TORRENT-00004812		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral			Unknown
	Cyclobenzaprine			S	Oral			Unknown
	Methadone			S	Oral			Unknown
	Pregabalin			S	Oral			Unknown
	Hydrocodone - Acetominophen			S	Oral			Unknown
	Warfarin			S	Oral			Unknown
	Hydroxychloroquine			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14241794	EXPEDITED (15-DAY)		DE	US-TORRENT-00004823		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide;	Carbamazepine			S	Oral			Unknown

Toxicity To Various Agents	Atenolol			S	Oral			Unknown
	Enalapril			S	Oral			Unknown
	Hydroxychloroquine			S	Oral			Unknown
	Hydrocodone - Acetominophen			S	Oral			Unknown
	Buspirone			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown
	Prednisone			S	Oral			Unknown
	Omeprazole			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14241898	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006550		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14242339	NON-EXPEDITED			US-PFIZER INC-2017512999		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Codeine			S		Unk		Not Reported
	Ibuprofen			S		Unk		Pfizer
	Prevnar			S		Unk		Pfizer
	Formaldehyde			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported

	Lanolin	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14242374	NON-EXPEDITED			US-PFIZER INC-2017513406		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14242471	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021921			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Hepatitis; Rash	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			C	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14242656	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3920		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14242792	NON-EXPEDITED			US-AMGEN-USASP2017178811		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Oral	Unk		Not Reported
	Mtx			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2017	14243125	EXPEDITED (15-DAY)		HO	CA-APOTEX-2017AP021967		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Nerve Compression; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Gabapentin			S	Unknown	300 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2017	13148181	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1847895-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Weight Decreased	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2017	14238212	NON-EXPEDITED			US-AMGEN-USASP2017177665		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	13143755	EXPEDITED (15-DAY)		HO	CA-ABBVIE-17P-028-1848123-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Eruption; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Femur Fracture; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14025307	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005457			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14246296	NON-EXPEDITED			US-AMGEN-USASP2017178893		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd, 30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14246691	NON-EXPEDITED			US-PFIZER INC-2017512768		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14246865	NON-EXPEDITED			US-PFIZER INC-2017514784			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Methotrexate Sodium			S		Unk			Pfizer
	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14246875	NON-EXPEDITED			US-PFIZER INC-2017515120		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14246938	NON-EXPEDITED			US-PFIZER INC-2017516947		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14247194	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2181610-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14247767	NON-EXPEDITED			US-AMGEN-USASP2017179314		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14249118	EXPEDITED (15-DAY)		OT	CA-SA-2017SA232086		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2017	14249397	NON-EXPEDITED			US-AMGEN-USASP2017178738		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Arava	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	12805185	EXPEDITED (15-DAY)		HO	LT-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-125180		52 YR	Female	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	13156965	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1848194-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	13669700	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017091877		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adnexa Uteri Mass; Anaphylactic Reaction; Anaphylactic Shock; Barrett'S Oesophagus; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Feeling Abnormal; Goitre; Impaired Gastric Emptying; Malaise; Oesophageal Operation; Pain; Pelvic Mass; Pharyngeal Swelling; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Thyroidectomy; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xalkori			S	Unknown	Unk		Not Reported
	Keflex			S	Unknown	Unk		Not Reported
	Augmentin			S	Unknown	Unk		Not Reported
	Progestin			S	Unknown	Unk		Not Reported
	Vicodin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	13692481	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003773		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Unknown	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Ciclosporin	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14230011	NON-EXPEDITED			US-PFIZER INC-2017509054		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Enbrel		S		Unk	Pfizer
	Humira		S		Unk	Not Reported
	Hydroxychloroquine		S		Unk	Not Reported
	Xeljanz		C		Unk	Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14239375	NON-EXPEDITED			US-PFIZER INC-2017512951		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14244152	NON-EXPEDITED			US-PFIZER INC-2017515420		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14249640	NON-EXPEDITED			US-AMGEN-USASP2017179636		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Maculopathy; Nausea; Pneumonitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk				Not Reported
	Sulfasalazine			C		Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14249713	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.-2017US21922			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Warfarin			S	Oral	Unk		Invagen
	Diltiazem			S	Oral	Unk		Not Reported
	Hydrochloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14250855	NON-EXPEDITED			US-PFIZER INC-2017518251		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14251687	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2017VAL001605		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Rash Erythematous	Furosemide			S				Validus
	Plaquenil /00072603/			S	Oral	2 Df, Qd		Not Reported
	Bactrim			S	Oral	2 Df, Qd		Not Reported
	Speciafoldine			S	Oral			Not Reported
	Procoralan			S	Oral	2 Df, Qd		Not Reported
	Aldactone /00006201/			S	Oral			Not Reported

	Triatec /00885601/			S					Not Reported
	Previscan /00789001/			S	Oral	Unk, Qd			Not Reported
	Cerazette (Desogestrel)			S					Not Reported
	Tavanic			S	Oral	2 Df, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14253367	NON-EXPEDITED			US-AMGEN-USASP2017178911			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Dyspnoea; Vision Blurred	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2017	14254332	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2017GSK184739		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tamsulosin			S	Oral	Unk		Glaxosmithkline
	Ranitidine			S	Oral	Unk		Glaxosmithkline
	Salicylate			S	Oral	Unk		Not Reported
	Atropine + Diphenoxylate			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	11410170	NON-EXPEDITED		OT	US-BAYER-2015-400653		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dysuria; Emotional Distress; Fatigue; Fibromyalgia;	Avelox			S	Oral	400 Mg, Unk		Bayer
	Lidocaine			C		Unk		Not Reported

Hypoaesthesia; Impaired Work Ability; Injury; Insomnia; Memory Impairment; Muscular Weakness; Neuropathy Peripheral; Pain; Pain; Pain In Extremity; Paraesthesia; Polyneuropathy; Small Fibre Neuropathy; Tenderness; Tinnitus	Zithromax	C	Unk	Not Reported
	Flonase	C	Unk	Not Reported
	Xanax	C	Unk	Not Reported
	Medrol	C	Unk	Not Reported
	Plaquenil	C	Unk	Not Reported
	Zonegran	C	Unk	Not Reported
	Ultram	C	Unk	Not Reported
	Estring	C	Unk	Not Reported
	Diflucan	C	Unk	Not Reported
	Gabapentin	C	Unk	Not Reported
	Nortriptyline	C	Unk	Not Reported
	Ketamine	C	Unk	Not Reported
	Elavil	C	Unk	Not Reported
	Lyrica	C	Unk	Not Reported
	Mexiletine	C	Unk	Not Reported
	Immunoglobulin [Immunoglobulin]	C	Unk	Not Reported
	Pyridium	C	Unk	Not Reported
	Reglan	C	Unk	Not Reported
	Toradol	C	Unk	Not Reported
	Plaquenil	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	13049759	EXPEDITED (15-DAY)		OT	CA-ROCHE-1869685		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Sodium Aurothiomalate			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Arava			C	Unknown				Not Reported
		Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	13562256	EXPEDITED (15-DAY)		OT	CA-ROCHE-1933628		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clavulin			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	13668927	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA105816		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported

Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown	Form: Powder For Solution Intravenous	Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown	Form: Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown	Every 4 Week	Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown	Form: Solution Subcutaneous	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14061445	NON-EXPEDITED			US-AMGEN-USASP2017150787		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14243926	NON-EXPEDITED			US-PFIZER INC-2017514745		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14254220	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006580		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Plaquenil Tablet			S	Oral			Concordia

Losartan	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14254631	NON-EXPEDITED			US-PFIZER INC-2017518888		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Diclofenac Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Nabumetone			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2017	14254732	NON-EXPEDITED			US-PFIZER INC-2017519179		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	13669754	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105859		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Increased; Drug Ineffective; Impaired Healing; Joint Range Of	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Motion Decreased; Joint Swelling; Lichen Planus; Musculoskeletal Pain; Rosacea; Shoulder Operation; Spinal Stenosis; Synovitis; Treatment Failure	Salazopyrin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14160716	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006265			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Injection Site Reaction; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14198802	NON-EXPEDITED			US-PFIZER INC-2017492639		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14258579	NON-EXPEDITED			US-PFIZER INC-2017520658		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Percocet			S		Unk		Not Reported
	Tricor			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported
	Requip			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14258680	NON-EXPEDITED			US-PFIZER INC-2017521155			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Pregabalin			S		Unk		Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Abatacept			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Zolpidem			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14260762	EXPEDITED (15-DAY)		OT	CA-SA-2015SA014036		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14260768	EXPEDITED (15-DAY)		OT	CA-SA-2016SA060744		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Enbrel			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown	Powder For Solution Intravenous		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prevacid			C				Not Reported
	Folate Sodium			C				Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2017	14260783	EXPEDITED (15-DAY)		OT	CA-SA-2016SA073104		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein; Cough; Drug Ineffective; Impaired Healing; Joint Range Of Motion Decreased; Joint Swelling; Lichen Planus; Lower Respiratory Tract Infection; Musculoskeletal Pain; Nasal Congestion; Rhinorrhoea; Rosacea; Shoulder Operation; Spinal Stenosis; Synovitis; Treatment Failure	Plaquenil	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Salazopyrin	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	12365744	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016059269		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Intolerance; Glaucoma; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Osteoarthritis; Pain; Rheumatoid Arthritis; Sinusitis; Therapeutic Product Effect Decreased; Vertigo	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	50 Mg, Every 21 Days		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	7.5 Mg, Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	13915422	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017128674		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Fatigue; Rheumatoid Arthritis; Treatment Failure; Visual Impairment; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk				Amgen
	Methotrexate			S	Unknown	Unk				Not Reported
	Plaquenil			S	Unknown	Unk				Not Reported
	Arava			S	Unknown	Unk				Not Reported
	Humira			S	Subcutaneous	Unk				Not Reported
	Orencia			C		Unk				Not Reported
	Meloxicam			C		Unk				Not Reported
	Prednisone			C		Unk				Not Reported
	Xeljanz			C		5 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14189638	NON-EXPEDITED			US-AMGEN-USASP2017170809		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Skin Infection	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14262448	NON-EXPEDITED			US-AMGEN-USASP2017180930		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14262464	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-4028		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Interstitial Lung Disease; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 To 15 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Monday To Friday		Not Reported
	Imuran			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14262830	EXPEDITED (15-DAY)		OT	AU-IPCA LABORATORIES LIMITED-IPC-2017-AU-003653		54 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14263657	NON-EXPEDITED			US-PFIZER INC-2017520570		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2017	14263729	EXPEDITED (15-DAY)		DS, OT	CA-BAXTER-2017BAX040502		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Metronidazole 5mg/Ml Injection	S	Unknown	Dosage Form: Not Specified.	Baxter
	Apo Sulfasalazine	S	Unknown	Dosage Form: Tablet	Not Reported
	Apo-Bisoprolol	S	Unknown	Dosage Form: Tablet	Not Reported
	Apo-Leflunomide	S	Unknown	Dosage Form: Tablet	Not Reported
	Apo-Norflox	S	Unknown	Dosage Form: Tablet	Not Reported
	Apo-Prednisone	S	Unknown	Dosage Form: Tablet	Not Reported
	Arava	S	Unknown	Dosage Form: Tablet	Not Reported
	Arthrotec	S	Unknown	Dosage Form: Tablet	Not Reported
	Ceclor	S	Unknown	Dosage Form: Not Specified	Not Reported
	Celebrex	S	Oral		Not Reported
	Demerol	S	Unknown	Dosage Form: Not Specified	Not Reported
	Erythro-Ec	S	Unknown	Dosage Form: Enteric Coated Capsule	Not Reported
	Humira	S	Subcutaneous	Dosage Form: Subcutaneous Solution	Not Reported
	Levofloxacin Hemihydrate	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Meperidine Hydrochloride	S	Unknown		Not Reported
	Methotrexate	S	Oral	Dosage Form: Not Specified	Not Reported
	Plaquenil	S	Oral	Dosage Form: Tablet	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2017	14265804	EXPEDITED (15-DAY)		HO, OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006611		44 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction	Plaquenil 200 Mg Tablet			S	Oral			Concordia

	Valmetrol-3			C						Not Reported
	Omeprazole			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	13884050	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-17K-163-1955806-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blindness; Drug Eruption; Drug Hypersensitivity; Macular Degeneration; Procedural Pain; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Mobic			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Tramadol			C				Not Reported
	Lipitor			C				Not Reported
	Sucralfate			C				Not Reported
	Protonix			C				Not Reported
	Forticol			C				Not Reported
	Diazepam			C				Not Reported
	Lunesta			C				Not Reported
	Aspirin			C				Not Reported
	Paroxetine			C				Not Reported
	Benadryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14128364	NON-EXPEDITED		OT	US-PFIZER INC-2017461247		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14248795	EXPEDITED (15-DAY)		OT	PHHY2017CA175915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Diclofenac			S	Unknown	Unk		Novartis
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tecta			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14266187	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2182739-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Tecta			C				Not Reported
	Diclofenac			C				Not Reported
	Depo-Medrol			C	Other			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14266766	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032923		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14267182	NON-EXPEDITED			US-PFIZER INC-2017525017			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium			S	Unk			Pfizer	
	Plaquenil			S	Unk			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14267320	NON-EXPEDITED			US-PFIZER INC-2017527081		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Tessalon			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14267337	NON-EXPEDITED			US-PFIZER INC-2017527194		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Rasuvo			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14267629	NON-EXPEDITED			US-PFIZER INC-2017527429		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14268464	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2017GSK189169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Glaxosmithkline
	Arava			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14270983	EXPEDITED (15-DAY)		HO	CA-SA-2015SA102602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Motrin			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

Decreased	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271094	EXPEDITED (15-DAY)		OT	CA-SA-2017SA245620			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2017	14271397	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017527132		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Furuncle; Herpes Zoster;	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer

Immunosuppression; Macular Degeneration; Pyrexia; Urinary Tract Infection	Methotrexate Sodium	S		Unk		Pfizer
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S		Unk		Not Reported
	Plaquenil	S		Unk		Not Reported
	Medrol /00049601/	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	12251758	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1600381-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	12251779	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1600384-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Peripheral Swelling; Therapy Non-Responder	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Remicade		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	13124048	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007993		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein; Cough; Drug Ineffective; Impaired Healing; Joint Range Of Motion Decreased; Joint Swelling; Lichen Planus; Lower Respiratory Tract Infection; Musculoskeletal Pain; Nasal Congestion; Rhinorrhoea; Rosacea; Shoulder Operation; Spinal Stenosis; Synovitis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Salazopyrin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	13124084	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000441		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Enbrel			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Actemra			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	13227449	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA102603		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Unknown	Form- Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	13687631	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003765		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis;	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Swelling; Therapeutic Product Effect Decreased	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Actonel		C			Not Reported
	Folate		C			Not Reported
	Prevacid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	13692180	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003775		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	13692485	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003797		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Increased; Drug	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Ineffective; Impaired Healing; Joint Range Of Motion Decreased; Joint Swelling; Lichen Planus; Musculoskeletal Pain; Rosacea; Shoulder Operation; Spinal Stenosis; Synovitis; Treatment Failure	Methotrexate Sodium	S	Unknown		Not Reported
	Salazopyrin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14181766	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2157394-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Antinuclear Antibody Positive; Arthralgia; Fatigue; Influenza Like Illness; Lupus-Like Syndrome; Nausea	Humira Vial			S	Subcutaneous			Not Reported
	Humira Vial			S	Subcutaneous			Not Reported
	Humira Vial			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14275534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2033690		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Actemra			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14275611	NON-EXPEDITED			US-AMGEN-USASP2017182678		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14275795	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006632		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actonel			C				Not Reported
	Folate Sodium			C				Not Reported

	Prevacid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032974		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 790 Nos		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Therapy Duration: 8 Months		Not Reported
	Sulfasalazine			C	Unknown	Therapy Duration: 3 Years		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14276847	EXPEDITED (15-DAY)		OT	NZ-BAXTER-2017BAX041600			Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; Carpal Tunnel Syndrome; Demyelination; Disease Progression; Disease Recurrence; Joint Effusion; Neuropathy	Endoxan, 2000mg, Powder For Injection			S	Unknown			Baxter
	Endoxan, 2000mg, Powder For Injection			S				Baxter
	Endoxan, 2000mg, Powder For Injection			S				Baxter

Peripheral; Polyarthritis; Prostatism; Rheumatic Disorder; Supraventricular Tachycardia; Treatment Failure	Metoprolol Succinate	S	Oral	Tablet Modified Release	Not Reported
	Verapamil	S	Unknown		Not Reported
	Sulphasalazine	S	Unknown		Not Reported
	Methotrexate	S	Oral	Once Weekly On Monday	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methylprednisolone	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Enbrel	S	Intramuscular		Not Reported
	Allopurinol	C	Unknown		Not Reported
	Celecoxib	C	Oral		Not Reported
	Colecalciferol	C	Unknown		Not Reported
	Folic Acid	C	Oral	Weekly On Friday	Not Reported
	Micreme H	C	Topical		Not Reported
	Nortriptyline	C	Unknown	Nocte	Not Reported
	Omeprazole	C	Oral	Modified Release	Not Reported
	Paracetamol	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Salbutamol	C	Respiratory (inhalation)	Route Of Admin: Inhalation, Dose: Pressurized 100 Mcg/Actuation And 2 Actuation Qid Inhaled As Neede	Not Reported
	Naprosyn	C	Unknown		Not Reported
	Aspirin	C	Unknown		Not Reported
	Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14277174	NON-EXPEDITED			US-AMGEN-USASP2017182668		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Unk		Amgen
	Methotrexate		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Rituxan		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14277816	NON-EXPEDITED			US-PFIZER INC-2017525322		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Simponi Aria			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14277913	NON-EXPEDITED			US-PFIZER INC-2017526715		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14278012	EXPEDITED (15-DAY)		OT	PHHY2017GB181547			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Toxicity; Visual Field Defect	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2017	14278026	EXPEDITED (15-DAY)		OT	PHHY2017GB181542			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Toxicity; Visual Field Defect	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	13127172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1648784-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	For Many Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			C		For Many Years		Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Prevnar 13			C				Not Reported
	Tetanus Vaccine			C				Not Reported
	Haemophilus Influenzae			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	13319320	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902922		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Methotrexate			C	Unknown	Not Reported
	Arava			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14159579	NON-EXPEDITED			US-PFIZER INC-2017472636		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14194743	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017171726			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Insomnia; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Advil			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14198937	NON-EXPEDITED			US-PFIZER INC-2017493722		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unk		Pfizer
	Sulfasalazine	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14279022	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006630		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14279221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2033873		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported

	Methotrexate Sodium			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil			S	Oral				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Form: Powder For Solution Intravenous			Not Reported
	Simponi			S	Subcutaneous	Form: Solution Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14279540	NON-EXPEDITED			US-AMGEN-USASP2017183624		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14279608	NON-EXPEDITED			US-AMGEN-USASP2017183727		57 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14280083	EXPEDITED (15-DAY)		HO, OT	DE-ABBVIE-17K-062-2187922-00		53 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain Upper; Acute Kidney Injury; Acute Kidney Injury; Blood Creatinine Increased; Chills; Constipation; Decreased Appetite; Drug Ineffective; Drug Specific Antibody; Gastrointestinal Disorder; Glucose Tolerance Impaired; Hypercalcaemia; Infection; Interstitial Lung Disease; Lacrimation Increased; Liver Disorder; Malaise; Nausea; Peripheral Venous Disease; Proteinuria; Pyrexia; Sinusitis; Sjogren'S Syndrome; Sleep Apnoea Syndrome; Spinal Pain; Supraventricular Tachycardia; Tendonitis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Buscopan			C				Not Reported
	Pantoprazol			C				Not Reported
	Spiricort			C				Not Reported
	Lodotra			C		1mg/Dl		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14280152	NON-EXPEDITED			US-AMGEN-USASP2017183533			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14280647	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281602	NON-EXPEDITED			US-PFIZER INC-2017531268		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Sulfasalazine			S		Unk				Pfizer
	Hydroxychloroquine			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281666	EXPEDITED (15-DAY)		DE	US-PERRIGO-17US031105		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ranitidine Hydrochloride			S	Oral	Unknown, Unknown		Perrigo
	Salicylates Nos			S	Oral	Unknown, Unknown		Not Reported
	Atropine W/Diphenoxylate /00034001/			S	Oral	Unknown, Unknown		Not Reported
	Plaquenil /00072602/			S	Oral	Unknown, Unknown		Not Reported
	Tamsulosin			S	Oral	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281764	NON-EXPEDITED			US-PFIZER INC-2017530792			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282051	NON-EXPEDITED			US-PFIZER INC-2017527564			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Disorder; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282770	EXPEDITED (15-DAY)		OT	CA-SA-2017SA245546		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Eye Disorder; Retinal Toxicity; Vomiting	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Mobicox			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	From Prior To 2000; Has Been On For Many Years.		Not Reported
	Risedronate			C	Unknown			Not Reported
	Diclofenac			C	Oral	Diclofenac 50 Mg Prn Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	11923402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539201-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	13516291	EXPEDITED (15-DAY)		HO, OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-139850		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection	Hydroxychloroquine			S	Unknown	Unk, 1/Week		Ipca
	Methotrexate			S	Unknown	Unk, 1/Week		Sun

	Sulfasalazine			S	Unknown	Unk, 1/Week			Sun	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14225504	NON-EXPEDITED			US-PFIZER INC-2017506978		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14225894	NON-EXPEDITED			US-PFIZER INC-2017507111		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14284231	EXPEDITED (15-DAY)		OT	US-ROCHE-2034874		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Therapeutic Response Decreased; Therapeutic Response Shortened; Therapy Non-Responder; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Arava			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Cimzia			S	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14285766	EXPEDITED (15-DAY)		HO, OT	CA-CANTON LABORATORIES, LLC-2037188		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Foot Operation; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Naprosyn			S	Unknown			Canton Laboratories
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14287447	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2189829-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D Deficiency	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Norvasc	S	Oral	Not Reported
	Asacol	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Amlodipine Besilate	C		Not Reported
	Depo-Medrol	C		Not Reported
	Vitamin D3	C		Not Reported
	Atacand Plus	C		Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Tylenol	C		Not Reported
	Omega Allergenic Extracts	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	9743212	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2013348039		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Neutropenia	Xalkori			S	Oral	250 Mg, 2x/Day		Pfizer
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Valium			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Docusate			C		Unk		Not Reported
	Ventolin			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Remeron			C		Unk		Not Reported
	Percocet			C		Unk		Not Reported

	Ipratropium-Albuterol	C	Unk	Not Reported
	Tacrolimus	C	Unk	Not Reported
	Neurontin	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Voltaren	C	Unk	Not Reported
	Azathioprine	C	Unk	Not Reported
	Flexeril	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	11926221	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1539487-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin			S	Unknown			Not Reported
	Motrin			S				Not Reported

	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Voltaren	S	Unknown		Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Naprosyn	S	Unknown		Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	12715328	EXPEDITED (15-DAY)		OT	CA-ROCHE-1825208		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported

	Levothyroxine	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Tylenol #2 (Canada)	S	Unknown			Not Reported
	Ramipril	S	Unknown			Not Reported
	Plaquenil	C	Unknown			Not Reported
	Cosopt	C	Unknown			Not Reported
	Acetaminophen/Caffeine/Codeine Phosphate/Meprobamate	C	Unknown	As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14241896	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006545		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Reaction With Eosinophilia And Systemic Symptoms; Prothrombin Time Prolonged; Supraventricular Tachycardia; Vasodilatation	Hydroxychloroquine			S	Unknown			Concordia
	Pilocarpine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14287715	EXPEDITED (15-DAY)		OT	CA-ROCHE-2035078		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Injection Site Reaction; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic			Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Levothyroxine	C	Unknown			Not Reported
Plaquenil	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Ramipril	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14288040	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Motrin			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2017	14289075	NON-EXPEDITED			US-PFIZER INC-2017532165		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	13229723	EXPEDITED (15-DAY)		HO, OT	JP-AMGEN-JPNCT2017018499		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bacterial Infection; Chorioretinopathy; Conjunctival Haemorrhage; Conjunctival Oedema; Pain In Extremity; Pyrexia; Pyrexia; Viral Infection; White Blood Cell Count Increased	Darbepoetin Alfa			S	Subcutaneous	30 Mug, Q2wk		Amgen
	Darbepoetin Alfa			S	Subcutaneous	30 Mug, Qd		Amgen
	Darbepoetin Alfa			S	Subcutaneous	60 Mug, Q4wk		Amgen
	Darbepoetin Alfa			S	Subcutaneous	30 Mug, Qd		Amgen
	Darbepoetin Alfa			S	Subcutaneous	60 Mug, Qd		Amgen
	Darbepoetin Alfa			S	Subcutaneous	90 Mug, Qd		Amgen
	Darbepoetin Alfa			S	Subcutaneous	60 Mug, Qd		Amgen
	Darbepoetin Alfa			S	Subcutaneous	60 Mug, Qd		Amgen
	Darbepoetin Alfa			S	Subcutaneous	120 Mug, Q4wk		Amgen
	Darbepoetin Alfa			S	Subcutaneous	120 Mug, Q3wk		Amgen
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Pariet			C	Oral	5 Mg, Qd		Not Reported
	Baktar			C	Oral	1 Df, Qd		Not Reported
	Prograf			C	Oral	3 Mg, Qd		Not Reported
	Juvela N			C	Oral	100 Mg, Tid		Not Reported
	Rebamipide			C	Oral	100 Mg, Tid		Not Reported
	Miya Bm			C	Oral	1 Df, Tid		Not Reported
	Pletaal			C	Oral	100 Mg, Bid		Not Reported

	Predonine	C	Oral	5 Mg, Bid	Not Reported
	Fluitran	C	Oral	1 Mg, Qd	Not Reported
	Cellcept	C	Oral	500 Mg, Bid	Not Reported
	Amlodipine	C	Oral	10 Mg, Qd	Not Reported
	Tramcet	C	Oral	1 Df, Tid	Not Reported
	Diart	C	Oral	60 Mg, As Necessary	Not Reported
	Calonal	C	Oral	500 Mg, As Necessary	Not Reported
	Lasix	C	Oral	20 Mg, Unk	Not Reported
	Neurovitan	C	Oral	1 Df, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	13798077	NON-EXPEDITED			US-PFIZER INC-2017324142		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14234178	NON-EXPEDITED			US-AMGEN-USASP2017177371			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14255156	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tecta (Pantoprazole Magnesium)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14267247	NON-EXPEDITED			US-PFIZER INC-2017525041		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14281836	NON-EXPEDITED		OT	US-PFIZER INC-2017529200		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14294489	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2017050861		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Cimzia			S	Subcutaneous	Unk		Ucb
	Celebrex			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Neoral			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14294517	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050692		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295388	NON-EXPEDITED			US-PFIZER INC-2017532901			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295429	NON-EXPEDITED			US-PFIZER INC-2017535399		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Procardia			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Adalat			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295534	NON-EXPEDITED			US-PFIZER INC-2017537103			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295577	NON-EXPEDITED			US-PFIZER INC-2017536518		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295583	NON-EXPEDITED			US-PFIZER INC-2017536874			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295627	NON-EXPEDITED			US-PFIZER INC-2017538295		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295628	NON-EXPEDITED			US-PFIZER INC-2017538756		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14296442	EXPEDITED (15-DAY)		OT	PHHY2017JP181371			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis Pneumococcal	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14296769	EXPEDITED (15-DAY)		OT	PHHY2017JP181405			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinal Atrophy; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298001	EXPEDITED (15-DAY)		DE, HO	US-BAYER-2017-239538		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Overdose; Toxicity To Various Agents	Acetylsalicylic Acid (> 100 Mg)		Y	S	Oral			Bayer
	Atropine W/Diphenoxylate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tamsulosin			S	Oral			Not Reported
	Ranitidine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298435	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050714		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298510	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050718		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		1 Ml, Weekly (Qw)		Not Reported
	Prednisone			S		7 Mg, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298594	NON-EXPEDITED			US-PFIZER INC-2017538753		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298605	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050832			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Weekly (Qw)		Ucb
	Actemra			S		640 Mg, Weekly (Qw)		Not Reported
	Arava			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly (Qw)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14298986	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050844			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia;	Cimzia			S	Subcutaneous	Unk		Ucb

Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S		Unk	Not Reported
	Arava	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299030	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050850		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Cimzia			S	Subcutaneous			Ucb
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S		Unk		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Tofacitinib			S		5 Mg, Unk			Not Reported
	Sulfasalazine			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299033	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050853		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Peripheral Swelling	Cimzia			S	Subcutaneous	Unk		Ucb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299059	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050858		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Cimzia			S	Subcutaneous	Unk		Ucb
	Abatacept			S				Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Leflunomide			S				Not Reported

	Methotrexate	S	Parenteral	25 Mg, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	22.5 Mg, Weekly (Qw)	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder And Solvent For Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	C			Not Reported
	Prednisone	C		6 Mg, 2x/Day (Bid)	Not Reported
	Penicillamine	C			Not Reported
	Minocycline	C			Not Reported
	Ciclosporin	C		Unk	Not Reported
	Azathioprine	C		1 Df, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299082	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050863		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous			Ucb
	Enbrel			S	Subcutaneous	1 Df, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tofacitinib Citrate			C		Unk		Not Reported

	Tofacitinib Citrate			C	Oral	5 Mg, 2x/Day (Bid)			Not Reported
	Prednisone			C	Oral				Not Reported
	Lyrica			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299119	EXPEDITED (15-DAY)		DS	CA-UCBSA-2017050880		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder And Solvent For Solution For Injection/Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299134	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050884		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			C				Not Reported

	Arava			C		20 Mg, Once Daily (Qd)				Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299170	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050891		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Imuran			C				Not Reported
	Ergocalciferol			C				Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299171	EXPEDITED (15-DAY)		HO	CA-UCBSA-2017050893		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Abnormal; Pharyngeal Oedema; Rash; Swelling; Wheezing	Cimzia			S	Subcutaneous	Unk		Ucb
	Sulfasalazine			S		Strength: 500 Mg		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Prednisone			S	Oral	5 Mg, Once Daily (Qd)		Not Reported
	Apo-Prednisone			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Arava			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299172	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050894		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Cimzia			S	Subcutaneous	Unk		Ucb
	Sulfasalazine			S		500 Mg Tablet		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Metoprolol			S		Unk		Not Reported
	Apo-Prednisone			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Naprosyn			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14299184	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2017050906		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Abnormal; Liver Function Test Increased; Pharyngeal Oedema; Rash; Swelling; Wheezing	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S		Unk		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Methotrexate Sodium			S		20 Mg, Unk		Not Reported
	Prednisone			S	Oral	20 Mg, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tofacitinib			C		5 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	12808359	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037701		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) (Formulation: Solution)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Metoprolol			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

Crestor	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Naprelan	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	13963023	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005075		37 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning Sensation; Drug Eruption; Erythema; Myalgia; Pain; Pruritus; Pyrexia; Rash Maculo-Papular; Skin Lesion; Urticaria	Plaquenil Tablet			S	Oral	At An Alternate Dose Of 1 Tablet Daily And 2 Tablets Daily		Concordia
	Allelock			C				Not Reported
	Predonine			C				Not Reported
	Prednisolone			C				Not Reported
	Olopatadine Hydrochloride			C				Not Reported
	Calfina			C				Not Reported
	Dermovate			C				Not Reported
	Heparinoid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	13963134	NON-EXPEDITED			US-PFIZER INC-2017393097			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Stomatitis	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14144727	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006073		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14257304	EXPEDITED (15-DAY)		OT	QA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006555		25 YR	Female	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; C-Reactive Protein Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Hypotension; Jaundice; Leukocytosis; Lymphocytosis; Nausea; Oropharyngeal Pain; Pharyngeal Erythema; Pyrexia; Rash; Rash Maculo-Papular; Scleral Discolouration; Sinus Tachycardia; Swelling Face; Thrombocytopenia; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Vitamin-D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14258757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea;	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

Dizziness; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown	For 7 Years	Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Humira	C	Unknown	For 7 Years	Not Reported
	Diclofenac	C			Not Reported
	Depo-Medrol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14261790	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-4015		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Skin Discolouration	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14285010	NON-EXPEDITED		OT	US-AMGEN-USASP2017184154		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14288041	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006640		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pulmonary Toxicity; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Diclofenac			C				Not Reported
	Arava			C				Not Reported
	Tecta			C				Not Reported
	Depo-Medrol			C				Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299345	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006641			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Plaquenil	S	Unknown		Concordia
	Humira	S			Not Reported
	Methothrexate	C			Not Reported
	Enbrel	C			Not Reported
	Orencia	C			Not Reported
	Rituxan	C			Not Reported
	Xeljanz Xr	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299346	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006647		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Eye Disorder; Retinal Toxicity; Vomiting	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Omeprazole			C				Not Reported
	Mobicox			C				Not Reported
	Methotrexate			C				Not Reported
	Risedronate			C				Not Reported
	Diclofenac			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299347	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006663			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Humira			S	Unknown					Not Reported
	Cimzia			S	Unknown					Not Reported
	Simponi			S	Unknown					Not Reported
	Rituxan			S	Unknown					Not Reported
	Tofacitinib			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2038238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 6 Months		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 790 Nos		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown	Extended Release		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14299455	EXPEDITED (15-DAY)		HO	SE-CONCORDIA PHARMACEUTICALS INC.-E2B_00008864		81 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol			S				Not Reported
	Plaquenil			S				Concordia
	Citalopram			C				Not Reported
	Prednisolone			C				Not Reported
	Atorvastatin			C				Not Reported
	Kalcipos			C				Not Reported
	Xarelto			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14301441	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006649		67 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Plaquenil			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Citalopram			C				Not Reported
	Megafol			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305842	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1462822-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug-Induced Liver Injury; Fatigue; Hepatic Enzyme Abnormal; Loss Of	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14305992	NON-EXPEDITED			US-PFIZER INC-2017539135		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Diclofenac Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	11927872	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016001428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Tendon Disorder	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S		20 Mg, Weekly (Qw)		Not Reported
	Bactrim			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	12815297	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016037798		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Solution		Not Reported
	Gold			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Orencia			S		Unk, Powder For Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Solution		Not Reported
	Simponi			S	Subcutaneous	Unk, Solution		Not Reported
	Humira			C	Subcutaneous	Unk, Solution		Not Reported
	Methotrexate			C		1 Ml, Weekly (Qw)		Not Reported
	Celebrex			C		Unk		Not Reported
	Prednisone			C		7 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13110315	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017001292			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported

	Plaquenil	S		Unk	Not Reported
	Sulfasalazin	S	Oral	Unk	Not Reported
	Sulfasalazin	S	Oral	1 G, 2x/Day (Bid)	Not Reported
	Methotrexate Sodium	S		25 Mg, Weekly (Qw)	Not Reported
	Hydroxychloroquine	S		200 Mg, 2x/Day (Bid)	Not Reported
	Tofacitinib Citrate	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13111723	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Increased; Drug Ineffective; Impaired Healing; Joint Range Of Motion Decreased; Joint Swelling; Lichen Planus; Musculoskeletal Pain; Rheumatoid Arthritis; Rosacea; Spinal Stenosis; Synovitis	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Arava			S		Unk		Not Reported
	Salazopyrin			S	Oral	500 Mg, 4x/Day (Qid)		Not Reported
	Plaquenil			S		400 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13116029	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001458		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Actemra			S		1 Df, Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

Failure	Plaquenil	S	Unk	Not Reported
	Potassium Chloride	C	1500 Mg, Once Daily (Qd)	Not Reported
	Calcium	C	500 Mg, Once Daily (Qd)	Not Reported
	Dorzolamide	C	Unk, 2x/Day (Bid)	Not Reported
	Ergocalciferol	C	Unk, Weekly (Qw)	Not Reported
	Estrogel	C	6 %, 3x/Day (Tid)	Not Reported
	Furosemide	C	40 Mg, Once Daily (Qd)	Not Reported
	Valsartan	C	320 Mg, Once Daily (Qd)	Not Reported
	Xalatan	C	50 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13118493	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001457			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Musculoskeletal Pain; Rheumatoid Arthritis; Unevaluable Event	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Hydroxychloroquine			S	Oral	300 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13980399	EXPEDITED (15-DAY)		OT	CA-ROCHE-1983556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatitis;	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Failure	Adalimumab	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	For 18 Months		Not Reported
	Hydroxychloroquine	S	Unknown	For 18 Months		Not Reported
	Orencia	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	13980447	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14306482	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006652		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

	Remicade			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14306761	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016048930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Cimzia			S	Subcutaneous	Unk		Ucb
	Methotrexate Sodium			S	Oral	17.5 - 25 Mg		Not Reported
	Leflunomide			S		Lower Dose Than 20 Mg		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Plaquenil			S		400 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307522	NON-EXPEDITED			US-PFIZER INC-2017540625		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307685	EXPEDITED (15-DAY)		HO, OT	ES-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-111586		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small Cell Lung Cancer	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Dolquine			S	Oral			Not Reported
	Prednisona			S	Oral			Not Reported
	Metoject			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Paracetamol			C	Oral			Not Reported

	Simvastatina			C	Oral					Not Reported
	Fosavance			C	Oral					Not Reported
	Risperidona			C	Oral					Not Reported
	Tramadol			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307740	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00005468		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Sertraline Hydrochloride			S	Oral			Unknown
	Hydroxychloroquine			S	Oral			Unknown
	Diltiazem Hydrochloride			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307832	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051044		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		1 Df, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Dorzolamide Hcl And Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported

	Potassium Chloride			C						Not Reported
	Estradiol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307854	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050896		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307927	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050842		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		1 Ml, Weekly (Qw)		Not Reported
	Prednisone			S		7 Mg, Once Daily (Qd)		Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14307981	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14308158	EXPEDITED (15-DAY)		OT	NZ-ORION CORPORATION ORION		63 YR	Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; Carpal Tunnel Syndrome; Demyelination; Joint Effusion; Neuropathy Peripheral; Polyarthritis; Prostatism; Rheumatic Disorder; Supraventricular Tachycardia; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 10 Mg; On Monday Of Week		Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Enbrel			S	Intramuscular			Not Reported
	Metoprolol			S	Oral			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Verapamil			S	Unknown			Not Reported
	Sulphasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Celecoxib			C	Unknown			Not Reported
	Colecalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Micreme H			C	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14309590	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis	Cimzia	S	Subcutaneous	200 Mg, Ev 15 Days	Ucb
	Enbrel	S	Subcutaneous	50 Mg, Weekly (Qw)	Not Reported
	Arava	S		20 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S		Unk	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Mg, Ev 15 Days	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Methotrexate Sodium	S	Oral	17.5 Mg, Weekly (Qw)	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly (Qw)	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Ev 4 Weeks	Not Reported
	Leucovorin	C		Unk	Not Reported
	Vitamin D2	C		Unk	Not Reported
	Ergocalciferol	C		2000 Iu, Unk	Not Reported
	Coversyl	C		4 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14309665	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051038		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Infliximab			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

		Simponi			S	Subcutaneous	Unk			Not Reported
		Sulfasalazine			S		Unk			Not Reported
		Orencia			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14309824	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016038843		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Joint Range Of Motion Decreased; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; No Adverse Event; Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Swelling; Synovitis	Cimzia			S	Subcutaneous			Ucb
	Asa			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Calcium Carbonate W/Vitamin D			C				Not Reported
	Citalopram			C				Not Reported
	Domperidone			C				Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Gliclazide			C				Not Reported
	Lipitor			C				Not Reported
	Nifedipine			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Risedronate			C		35 Mg, Unk		Not Reported
	Synthroid			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Tylenol			C		650 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2017	14310576	EXPEDITED (15-DAY)		OT	CA-SA-2017SA165578			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg 3/7, 200 Mg 2/7 Days Of The Week		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C		Sq		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14277965	EXPEDITED (15-DAY)		OT	CA-SA-2017SA244717		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pulmonary Toxicity; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Tecta			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14289214	NON-EXPEDITED			US-PFIZER INC-2017536605			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer

	Advil	S	Unk		Pfizer
	Erythromycin	S	Unk		Pfizer
	Amoxicillin	S	Unk		Pfizer
	Actonel	S	Unk		Not Reported
	Aspirin	S	Unk		Not Reported
	Bactrim	S	Unk		Not Reported
	Clarithromycin	S	Unk		Not Reported
	Keflex	S	Unk		Not Reported
	Pamelor	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Ultram	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14298595	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050830		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14299071	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050862			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported

Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Enbrel	S		50 Mg, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S		200 Mg, 2x/Day (Bid)	Not Reported
	Orencia	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Injection Or Infusion	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S		2000 Mg, Unk	Not Reported
	Tylenol	S		Unk	Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S			Not Reported
	Leflunomide	S		20 Mg, Once Daily (Qd)	Not Reported
	Paracetamol W/Codeine/Caffeine	C			Not Reported
	Methotrexate	C		Unk, Weekly (Qw)	Not Reported
	Meloxicam	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14299081	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050865		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14299216	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2017050925		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise; Osteomyelitis; Wound Infection	Cimzia			S	Subcutaneous	Unk		Ucb
	Leflunomide			S		20 Mg, Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S		400 Mg, Once Daily (Qd)		Not Reported
	Enbrel			C		50 Mg, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14311563	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050913		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Xalatan			C				Not Reported
	Valsartan			C				Not Reported
	Potassium Chloride			C				Not Reported
	Morphine			C				Not Reported
	Furosemide			C				Not Reported
	Estrogel			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Calcium			C				Not Reported
	Ergocalciferol			C				Not Reported
	Ginger			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14311617	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-146792		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Medication Error; Myopathy; Quadriparesis; Seizure; Sepsis; Staphylococcal Infection	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Ipca
	Prednisone			S	Unknown	10 Mg, Daily		Mutual
	Prednisone			S	Unknown	60 Mg, Daily		Mutual
	Prednisone			S	Unknown	30 Mg, Daily		Mutual
	Prednisone			S	Unknown	60 Unk, Unk		Mutual
	Prednisone			S	Unknown	1000 Mg, Daily		Mutual
	Mycophenolate Mofetil			S	Unknown	250 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14311749	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050963		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Gold			S		1 Df, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Parenteral	25 Mg, Weekly (Qw)		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported

	Tocilizumab			C						Not Reported
	Prednisolone			C						Not Reported
	Penicillamine			C						Not Reported
	Minocycline			C						Not Reported
	Ciclosporin			C						Not Reported
	Azathioprine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312335	EXPEDITED (15-DAY)		HO	PHHY2017SE188803		81 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol			S	Unknown	50 Mg, Qd		Novartis
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Citalopram			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Kalcipos			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312383	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1773008US		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Asacol 800			S	Oral	800 Mg, Tid		Allergan
	Methotrexate			S	Subcutaneous	25 Mg, Q Week		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Humira	S	Unknown	Unk		Not Reported
	Norvasc	S	Oral	5 Mg, Qd		Not Reported
	Plaquenil	S	Unknown	25 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Folic Acid	C				Not Reported
	Ferrous Gluconate	C				Not Reported
	Vitamin D3	C				Not Reported
	Depo-Medrol	C				Not Reported
	Tylenol	C				Not Reported
	Bisoprolol Fumarate	C				Not Reported
	Atacand Plus	C				Not Reported
	Amlodipine Besilate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14313434	EXPEDITED (15-DAY)		HO	SE-MYLANLABS-2017M1079745		81 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol			S		50 Mg, Qd		Not Reported
	Plaquenil /00072602/			S		200 Mg, Qd		Mylan
	Citalopram			C				Mylan
	Prednisolone			C				Mylan
	Atorvastatin			C				Mylan
	Kalcipos			C				Mylan
	Xarelto			C				Mylan
	Zopiclone			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14314032	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017543549		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14314264	NON-EXPEDITED			US-AMGEN-USASP2017187692		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Eye Disorder	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14315204	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016021497		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Treatment Failure	Cimzia			S	Subcutaneous	Unknown Dose		Ucb
	Orencia			S		Unknown Dose		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Actemra			S		One Dose		Not Reported
	Entocort			C		Till 24-Jun-2016		Not Reported
	Cefprozil			C		500 Mg, 2x/Day (Bid)		Not Reported
	Estrogel			C		Unknown Dose		Not Reported
	Calcium			C		Unknown Dose		Not Reported
	Xalatan			C		Unknown Dose		Not Reported
	Cosopt			C		Unknown Dose		Not Reported
	Furosemide			C		Unknown Dose		Not Reported
	Valsartan			C		Unknown Dose		Not Reported
	Vitamin D2			C		Unknown Dose		Not Reported

	Potassium Chloride	C	Unknown Dose		Not Reported
	Dorzolamide Hcl And Timolol Maleate	C			Not Reported
	Estrogel	C			Not Reported
	Dimenhydrinate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14213117	EXPEDITED (15-DAY)		DE	US-ROCHE-2025716		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Progressive Multifocal Leukoencephalopathy	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Imuran			C	Oral			Not Reported
	Prednisone			C	Oral	Ongoing Until Death		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14216129	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006458			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Seizure; Vomiting	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nucynta			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14318214	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP022789		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Pruritus; Rash; Skin Exfoliation; Ulcer Haemorrhage	Clopidogrel			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	150 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Dec-2017	14318529	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20171224235			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Infection; Obesity; Off Label Use; Osteoporosis; Product Use In Unapproved Indication; Tuberculosis	Infliximab, Recombinant			S	Intravenous (not otherwise specified)	0,2,6 And Then Every 8 Weeks		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14223198	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021495		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Drug Intolerance; Infection; Pericardial Effusion; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14223232	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021449			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Oral	1 G, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported
	Prednisone			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14317284	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006668			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Plaquenil Tablet			S	Oral	At Bedtime		Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Actonel			C				Not Reported
	Vitamin D3			C				Not Reported
	Calcium Ascorbate			C				Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14317286	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006681		48 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Dizziness; Hepatic Enzyme Increased; Night Sweats; Pancreatitis; Photosensitivity Reaction	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14322002	NON-EXPEDITED		OT	US-AMGEN-USASP2017188838			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Tuberculosis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14322314	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006690		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Skin Discolouration;	Plaquenil			S	Unknown			Concordia

Swelling	Arava			S	Oral					Not Reported
	Gabapentin			C						Not Reported
	Methotrexate			C						Not Reported
	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14322316	EXPEDITED (15-DAY)		HO	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006696		63 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Febrile Neutropenia; Hepatic Necrosis	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Prednison Streuli			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2017	14322539	NON-EXPEDITED			US-AMGEN-USASP2017188882			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	13224986	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006355		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective;	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Diclo			S	Unknown			Apotex

Gastrooesophageal Reflux Disease; Malaise; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased	Apo-Prednisone	S	Unknown			Apotex
	Apo-Pregabalin Capsules	S	Unknown	Unk		Not Reported
	Apo-Celecoxib	S	Unknown	Unk		Apotex
	Apo-Naproxen	S	Unknown			Not Reported
	Nifedipine	S	Unknown	Unk		Apotex
	Misoprostol	S	Unknown	Unk		Not Reported
	Elavil	S	Unknown	Unk		Apotex
	Amitriptyline	S	Unknown			Apotex
	Arthrotec	S	Unknown			Not Reported
	Celebrex	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Lyrica	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Naprosyn /00256201/	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk		Not Reported
	Etanercept	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14218524	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14222227	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14223524	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Disability; Drug Ineffective	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Methotrexate Sodium			S	Oral	17.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14225820	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021594		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide	Apo-Hydroxyquine			S	Unknown	Unk		Apotex

Antibody Positive; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Leflunomide	S	Unknown	20 Mg, Unk		Apotex
	Actemra	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel	S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Varenicline Tartrate	S	Oral	1 Every 1 Day		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	6 Every 1 Day		Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Oral	500 Mg, Bid		Not Reported
	Rosuvastatin Calcium	C	Oral	Unk, Qd		Not Reported
	Valtrex	C	Oral	1000 Mg, Bid		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14225838	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Femur Fracture; Mobility Decreased; Rheumatoid Arthritis; Treatment Failure	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Metformin			C	Oral	500 Mg, Tid		Not Reported
	Ramipril			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14225928	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Apo-Hydroxyquine		S	Unknown	Unk	Apotex
	Cyclosporine		S	Unknown	Unk	Apotex
	Actemra		S	Unknown	640 Mg, Q.Wk.	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
	Enbrel		S	Unknown	50 Mg, Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Imuran /00001501/		S	Unknown	Unk	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14230195	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastric Disorder; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Oral	Unk, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Diclofenac			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14230196	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Hypersensitivity	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Humira			C	Unknown	40 Mg, 1 Every 2 Week		Not Reported

		Methotrexate			C	Subcutaneous	25 Mg, Unk			Not Reported
		Sulfasalazine			C	Unknown	500 Mg, Qid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14234932	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021573		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Q.I.W		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.I.W		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14235033	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021680		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported

					Humira	S	Unknown	40 Mg, Once Every 2 Weeks	Not Reported
					Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
					Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
					Orencia	S	Unknown		Not Reported
					Remicade	S	Unknown	300 Mg, Once Every 6 Weeks	Not Reported
					Rituxan	S	Unknown		Not Reported
					Sulfasalazine	C	Unknown		Not Reported
					Wellbutrin	C	Unknown		Not Reported
					Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14235424	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021582		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Amitriptyline			S	Unknown	Unk		Apotex
	Apo-Diclo Rapide			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Diacerein			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14235426	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14235433	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021665		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Lyrica			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Oral	25 Mg, Q.Wk.		Not Reported
	Naproxen			C	Unknown	500 Mg, Qd		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14238493	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Hypersensitivity; Drug Ineffective	Apo-Hydroxyquine			S	Oral	200 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	9 Df, Q.I.W		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14241810	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Unk		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14241921	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021716		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Apotex
	Indomethacin	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd		Apotex
	Prednisone	S	Oral	25 Mg, Qd		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium	S	Oral	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Cymbalta	C	Oral	30 Mg, Qd		Not Reported
	Folic Acid	C	Oral	Unk, Q.Wk.		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14242686	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021958		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Unk		Not Reported

	Clonazepam			C	Oral	0.5 Mg, Unk			Not Reported
	Desipramine			C	Unknown	50 Mg, Unk			Not Reported
	Gabapentin			C	Oral	300 Mg, Unk			Not Reported
	Nitroglycerin			C	Unknown				Not Reported
	Rosuvastatin Calcium			C	Oral	20 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14243064	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Q.Wk.		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14243065	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex

Intolerance; Rheumatoid Arthritis	Actemra		S	Unknown	640 Mg, Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Unknown	200 Mg, Q.Wk.	Not Reported
	Enbrel		S	Unknown	50 Mg, Q.Wk.	Not Reported
	Humira		S	Unknown	40 Mg, Unk	Not Reported
	Imuran /00001501/		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14280646	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006617		54 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Eye Movement Disorder; Retinal Disorder; Retinal Fovea Disorder; Retinal Function Test Abnormal; Retinogram Abnormal; Toxicity To Various Agents; Visual Field Defect	Hydroxychloroquine			S	Oral	4.3 Mg/Kg Of Total Body Weight And A Cumulative Dose Of 1808 G		Concordia
	Olmetec			C				Not Reported
	Vytorin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14296304	EXPEDITED (15-DAY)		OT	AU-JNJFOC-20171215732			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Treatment Noncompliance	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Methotrexate				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323016	NON-EXPEDITED			US-AMGEN-USASP2017189661		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323037	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006693		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea; Paraesthesia; Paralysis; Rash	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323442	EXPEDITED (15-DAY)		OT	BR-ALKEM LABORATORIES LIMITED-BR-ALKEM-2017-01393		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Histoplasmosis; Hyperferritinaemia; Hypertriglyceridaemia; Hypofibrinogenaemia;	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Alkem
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported

Pancytopenia; Pyrexia; Splenomegaly

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14323598	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2203710-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Macrobid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2017	14324509	EXPEDITED (15-DAY)		OT	CA-SA-2017SA254009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Fibrosis; Liver Function Test Increased; Pain	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Rabeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	12935021	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007902		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported

Pain; Rheumatoid Arthritis	Methotrexate	S	Oral	Not Reported
	Humira	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	13233999	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008022		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8 Mg/Kg Monthly		Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Ergocalciferol			C				Not Reported
	Naprosyn			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Vitamin D Nos			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Lozide			C	Unknown			Not Reported

	Lantus			C	Unknown					Not Reported
	Naproxen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	13250622	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001150		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Lantus			C				Not Reported
	Prednisone			C				Not Reported
	Naprosyn			C				Not Reported
	Ramipril			C				Not Reported
	Asa Arthritis Strength Aspirin			C				Not Reported
	Metformin			C				Not Reported
	Vitamin D2			C				Not Reported
	Calcium			C				Not Reported

	Naproxen			C						Not Reported
	Lozide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14239413	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021689		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Joint Swelling; Pain In Extremity; Treatment Failure	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Salazopyrin			S	Oral	1 G, Bid		Not Reported
	Salazopyrin			S	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14241947	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021741		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14314096	NON-EXPEDITED			US-PFIZER INC-2017542680			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfadiazine Silver			S		Unk		Pfizer
	Vioxx			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14326186	NON-EXPEDITED			US-PFIZER INC-2017545244		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14326777	EXPEDITED (15-DAY)		HO, LT	BR-BAXTER-2017BAX043299		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Histoplasmosis Disseminated	Genuxal			S	Unknown			Baxter
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14327362	NON-EXPEDITED			US-PFIZER INC-2017541774		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil			S		Unk				Not Reported
	Prednisone			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14327547	NON-EXPEDITED			US-PFIZER INC-2017544931			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Plaquenil /00072602/			S		200 Mg, Unk		Not Reported
	Simponi			S		50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14327746	NON-EXPEDITED			US-PFIZER INC-2017547453		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14327767	NON-EXPEDITED			US-PFIZER INC-2017547408		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14328911	NON-EXPEDITED			US-PFIZER INC-2017550465		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Diclofenac Sodium			S		Unk		Pfizer

	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14329570	EXPEDITED (15-DAY)		OT	CA-SA-2017SA255301		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Skin Discolouration; Swelling	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Gabapentin			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2017	14330370	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Fibrosis; Liver Function Test Increased; Pain	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	12412382	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-039861		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Abilify			S	Oral	10 Mg, Qd		Bristol Myers Squibb
	Abilify			S	Unknown			Bristol Myers Squibb
	Dafalgan Codeine			S	Unknown	2 Tab, Tid		Bristol Myers Squibb
	Dafalgan Codeine			S	Unknown			Bristol Myers Squibb

					Fluoxetine Hydrochloride		S	Oral	30 Mg, Qd	Not Reported
					Fluoxetine Hydrochloride		S	Unknown		Not Reported
					Loxapac /00401801/		S	Oral	1 Df, Unk	Not Reported
					Theralene		S	Oral	1 Df, Qd	Not Reported
					Theralene		S	Unknown		Not Reported
					Tranxene		S	Oral	1 Df, Unk	Not Reported
					Tranxene		S	Unknown		Not Reported
					Noctamide		S	Oral	1 Tab, Qd	Not Reported
					Noctamide		S	Unknown		Not Reported
					Lepticur		S	Unknown	2 Tab, Qd	Not Reported
					Lepticur		S	Unknown		Not Reported
					Imeth		S	Oral	20 Mg, Qwk	Not Reported
					Imeth		S	Unknown		Not Reported
					Plaquenil /00072602/		S	Oral	400 Mg, Qd	Not Reported
					Speciafoldine		C	Unknown	4 Tab, Unk	Not Reported
					Speciafoldine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14281494	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2017527810		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Atropine Sulfate/Diphenoxylate Hydrochloride			S	Oral	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Tamsulosin			S	Oral	Unk		Not Reported
	Ranitidine			S	Oral	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14299306	EXPEDITED (15-DAY)		HO	ES-CONCORDIA PHARMACEUTICALS		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small Cell Lung Cancer	Hydroxychloroquine			S	Oral			Concordia
	Metoject			S	Subcutaneous			Not Reported
	Orencia 125			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Fosavance			C	Oral			Not Reported
	Tramadol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Simvastatin 20			C	Oral			Not Reported
	Risperidone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14313805	EXPEDITED (15-DAY)		HO, OT	DE-JNJFOC-20171219251		53 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain Upper; Acute Kidney Injury; Acute Kidney Injury; Blood Creatinine Increased; Chills; Constipation; Decreased Appetite; Drug Ineffective; Drug Specific Antibody; Gastrointestinal Disorder; Glucose Tolerance Impaired; Hypercalcaemia; Infection; Interstitial Lung Disease; Lacrimation Increased; Liver Disorder; Malaise;	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Spiricort			C	Unknown			Not Reported
	Buscopan			C	Unknown			Not Reported
	Pantoprazol			C	Unknown			Not Reported
	Lodotra			C	Unknown	1 Mg/Dl		Not Reported

Nausea; Peripheral Venous Disease; Proteinuria; Pyrexia; Sinusitis; Sjogren'S Syndrome; Sleep Apnoea Syndrome; Spinal Pain; Supraventricular Tachycardia; Tendonitis; Therapeutic Product Effect Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14329597	EXPEDITED (15-DAY)		OT	CA-SA-2017SA259763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Retinopathy	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Humira			C				Not Reported
	Simponi			C				Not Reported
	Orencia			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14330803	NON-EXPEDITED			US-AMGEN-USASP2017190894			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14330910	EXPEDITED (15-DAY)		HO	SE-TEVA-2017-SE-835930		81 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol			S	Unknown			Actavis
	Plaquenil			S	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Kalcipos			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14332071	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017191043		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intracranial Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Voltaren			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333368	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182877		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis; Condition Aggravated;	Plaquenil			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Leflunomide	S	Oral		Not Reported
	Amlodipine Besilate	S	Oral		Not Reported
	Amlodipine Besilate	S	Oral		Not Reported
	Asacol	S	Oral	Freq: 3 Every 1 Day	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Atacand Plus	C	Oral		Not Reported
	Bisoprolol Fumarate	C	Oral		Not Reported
	Depo-Medrol	C	Unknown	Suspension Intraarticular	Not Reported
	Depo-Medrol	C	Intramuscular		Not Reported
	Depo-Medrol	C	Unknown		Not Reported
	Ferrous Gluconate	C	Oral		Not Reported
	Folic Acid	C	Oral		Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported
	Amlodipine Besilate	C	Oral		Not Reported
	Norvasc	C	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14334649	NON-EXPEDITED			US-AMGEN-USASP2017190877			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14336874	DIRECT		DS			48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy; Neuropathy Peripheral	Plaquenil			S	Oral	Quantity:1 Capsule(S);		Concordia
	Methotrexate			C				Not Reported
	Relefen			C				Not Reported
	Ranitidine			C				Not Reported
	Estradiol			C				Not Reported
	Progesterone			C				Not Reported
	Vitamin D3			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14337030	DIRECT		DS				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Decreased Appetite; Diarrhoea; Fatigue; Hyperhidrosis; Nausea; Tremor; Vision Blurred	Hydroxychlorquine			S	Oral	Quantity:60 Tablet(S);		Not Reported
	Metoprolol Succ Er			C				Not Reported
	Atorvastatin			C				Not Reported
	Lisinopril-Hctz			C				Not Reported
	Isosorbide Mn Er			C				Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	13640237	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003399		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Deformity; Pain; Pneumonia; Swelling	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	13640751	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003357		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Infection	Plaquenil Tablet			S	Oral			Concordia
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14058054	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182645		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Condition Aggravated; Drug Hypersensitivity; Joint Destruction; Joint Range Of Motion Decreased; Joint Swelling; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14219615	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006461		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil Tablet			S	Oral	400 Mg (2 Tablets)		Concordia
	Thyradin-S			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14334952	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006703		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Disseminated Intravascular Coagulation	Plaquenil Tablet			S	Oral			Concordia
	Aprovel			C				Not Reported
	Lodoz			C				Not Reported
	Betamethasone			C				Not Reported
	Biocidan			C				Not Reported
	Lipanthyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14335386	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2017AP023244		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ranitidine			S	Oral	Unk		Apotex
	Atropine Sulfate W/Diphenoxylate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Tamsulosin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14338400	EXPEDITED (15-DAY)		HO	CA-SA-2017SA268433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Viread			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2017	14300579	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017187334		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inappropriate Schedule Of Product Administration; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Amgen
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	50 Mg, Qmo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2017	14339534	EXPEDITED (15-DAY)		DE	US-TORRENT-00005103		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Completed Suicide; Toxicity To Various Agents	Lorazepam			S	Oral	Unknown
	Zolpidem Tartrate			S	Oral	Unknown
	Ropinirole Hcl			S	Oral	Unknown
	Hydroxychloroquine			S	Oral	Unknown
	Alprazolam			S	Oral	Unknown
	Duloxetine			S	Oral	Unknown
	Gabapentin			S	Oral	Unknown
	Potassium Chloride			S	Oral	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2017	14181437	NON-EXPEDITED			US-AMGEN-USASP2017169229		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2017	14243129	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021953		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

		Humira			S	Subcutaneous	Unk			Not Reported
		Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.			Not Reported
		Sulfasalazine			S	Oral	1 G, Qd			Not Reported
		Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	12739279	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007831		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Arthralgia; Constipation; Cough; Depressed Mood; Fatigue; Gait Inability; Inflammation; Irritability; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	12931683	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007904		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis;	Plaquenil			S	Oral			Concordia

Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Infection	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Folic Acid	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported
	Cymbalta	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	13640269	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003309		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Infection; Rheumatoid Arthritis; Sepsis	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	13987270	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2105439-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity; Fatigue; Rheumatoid Arthritis; Treatment Failure; Treatment Failure; Visual	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Impairment; White Blood Cell Count Decreased	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	C		Not Reported
	Meloxicam	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	14067006	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005648		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Plaquenil Tablet			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	14334953	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006704		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Sensory Neuropathy	Plaquenil Tablet			S	Oral			Concordia
	Cortancyl			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2018	14340449	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000003		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Oral Disorder; Rash Maculo-Papular	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	12895789	NON-EXPEDITED			US-AMGEN-USASP2016145684		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk, Qmo		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14306959	EXPEDITED (15-DAY)		OT	NZ-AMGEN-NZLSP2017188217			Male	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; Carpal Tunnel Syndrome; Demyelination; Disease Progression; Disease Recurrence; Joint Effusion; Neuropathy Peripheral; Polyarthritis;	Enbrel			S	Intramuscular	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Oral	10 Mg, Twice Daily On Monday Of Week		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Metoprolol			S	Oral	47.5 Mg, 2x/Day		Not Reported

Prostatism; Rheumatic Disorder; Supraventricular Tachycardia; Treatment Failure	Cyclophosphamide	S	Unknown	200 Mg, Unk	Not Reported
	Cyclophosphamide	S	Unknown	Unk	Not Reported
	Cyclophosphamide	S			Not Reported
	Verapamil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulphasalazine	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Celecoxib	C	Oral	200 Mg, Unk	Not Reported
	Colecalciferol	C		1.25 Mg, Monthly	Not Reported
	Folic Acid	C	Oral	5 Mg, Weekly On Friday	Not Reported
	Micreme H	C	Topical	20 Milligram Per Gram, 2x/Day	Not Reported
	Nortriptyline	C		10 Mg, Daily-Nocte	Not Reported
	Omeprazole	C	Oral	20 Mg, 2x/Day	Not Reported
	Paracetamol	C	Oral	1000 Mg, 4x/Day	Not Reported
	Prednisone	C		10 Mg, 1x/Day	Not Reported
	Salbutamol	C	Respiratory (inhalation)	Pressurized 100 Mcg/Actuation And 2 Actuation Qid Inhaled As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14340910	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006724		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash Maculo-Papular	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Ludeal			C				Not Reported
	Ibuprofene			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14340915	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS			Female	USA

INC.-GSH201801-000005

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S				Concordia
	Nabumetone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14341428	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000006		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome; Normocytic Anaemia	Plaquenil			S	Oral			Concordia
	Imurel			S	Unknown			Not Reported
	Vitamin D3			C				Not Reported
	Diffu K			C				Not Reported
	Cortancyl			C				Not Reported
	Calcium Carbonate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14341953	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017192402			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Retro-Orbital Neoplasm	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14342980	EXPEDITED (15-DAY)		OT	CA-SA-2016SA057745		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Hypertension; Insomnia; Pain; Rash; Seronegative Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Visual Impairment	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Effexor			C	Oral			Not Reported
	Methotrexate			C				Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown			Not Reported
	Zopiclone			C				Not Reported
	Ultram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2018	14343396	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268809			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Form:Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown	Form: Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	13640270	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003310		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Feeling Hot; Gait Inability; Immunisation Reaction; Ocular Vascular Disorder; Ophthalmic Vein Thrombosis; Pain; Pyrexia	Plaquenil Tablet			S	Unknown			Concordia
	Cymbalta			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Zostavax			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	13640365	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003356		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Cataract; Cough; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Lung Infiltration; Pain In Extremity	Plaquenil Tablet			S	Oral			Concordia
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	13640367	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased;	Plaquenil Tablet			S	Oral			Concordia

Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Aleve		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	13640755	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003388		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Diverticulitis; Diverticulum; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Joint Destruction; Limb Injury; Nausea; Rheumatoid Arthritis; Stomal Hernia	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Methotrexate Sodium			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lotemax			C				Not Reported
	Oxycodone Hydrochloride			C				Not Reported
	Dexamethasone Tobramycin			C				Not Reported
	Folic Acid			C				Not Reported
	Lorazepam			C				Not Reported
	Vitamin D3			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14344947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2048721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Joint Swelling; Musculoskeletal	Actemra			S	Subcutaneous	Therapy Duration 91 Days		Not Reported
	Enbrel			S	Subcutaneous	Frequency: Qwk		Not Reported

Stiffness	Methotrexate	S	Subcutaneous	Frequency: Qwk		Not Reported
	Orencia	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	Frequency: 3/7 Days A Week		Not Reported
	Hydroxychloroquine	S	Unknown	Frequency: 2/7 Days A Week		Not Reported
	Leflunomide	C				Not Reported
	Sulfasalazine	C				Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14344988	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-17K-028-2207772-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Statex (Morphine Sulfate)			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold Injections			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345088	EXPEDITED (15-DAY)		OT	CL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-120039		49 YR	Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis	Glucophage	S	Oral	Unk Unk, Qd		Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	480 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Oral	Unk Unk, Qd		Not Reported
	Prednisone	S	Oral	Unk Unk, Qd		Not Reported
	Acetylcysteine	C	Oral			Not Reported
	Xeloda	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345451	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000024			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Plaquenil			S	Unknown			Concordia
	Lasix			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Synvisc-One			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345453	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010650		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Vomiting	Hydroxychloroquine			S	Oral			Concordia
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

	Methotrexate Sodium			S	Subcutaneous					Not Reported
	Naprosyn			S	Unknown					Not Reported
	Orencia			S	Subcutaneous					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14345541	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2017-00530		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Alkem
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14346254	NON-EXPEDITED			US-PFIZER INC-2018000807		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14346800	NON-EXPEDITED			US-PFIZER INC-2018000459		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk		Pfizer
	Prednisone	S	Unk		Pfizer
	Cortisone	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14347514	NON-EXPEDITED			US-PFIZER INC-2017554103		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Benzylpenicillin Potassium			S		20000000 Iu, Unk		Pfizer
	Erythromycin			S		250 Mg, Unk		Not Reported
	Cyclobenzaprine			S		10 Mg, Unk		Not Reported
	Bactrim Ds			S		Unk		Not Reported
	Plaquenil /00072603/			S		200 Mg, Unk		Not Reported
	Chloroquine Phosphate			S		250 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14347711	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268419			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rheumatoid Arthritis; Swelling	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Simponi			S	Unknown	Form:Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

	Arthrotec	C	Unknown		Not Reported
	Mefenamic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2018	14348138	EXPEDITED (15-DAY)		OT	CA-SA-2017SA260795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Drug Ineffective; Duodenal Ulcer	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Zantac			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	13304003	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008054		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Plaquenil			S				Concordia
	Plaquenil			S				Concordia
	Plaquenil			S	Unknown			Concordia
	Gabapentin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Nexium			S	Unknown			Not Reported

		Nexium			S	Unknown				Not Reported
		Xeljanz			S	Oral				Not Reported
		Xeljanz			S	Oral				Not Reported
		Xeljanz			S	Oral				Not Reported
		Xeljanz			S	Oral				Not Reported
		Methotrexate Sodium			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	13560368	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086380		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form: Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Voltaren			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Unknown	Form: Powder For Suspension Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	13640914	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Arthralgia; Asthenia; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Nexium			S	Oral			Not Reported
	Nexium			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14067008	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005650		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Eye Disorder; Rash; Rheumatoid Arthritis;	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported

Urticaria	Enbrel		S	Unknown	Not Reported
	Humira		C	Unknown	Not Reported
	Orencia		C	Unknown	Not Reported
	Rituxan		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14067015	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005672		87 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Disease Recurrence; Drug Ineffective; Heart Rate Increased; Macular Degeneration	Plaquenil Tablet			S	Oral			Concordia
	Arthrotec			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Arava			C				Not Reported
	Lucentis			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14067017	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005683		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Pulmonary Fibrosis	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14067024	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005711		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14069412	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005710		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Plaquenil Tablet			S	Unknown			Concordia
	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Depo-Medrol			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin D3			C				Not Reported
	Amlodipine Besilate			C				Not Reported
	Norvasc			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14224592	NON-EXPEDITED			US-AMGEN-USASP2017176631		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14242641	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown	Unk		Apotex
	Avelox			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14348765	NON-EXPEDITED			US-AMGEN-USASP2017193028		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14348774	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2209556-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Drug Ineffective; Drug Ineffective; Drug Ineffective; Leukopenia; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14348851	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000012		21 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Suicide Attempt	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14348852	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010606			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Resistance; Inflammation; Mouth Ulceration; Rheumatoid Arthritis;	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported

Therapeutic Response Decreased	Methotrexate		S	Unknown		Not Reported
	Rituxan		C			Not Reported
	Humira		C			Not Reported
	Orencia		C			Not Reported
	Actemra		C			Not Reported
	Prednisone		C			Not Reported
	Indocin		C			Not Reported
	Tramadol		C			Not Reported
	Sulfasalazine		C			Not Reported
	Amoxicillin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14348995	EXPEDITED (15-DAY)		OT	IL-ROCHE-2045562		60 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Squamous Cell Carcinoma Of Lung	Tocilizumab			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Omnic			C				Not Reported
	Caltrate 600 + D			C				Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Fenta			C	Unknown			Not Reported
	Incruse Ellipta			C	Unknown			Not Reported
	Micropirin			C	Unknown			Not Reported
	Omepradex			C	Unknown			Not Reported
	Omnic			C	Unknown			Not Reported
	Optalgin			C	Unknown			Not Reported
	Oxycod			C	Unknown			Not Reported
	Relvar Ellipta			C	Unknown	1 Puff		Not Reported
	Ursolit			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349233	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349234	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000019		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity	Hydroxychloroquine			S	Oral			Concordia
	Baclofen			C				Not Reported
	Amoxicillin			C				Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14349251	EXPEDITED (15-DAY)		OT	HR-IPCA LABORATORIES LIMITED-IPC-2017-HR-004088		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	500 Mg, Qd		Ipca
	Prednisolone			C		10 Mg, Qd		Not Reported
	Azathioprine			C		50 Mg, Bid		Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352103	NON-EXPEDITED			US-PFIZER INC-2017551458		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352839	NON-EXPEDITED			US-PFIZER INC-2017547435			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypertension; Urine Odour Abnormal	Xeljanz Xr			S	Oral	11 Mg, Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported
	Carvedilol			C		12.5 Mg, Unk		Not Reported
	Carvedilol			C		25 Mg, Unk		Not Reported
	Lisinopril			C	Oral	20 Mg, 1x/Day		Not Reported
	Procet [Hydrocodone,Paracetamol]			C		Unk, [Hydrocodone Bitartrate 7.5mg]/ [Paracetamol 325mg]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352848	NON-EXPEDITED		OT	US-PFIZER INC-2017547209		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Thrombocytopenia	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Plaquenil /00072602/			S		200 Mg, Unk		Not Reported
	Prednisone			C		5 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	13575254	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		65 YR	Male	CAN

INC.-GSH201705-003058

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Voltaren			C				Not Reported
	Xeljanz			C				Not Reported
	Zostavax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	13642284	EXPEDITED (15-DAY)		OT	US-VALIDUS PHARMACEUTICALS LLC-US-2017VAL000867		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Off Label Use	Pentoxifylline			S	Unknown	400 Mg, Tid		Validus
	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Weekly		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported

	Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Quinacrine	S	Unknown	100 Mg, Qd		Not Reported
	Dapsone	S	Unknown	100 Mg, Qd		Not Reported
	Acitretin	S	Unknown	20 Mg, Qd		Not Reported
	Tacrolimus	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	13676283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP013040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Once Every Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8 Mg Per Kg Monthly		Not Reported
	Ramipril			C	Unknown			Not Reported
	Asa			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Vitamin D /00107901/			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Lozide /00340101/			C	Unknown			Not Reported

	Naprosyn /00256201/			C	Unknown					Not Reported
	Naproxen			C	Unknown	Unk				Not Reported
	Asa Arthritis Strength Aspirin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14061606	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005651		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14067002	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005644		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Anxiety; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Palpitations; Rash; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14067012	EXPEDITED (15-DAY)		LT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-		74 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Chills; Cough; Dyspnoea; Endotracheal Intubation; Fatigue; Hyperthermia; Hypoxia	Hydroxychloroquine			S	Oral			Concordia
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Acebutolol			C				Not Reported
	Bromazepam			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Folic Acid			C				Not Reported
	Fosinopril			C				Not Reported
	Pantoprazole			C				Not Reported
	Calcium And Vit D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14067565	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005681		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14071324	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Condition Aggravated; Drug Hypersensitivity; Joint Destruction; Joint Range Of Motion Decreased; Joint Swelling; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14182558	NON-EXPEDITED			US-PFIZER INC-2017484931		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14295116	EXPEDITED (15-DAY)		OT	FI-CONCORDIA PHARMACEUTICALS INC.-E2B_00008842			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Prednisolone			S				Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14340479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2045681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Barrett'S Oesophagus; Drug Ineffective; Dysstasia; Nausea; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14346781	NON-EXPEDITED			US-PFIZER INC-2018000392		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14346804	NON-EXPEDITED			US-PFIZER INC-2018000314			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14353204	EXPEDITED (15-DAY)		DE, HO, OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006717		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Cerebral Ischaemia; Chills; Confusional State; Haemolytic Anaemia; Muscular Weakness; Neurological Decompensation; Pyrexia; Renal Impairment; Thrombocytopenia; Thrombotic Thrombocytopenic Purpura; Urine Output Decreased	Hydroxychloroquine			S	Oral			Concordia
	Calcium			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Aspirin			C		Low-Dose		Not Reported
	Metoprolol			C				Not Reported
	Medroxyprogesterone			C				Not Reported
	Oestradiol Valerate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14353366	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000029		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cataract; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Grip Strength Decreased; Heart Rate Increased; Impaired Self-Care; Joint Effusion; Joint Swelling; Pre-Existing Condition Improved; Synovitis; Therapeutic Response Unexpected	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C				Not Reported
	Depo-Medrol			C				Not Reported
	Ergocalciferol			C				Not Reported
	Macrogol			C				Not Reported
	Meloxicam			C				Not Reported
	Telmisartan			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14353395	NON-EXPEDITED			US-AMGEN-USASP2018000540			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14353911	EXPEDITED (15-DAY)		DS	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000033		49 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Flatulence; Gastrointestinal Disorder	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355154	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Duodenal Ulcer	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Ramipril			C				Not Reported

	Zantac	C		Not Reported
	Gabapentin	C		Not Reported
	Sulfasalazine	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355416	NON-EXPEDITED			US-PFIZER INC-2018003930		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Urinary Tract Infection	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14355550	NON-EXPEDITED			US-PFIZER INC-2018003810		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Minocin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2018	14357051	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA268239		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Drug Intolerance; Infection; Pericardial Effusion; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Arava			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360321	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00012310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immunodeficiency; Lyme Disease	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2018	14360382	EXPEDITED (15-DAY)		DE, HO, OT	AU-IPCA LABORATORIES LIMITED-IPC-2017-AU-004162			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine			S	Unknown			Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14098656	NON-EXPEDITED			US-AMGEN-USASL2017155157		91 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Hepatic Enzyme Increased; Nasopharyngitis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14258366	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201712-		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Hydroxychloroquine			S	Oral			Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Dexamethasone			C				Not Reported
	Ciclosporin			C				Not Reported
	Lisinopril			C				Not Reported
	Danazol			C				Not Reported
	Dapsone			C				Not Reported
	Cyclophosphamide			C				Not Reported
	Atenolol			C				Not Reported
	Vincristine			C				Not Reported
	Prednisolone			C				Not Reported
	Bendroflumethiazide			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14336547	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006716			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Retinopathy	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Humira			C				Not Reported
	Simponi			C				Not Reported
	Orencia			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14361153	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000022		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Neutrophil Count Increased; Rash	Plaquenil			S	Unknown			Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14361154	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000043			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14361156	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000045		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Intentional Product Misuse; Product Use Issue; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin B12			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14361159	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000050		25 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyelonephritis	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Tacrolimus			C				Not Reported
	Rinderon [Betamethasone]			C				Not Reported
	Lidomex			C				Not Reported
	Furozin			C				Not Reported
	Edirol			C				Not Reported
	Isodine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2018	14361184	EXPEDITED (15-DAY)		OT	CO-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-154387		51 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Simplex Meningitis; Viral Uveitis	Methotrexate			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	13640271	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003354		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Bone Erosion; C-Reactive Protein Abnormal; Drug	Plaquenil			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Drug Intolerance; Fear Of Disease; Gait Inability; Infection; Nodule; Osteitis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14361666	NON-EXPEDITED			US-AMGEN-USASP2018001173			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Rash	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14362414	NON-EXPEDITED			US-DEXPHARM-20171767		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Frequent Bowel Movements	Omeprazole Delayed Release Tablets 20 Mg			S	Oral	20 Mg, Qd		Dexcel
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Norvasc			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported

	Vitamin D Nos			C	Unknown	Unk				Not Reported
	Vitamin C			C	Unknown	Unk				Not Reported
	Omega 3			C	Unknown	Unk				Not Reported
	Glucosamine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14363551	EXPEDITED (15-DAY)		OT	PHHY2018HR000465		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Phospholipidosis; Proteinuria; Renal Disorder	Hydroxychloroquine			S	Unknown	500 Mg, Qd		Novartis
	Prednisolone			C	Unknown	10 Mg, Qd		Not Reported
	Azathioprine			C	Unknown	50 Mg, Bid		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14364444	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268719		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug Ineffective; Drug Intolerance; Retinopathy	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2018	14364732	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1800054US		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Condition Aggravated; Hypoacusis; Rheumatoid Arthritis	Actonel 5 Mg			S	Unknown			Allergan
	Calcium Carbonate And Vitamin D			S	Unknown			Not Reported

	Celebrex		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Minerals Nos W/Vitamins Nos		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	13640912	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003413		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; Respiratory Arrest; Visual Impairment	Plaquenil Tablet			S	Oral			Concordia
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	13986718	NON-EXPEDITED			US-AMGEN-USASP2017140244		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14328495	EXPEDITED (15-DAY)		HO, LT, OT	CA-GLAXOSMITHKLINE-CA2017GSK085597		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniorrhoea; Anaesthetic Complication; Caesarean Section; Exposure During Pregnancy; Live Birth; Premature Delivery; Uterine Contractions During Pregnancy	Benlysta			S		1000 Mg, Unk		Glaxosmithkline
	Benlysta			S				Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14338379	EXPEDITED (15-DAY)		DS, HO	CA-SA-2017SA268173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting	Hydroxychloroquine Sulfate			S	Unknown	2 Every 1 Day		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Advair			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Folic Acid/Ascorbic Acid/Ferrous Gluconate/Copper Sulfate/Magnesium Sulfate			C				Not Reported
	Calcium			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported

Ergocalciferol	C	Unknown	Dose : 3000	Not Reported
Ferrous Gluconate	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Olmesartan Medoxomil	C	Unknown		Not Reported
Oxybutynin	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Rabeprazole	C	Unknown		Not Reported
Senna Alexandrina	C			Not Reported
Tiotropium Bromide	C			Not Reported
Tylenol	C	Unknown		Not Reported
Vitamin B12	C	Sublingual		Not Reported
Vitamin C	C	Unknown		Not Reported
Zinc Gluconate	C	Unknown		Not Reported
Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14365801	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000057		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Fear Of Disease; Gait Inability; Hypersensitivity; Infection; Nodule; Osteitis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Skin	Plaquenil			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

Lesion; Synovitis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14366117	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-001237		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Chelonae Infection	Prednisone			S		Unk		Aurobindo
	Mycophenolate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14367872	EXPEDITED (15-DAY)		CA, HO	PHHY2018PT001935			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Foetal Exposure During Pregnancy; Heart Block Congenital	Salbutamol			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg		Novartis
	Dexamethasone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368077	EXPEDITED (15-DAY)		HO	PHHY2018CN001562		52 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Product Use In Unapproved Indication; Respiratory Tract Infection	Tacrolimus			S	Unknown	1 Mg, Bid		Not Reported
	Tacrolimus			S	Unknown	2 Mg, Bid		Not Reported
	Methylprednisolone			S	Unknown	24 Mg, Bid		Not Reported
	Methylprednisolone			S	Unknown	12 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	40 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis
	Cyclophosphamide			S	Unknown	Given For 8 Times (Accumulated Dose Reaching 5g)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368167	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268204		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368781	NON-EXPEDITED			US-PFIZER INC-2017548678		32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Myochrysine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368786	NON-EXPEDITED			US-PFIZER INC-2018003848		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14368806	NON-EXPEDITED			US-PFIZER INC-2018003923		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2018	14369420	NON-EXPEDITED			US-AMGEN-USASP2018002386			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	13009723	EXPEDITED (15-DAY)		OT	CA-SA-2016SA220485			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coronary Artery Occlusion; Drug Ineffective; Infection; Pain In Extremity	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Actemra			C	Unknown	162 Mg Weekly		Not Reported
	Cimzia			C	Unknown	Frequency- Q 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	13716670	EXPEDITED (15-DAY)		HO	US-ACTELION-A-		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Catheter Site Irritation; Catheter Site Pruritus; Diarrhoea; Dyspnoea Exertional; Malaise; Pyrexia; Rash; Vomiting	Veletri			S	Intravenous (not otherwise specified)	21 Ng/Kg, Per Min		Actelion
	Plaquinol			S	Unknown			Not Reported
	Adcirca			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	13904773	NON-EXPEDITED			US-PFIZER INC-2017366961		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, 1x/Day (11 Mg, Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14177164	NON-EXPEDITED			US-PFIZER INC-2017484538		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

	Actemra			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14250769	NON-EXPEDITED			US-PFIZER INC-2017516795			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14250823	NON-EXPEDITED			US-PFIZER INC-2017518272		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		15.6 Mg, Weekly		Pfizer
	Prednisone			S		5 Mg, Daily		Not Reported
	Prednisone			S		2.50 Mg, Daily		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Atenolol			C		50 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14258423	NON-EXPEDITED			US-PFIZER INC-2017518602		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14307454	NON-EXPEDITED			US-PFIZER INC-2017539134			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel		S	Unk		Pfizer
	Sulfasalazine		S	Unk		Pfizer
	Plaquenil		S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14319684	NON-EXPEDITED			US-PFIZER INC-2017545781		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14328383	NON-EXPEDITED			US-PFIZER INC-2017548618		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Meloxicam			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14369745	NON-EXPEDITED			US-AMGEN-USASP2018001062			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Sinusitis; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14370030	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159384		72 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lipoma	Pantoprazol			S	Oral	20 Mg, Daily		Sun
	Hytacand, Comprime			S	Oral	1 Df, Daily		Not Reported
	Plaquenil, Comprime Pellicule			S	Oral	400 Mg, Daily		Not Reported
	Uvedose 100 000 Ui, Solution Buvable En Ampoule			C	Oral	1 Df, 6 Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14371041	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-00		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extrapulmonary Tuberculosis; Infective Myositis	Hydroxychloroquine			S	Unknown	High-Dose		Hikma
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Cephalexin			C	Unknown			Not Reported
	Clindamycin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14372403	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00009392		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Dysaesthesia; Herpes Zoster; Nausea	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown	20-25 (Unit Not Reported)		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Last Dose Of Rituximab: Sep/2016		Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14372887	NON-EXPEDITED			US-PFIZER INC-2018009927		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14372902	NON-EXPEDITED			US-PFIZER INC-2018009870		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14373141	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2018M1000259		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	500 Mg Daily		Not Reported
	Prednisolone			C	Unknown	10 Mg Daily		Mylan
	Azathioprine			C	Unknown	2 X 50 Mg Daily		Mylan
	Levothyroxine			C	Other	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2018	14373468	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268475		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Arava	S	Oral			Not Reported
	Plaquenil	S	Oral			Not Reported
	Enbrel	S	Subcutaneous	Duration 4 Yaer		Not Reported
	Humira	S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate Sodium	S	Unknown	Duration 17yrs		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	12251863	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1600565-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Eruption; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Femur Fracture; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	13981445	NON-EXPEDITED			US-PFIZER INC-2017399529		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer

	Methotrexate Sodium		S		Unk		Pfizer
	Plaquenil		S		Unk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14273139	EXPEDITED (15-DAY)		HO, OT	FR-OTSUKA-2016_011211		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Abilify			S	Oral	10 Mg, Qd		Otsuka
	Dafalgan Codeine			S	Unknown	2 Tab, Tid		Not Reported
	Fluoxetine Hydrochloride			S	Oral	30 Mg, Qd		Not Reported
	Loxapac			S	Oral	1 Df, Unk 50 Drop (1/12 Millilitre)		Not Reported
	Theralene			S	Oral	1 Df, Qd 50 Drop (1/12 Millilitre)		Not Reported
	Tranxene			S	Oral	1 Df, Unk		Not Reported
	Noctamide			S	Oral	1 Tab, Qd		Not Reported
	Lepticur			S	Unknown	2 Tab, Qd		Not Reported
	Imeth			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Paracetamol Codeine			S	Oral	2 Tab, Tid Si Douleur		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Speciafoldine			C	Oral	4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14371062	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000103			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia

	Leflunomide			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14373990	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-159599		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Fluoxetine			S	Oral	30 Mg, Qd		Sun
	Loxapac			S	Oral	1 Df, Unk 50 Drop (1/12 Millilitre)		Not Reported
	Theralene			S	Oral	1 Df, Qd 50 Drop (1/12 Millilitre)		Not Reported
	Paracetamol/Codeine Phosphate			S	Oral	2 Tab, Tid Si Douleur		Not Reported
	Noctamide			S	Oral	1 Tab, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Dafalgan Codeine			S	Unknown	Unk, Tid		Not Reported
	Fluoxetine Hydrochloride			S	Oral	30 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Lepticur			S	Oral	2 Tab, Qd		Not Reported
	Tranxene			S	Oral	1 Df		Not Reported
	Imeth			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Speciafoldine			C	Oral	4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374402	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000074		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock;	Plaquenil			S	Oral			Concordia

Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Hypertension; Insomnia; Pain; Rash; Seronegative Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Visual Impairment	Leflunomide		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Venlafaxine Hydrochloride		S	Oral		Not Reported
	Xeljanz		C			Not Reported
	Effexor		C			Not Reported
	Methotrexate		C			Not Reported
	Reactine [Cetirizine Hydrochloride]		C			Not Reported
	Zopiclone		C			Not Reported
	Ultram		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374403	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000095		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Citalopram			C				Not Reported
	Folic Acid			C				Not Reported
	Losec			C				Not Reported
	Naprosyn			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374404	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000106		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

			Humira			S	Subcutaneous			Not Reported
			Methotrexate Sodium			S	Unknown			Not Reported
			Celecoxib			C				Not Reported
			Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374405	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14374407	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011447		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Plaquenil			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Tranxene			S	Oral			Not Reported
	Lepticur			S	Oral			Not Reported

	Loxapac	S	Oral	50 Drops		Not Reported
	Theralene	S	Oral	50 Drops		Not Reported
	Noctamide	S	Oral			Not Reported
	Abilify	S	Oral			Not Reported
	Dafalgan Codeine	S	Oral			Not Reported
	Imeth	S	Oral			Not Reported
	Codeine Phosphate/Paracetamol	S	Oral	Morning, Noon And Evening If Pain		Not Reported
	Methotrexate	S	Oral			Not Reported
	Speciafoldine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14375052	NON-EXPEDITED			US-PFIZER INC-2018012055		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14376225	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-845371		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Condition Aggravated; Hypoacusis; Rheumatoid Arthritis	Actonel			S	Unknown	Strength: 5mg		Teva
	Celebrex			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minerals Nos W/Vitamins Nos			S	Unknown			Not Reported
	Calcium Carbonate And Vitamin D			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14377759	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA268850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Infection; Weight Decreased	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 4 Week(S)		Not Reported
	Prednisone			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Esomeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2018	14378379	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Arava			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown	Every 24 Hrs		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

	Simponi			S	Subcutaneous	Solution Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14166283	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210637		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Form: Powder For Solution Intravenous		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14374401	EXPEDITED (15-DAY)		DE, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000066		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anogenital Warts; Vulvovaginal Warts	Plaquenil			S	Oral	2 Cp Par Jour		Concordia
	Prednisolone			S	Unknown			Concordia
	Dectancyl			S	Unknown			Not Reported
	Mabthera			S	Intravenous (not			Not Reported

						otherwise specified)				
		Mabthera			S	Intravenous (not otherwise specified)	In Total			Not Reported
		Bactrim			C					Not Reported
		Tardyferon			C					Not Reported
		Speciafoldine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14378519	NON-EXPEDITED			US-AMGEN-USASP2018003600			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14378555	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000128		16 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Skin Toxicity	Hydroxychloroquine			S	Unknown			Concordia
	Cyclophosphamide			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379106	EXPEDITED (15-DAY)		DS, HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000051			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actonel			C				Not Reported
	Advair			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid/Copper Sulfate/Cyanocobalamin/Ferrous Gluconate/Folic Acid/Magnesium Sulfate			C				Not Reported
	Calcium			C				Not Reported
	Citalopram			C				Not Reported
	Ergocalciferol			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Olmesartan Medoxomil			C				Not Reported
	Oxybutynin			C				Not Reported
	Prednisone			C				Not Reported
	Rabeprazole			C				Not Reported
	Senna Alexandrina			C				Not Reported
	Tiotropium Bromide			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Zopiclone			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379108	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000054			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Oxycodone Hydrochloride			C				Not Reported
	Paracetamol							
	Esomeprazole Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379110	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rheumatoid Arthritis; Swelling	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported

					Simponi		S	Unknown			Not Reported
					Sulfasalazine		S	Oral			Not Reported
					Acetaminophen		C				Not Reported
					Arthrotec		C				Not Reported
					Mefenamic Acid		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379117	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000085		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug Ineffective; Drug Intolerance; Retinopathy	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379130	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000149		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14379876	NON-EXPEDITED			US-PFIZER INC-2018012359		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380305	NON-EXPEDITED			US-PFIZER INC-2018014585		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380881	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000088		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Drug Intolerance; Infection; Pericardial Effusion; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380882	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Latent Tuberculosis; Rash; Rheumatoid Arthritis; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380888	EXPEDITED (15-DAY)		HO, OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000134		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380890	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure;	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported

Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Infection; Weight Decreased	Actemra	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown		Not Reported
	Actonel	C			Not Reported
	Esomeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380891	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000150		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14380893	EXPEDITED (15-DAY)		DS, HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000155		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Plaquenil Tablet	S	Oral	Concordia
	Abatacept	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actonel	C		Not Reported
	Advair	C		Not Reported
	Amlodipine	C		Not Reported
	Ascorbic Acid	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Citalopram	C		Not Reported
	Docusate Sodium Sennosides	C		Not Reported
	Ergocalciferol	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Olmesartan Medoxomil	C		Not Reported
	Oxybutynin	C		Not Reported
	Prednisone	C		Not Reported
	Rabeprazole	C		Not Reported
	Rabeprazole Sodium	C		Not Reported
	Senna Alexandrina	C		Not Reported
	Spiriva	C		Not Reported
	Tiotropium Bromide	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin B12	C		Not Reported
	Zinc Gluconate	C		Not Reported
	Zopiclone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2018	14381920	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017247072		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sensitivity To Weather	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer

Change	Leflunomide	S		20 Mg, Daily	Not Reported
	Hydroxychloroquine /00072603/	S		400 Mg, 1x/Day	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	12881457	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016491851		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Musculoskeletal Stiffness; Sleep Disorder; Swelling	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		400 Mg, Daily		Not Reported
	Prednisone			S		Unk		Not Reported
	Elavil /00002202/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14316535	NON-EXPEDITED			US-AMGEN-USASP2017188843			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14375074	NON-EXPEDITED			US-PFIZER INC-2018011920		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14383284	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-012769		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Diphenoxylate Hci & Atropine Sulfate			S	Oral	Unk Unk, Unknown		Par
	Tamsulosin Hcl			S	Oral	Unk Unk, Unknown		Par
	Ranitidine			S	Oral	Unk Unk, Unknown		Par
	Salicylates Nos			S	Oral	Unk Unk, Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14384129	NON-EXPEDITED			US-PFIZER INC-2018014469		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14384180	NON-EXPEDITED			US-PFIZER INC-2018016840		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14384191	NON-EXPEDITED			US-PFIZER INC-2018016895		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance	Sulfasalazine		S		Unk	Pfizer
	Plaquenil		S		Unk	Not Reported
	Arava		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14384204	NON-EXPEDITED			US-PFIZER INC-2018016666		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14384288	NON-EXPEDITED			US-PFIZER INC-2018014748			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14385047	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00009421		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Gastritis	Hydroxychloroquine			S	Unknown			Concordia
	Rituximab			S	Unknown	Last Cycle Of Rituximab Was Administered On 06/Sep/2016		Not Reported
	Methotrexat			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2018	14385056	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000171			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia
	Pitocin			S				Not Reported
	Gabapentin			S				Not Reported
	Lyrica			S				Not Reported
	Nortriptyline			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14214178	NON-EXPEDITED			US-AMGEN-USASP2017174434		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14355153	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection	Plaquenil			S				Concordia
	Leflunomide			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390432	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2018-013272		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Rheumatrex Tablets 2.5 Mg			S	Oral	Unk Unk, Unknown		Dava
	Hydroxychloroquine			S	Oral	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390557	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2223635-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2053131			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14390792	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1684		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sensitivity To Weather Change	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391355	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000127		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Gastritis	Hydroxychloroquine			S	Unknown			Concordia
	Rituximab			S	Unknown			Not Reported

	Methotrexate				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391363	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000166			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391365	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000180			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity	Plaquenil			S				Concordia
	Naproxen			S				Not Reported
	Flexeril			S				Not Reported
	Enbrel			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391366	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000183			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cataract; Dry Mouth; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Vitamin D Nos			C				Not Reported
	Aludrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14391368	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000213		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Plaquenil Tablet			S	Oral			Concordia
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14392221	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018GSK004942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mobility Decreased; Pain; Systemic Lupus Erythematosus	Benlysta			S		600 Mg, Unk		Glaxosmithkline
	Plaquenil			S	Oral	1 Df, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2018	14393421	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2223707-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported

Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Naprosyn		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Tramadol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	13618148	EXPEDITED (15-DAY)		OT	CA-SA-2017SA098204		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Indocin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Indomethacin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	13709170	NON-EXPEDITED			US-AMGEN-USASP2017097731		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Enbrel			S	Unknown	Unk			Amgen
	Tramadol			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Sulindac			S	Unknown	Unk			Not Reported
	Meloxicam			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Triamterene			S	Unknown	Unk			Not Reported
	Cymbalta			C		Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid			Not Reported
	Dyazide			C	Unknown	Unk			Not Reported
	Lyrica			C	Unknown	Unk			Not Reported
	Synthroid			C		Unk			Not Reported
	Motrin			C	Unknown	Unk			Not Reported
	Excedrin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	13981588	NON-EXPEDITED			US-AMGEN-USASP2017138338		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Disorder; Headache; Rash	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14398622	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2224730-00		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pneumonia; Weight Increased	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14398625	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224762-00		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Hip Arthroplasty; Hypertension; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14398776	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224628-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
		Rituxan			S		Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14398801	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224196-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Cough; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Lung Infiltration; Pain In Extremity	Humira			S	Subcutaneous			Not Reported
	Apo Prednison			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14398820	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2224398-00		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
	Amitriptyline			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14399410	NON-EXPEDITED		OT	US-JNJFOC-20171203450			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400444	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224553-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

						otherwise specified)				
		Rituxan			S	Unknown				Not Reported
		Infliximab			S	Unknown				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400543	NON-EXPEDITED			US-AMGEN-USASP2018005572			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400649	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Spiriva			S	Unknown			Boehringer Ingelheim
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lipitor			S	Unknown			Not Reported
	Zenhale			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400718	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2224419-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400797	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000156		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Peripheral Swelling	Plaquenil Tablet			S	Oral			Concordia
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400803	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000191		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Therapeutic Product Ineffective	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400827	NON-EXPEDITED			US-AMGEN-USASP2018005610			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Infection; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400975	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000218		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Plaquenil Tablet		S	Oral	Concordia
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400978	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000223			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Eye Disorder; Headache; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Skin Erosion	Plaquenil Tablet			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400980	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000225		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400981	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		47 YR	Male	CAN

INC.-GSH201801-000226

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Still'S Disease	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400983	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000229			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Abnormal; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			C				Not Reported
	Celebrex			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400991	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000204		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Decreased; Fatigue; Nasopharyngitis; Nausea; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine	S	Oral		Concordia
	Diphenhydramine	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C			Not Reported
	Diphenhydramine Hydrochloride	C			Not Reported
	Filgrastim	C			Not Reported
	Melatonin	C			Not Reported
	Methylprednisolone	C			Not Reported
	Naproxen	C			Not Reported
	Percocet	C			Not Reported
	Tecta	C			Not Reported
	Vitamin C	C			Not Reported
	Cyclinex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14400995	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000207		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Jc Virus Infection; Joint Lock; Joint Swelling; Multiple Sclerosis; Oxygen Saturation Decreased; Spinal Disorder	Hydroxychloroquine			S	Oral			Concordia
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Alendronate			C				Not Reported
	Azathioprine			C				Not Reported
	Diphenhydramine			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Omeprazole			C				Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401571	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2223649-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Humira			S	Subcutaneous			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Desoximetasone			C				Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401724	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224879-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Ineffective; Hypersensitivity; Hypersensitivity; Hypersensitivity; Hypersensitivity; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Dosage Form Was Given As Solution		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Celebrex			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

	Hydroxychloroquine Sulphate	C			Not Reported
	Morphine	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Tofacitinib	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401739	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2018-0008269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Dilaudid			S	Unknown	Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tylenol Regular			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401908	EXPEDITED (15-DAY)		HO	PHHY2018SE005054		81 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14402442	NON-EXPEDITED			US-PFIZER INC-2018018804		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lidocaine Hcl			S		Unk		Unknown
	Morphine Sulfate			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14402586	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2225742-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dyspnoea; Joint Lock; Mass; Peripheral Swelling; Physical Disability	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14402905	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2225731-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported

	Methotrexate			S	Oral					Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403057	DIRECT		DS			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Dizziness; Tinnitus; Tinnitus	Hydroxychloroquine (Plaquenil Generic) 200mg			S	Oral	1 Pill For 2 Wks Then 1am 1 Pm, Am & Pm With Food, Mouth		Zydus Pharm
	Armour			C				Not Reported
	Ester Vit C			C				Not Reported
	Calcium Citrate			C				Not Reported
	D3			C				Not Reported
	Magnesium			C				Not Reported
	Selenium			C				Not Reported
	B Complex			C				Not Reported
	Renew Life Cleanse More			C				Not Reported
	Fish Oil			C				Not Reported
	Ubravinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403078	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403080	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000238		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C				Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14403420	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2224304-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Myochrysine	S	Parenteral	Form Of Administration Was Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown	Form Of Administration Was Powder For Solution Intravenous, Duration Was 365	Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown	Form Of Administration Was Solution Intravenous, Duration Was 365	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14404608	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224269-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthropathy; Body Height Decreased; Deep Vein Thrombosis; Depressed Mood; Drug Ineffective; Drug Ineffective; Emotional Distress; Feeling Abnormal; Gait Inability; Impaired Quality Of Life; Osteoporosis; Osteoporotic Fracture; Pelvic Fracture; Pruritus Allergic; Psoriasis; Psoriasis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Orencia	C		Not Reported
	Otezla	C		Not Reported
	Vioxx	C		Not Reported
	Warfarin	C		Not Reported
	Methotrexate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14404649	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2225300-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Joint Laxity; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate Sodium			S	Unknown	Not Reported
	Prednisone Acetate			S	Unknown	Not Reported
	Plaquenil			C	Unknown	Not Reported
	Folic Acid			C		Not Reported
	Hydroxychloroquine			C		Not Reported
	Methotrexate			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	12891488	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2102		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Sleep Disorder; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Elavil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13016569	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006332			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coronary Artery Occlusion; Drug Ineffective; Infection; Pain In Extremity	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Actemra			C				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13386926	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cortisone			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13386928	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Plaquenil Tablet			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			C				Not Reported
	Motrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13394679	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Tuberculin Test Positive	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13394725	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Ketoprofen			C				Not Reported
	Losec			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Xeljanz			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	13941692	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017382252		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Condition Aggravated	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S		11 Mg, Daily		Pfizer
	Methylprednisolone			S		4 Mg, Unk (4 Mg X1)		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk (200mg X1)		Not Reported
	Leflunomide			S		20 Mg, Unk (20 Mg X1)		Not Reported
	Celecoxib			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14064486	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Hypersensitivity; Pneumonia; Pneumonitis; Renal Impairment; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Orencia			C	Unknown			Not Reported
	Simponi			C	Unknown	Form:Solution Subcutaneous		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14206468	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2017172972		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Buttock Injury; Discomfort; Drug	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen

Ineffective; Infection; Joint Effusion; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Osteomyelitis; Pancreatitis; Renal Failure; Rheumatoid Arthritis; Ulcer	Enbrel		S	Unknown	Unk	Amgen
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Plaquenil		S	Oral	200 Mg, Bid	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Voltaren		C	Unknown	Unk	Not Reported
	Methotrexate		C		Unk	Not Reported
	Xeljanz Xr		C	Oral	11 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14211167	NON-EXPEDITED			US-PFIZER INC-2017499981		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Azulfidine			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14306271	NON-EXPEDITED			US-AMGEN-USASP2017187073		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Nausea; Peripheral Swelling; Vision	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

Blurred; Vomiting	Arava	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14391089	NON-EXPEDITED			US-PFIZER INC-2018018160		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14398672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224368-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Fatigue; Fibromyalgia; Foot Operation; Gait Disturbance; Hip Arthroplasty; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pain In Extremity; Pollakiuria	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Folic Acid Tab 5mg			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Plaquenil		S	Oral	Not Reported
	Sulfasalazine		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14405215	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2223721-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Oral			Not Reported
	Apo Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoprazole Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14405471	NON-EXPEDITED			US-PFIZER INC-2018018947		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

	Orencia	S	Unk		Not Reported
	Remicade	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14407455	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT005250		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Exposure During Pregnancy; Listeriosis; Platelet Count Decreased; Premature Delivery; Pyrexia	Acetylsalicylic Acid			S	Unknown	100 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14407578	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018023506		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperpyrexia; Respiratory Failure	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer
	Plaquenil /00072603/			S	Oral	400 Mg, 1x/Day		Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14407703	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006059		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

		Methotrexate Sodium			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported
		Coversyl			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14407952	NON-EXPEDITED		OT	US-DEPOMED, INC.-US-2017DEP002309			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Product Use In Unapproved Indication; Seizure; Vomiting	Nucynta			S		Unk		Depomed
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14408079	EXPEDITED (15-DAY)		HO	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000261		69 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatosis; Pustule; Pyrexia; Rash Erythematous; Stevens-Johnson Syndrome; Systemic Inflammatory Response Syndrome	Hydroxychloroquine			S				Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14408268	EXPEDITED (15-DAY)		OT	US-SA-2017SA262518		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Chills; Dizziness; Headache; Infection; Nausea; Palpitations; Pharyngitis; Pruritus; Rash; Rectal Haemorrhage; Therapeutic Product Effect Decreased	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14408411	NON-EXPEDITED			US-AMGEN-USASP2018006443			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hidradenitis; Off Label Use; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2018	14408568	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2225737-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Unknown	Intravenous		Not Reported
	Rituxan	S	Unknown	Intravenous, Solution		Not Reported
	Zostavax	S	Subcutaneous	Powder For Suspension		Not Reported
	Enbrel	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Diclofenac	C	Oral			Not Reported
	Desoximetasone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	12855959	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016142542		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	13397329	EXPEDITED (15-DAY)		HO, LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002107		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Anaphylactic Shock; Autoimmune Disorder;	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia

Cognitive Disorder; Cushing'S Syndrome; Headache; Heart Rate Increased; Hypersensitivity; Infusion Related Reaction; Kidney Infection; Leukopenia; Muscular Weakness; Paralysis; Pneumonia; Proteinuria; Psychotic Disorder; Swelling; Therapeutic Response Decreased	Azathioprine	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Cyclophosphamide	S	Unknown	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Methylprednisolone	C		Not Reported
	Solumedrol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	13431280	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1936038-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Depression; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral	Duration: For Years		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			C		Tapering Dose		Not Reported
	Plaquenil			C				Not Reported
	Celebrex			C				Not Reported

	Vitamin D Nos			C						Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	13640909	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003377		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Shingles Vaccine			C				Not Reported
	Indomethacin			C				Not Reported
	Indocin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	13647009	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2002145-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported

Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported
	Arava	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Lyrica	S	Oral			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Cellcept	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Piroxicam	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	13694297	NON-EXPEDITED			US-PFIZER INC-2017279296		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Tramadol			S		Unk		Not Reported
	Sulindac			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Triamterene			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14058075	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA182873		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Drug Ineffective; Fatigue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14246500	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006556		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Rash Erythematous	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Bactrim			S	Oral			Not Reported
	Procoralan			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Cerazette (Desogestrel)			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Aldactone			C				Not Reported
	Speciafoldine			C				Not Reported
	Lasilix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14257441	NON-EXPEDITED			US-AMGEN-USASP2017181892			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hepatic Enzyme Increased; Nausea; Peripheral Swelling; Rash; Swelling Face; Therapeutic Product Effect Incomplete; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Aclexa			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14379022	EXPEDITED (15-DAY)			CA-ABBVIE-18K-028-2219216-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hepatic Enzyme Increased; Pyrexia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14404686	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2225763-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Decreased	Anakinra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Cimzia	S	Subcutaneous	Solution		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14409375	EXPEDITED (15-DAY)		CA, HO, OT	PT-GLAXOSMITHKLINE-PT2018003537		23 DAY	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Foetal Exposure During Pregnancy; Heart Block Congenital; Lung Infiltration; Lupus Pneumonitis; Respiratory Failure	Dexamethasone			S	Transplacental	Maternal Dose: 8 Mg/D On Week 26		Glaxosmithkline
	Prednisolone			S	Transplacental	Unk		Glaxosmithkline
	Salbutamol			S	Transplacental	Maternal Dose: 32mg/D On Week 26		Glaxosmithkline
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14409402	NON-EXPEDITED			US-AMGEN-USASP2018006474			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Methotrexate			C		Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14410008	NON-EXPEDITED			US-PFIZER INC-2018022319		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14410036	NON-EXPEDITED			US-PFIZER INC-2018022866		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14410815	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP005241			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis;	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported

Shoulder Arthroplasty; Vomiting; Weight Decreased	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14410884	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005276		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bone Pain; Carpal Tunnel Syndrome; Depression; Hypersensitivity; Micturition Urgency; Pollakiuria; Pruritus; Rash; Rheumatoid Arthritis; Scab; Sedation; Swelling; Weight Increased	Diphenhydramine			S	Oral	50 Mg, Unk		Apotex
	Rituxan			S	Unknown			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Cetrizine			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Detrol La			C	Unknown			Not Reported
	Docosahexanoic Acid W/Eicosapentaenoic Acid			C	Unknown	Unk		Not Reported
	Estrace			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Naproxen			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Robaxacet			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Tylenol No.2			C	Unknown			Not Reported

	Vitamin B 12			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411367	EXPEDITED (15-DAY)		HO	SE-MYLANLABS-2018M1003335			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411644	EXPEDITED (15-DAY)		DE, HO, OT	AU-APOTEX-2018AP005060		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine			S	Oral	200 Mg, Daily		Apotex
	Fluconazole			S	Unknown	Unk		Apotex
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported
	Piperacilin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Qid		Not Reported
	Methotrexate			C	Unknown	Unk, Q.Wk.		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Medroxyprogesterone			C	Unknown	Unk		Not Reported
	Oestradiol Valerate			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Intravenous (not	2 G Total, Unk		Not Reported

				otherwise specified)		
	Ceftriaxone	C				Not Reported
	Ceftriaxone	C				Not Reported
	Midazolam Hydrochloride	C	Intravenous (not otherwise specified)	3.5 Mg Total, Unk		Not Reported
	Phenytoin	C	Intravenous (not otherwise specified)	900 Mg, Unk		Not Reported
	Acyclovir /00587301/	C	Intravenous (not otherwise specified)	500 Mg, Tid		Not Reported
	Acyclovir /00587301/	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411685	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000175			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411686	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000246			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411687	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000262			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Diarrhoea;	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

Fatigue; Injection Site Induration; Injection Site Pain; Injection Site Rash; Injection Site Swelling; Treatment Failure	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Xeljanz		C			Not Reported
	Ibuprofen		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411844	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003915		33 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	1.25 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411847	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003917		40 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	30 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	25 Mg/Day		Not Reported
	Cyclophosphamide			S	Oral	33.3 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411848	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003914		40 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	5 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	500 [Unit Not Stated]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411849	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003913		44 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	1.25 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411851	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003911		42 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	5 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411961	EXPEDITED (15-DAY)		DE, OT	TW-MYLANLABS-2018M1003936		54 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	18.75 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Oral	75 Mg/Day		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411962	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003937		8 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	10 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411971	EXPEDITED (15-DAY)		DE, OT	TW-MYLANLABS-2018M1003940		74 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone	S	Unknown	5 Mg/Day	Not Reported
	Azathioprine	S	Unknown	50 Mg/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411972	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003944		42 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	20 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14411975	EXPEDITED (15-DAY)		OT	TW-MYLANLABS-2018M1003941		26 YR	Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B; Hepatitis B Reactivation	Prednisolone			S	Unknown	2.5 Mg/Day		Not Reported
	Azathioprine			S	Unknown	25 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14412201	EXPEDITED (15-DAY)		HO	PHHY2018IT007901			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Acetylsalicylic Acid			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 400 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 25 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 7.5 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14412668	EXPEDITED (15-DAY)		OT	CA-AMGEN-KDL292458		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk, Qwk		Amgen
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14413333	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224904-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Pain; Pruritus; Rash; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14413716	EXPEDITED (15-DAY)		OT	PHHY2018TR007452			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	6.5 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14413717	EXPEDITED (15-DAY)		OT	PHHY2018TR007458			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	6.5 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14413861	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2225751-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C				Not Reported
	Amoxil			C				Not Reported
	Bcg			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2018	14416750	DIRECT	Y	HO			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Depressed Level Of Consciousness; Dysphagia; Hypotension; Myopathy; Unresponsive To Stimuli; Weaning Failure	Hydroxychloroquine			S	Oral			Not Reported
	Docusate			C				Not Reported
	Folic Acid			C				Not Reported
	Guafenesin			C				Not Reported
	Ibuprofen			C				Not Reported
	Lidocaine			C				Not Reported
	Loratadine			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Melatonin			C				Not Reported
	Methotrexate			C				Not Reported
	Morphine			C				Not Reported
	Sodium Chloride			C				Not Reported
	Thiamine			C				Not Reported
	Triamcinolone Cream			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2018	14067004	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Hypersensitivity; Pneumonia; Pneumonitis; Renal Impairment; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2018	14340448	EXPEDITED (15-DAY)		OT	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006725		36 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Immune Thrombocytopenia; Platelet Count Decreased	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2018	14391356	EXPEDITED (15-DAY)		OT	BR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000130		10 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antiphospholipid Antibodies Positive; Biopsy Skin Abnormal; Dermatitis Bullous; Double Stranded Dna Antibody Positive; Drug Ineffective; Nasal Mucosal Disorder; Oral Mucosal Blistering; Proteinuria; Pyrexia; Systemic Lupus Erythematosus Rash	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2018	14415192	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000308		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stillbirth	Hydroxychloroquine Tablet			S	Oral			Concordia

	Folic Acid			C						Not Reported
	Prednisone			C						Not Reported
	Misoprostol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	13692819	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2018172-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Hypersensitivity; Impaired Work Ability; Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14169221	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210705		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Polyneuropathy; Rash; Sepsis	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14198028	NON-EXPEDITED		OT	US-AMGEN-USASP2017172024		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cyanosis; Drug Hypersensitivity; Fibromyalgia; Neck Surgery; Osteoarthritis; Pain In Extremity; Rash; Surgery; Thoracic Outlet Syndrome; Thrombosis	Enbrel	S	Unknown	50 Mg, Qwk		Amgen
	Enbrel	S	Unknown	50 Mg, Qwk		Amgen
	Enbrel	S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Plaquenil	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported
	Vitamin D3	C		Unk		Not Reported
	Amitriptyline	C		Unk		Not Reported
	Lyrica	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14415774	NON-EXPEDITED			US-AMGEN-USASP2018007239			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Skin Reaction; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416139	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2224311-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported

Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Enbrel		S	Unknown		Not Reported
	Diclofenac		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Motrin		S	Unknown		Not Reported
	Naprosyn		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Tramadol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2224412-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14416902	NON-EXPEDITED			US-PFIZER INC-2018027819			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hidradenitis; Product Use In Unapproved Indication; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14417032	NON-EXPEDITED			US-PFIZER INC-2018025226			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14419472	EXPEDITED (15-DAY)		OT	PT-IMPAX LABORATORIES, INC-2018-IPXL-00137		75 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolic Cerebral Infarction	Doxycycline Hyclate Delayed Release			S	Unknown	Unk		Impax
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2018	14420670	NON-EXPEDITED			US-ROCHE-2006825			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	12470334	EXPEDITED (15-DAY)		HO	NL-ROCHE-1776650		59 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14172663	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006285		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14257306	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006595			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14418593	EXPEDITED (15-DAY)		HO, LT	PHHY2018CA007718			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Novartis
	Methotrexate			S				Novartis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Humira	S	Subcutaneous	Unk		Not Reported
	Gen-Hydroxychloroquine	S	Unknown			Not Reported
	Gen-Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Gen-Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422110	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000264			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Liver Disorder	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Remicad			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422111	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000293			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

Ineffective	Methotrexate			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422113	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000309		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Coversyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422114	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000310			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Chills; Dizziness; Headache; Infection; Nausea; Palpitations; Pharyngitis; Pruritus; Rash; Rectal Haemorrhage; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422118	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000322		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Barrett'S Oesophagus; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Feeling Abnormal; Impaired Gastric Emptying; Malaise; Pelvic Mass; Pharyngeal Swelling; Weight Decreased	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14422663	EXPEDITED (15-DAY)		OT	US-ROCHE-2055173			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Off Label Use; Therapeutic Response Decreased; Treatment Failure; Tuberculosis	Cellcept			S	Unknown	Ongoing		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown	Ongoing		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14423536	NON-EXPEDITED			US-PFIZER INC-2018027104		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14423605	NON-EXPEDITED			US-PFIZER INC-2018027895		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Hctz			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14425034	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Azulfidine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14425039	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000340		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Vomiting	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2018	14425861	DIRECT		DS, HO, LT			79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Hydroxychloroquine (Plaquenil)			S	Oral			Not Reported
	Fluoxetine			C				Not Reported
	Levothyroxine			C				Not Reported
	Losartan/Hctz			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin B			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	13403645	EXPEDITED (15-DAY)		OT	BR-ABBVIE-16K-020-1805052-00			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Oral Mucosal Blistering; Osteoarthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Reuquinol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14385104	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000129		4 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Off Label Use; Rebound Effect; Skin Lesion; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14391358	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000137		10 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Off Label Use; Rebound Effect; Skin Lesion; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14430937	NON-EXPEDITED			US-AMGEN-USASP2018009115			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Gastrointestinal Disorder; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14431431	NON-EXPEDITED			US-PFIZER INC-2018031306		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14433167	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1803425US		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Botox			S	Intramuscular	Unk, Single		Allergan
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14433768	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1004872			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myeloid Leukaemia; Myelodysplastic Syndrome	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14433769	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1004873			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Myeloid Leukaemia	Azathioprine			S	Unknown	Unk				Not Reported
	Hydroxychloroquine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14433996	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1004875			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14434012	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1004880			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14434013	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1004878			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2018	14435485	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation	Forteo 600 Mcg/2.4 Ml Lilly			S	Subcutaneous			Eli Lilly And Co
	Hydroxychloroquine			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	12340598	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016056061		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14031837	NON-EXPEDITED			US-AMGEN-USASP2017147644			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pain	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14306893	EXPEDITED (15-DAY)		OT	CA-TEVA-2017-CA-835430			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Duramed
	Enbrel			S	Subcutaneous	50mg		Not Reported
	Enbrel			S	Unknown	50mg		Not Reported
	Enbrel			S	Unknown	50mg		Not Reported
	Enbrel			S	Subcutaneous	50mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Unknown			Not Reported
	Norvasc			S	Oral	5 Milligram Daily; 5mg Qd Oral		Not Reported
	Norvasc			S	Oral	5mg Qd Oral		Not Reported
	Asacol			S	Unknown	2400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Omega Allergenic Extracts			C				Not Reported
	Vitamin D3			C				Not Reported
	Depo-Medrol			C				Not Reported
	Tylenol			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Atacand Plus			C				Not Reported
	Amlodipine Besilate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14391354	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000126		5 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Off Label Use; Rebound Effect; Skin Lesion; Systemic Lupus Erythematosus	Hydroxychloroquine			S				Concordia
	Prednisolone			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14434797	NON-EXPEDITED			US-AMGEN-USASP2018009109			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14435043	EXPEDITED (15-DAY)		DE, OT	FR-ROCHE-2060722		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anogenital Warts; Vulvovaginal Warts	Mabthera			S	Intravenous (not otherwise specified)	375mg/M2		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil	S	Oral	2 Cp Par Jour		Not Reported
	Solupred (France)	S	Unknown			Not Reported
	Dectancyl	S	Unknown			Not Reported
	Bactrim	C	Unknown			Not Reported
	Tardyferon (France)	C	Unknown			Not Reported
	Speciafoldine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14437152	NON-EXPEDITED		OT	US-ABBVIE-17K-163-1896241-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Skin; Feeling Abnormal; Immunosuppression; Impaired Healing; Infection; Procedural Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14437765	NON-EXPEDITED			US-ABBVIE-17K-163-1920501-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Lodine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14438209	NON-EXPEDITED			US-PFIZER INC-2018028064		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Sulfasalazine		S		Unk	Pfizer
	Actemra		S		Unk	Not Reported
	Plaquenil		S		Unk	Not Reported
	Remicade		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14439962	NON-EXPEDITED			US-PFIZER INC-2018031150		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14442481	NON-EXPEDITED			US-ABBVIE-17K-163-1991986-00		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14442697	NON-EXPEDITED			US-ABBVIE-17K-163-2059298-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14442775	NON-EXPEDITED			US-ABBVIE-17K-163-2009928-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Gastrointestinal Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ssz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14442881	NON-EXPEDITED			US-ABBVIE-17K-163-2054939-00		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Gastrointestinal Disorder; Local Reaction; Psoriasis; Sinusitis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14442909	NON-EXPEDITED			US-ABBVIE-17K-163-2059638-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Nausea; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443143	NON-EXPEDITED			US-ABBVIE-17K-163-2054468-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Leukopenia; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443180	NON-EXPEDITED			US-ABBVIE-17K-163-2058970-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443248	NON-EXPEDITED			US-ABBVIE-17K-163-2009411-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituxan			S	Unknown					Not Reported
	Enbrel			S	Unknown					Not Reported
	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443261	NON-EXPEDITED			US-ABBVIE-17K-163-2054562-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Depression; Depression; Fatigue; Hepatic Enzyme Increased; Joint Lock; Musculoskeletal Stiffness; Pulmonary Mass; Red Blood Cell Sedimentation Rate Increased; Retroperitoneal Mass	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydrocodone			C				Not Reported
	Naproxen			C				Not Reported
	Leflunomide			C	Oral			Not Reported
	Prednisone			C	Oral	2 Refills		Not Reported
	Singulair			C	Oral	6 Refills		Not Reported
	Zantac			C	Oral	5 Refills		Not Reported
	Zyrtec			C	Oral	6 Refills		Not Reported
	Nabumeton			C	Oral	3 Refills		Not Reported
	Triamcinolone Acetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443607	NON-EXPEDITED			US-ABBVIE-17K-163-2047546-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443636	NON-EXPEDITED			US-ABBVIE-17K-163-1989036-00		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Allergy To Vaccine; Alopecia; Arthralgia; Bursitis; Drug Ineffective; Drug Ineffective; Epicondylitis; Fall; Fibromyalgia; Gastrointestinal Disorder; Hypertension; Injection Site Irritation; Iron Deficiency Anaemia; Leukopenia; Lung Hyperinflation; Musculoskeletal Pain; Osteopenia; Osteoporosis; Rheumatoid Arthritis; Rotator Cuff Syndrome; Sjogren'S Syndrome; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Duloxetine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Six Tablet		Not Reported
	Gabapentin			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Afluria			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Triamcinolone Acetonide			C				Not Reported
	Atorvastatin			C				Not Reported
	Omeprazole			C				Not Reported
	Iron			C				Not Reported
	Losartan Potassium			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Pentoxifylline			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443649	NON-EXPEDITED			US-ABBVIE-17K-163-2051398-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported

	Methotrexate			S	Unknown					Not Reported
	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14443737	NON-EXPEDITED			US-ABBVIE-17K-163-2059610-00		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			C	Oral	80 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	12935470	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Polyneuropathy; Rash	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	13118608	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA121411		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hospitalisation	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

					Enbrel		S	Unknown		Not Reported
					Viread		C	Unknown		Not Reported
					Humira		C	Unknown		Not Reported
					Arava		C	Unknown		Not Reported
					Cimzia		C	Unknown		Not Reported
					Remicade		C	Unknown		Not Reported
					Rituxan		C	Unknown		Not Reported
					Naproxen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	13975630	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166548		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	13975716	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166564		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Arthralgia; Asthenia; Blood Creatinine Increased; Condition Aggravated; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prolia			S	Unknown	Form: Solution Subcutaneous (Pre-Filled Syringe. Preservative-Free.)		Not Reported
	Cymbalta			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	13988166	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166806		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Calcium D			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

Decreased; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence; Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14025310	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005465		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Nodule; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Oral			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			C		Increased Dose		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14062221	NON-EXPEDITED			US-PFIZER INC-2017430371		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dyspnoea	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14348292	NON-EXPEDITED			US-PFIZER INC-2017553817		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil /00072602/	S	Unk		Not Reported
	Remicade	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14369868	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000080		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Psychotic Disorder	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Ethinylestradiol Levonorgestrel			C				Not Reported
	Immunoglobulin (Ivig)			C		1 G/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14444753	NON-EXPEDITED			US-ABBVIE-17K-163-2062004-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14444834	NON-EXPEDITED			US-ABBVIE-17K-163-2074398-00		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445064	NON-EXPEDITED			US-PFIZER INC-2018033239		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		500 Mg, 3x/Day		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445073	NON-EXPEDITED			US-PFIZER INC-2018032218		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445163	NON-EXPEDITED		OT	US-PFIZER INC-2018033168			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445182	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018010354			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Quality Of Life Decreased; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445318	NON-EXPEDITED			US-ABBVIE-17K-163-2068465-00		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown	Less Than 6 Years		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445341	NON-EXPEDITED			US-ABBVIE-17K-163-2063981-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Asthma; Back Disorder; Blood Cholesterol Increased; Blood Count Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspareunia; Hypertension; Micturition Urgency; Muscle Spasms;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Effexor			S	Unknown	Two Capsules Daily		Not Reported

Nervousness; Peripheral Swelling

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445356	NON-EXPEDITED			US-ABBVIE-17K-163-2073936-00		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445374	NON-EXPEDITED			US-ABBVIE-17K-163-2067969-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Cimzia			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445382	NON-EXPEDITED			US-ABBVIE-17K-163-2068479-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Xeljanz				C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445543	NON-EXPEDITED			US-ABBVIE-17K-163-2068462-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Therapy Non-Responder; Therapy Non-Responder	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445650	NON-EXPEDITED			US-ABBVIE-17K-163-2074639-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445737	NON-EXPEDITED			US-ABBVIE-17K-163-2066966-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Neuralgia	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445782	NON-EXPEDITED			US-ABBVIE-17K-163-2068450-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445824	NON-EXPEDITED			US-ABBVIE-17K-163-2068509-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Wound Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445861	NON-EXPEDITED			US-ABBVIE-17K-163-2086615-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure; Treatment Failure; Treatment Failure	Humira			S	Subcutaneous	Not Reported
	Actemra			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Ibuprofen			C		Not Reported
	Arava			C		Not Reported
	Sulfasalazine			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445893	NON-EXPEDITED			US-ABBVIE-17K-163-2073952-00		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445902	NON-EXPEDITED			US-ABBVIE-17K-163-2074248-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dizziness; Drug Ineffective; Drug Ineffective; Nausea; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14445910	NON-EXPEDITED			US-ABBVIE-17K-163-2074535-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Ineffective	Methotrexate			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Cosentyx			S	Unknown	Not Reported
	Plaquinol			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446032	NON-EXPEDITED			US-ABBVIE-17K-163-2100610-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446042	NON-EXPEDITED			US-ABBVIE-17K-163-2087377-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446055	NON-EXPEDITED			US-ABBVIE-17K-163-2086541-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Local Reaction	Humira			S	Subcutaneous			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Enbrel			S	Unknown				Not Reported
		Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446126	NON-EXPEDITED			US-ABBVIE-17K-163-2086640-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Bone Erosion; Bronchitis; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446133	NON-EXPEDITED			US-ABBVIE-17K-163-2086583-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446253	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anxiety; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Stress	Plaquenil		S	Oral		Concordia
	Arava		S	Oral		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Prednisone		S	Unknown		Not Reported
	Celebrex		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Domperidone		C			Not Reported
	Leflunomide		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446255	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000317		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Zenhale			S				Not Reported
	Spiriva			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446256	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000318		19 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence;	Hydroxychloroquine			S	Oral			Concordia

Dyspnoea; Endocarditis Q Fever; Heart Valve Incompetence; Inappropriate Schedule Of Product Administration; Off Label Use; Pyrexia	Doxycycline Salt Not Specified	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446258	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000328			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retro-Orbital Neoplasm	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446259	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000335			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Hydroxychloroquine 200 Mg Tablet			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446260	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000336		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Polyneuropathy; Rash; Sepsis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446303	NON-EXPEDITED			US-PFIZER INC-2018035366		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446402	NON-EXPEDITED		OT	US-ABBVIE-17K-163-2090951-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cholecystectomy; Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Fibromyalgia; Hypertension; Joint Injury; Nasal Congestion; Nasal Injury; Nephrolithiasis; Rheumatoid Arthritis; Spinal Fracture; Vomiting; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	8 Tablets		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Voltaren			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			C				Not Reported
	Orencia			C				Not Reported
	Folic Acid			C				Not Reported
	Losartan			C				Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446544	NON-EXPEDITED			US-ABBVIE-17P-163-2059726-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Disorder; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Simponi			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446617	NON-EXPEDITED			US-ABBVIE-17K-163-2119567-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14446704	NON-EXPEDITED			US-ABBVIE-17K-163-2114610-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Trial			C	Oral			Not Reported
	Interimun			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447047	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201800976		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Potentiating Drug Interaction; Torsade De Pointes; Ventricular Tachycardia	Ondansetron (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447479	NON-EXPEDITED			US-ABBVIE-17K-163-2119509-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Indometacin			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447551	NON-EXPEDITED			US-ABBVIE-17K-163-2106523-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Bacterial; Arthropathy; Condition Aggravated; Drug Ineffective; Eye Prosthesis User; Fatigue; Hepatic Steatosis; Hypersensitivity; Hypertension; Immunosuppressant Drug Therapy; Injection Site Reaction; Intervertebral Disc Degeneration; Joint Stiffness; Persistent Depressive Disorder; Pulmonary Mass; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Sinusitis; Skin Mass;
Vitamin D Deficiency

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447576	NON-EXPEDITED			US-ABBVIE-17K-163-2119539-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447642	NON-EXPEDITED			US-ABBVIE-17K-163-2118908-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hypertension	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447653	NON-EXPEDITED			US-ABBVIE-17K-163-2114621-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Liver Function Test Abnormal; Myalgia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447705	NON-EXPEDITED			US-ABBVIE-17K-163-2114634-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contusion; Drug Ineffective; Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447709	NON-EXPEDITED			US-ABBVIE-17K-163-2106556-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Lung Disorder; Rash; Rash; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447712	NON-EXPEDITED			US-ABBVIE-17K-163-2109193-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Nausea	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447720	NON-EXPEDITED			US-ABBVIE-17K-163-2131042-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Iv+Sq		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14447904	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-00		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Hypokalaemia; Hypotension; Overdose; Sinus Tachycardia; Torsade De Pointes; Ventricular Arrhythmia	Hydroxychloroquine			S	Oral			Hikma
	Ondansetron			S	Intravenous (not otherwise specified)			Hikma
	Activated Charcoal			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2018	14448063	EXPEDITED (15-DAY)		OT	PHHY2018US003897		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Torsade De Pointes; Ventricular Arrhythmia; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Novartis
	Hydroxychloroquine			S	Oral	4 Ug/L, Unk		Not Reported
	Activated Charcoal			C	Oral	50 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2018	14449524	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Humira			C				Not Reported
	Actemra			C				Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2018	14454523	DIRECT		HO, LT, OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Cognitive Disorder; General Physical Health Deterioration; Product Substitution Issue; Schizoaffective Disorder	Hydroxychloroquine Sulfate			S				Not Reported
	Cellcept			C				Not Reported
	Ibuprofen			C				Not Reported
	Haldol			C				Not Reported
	Cogentin			C				Not Reported
	Vitron-C			C				Not Reported
	Red Yeast Rice			C				Not Reported
	Glucosamine			C				Not Reported
	Chondroitin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	12708711	EXPEDITED (15-DAY)		OT	CA-SA-2016SA159217			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure;	Leflunomide			S	Unknown			Not Reported

Therapeutic Response Decreased; White Blood Cell Count Decreased	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	13395772	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	13881276	NON-EXPEDITED			US-PFIZER INC-2017354957			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Bentyl			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14061609	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005682		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Cellulitis; Gastric Ulcer	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported

	Voltaren			S	Unknown				Not Reported
	Metformin			C					Not Reported
	Oxyneo			C					Not Reported
	Prednisone			C					Not Reported
	Amitriptyline			C					Not Reported
	Ergocalciferol			C					Not Reported
	Folic Acid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14066996	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005639		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Asthma; Gait Disturbance; Infection; Lung Disorder	Plaquenil Tablet			S	Oral			Concordia
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Calcium			C				Not Reported
	Folic Acid			C				Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14066998	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005640		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Drug Ineffective; Fatigue; Rheumatoid Arthritis; Therapeutic	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

Product Effect Decreased	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14322313	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006684		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14328167	EXPEDITED (15-DAY)		DE	IL-PFIZER INC-2017546081		54 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Salmonellosis	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Plaquenil /00072603/			S		200 Mg, 1x/Day		Not Reported
	Arava			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14347469	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268482		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Cimzia			S	Subcutaneous	Form- Solution Subcutaneous		Not Reported

	Enbrel	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Humira	S	Unknown	Form- Solution Subcutaneous		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Unknown	Form- Solution Intravenous		Not Reported
	Actemra	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Lyrica	C	Oral			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14382981	NON-EXPEDITED			US-ABBVIE-17K-163-2142986-00		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Furuncle; Herpes Zoster; Immunosuppression; Macular Degeneration; Pyrexia; Urinary Tract Infection; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450071	NON-EXPEDITED			US-AMGEN-USASP2018010975			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen

				Methotrexate		S	Unknown	Unk	Not Reported
				Plaquenil		S	Unknown	Unk	Not Reported
				Prednisone		S	Unknown	Unk	Not Reported
				Otezla		S	Unknown	Unk	Not Reported
				Humira		S	Unknown	Unk	Not Reported
				Orencia		S	Unknown	Unk	Not Reported
				Celebrex		S	Unknown	Unk	Not Reported
				Xeljanz Xr		C	Oral	11 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2057120			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450354	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-000126		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Overdose; Torsade De Pointes; Toxicity To Various	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Ipca
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Ipca

Agents; Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450417	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000353			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Heart Rate Irregular; Peripheral Swelling; Tremor	Plaquenil			S				Concordia
	Sulfasalazine			S				Not Reported
	Arava			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450418	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000377			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Hydroxychloroquine			S				Concordia
	Enbrel			S				Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S				Not Reported
	Penicillin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450421	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000384			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S	Unknown			Concordia
	Penicillin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450422	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000386			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Penicillin			S				Not Reported
	Sulfonamide			S				Not Reported
	Cephalosporin			S				Not Reported
	Arava			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450423	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000388		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Increased; Double Stranded Dna Antibody Positive; Injection Site Pain	Plaquenil 200 Mg			S	Oral			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous	40mg/0.8ml		Not Reported
	Methotrexate			S	Oral			Not Reported
	Risperidone			C				Not Reported
	Wellbutrin			C				Not Reported
	Verapamil			C				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450424	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000390			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biopsy Skin; Feeling Abnormal; Immunosuppression;	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

Impaired Healing; Infection; Procedural Pain	Methotrexate				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450426	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000396		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450453	EXPEDITED (15-DAY)		HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-161547		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose; Potentiating Drug Interaction; Torsade De Pointes	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg		Natco Pharma
	Hydroxychloroquine			S	Oral	4 Df		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450911	NON-EXPEDITED			US-ABBVIE-17K-163-2171404-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450922	NON-EXPEDITED			US-ABBVIE-17K-163-2178742-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450939	NON-EXPEDITED			US-ABBVIE-17K-163-2178326-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Rash	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14450968	NON-EXPEDITED			US-PFIZER INC-2018033443		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ibuprofen			S				Pfizer
	Levaquin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451012	NON-EXPEDITED			US-PFIZER INC-2018032642		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451039	NON-EXPEDITED			US-ABBVIE-17K-163-2161709-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hepatic Steatosis; Rash; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451061	NON-EXPEDITED			US-ABBVIE-17K-163-2162022-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451160	NON-EXPEDITED			US-ABBVIE-17K-163-2150399-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451192	NON-EXPEDITED			US-ABBVIE-17K-163-2140353-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451239	NON-EXPEDITED			US-ABBVIE-17K-163-2162059-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451246	NON-EXPEDITED			US-ABBVIE-17K-163-2178784-00		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451265	NON-EXPEDITED			US-ABBVIE-17K-163-2181460-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Injection Site Reaction; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Indomethacin		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451272	NON-EXPEDITED			US-ABBVIE-17K-163-2178543-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Hcq			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451273	NON-EXPEDITED			US-ABBVIE-17K-163-2195364-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451305	NON-EXPEDITED			US-ABBVIE-17K-163-2161716-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Pruritus; Rash; Rash	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451325	NON-EXPEDITED			US-ABBVIE-17K-163-2166765-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Antibodies; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451343	NON-EXPEDITED			US-ABBVIE-17K-163-2161703-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451360	NON-EXPEDITED			US-ABBVIE-17K-163-2186711-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hidradenitis; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451382	NON-EXPEDITED			US-ABBVIE-17K-163-2186558-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451430	NON-EXPEDITED			US-ABBVIE-17K-163-2199041-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451435	NON-EXPEDITED			US-ABBVIE-17K-163-2177225-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451453	NON-EXPEDITED		OT	US-ABBVIE-17K-163-2207244-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451538	NON-EXPEDITED			US-ABBVIE-17K-163-2201662-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451575	NON-EXPEDITED			US-ABBVIE-17K-163-2206869-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Infection; Nausea	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451592	NON-EXPEDITED			US-ABBVIE-17K-163-2206728-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Drug Ineffective; Tinnitus	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451618	NON-EXPEDITED			US-ABBVIE-17K-163-2189680-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451700	NON-EXPEDITED			US-ABBVIE-17K-163-2176590-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451724	NON-EXPEDITED			US-ABBVIE-17K-163-2152392-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Humira			S	Subcutaneous				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451782	NON-EXPEDITED			US-ABBVIE-17K-163-2135418-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451804	NON-EXPEDITED			US-ABBVIE-17K-163-2201771-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451850	NON-EXPEDITED			US-ABBVIE-17K-163-2152258-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451857	NON-EXPEDITED			US-ABBVIE-17K-163-2161737-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Influenza Like Illness; Sinusitis	Humira			S	Subcutaneous	Prior To Aug 2015		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown	Prior To Aug 2015		Not Reported
	Methotrexate			S	Unknown	Prior To Aug 2015		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451860	NON-EXPEDITED			US-ABBVIE-17K-163-2178802-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction; Liver Disorder	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451900	NON-EXPEDITED			US-ABBVIE-17K-163-2181893-00		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Butterfly Rash; Drug Ineffective; Gastrointestinal Disorder; Mental Status Changes; Pruritus	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451903	NON-EXPEDITED			US-ABBVIE-17K-163-2206708-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Thrombocytopenia	Plaquenil		S	Unknown			Not Reported
	Methotrexate		S	Unknown			Not Reported
	Xeljanz		C	Occlusive dressing technique	14 Days, 14 Tablets		Not Reported
	Xeljanz		C	Oral	Up To 28 Days, 28 Tablets, 5 Refills		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451911	NON-EXPEDITED		OT	US-ABBVIE-17K-163-2181602-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Interstitial Lung Disease; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451928	NON-EXPEDITED		OT	US-ABBVIE-17K-163-2165431-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Malignant Melanoma	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451941	NON-EXPEDITED			US-ABBVIE-17K-163-2205467-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Ophthalmological Examination Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451944	NON-EXPEDITED			US-ABBVIE-17K-163-2205788-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451947	NON-EXPEDITED			US-ABBVIE-17K-163-2206911-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Furuncle	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14451978	NON-EXPEDITED			US-ABBVIE-17K-163-2161756-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452002	NON-EXPEDITED			US-ABBVIE-17K-163-2135742-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Gastrointestinal Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452028	NON-EXPEDITED			US-ABBVIE-17K-163-2199034-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Off Label Use; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452063	NON-EXPEDITED			US-ABBVIE-17K-163-2154478-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Remicade			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452101	NON-EXPEDITED			US-ABBVIE-17K-163-2186659-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Liver Function Test Increased; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452145	NON-EXPEDITED			US-ABBVIE-17K-163-2154129-00		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Headache; Nausea; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452157	NON-EXPEDITED			US-ABBVIE-17K-163-2168223-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension; Urine Odour Abnormal	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Prednisone			C				Not Reported

	Carvedilol			C						Not Reported
	Carvedilol			C						Not Reported
	Lisinopril			C	Oral					Not Reported
	Acetaminophen W/Hydrocodone			C		7.5/325 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452786	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016248846		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14452822	NON-EXPEDITED			US-PFIZER INC-2018035288			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2018	14455479	NON-EXPEDITED		OT	US-AMGEN-USASP2018009355			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Diarrhoea; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Arava			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	12213745	EXPEDITED (15-DAY)		OT	CA-SA-2016SA060799		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Nasopharyngitis; Nasopharyngitis	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13224398	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrolithiasis	Hydroxychloroquine			S				Concordia
	Enbrel			C				Not Reported
	Celebrex			C				Not Reported
	Hydromorph			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13834494	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004527		85 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil			S	Oral			Concordia
	Monicor			C				Not Reported
	Aspegic Nourrissons			C				Not Reported
	Levothyrox			C				Not Reported
	Amlor			C				Not Reported
	Inegy			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13972788	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA166536		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Somnolence; Weight Increased	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form For Humira I.E Solution Subcutanous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13976114	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA166593		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Hand Deformity; Joint Arthroplasty; Knee Arthroplasty; Mobility Decreased; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Swelling; Urticaria	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous 40 Mg 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arthrotec			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Mefenamic Acid	C		Not Reported
	Tylenol	C		Not Reported
	Ramipril	C		Not Reported
	Actemra	C		Not Reported
	Remicade	C		Not Reported
	Percocet	C		Not Reported
	Paracetamol/Oxycodone Hydrochloride/Oxycodone Terephthalate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13976158	EXPEDITED (15-DAY)		HO	CA-SA-2017SA166603		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Drug Ineffective; Haematemesis; Hepatitis; Hepatotoxicity; Jaundice; Joint Swelling; Nausea; Platelet Count Increased; Rheumatoid Arthritis; Treatment Failure; Vitamin D Decreased; Vomiting	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Betahistine			C				Not Reported
	Desoximetasone			C				Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Vitamin C			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13976523	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166687		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Surgery	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C	Unknown			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported
	Budesonide			C	Unknown	2 Inhalations A Day For 30 Days		Not Reported
	Cefuroxime Axetil			C	Unknown	500 Mg For 6 Days		Not Reported
	Fluorouracil			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Nebivolol Hydrochloride			C	Unknown			Not Reported
	Oseltamivir			C	Unknown	75 Mg For 3 Days		Not Reported
	Azithromycin			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Remicade			C	Unknown	Powder For Solution Intravenous		Not Reported
	Winpred			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13976599	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Tylenol			C	Unknown	1 To 2 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	13984368	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166815		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14029896	NON-EXPEDITED			US-PFIZER INC-2017419783		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Doxofylline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14065935	NON-EXPEDITED			US-AMGEN-USASP2017151269		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Oral	2.5 Mg, 7 Tabs Orally Once A Week On Sundays		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	1 Mg, 3 Tabs Am, 2 Tabs Pm Once Day		Not Reported
	Folic Acid			C		1 Mg, Qd		Not Reported
	Reclast			C	Intravenous (not otherwise specified)	5 Mg/100 Ml Soultion As Needed		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)			C		1 Gtt In Each Eye, Bid		Not Reported
	Systane			C		Apply To Each Eye At Night		Not Reported
	Dulcolax			C	Oral	5 Mg, Qd		Not Reported
	Align			C	Oral	4 Mg, Qd		Not Reported
	Lovastatin			C	Oral	10 Mg, Qd		Not Reported

Tylenol	C	Oral	500 Mg, Bid	Not Reported
Metformin	C	Oral	500 Mg, Bid	Not Reported
Lisinopril	C	Oral	2.5 Mg, Qd	Not Reported
Dexilant	C	Oral	60 Mg, Qd	Not Reported
Zantac	C	Oral	150 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14067005	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14067014	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005671		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Nephrolithiasis; Nephrolithiasis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14067560	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005660		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Finger Deformity; Hepatic Enzyme Increased; Joint Swelling; Mouth Ulceration; Mouth Ulceration; Rheumatoid Arthritis; Treatment Failure; Wrist Deformity	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			C				Not Reported
	Meloxicam			C				Not Reported
	Pariet			C				Not Reported
	Prednisone			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Apo-Meloxicam			C				Not Reported
	Actonel			C				Not Reported
	Depo-Medrol			C				Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14067563	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005675		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Plaquenil Tablet			S	Oral			Concordia
	Anakinra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Arava			C				Not Reported
	Arava			C				Not Reported
	Arava			C				Not Reported
	Xeljanz			C	Oral			Not Reported

Meloxicam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14069406	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005655		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14157894	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006206		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Altace	C		Not Reported
Atorvastatin	C		Not Reported
Cipralex	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Cymbalta	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Hydromorphone Hydrochloride	C		Not Reported
Prednisone	C		Not Reported
Shark-Liver Oil	C		Not Reported
Tapentadol Hydrochloride	C		Not Reported
Taro Mupirocin	C		Not Reported
Tramacet	C		Not Reported
Tramadol Hydrochloride	C		Not Reported
Estrogens Conjugated	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14174005	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006295		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Altace			C				Not Reported

	Atorvastatin		C	Not Reported
	Cipralex		C	Not Reported
	Citalopram Hydrobromide		C	Not Reported
	Estrogens Conjugated		C	Not Reported
	Cymbalta		C	Not Reported
	Gabapentin		C	Not Reported
	Estrace		C	Not Reported
	Prednisone		C	Not Reported
	Tapentadol		C	Not Reported
	Mupirocin		C	Not Reported
	Tramacet		C	Not Reported
	Tramadol Hydrochloride		C	Not Reported
	Shark-Liver Oil		C	Not Reported
	Hydrochlorothiazide		C	Not Reported
	Hydromorphone Hydrochloride		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14216126	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006456			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Malignant Melanoma	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14223814	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006460		33 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Exposure During Pregnancy; Off Label Use; Steroid Diabetes	Plaquenil			S	Unknown			Concordia
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

		Prednisolone			S	Unknown				Not Reported
		Ritodrine Hydrochloride			S	Intravenous (not otherwise specified)				Not Reported
		Magnesium Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14306929	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004138		22 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Autoimmune Hepatitis; Blister; Blood Alkaline Phosphatase Increased; Blood Immunoglobulin G Increased; Condition Aggravated; Drug Ineffective; Eosinophilia; Erythema Annulare; Joint Stiffness; Joint Swelling; Leukocytosis; Off Label Use; Post Inflammatory Pigmentation Change; Rebound Effect; Smooth Muscle Antibody Positive	Plaquenil			S	Unknown			Concordia
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Desoximetasone			C	Topical			Not Reported
	Clobetasol			C	Topical			Not Reported
	Triamcinolone			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14372906	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268477		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Anakinra		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14422112	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000305			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Malignant Melanoma	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14455740	NON-EXPEDITED			US-AMGEN-USASP2018011198			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14455741	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000375			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hidradenitis; Upper Respiratory Tract Infection	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14455743	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000387			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Amantadine			S				Not Reported
	Arava			S				Not Reported
	Bactrim			S				Not Reported
	Codeine Sulfate			S				Not Reported
	Sulfa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14455745	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000404			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Tuberculosis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14455770	NON-EXPEDITED			US-AMGEN-USASP2018011004			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	25 Mg/Ml, Qwk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14457410	NON-EXPEDITED			US-PFIZER INC-2018034849		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		25 Mg/Ml, Weekly		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14459530	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Torsade De Pointes; Ventricular Arrhythmia; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Glenmark
	Hydroxychloroquine 200mg Tablets			S	Oral	In Total		Not Reported
	Activated Charcoal			C	Oral	50 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14459650	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000395		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accommodation Disorder; Diarrhoea; Purpura	Plaquenil			S	Oral			Concordia
	Speciafoldine			C				Not Reported
	Levothyrox			C				Not Reported
	Metoject			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14459651	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000400			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz Xr			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14459652	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000415			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14459760	EXPEDITED (15-DAY)		HO	US-SA-2018SA021045		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma; Cranial Nerve Paralysis; Epstein-Barr Virus Antigen Positive; Epstein-Barr Virus Associated Lymphoma; Intracranial Mass; Motor Dysfunction; Off Label Use; Paresis; Rash Morbilliform; Sensory Loss; Substance-Induced Psychotic Disorder	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral	Decreased Dose		Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral	2-Week Tapering		Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral	Within 6 Months		Not Reported
	Prednisone			S	Oral	Decreased To Pre-Mmf Level		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Within 6 Months		Not Reported
	Methotrexate			S		Within 6 Months		Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydrocortisone		Y	S	Unknown	1%		Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral	Within 1 Month		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2018	14464739	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2236694-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Retro-Orbital Neoplasm	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	11723855	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2015-026033			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Iron Deficiency Anaemia; Off Label Use; Systemic Lupus Erythematosus; Therapeutic Response Decreased	Prednisolone			S	Unknown			Bausch And Lomb
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14027808	NON-EXPEDITED			US-PFIZER INC-2017419754		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pain	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14431560	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0183		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14465986	NON-EXPEDITED			US-AMGEN-USASP2018011843		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Transaminases Increased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14466086	NON-EXPEDITED			US-AMGEN-USASP2018010120		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen

	Hydroxychloroquine			S	Unknown	Unk				Not Reported
	Methotrexate			C		Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14466318	EXPEDITED (15-DAY)		OT	US-ACCORD-062983		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Ventricular Arrhythmia	Ondansetron			S	Intravenous (not otherwise specified)			Accord
	Hydroxychloroquine			S	Oral	Four 200 Mg Hcq Tablets		Not Reported
	Charcoal/Activated			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14468102	NON-EXPEDITED			US-PFIZER INC-2018040903		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14468941	NON-EXPEDITED			US-PFIZER INC-2018039301		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14470326	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2018042093		85 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer
	Fenle (Hydroxychloroquine Sulfate)			S	Oral	0.2 G, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14471959	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2018016023			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Buttock Injury; Discomfort; Drug Ineffective; Infection; Joint Effusion; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Osteomyelitis; Pancreatitis; Pancreatitis; Renal Failure; Ulcer	Voltaren Emulgel			S	Unknown	Unk		Glaxosmithkline
	Enbrel			S	Unknown	1 Df, Q2w		Not Reported
	Enbrel			S	Unknown	1 Df, Q2w		Not Reported
	Enbrel			S	Unknown	1 Df, Q2w		Not Reported
	Plaquenil			S	Unknown	2 Df, Qd		Not Reported
	Sulfasalasin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2018	14472209	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1006307		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia;	Ondansetron			S	Intravenous (not otherwise specified)	4mg		Not Reported
	Hydroxychloroquine			S	Oral	Four 200 Mg Tablets		Not Reported

Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	12215595	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA060813		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Leucovorin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	13988246	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166771		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Limb Deformity; Musculoskeletal Pain; Pain In Extremity; Rash; Skin Cancer; Squamous Cell Carcinoma; Treatment Failure	Gold			S	Parenteral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral	Dose: Upto 25 Mg Qwk		Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Rituxan			S	Unknown	Form: Solution Intravenous			Not Reported
	Celexa			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14271807	NON-EXPEDITED			US-PFIZER INC-2017529051		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Piroxicam			S		Unk		Pfizer
	Meloxicam			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14289197	NON-EXPEDITED			US-PFIZER INC-2017533080		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14472479	NON-EXPEDITED			US-AMGEN-USASP2018012689			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14472488	NON-EXPEDITED			US-AMGEN-USASP2018012705			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473191	NON-EXPEDITED			US-AMGEN-USASP2018010941			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473223	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000398			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis C Virus Test Positive; Localised Infection; Malaise; Oropharyngeal Pain; Rheumatoid Arthritis; Seasonal Allergy	Plaquenil			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Meloxicam			C				Not Reported
	Enbrel			C				Not Reported
	Simponi			C				Not Reported

	Methotrexate			C						Not Reported
	Leflunomide			C						Not Reported
	Orencia			C						Not Reported
	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473224	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000405			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cardiac Disorder; Drug Ineffective; Fatigue; Iron Deficiency Anaemia; Rhinorrhoea; Sjogren'S Syndrome; Suicidal Behaviour; Viral Infection	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sotalol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473225	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000422			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contusion; Drug Ineffective; Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473226	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000425			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mental Disorder	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473227	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000436		1 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Plaquenil			S	Oral			Concordia
	Adcirca			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473228	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000442			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Plaquenil			S				Concordia
	Morphine			S				Not Reported
	Humira			S				Not Reported
	Enbrel			S				Not Reported
	Remicade			S				Not Reported
	Orencia			S				Not Reported
	Rituxan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14473850	NON-EXPEDITED			US-PFIZER INC-2018045001		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14476819	NON-EXPEDITED			US-AMGEN-USASP2018014101			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25/Ml		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14477838	NON-EXPEDITED			US-AMGEN-USASP2018013126			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14477911	NON-EXPEDITED			US-AMGEN-USASP2018013272			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	13976117	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166588		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14278231	NON-EXPEDITED			US-PFIZER INC-2017529337		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

	Prednisone			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14334956	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006714			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Oral			Concordia
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14361158	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity; Myocardial Infarction	Plaquenil			S	Oral			Concordia
	Atorvastatin			C				Not Reported
	Amitriptyline			C				Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14412899	EXPEDITED (15-DAY)		DE	IL-SA-2018SA013267		54 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Salmonellosis	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14468029	NON-EXPEDITED			US-PFIZER INC-2018039382		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14479140	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000449			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14479378	EXPEDITED (15-DAY)		HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2018-GB-000214		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Drug Reaction With Eosinophilia And Systemic Symptoms; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown			Ipca
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14481549	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166652		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	14482503	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-018934		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Hydroxychloroquine			S	Oral			Zydus Pharm
	Ondansetron			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	13989282	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		48 YR	Male	CAN

INC.-GSH201709-005279

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Surgery	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Clavulin			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Budesonide			C				Not Reported
	Cefuroxime Axetil			C				Not Reported
	Fluorouracil			C				Not Reported
	Humira			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nebivolol Hydrochloride			C				Not Reported
	Oseltamivir			C				Not Reported
	Azithromycin			C				Not Reported
	Prednisone			C				Not Reported
	Remicade			C				Not Reported
	Winpred			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	13989295	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005371		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Limb Deformity; Musculoskeletal Pain; Pain In Extremity; Rash; Skin Cancer; Squamous	Plaquenil Tablet			S	Oral			Concordia
	Gold			S	Parenteral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Cell Carcinoma; Treatment Failure	Methotrexate Sodium			S	Oral					Not Reported
	Sulfasalazine			S	Oral					Not Reported
	Rituxan			S	Unknown					Not Reported
	Celexa			C						Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	13989296	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005372		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil			C				Not Reported
	Folic Acid			C				Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14425036	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000313		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus	Hydroxychloroquine 200 Mg Tablet			S	Oral	4 Tablet		Concordia
	Ondansetron Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported

Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14482922	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201503-003456		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Condition Aggravated; Whipple'S Disease	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14486668	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Plaquenil			S				Not Reported
	Xeljanz Tabs 5mg Pfizer			S	Oral			Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2018	14487698	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Refusal Of Treatment By Patient; Therapy Interrupted	Forteo Pen Inj 600mcg/2.4ml Lilly			S	Subcutaneous			Eli Lilly And Co
	Hydroxychloriquine Tab 200mg Unknown			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2018	12769701	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076848			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Cortisone			C	Unknown	10 Mg, Unk		Not Reported
	Diclofenac			C	Unknown	100 Mg, Qd		Not Reported
	Zostavax			C	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown	10 Mg, Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	12586941	NON-EXPEDITED			US-PFIZER INC-2016357217			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Tindamax			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	12724902	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004440			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	12976467	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16P-028-1792212-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Synthroid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg Qw		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Voltaren			S	Oral	75 Mg, Bid		Not Reported
	Prinivil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	12977589	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007921		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Pneumonia; Rash; Sinusitis; Somnolence	Plaquenil	S	Unknown		Concordia
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13124355	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007992		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hospitalisation	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Viread			C				Not Reported
	Humira			C				Not Reported
	Arava			C				Not Reported
	Cimzia			C				Not Reported
	Remicade			C				Not Reported
	Rituxan			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13128827	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000490			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Plaquenil			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Arava	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Rituxan	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Prednisone	C			Not Reported
	Celexa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13147233	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005027		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pneumonia; Weight Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13517211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Headache; Hypoaesthesia; Off Label Use; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown	40 Mg, Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported

	Methotrexate	S	Oral	1 Df, Qwk		Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Pregabalin	C	Oral	50 Mg, Qd		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Tenofovir Disoproxil	C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown			Not Reported
	Zopiclone	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13989285	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005361		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein; Diarrhoea; Drug Ineffective; Fatigue; Gait Disturbance; Joint Swelling; Nausea; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13989289	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13989293	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005368		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Drug Ineffective; Haematemesis; Hepatitis; Hepatotoxicity; Jaundice; Joint Swelling; Nausea; Platelet Count Increased; Rheumatoid Arthritis; Treatment Failure; Vitamin D Decreased; Vomiting	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Vitamin C	C		Not Reported
	Xeljanz	C		Not Reported
	Betahistine	C		Not Reported
	Desoximetasone	C		Not Reported
	Rosuvastatin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13989427	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005385		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Somnolence; Weight Increased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13990006	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005377		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence; Somnolence	Xeljanz	S	Oral		Not Reported
	Calcium D	C			Not Reported
	Plaquenil	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	13994754	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005381		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Arthralgia; Asthenia; Blood Creatinine Increased; Condition Aggravated; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prolia			S	Unknown			Not Reported
	Cymbalta			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14380883	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000104		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14483677	NON-EXPEDITED			US-AMGEN-USASP2018014699			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14484058	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-E2B_00009706			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Maternal Dose: 400 Mg, Qd		Concordia
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 7.5 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 25 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14484098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2062374			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Actemra			S	Unknown	Discontinued		Not Reported
	Enbrel			S	Unknown	Discontinued		Not Reported
	Arava			S	Unknown	Discontinued		Not Reported
	Methotrexate			S	Oral	Discontinued		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14484391	NON-EXPEDITED			US-AMGEN-USASP2018014828			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14484488	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005380			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14484490	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000466		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity;	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

Loss Of Consciousness; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14485214	NON-EXPEDITED			US-PFIZER INC-2018045639		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Zyrtec			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported
	Lexapro			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Valtrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14487366	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2244856-00		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiac Failure; Cardiac Failure Congestive; Cardiomyopathy; Chronic Kidney Disease; Chronic	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Kidney Disease; Hepatic Fibrosis; Intracardiac Thrombus; Intraductal Proliferative Breast Lesion; Pneumonia	Lisinopril	S	Unknown		Not Reported
	Alendronate	C			Not Reported
	Allopurinol	C			Not Reported
	Metoprolol Er	C			Not Reported
	Nortriptyline	C			Not Reported
	Prednisone	C			Not Reported
	Prevacid	C			Not Reported
	Crestor	C			Not Reported
	Calcium With Vitamin D	C			Not Reported
	Coq10	C			Not Reported
	Magnesium	C			Not Reported
	Probiotic	C			Not Reported
	Vitamin B 12	C			Not Reported
	Vitamin D Nos	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14487680	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-006752		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Erythema; Granuloma Skin; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Ulcer	Abatacept			S	Unknown	780 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Mg, Q4wk		Not Reported
	Actemra			S	Unknown	680 Mg, Q4wk		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Q4wk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Qwk		Not Reported

	Methotrexate Sodium	S	Oral	12.5 Mg, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
	Myochrysine	C	Unknown	50 Mg, Qmo	Not Reported
	Prednisolone	C	Unknown	10 Mg, Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2018	14488220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007259		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Mg, Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	12171252	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-113030		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Pantoprazole			S	Unknown	40 Mg, Qd		Sun
	Folic Acid			S	Unknown	5 Mg, 2/Week		Sun
	Folic Acid			S	Unknown	Unk		Sun
	Methotrexate			S	Oral	20 Mg, 1/Week		Sun
	Methotrexate			S	Oral	25mg, Q2weeks		Sun
	Sulfasalazine			S	Oral	1000 Mg, Qd		Sun
	Sulfasalazine			S	Oral	1000 Mg, Bid		Sun
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Co-Atenolol			S	Unknown	25 Mg, Qd		Not Reported
	Naprosyn			S	Oral	1000 Mg, Qd		Not Reported
	Pantoloc			S	Unknown	40 Mg, Qd		Not Reported
	Palafer Cf			S	Unknown	1 Df, Qd		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qod		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Pms-Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Orencia	S	Unknown			Not Reported
	Apo-Folic Acid	S	Unknown	5 Mg, 2/Week		Not Reported
	Apo-Sulfasalazine	S	Oral	500 Mg, Bid		Not Reported
	Apo-Sulfasalazine	S	Oral	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	12416030	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016277363		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis Infective; Blood Uric Acid Decreased; Blood Uric Acid Increased; Candida Infection; Crystal Urine Present; Decreased Immune Responsiveness; Fungal Skin Infection; Gastrointestinal Bacterial Infection; Gastrointestinal Candidiasis; Hepatotoxicity; Liver Disorder; Renal Disorder; Retinal Disorder; Toxicity To Various Agents; Vitamin B12 Deficiency; Weight Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Curcumen			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Vitamin B12			C		5000 Mu, Unk		Not Reported
	Iron			C		Unk		Not Reported
	Biotin			C		Unk		Not Reported
	Vitamin B6			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Milk Thistle			C		Unk		Not Reported
	Curcumin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	13394656	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010760		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint	Plaquenil			S	Unknown			Concordia

Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	13517082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038527		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	13519992	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038647		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Activities; Nail Disorder; Onychomadesis; Onychomycosis	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Xeljanz		S	Unknown	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14317285	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006680		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Buttock Injury; Discomfort; Drug Ineffective; Infection; Joint Effusion; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Osteomyelitis; Pancreatitis; Pancreatitis; Renal Failure; Rheumatoid Arthritis; Ulcer	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Voltaren Gel			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14380886	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000117		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14384287	NON-EXPEDITED			US-PFIZER INC-2018014990		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14468068	NON-EXPEDITED			US-PFIZER INC-2018039096		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14485123	NON-EXPEDITED			US-PFIZER INC-2018045719		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14489796	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2018-GB-000169		24 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Episcleritis; Urticaria	Hydroxychloroquine			S		400 Mg, Qd		Ipca
	Azathioprine			S		200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14490098	NON-EXPEDITED			US-AMGEN-USASP2018014766			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14490705	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000483		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Sulfa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14490706	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00012327			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Pain; Peripheral Swelling; Retinopathy; Sinusitis	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14490911	NON-EXPEDITED			US-PFIZER INC-2018045415		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14492019	NON-EXPEDITED			PHEH2018US003606			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hidradenitis; Upper Respiratory Tract Infection; Urinary Tract Infection	Cosentyx	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown			Novartis
	Humira	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14492469	NON-EXPEDITED			US-PFIZER INC-2018049898		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Xeljanz Xr			S	Oral	11 Mg, Once A Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14495733	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000444			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Malaise; Nausea; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14495736	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000487			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Hypoacusis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14369715	NON-EXPEDITED			US-AMGEN-USASP2018002793		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Weight Increased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Gabapentin			C		Unk		Not Reported
	Citalopram			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14485228	NON-EXPEDITED			US-PFIZER INC-2018045958		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14495858	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007156		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Diarrhoea; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea	Leflunomide			S	Unknown	Unk			Not Reported
	Methotrexate Sodium			S	Oral	1 G, Bid			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Oral	1 G, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14496407	NON-EXPEDITED			US-AMGEN-USASP2018015522			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Simponi Aria			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14496851	NON-EXPEDITED			US-PFIZER INC-2018050665		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Sulfasalazine			S		Unk		Pfizer
	Otezla			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14496905	NON-EXPEDITED			US-PFIZER INC-2018051635		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14497687	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000474			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Ear Infection; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Heart Rate Irregular; Influenza; Nasopharyngitis; Sinusitis; Upper Respiratory Tract Infection	Plaquenil			S	Unknown			Concordia
	Xeljanz Xr			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14497689	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000511			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Vision Blurred	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14497774	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-053136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia;	Orencia			S	Unknown			Bristol Myers Squibb
	Gold			S	Unknown			Not Reported

Vomiting	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Methotrexate Sodium	C	Oral			Not Reported
	Xeljanz	C	Oral	Unk		Not Reported
	Lyrica	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14497820	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000508			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Thrombocytopenia	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Occlusive dressing technique	14 Days, 14 Tablets (1 In 1 D)		Not Reported
	Xeljanz			C	Oral	Up To 28 Days, 28 Tablets, 5 Refills (1 In 2 D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2018	14499331	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1007573		19 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Dyspnoea; Endocarditis Q Fever; Heart Valve Incompetence; Inappropriate Schedule Of Product Administration; Off Label Use; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Doxycycline			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	11820557	NON-EXPEDITED			US-JNJFOC-20150615658		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Anxiety; Feeling Abnormal; Irritability; Muscle Spasms; Musculoskeletal Pain; Pain In Extremity	Imbruvica			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14254613	NON-EXPEDITED			US-PFIZER INC-2017519181		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14311549	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006666		59 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14449521	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000351		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Increased; Arthralgia; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Dermatitis; Erythema; Fatigue; Histiocytic Necrotising Lymphadenitis; Interleukin-2 Receptor Increased; Leukopenia; Lymphadenopathy; Off Label Use; Pigmentation Disorder; Pyrexia; Rash; Rash Papular; Rebound Effect; Skin Lesion	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	Dosage Of Psl Was Tapered.		Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	0.8 Mg/Kg/Day		Not Reported
	Prednisolone			S	Oral	Psl Was Tapered By 10% Per Every 2 Or 4 Weeks		Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	Psl Was Again Increased From 15 To 40 Mg/Day		Not Reported
	Prednisolone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	200/400 Mg On Alternating Days		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14501947	NON-EXPEDITED			US-AMGEN-USASP2018016879			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Steatosis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Simponi Aria	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502120	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000477		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502122	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010646		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Nasopharyngitis; Nasopharyngitis	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502124	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010652		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of	Plaquenil Tablet			S	Unknown			Concordia

Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Plaquenil Tablet		S	Unknown	Concordia
	Arava		S	Oral	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Cimzia		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Leucovorin		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14502125	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010657		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Nasopharyngitis; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S				Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	0.6 Millilitre(S)		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	0.2 Millilitre(S)		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Meloxicam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14503207	NON-EXPEDITED			US-PFIZER INC-2018052960		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hot Flush	Sulfasalazine	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14506738	EXPEDITED (15-DAY)		HO, OT	PHHY2018FR016916		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Fluoxetine Hydrochloride			S	Oral	30 Mg, Qd		Novartis
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Loxapac			S	Oral	1 Df, Unk 50 Drop (1/12 Millilitre)		Not Reported
	Theralene			S	Oral	1 Df, Qd 50 Drop (1/12 Millilitre)		Not Reported
	Paracetamol/Codeine			S	Oral	2 Df, Tid		Not Reported
	Noctamide			S	Oral	1 Df, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Dafalgan Codeine			S	Unknown	Unk, Tid		Not Reported
	Lepticur			S	Oral	2 Df, Qd		Not Reported
	Tranxene			S	Oral	1 Df, Unk		Not Reported
	Imeth			S	Oral	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Speciafoldine			C	Oral	4 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2018	14507800	NON-EXPEDITED			US-AMGEN-USASP2018016914			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported

	Humira			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Xeljanz			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14417039	NON-EXPEDITED			US-PFIZER INC-2018026722		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Liver Function Test Abnormal	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14442151	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018017741		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Disease Recurrence; Gastrointestinal Disorder; Herpes Virus Infection; Oral Herpes; Rash; Visual Impairment	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	12.5 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14509779	NON-EXPEDITED		OT	US-PFIZER INC-2018056637		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Sinusitis	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14511258	EXPEDITED (15-DAY)		OT	US-SA-2018SA020100			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2018	14511583	NON-EXPEDITED			US-AMGEN-USASP2018017545			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Rash; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Orencia	S	Unknown	Unk		Not Reported
	Actemra	C		Unk		Not Reported
	Rituxan	C		Unk		Not Reported
	Remicade	C		Unk		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, 2 Times/Wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14281212	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-17K-163-2190133-00		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Buttock Injury; Discomfort; Drug Ineffective; Infection; Joint Effusion; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Osteomyelitis; Pancreatitis; Pancreatitis; Renal Failure; Ulcer	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14349135	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2042593-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Methotrexate			S	Oral					Not Reported
	Methotrexate			S	Other					Not Reported
	Plaquenil			S	Unknown					Not Reported
	Actemra			S	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14515718	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000499			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Hydroxychloroquine			S				Concordia
	Remicade			S				Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14515719	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000516			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14515772	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple	Plaquenil			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported

Sclerosis; Nausea; Vomiting	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2018	14525860	DIRECT					37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Pruritus; Rash; Swelling	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);Other Frequency:Every Other Day;		Not Reported
	Famvir			C				Not Reported
	Ratinidine			C				Not Reported
	Multi Vitamin			C				Not Reported
	Biotin			C				Not Reported
	Cranberry			C				Not Reported
	D3			C				Not Reported
	Fish Oil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	13932585	NON-EXPEDITED			US-AMGEN-USASP2017132099		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Swelling; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14257433	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2181518-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14327580	NON-EXPEDITED			US-PFIZER INC-2017546310		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Infection; Pharyngitis; Sinusitis; Upper Respiratory Tract Infection	Celebrex			S		200 Mg, 2x/Day		Pfizer
	Plaquenil			S		400 Mg, Daily (2 Tablets At Bedtime)		Not Reported
	Plaquenil			S				Not Reported
	Bactrim Ds			C	Oral	Unk, 2x/Day, Sulfamethoxazole (800 Mg) + Trimethoprim (160 Mg)		Not Reported
	Mucinex			C	Oral	1200 Mg, 2x/Day		Not Reported
	Ventolin Hfa			C		2 Df, As Needed (Inhale 2 Puffs By Mouth Every 4 Hours)		Not Reported
	Lipitor			C	Oral	10 Mg, Daily		Not Reported
	Zoloft			C	Oral	50 Mg, Daily		Not Reported
	Neurontin			C		300 Mg, 3x/Day		Not Reported

	Fish Oil	C	Oral	500 Mg, Unk		Not Reported
	Armour Thyroid	C	Oral	30 Mg, Daily		Not Reported
	Armour Thyroid	C	Oral	45 Mg, Daily		Not Reported
	Nexium	C	Oral	20 Mg, Daily (1 Hour Before The First Meal Of The Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14391362	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000164			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral	30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14497688	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000510			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14516846	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2242191-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14516919	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018018292			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Retro-Orbital Neoplasm	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517258	EXPEDITED (15-DAY)		HO, OT	DE-ABBVIE-18K-062-2249876-00		56 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Meniscus Operation	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Quensyl	S	Unknown			Not Reported
	Quensyl	S	Unknown			Not Reported
	Quensyl	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Cyclosporine	C				Not Reported
	Cyclosporine	C				Not Reported
	Enbrel	C				Not Reported
	Leflunomide	C				Not Reported
	Orencia	C				Not Reported
	Simponi	C				Not Reported
	Cimzia	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517296	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000523			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517299	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000527			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Headache	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517310	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000446			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517666	NON-EXPEDITED			US-PFIZER INC-2018052710		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517909	NON-EXPEDITED			US-PFIZER INC-2018057796		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14517910	NON-EXPEDITED			US-PFIZER INC-2018058176		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Methotrexate Sodium	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Aleve	C	Unk	Not Reported
	Fish Oil	C	Unk	Not Reported
	Glucosamine - Chondroitin	C	Unk	Not Reported
	Tylenol	C	Unk	Not Reported
	Arthrotec	C	Unk	Not Reported
	Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14518659	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1008427			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 7.5 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 25 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 400 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14519003	EXPEDITED (15-DAY)		OT	PT-CELGENEUS-PRT-20180201350		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Progressive Multifocal Leukoencephalopathy	Thalidomide Celgene			S	Oral	Not Provided		Celgene
	Azathioprine			S	Unknown	Not Provided		Not Reported
	Cyclophosphamide			S	Unknown	Not Provided		Not Reported
	Hydroxychloroquine			S	Unknown	Not Provided		Not Reported

	Methotrexate			S	Unknown	Not Provided				Not Reported
	Rituximab			S	Unknown	Not Provided				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14519339	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2234905-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Rash; Rheumatoid Factor Positive; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14519340	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2018DEP000194		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown	Unk		Depomed
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14519343	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2018DEP000195		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Diclofenac Potassium	S	Unk	Depomed
	Arthrotec	S	Unk	Not Reported
	Celebrex	S	Unk	Not Reported
	Elavil /00002202/	S	Unk	Not Reported
	Enbrel	S	Unk	Not Reported
	Lyrica	S	Unk	Not Reported
	Methotrexate	S	Unk	Not Reported
	Naprosyn /00256201/	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Plaquenil /00072602/	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	13880284	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017122396			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Eye Disorder; Musculoskeletal Stiffness; Peripheral Swelling; Pruritus; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14412784	EXPEDITED (15-DAY)		OT	CA-SA-2018SA011644		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia;	Leflunomide			S	Oral			Not Reported

Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Plaquenil	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Arava	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14432874	EXPEDITED (15-DAY)		DS	CA-ABBVIE-18K-028-2233036-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Disability; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leucovorin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			C				Not Reported
	Naproxen			C	Oral			Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Calcium Magnesium Citrate			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Escitalopram Oxalate			C				Not Reported
	Clobetasol Propionate			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14456065	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0234		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Gastrointestinal Disorder; Nasal Herpes;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Oral Herpes; Rash; Visual Impairment	Methotrexate (Trade Name Unknown)	S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Superior To 15mg		Not Reported
	Xeljanz	S	Oral			Not Reported
	Plaquenil	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14523840	NON-EXPEDITED			US-AMGEN-USASP2018018937			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14523987	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0391		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxyzine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524216	EXPEDITED (15-DAY)		OT	US-CONCORDIA			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pruritus	Plaquenil			S	Unknown			Concordia
	Methotreaxate			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524220	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000581			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia
	Leflunomide			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524221	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000582		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Oedema; Tongue Oedema	Plaquenil			S	Oral			Concordia
	Perindopril			S	Oral			Not Reported
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14524366	NON-EXPEDITED			US-PFIZER INC-2018061900			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Neurontin			S		Unk		Pfizer

Drug Intolerance	Phenergan	S	Unk	Not Reported
	Ativan	S	Unk	Not Reported
	Inapsine	S	Unk	Not Reported
	Baclofen	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2018	14527375	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2018LAN000448		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Diphenoxylate Hcl; Atropine Sulfate			S	Oral	Unk		Lannett
	Ranitidine Hydrochloride			S	Oral	Unk		Lannett
	Salicylates Nos			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Tamsulosin			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	13291176	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001378		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Lantus	C			Not Reported
	Insulin	C			Not Reported
	Lozide	C			Not Reported
	Metformin	C			Not Reported
	Naprosyn	C			Not Reported
	Prednisone	C			Not Reported
	Ramipril	C			Not Reported
	Vitamin D2	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	13981358	NON-EXPEDITED			US-PFIZER INC-2017397573		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14312313	NON-EXPEDITED			US-AMGEN-USASP2017187782			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Depression; Drug Ineffective; Hepatic Enzyme Increased; Injection Site Reaction; Toxicity To Various Agents	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Minocycline	S	Unknown	Unk		Not Reported
	Cellcept	S	Unknown	Unk		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14412924	EXPEDITED (15-DAY)		DE, HO, OT	US-IMPAX LABORATORIES, INC-2018-IPXL-00079		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Hypersensitivity; Hypotension; Infection; Pseudomonas Infection; Psoriatic Arthropathy; Respiratory Arrest; Somnolence	Minocycline Hydrochloride			S	Unknown	Unk		Impax
	Minocycline Hydrochloride			S				Impax
	Minocycline Hydrochloride			S				Impax
	Corticosteroid Nos			S	Unknown	Unk		Not Reported
	Corticosteroid Nos			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Etanercept			S	Subcutaneous	25 Mg, 2 /Week		Not Reported
	Etanercept			S				Not Reported
	Prednisone			S	Unknown	60 Mg, Daily		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528250	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201802-		67 YR	Female	GBR

000587

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Onycholysis	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528251	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000588			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pneumonia; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528352	EXPEDITED (15-DAY)		OT	AU-ACCORD-063267			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Montelukast			S				Not Reported
	Ranitidine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Dapsone			S				Not Reported
	Ciclosporin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528451	EXPEDITED (15-DAY)		HO	AU-009507513-1802AUS006942			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Montelukast Sodium			S		Unk		Merck
	Methotrexate			S		Unk		Not Reported

	Cetirizine Hydrochloride	S	Unk	Not Reported
	Fexofenadine Hydrochloride	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Ranitidine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528471	EXPEDITED (15-DAY)		DS	CA-ABBVIE-18K-028-2254188-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528558	EXPEDITED (15-DAY)		DS	CA-ABBVIE-18K-028-2254584-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254242-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form Of Administration-Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528717	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254266-00		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Dependence; Drug Dependence; Drug Dependence; Drug Dependence; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528718	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2254712-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Synovitis	Xeljanz	S	Oral		Not Reported
	Methotrexate	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528965	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000567			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S				Concordia
	Humira			S				Not Reported
	Cimzia			S				Not Reported
	Celecoxib			S				Not Reported
	Apremilast			S				Not Reported
	Lisinopril			S				Not Reported
	Ascororbic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528966	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000585		63 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Cyclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528967	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000590			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Plaquenil			S	Unknown			Concordia
	Enbrel			S				Not Reported

	Arava			S						Not Reported
	Sulfasalazine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14528968	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000595		4 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rhabdomyolysis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530061	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254914-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Form Of Administration-Powder For Solution Intravenous		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530733	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2255018-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Humira	S	Subcutaneous			Not Reported
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530734	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2255006-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14530741	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254857-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cutaneous Vasculitis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2018	14532824	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254117-00		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Insomnia; Multiple Sclerosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	13741944	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-2030308-00		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Hypersensitivity; Immunosuppression; Pneumocystis Jirovecii Infection; Pneumonitis; Pulmonary Fibrosis; Respiratory Disorder; Synovitis; X-Ray Abnormal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	13981544	NON-EXPEDITED			US-PFIZER INC-2017401354		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Gabapentin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14122917	EXPEDITED (15-DAY)		OT	PT-ROCHE-2009802		71 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Infected Varicose Vein; Nocardiosis; Varicose Ulceration	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported

					Methylprednisolone		S	Unknown	Not Reported
					Methylprednisolone		S	Unknown	Not Reported
					Methylprednisolone		S	Unknown	Not Reported
					Methylprednisolone		S	Unknown	Not Reported
					Methylprednisolone		S	Unknown	Not Reported
					Methotrexate		S	Subcutaneous	Not Reported
					Salazopirina En		S	Unknown	Not Reported
					Hydroxychloroquine		S	Unknown	Not Reported
					Plaquinol		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14532930	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2255577-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Pregabalin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533025	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254684-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported
	Mobicox			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533033	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2254866-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris Single Use Vial			C	Subcutaneous	Powder For Solution		Not Reported
	Plaquenil			C				Not Reported
	Rituximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533075	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254824-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533093	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254128-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533224	NON-EXPEDITED			US-AMGEN-USASP2018019888			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533248	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254963-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C				Not Reported
	Amoxil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14533341	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2254974-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14535594	NON-EXPEDITED			US-PFIZER INC-2018063844			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14536709	EXPEDITED (15-DAY)		OT	CA-SA-2018SA032969		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; C-Reactive Protein; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder;	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria; Urticaria	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Kevzara	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537819	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000592			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Hydroxychloroquine Tablet			S	Oral			Concordia
	Penicillin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2018	14537821	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000604			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash Macular	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	13426719	EXPEDITED (15-DAY)		HO, OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002285		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Exposure During Pregnancy; Listeriosis; Platelet Count Decreased; Premature Baby; Pyrexia	Hydroxychloroquine			S	Oral			Concordia
	Acetylsalicylic Acid			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Prednisone		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14391511	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018005291		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deep Vein Thrombosis; Depressed Mood; Emotional Distress; Foot Fracture; Gait Inability; Hypophagia; Loss Of Personal Independence In Daily Activities; Osteoporosis; Pelvic Fracture; Quality Of Life Decreased; Rheumatoid Arthritis; Spinal Fracture; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Otezla			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Vioxx			C		Unk		Not Reported
	Methotrexate			C	Oral	20 Mg, Qwk		Not Reported
	Warfarin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14423120	NON-EXPEDITED		OT	US-JNJFOC-20171234787			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14484484	EXPEDITED (15-DAY)			US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000479		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rash Morbilliform	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral	2-Week Tapering Course Of Oral Prednisone		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14538342	NON-EXPEDITED			US-AMGEN-USASP2018021019			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Voltaren			C		Unk Unk, As Necessary		Not Reported
	Leflunomide			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14538347	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000596			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14538348	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000607			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Treatment Failure	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14541711	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-858310		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Gastritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown	Last Cycle Of Rituximab Was Administered On 06/Sep/2016		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2018	14544136	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018070506		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated;	Esomeprazole Magnesium			S		40 Mg, 1x/Day		Unknown

Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Methotrexate Sodium	S	Subcutaneous	25 Mg, 4 Times Every Week		Unknown
	Xeljanz	S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz	S	Oral	5 Mg, 1x/Day		Pfizer
	Xeljanz	S	Oral	5 Mg, Unk		Pfizer
	Apo-Folic Acid	S		1 Df (5 Mg), , 2x/Week		Not Reported
	Apo-Prednisone	S		5 Mg, 1x/Day		Not Reported
	Plaquenil /00072603/	S		200 Mg, 2x/Day		Not Reported
	Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2018	14223831	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2172912-00		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fall; Fatigue; Joint Swelling; Loss Of Consciousness; Musculoskeletal Pain; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2018	14544836	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-007832		28 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy	Furosemide			S	Unknown	60 Mg, Unk		Not Reported
	Furosemide			S	Unknown	40 Mg, Bid		Not Reported
	Labetalol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	60 Mg, Unk		Aurobindo
	Azathioprine			S	Unknown	50 Mg, Bid		Not Reported
	Methylpredisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Alpha-Methyldopa			S	Unknown	Unk				Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd				Not Reported
	Heparin			C	Unknown	()				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2018	14383620	NON-EXPEDITED			US-AMGEN-USASP2018004207			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14258511	NON-EXPEDITED			US-PFIZER INC-2017521813		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14369686	EXPEDITED (15-DAY)		OT	CA-ROCHE-2050787			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Spinal Compression Fracture	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Plaquenil	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14401119	NON-EXPEDITED			US-PFIZER INC-2018016242		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14518573	NON-EXPEDITED			US-PFIZER INC-2017538697		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Cellcept			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Minocycline			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14523783	NON-EXPEDITED			US-AMGEN-USASP2018019207			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Nabumetone			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14545794	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2254690-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C		Emulsion		Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14545850	EXPEDITED (15-DAY)		OT	CA-ROCHE-2071676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14546317	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-000273		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Ipca
	Hydroxychloroquine			S	Unknown	1314 G, Unk		Ipca
	Aldactone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	4 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14546860	NON-EXPEDITED			US-PFIZER INC-2018065279		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		200 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14546950	NON-EXPEDITED			US-PFIZER INC-2018067516		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14547026	NON-EXPEDITED			US-PFIZER INC-2018067788			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S				Pfizer
	Procardia			S				Pfizer
	Phenergan			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14547045	NON-EXPEDITED			US-PFIZER INC-2018070486		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		5 Mg, Daily		Not Reported
	Lamotrigine			C		100 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549454	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000594			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Deposits	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549455	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000609		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Furuncle; Herpes Zoster; Immunosuppression; Macular Degeneration; Pyrexia; Urinary Tract Infection; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549471	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000370			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Wound Infection	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2018	14549472	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000631		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Hypoaesthesia; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Muscular Weakness; Osteoarthritis; Renal Impairment	Plaquenil Tablet	S	Oral	Concordia
	Methotrexate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydrochlorothiazide	C		Not Reported
	Lyrica	C		Not Reported
	Prednisone	C		Not Reported
	Humira	C		Not Reported
	Asa	C		Not Reported
	Adalat Xl	C		Not Reported
	Coversyl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14249767	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006558		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Blood Pressure Increased; Dependence; Drug Ineffective; Fibromyalgia; Foot Operation; Gait Disturbance; Hip Arthroplasty; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To A General Medical Condition; Temperature Intolerance; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14446257	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000323		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14550742	NON-EXPEDITED			US-AMGEN-USASP2018022438			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14550842	NON-EXPEDITED			US-AMGEN-USASP2018022666			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Minocycline			S	Unknown	Unk		Not Reported
	Hydrocodone			S	Unknown	Unk		Not Reported
	Toradol			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Arava			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14551339	EXPEDITED (15-DAY)		HO	CA-AMGEN-CANSP2018022102		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Back Pain; Cough; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hypersensitivity; Injection Site Reaction; Lung Disorder; Muscle Disorder; Musculoskeletal Disorder; Pharyngitis Streptococcal; Psychomotor Hyperactivity; Red Blood Cell Sedimentation Rate Increased; Skin Discolouration; Skin Disorder; Viral Pharyngitis; Weight Increased	Enbrel			S	Unknown	Unk		Amgen
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14551495	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000630			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Squamous Cell Carcinoma	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	A 40mg/0.8ml		Not Reported
	Hydrochlor			C				Not Reported
	Pravastatin			C				Not Reported

		Metformin			C					Not Reported
		Levocetirizine			C					Not Reported
		Amilor			C					Not Reported
		Hydrochlorothiazide			C					Not Reported
		Advair Diskus (Seretide)			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14551496	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000634		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fibrosis; Pneumonia	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14551497	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000636			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity	Hydroxychloroquine 200 Mg Tablet			S	Oral			Concordia
	Melatonin			C				Not Reported
	Prozac			C				Not Reported
	Gabapentin			C				Not Reported
	Effexor			C				Not Reported
	Cymbalta			C				Not Reported
	Promethazine			C	Oral			Not Reported
	Allegra 180 Mg Tablet			C	Oral			Not Reported
	Armour Thyroid 90 Mg Tablet			C	Oral			Not Reported
	Flonase 50 Mcg/Actuation Spray			C	Nasal	1-2 Spray Once A Day		Not Reported
	Lexapro			C	Oral	5mg/5 Ml Solution (Took 20 Milliliters Oral Every Morning As Directed To		Not Reported

							Take), 20 Cc Teaspoon Daily			
	Lyrica			C	Oral		60 Capsules (Took 1 Capsule Oral Twice A Day As Directed			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14551499	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000640		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; C-Reactive Protein; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria; Urticaria	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C				Not Reported
	Kevzara			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14553016	EXPEDITED (15-DAY)		OT	US-SA-2018SA042317		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity; Fatigue; Rheumatoid Arthritis; Treatment Failure; Visual Impairment; White Blood Cell Count Decreased	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Meloxicam			C				Not Reported
	Prednisone			C				Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14553925	EXPEDITED (15-DAY)		OT	NL-NATCO PHARMA-2018NAT00050		46 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Ventricular Arrhythmia	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Once		Natco Pharma
	Hydroxychloroquine			S	Oral	800 Mg (Four 200-Mg Tablets), Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14553936	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263184-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14554182	EXPEDITED (15-DAY)		OT	US-SA-2018SA042444			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Systemic Lupus Erythematosus	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14555291	NON-EXPEDITED			US-PFIZER INC-2018062254		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2018	14559845	DIRECT	Y	DS, HO, LT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pancreatitis	Imuran			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	12980233	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-099318		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Chloroquine /00001002/			S	Unknown	200 Mg, Qd		Not Reported

	Tocilizumab				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	13446587	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017055626		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anger; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk (Solution Subcutaneous)		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14280065	NON-EXPEDITED			CA-AMGEN-CANSP2017174574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14345049	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000013			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Asthenia; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Urticaria	Plaquenil	S	Oral		Concordia
	Leflunomide	S	Oral		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Tums	C			Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14450419	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000381		62 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspnoea; Gastrointestinal Disorder; Haemorrhoidal Haemorrhage; Lacrimation Increased; Muscular Weakness; Pruritus; Tinnitus; Vision Blurred	Plaquenil			S	Oral			Concordia
	Euthyral			C				Not Reported
	Efferalgan			C				Not Reported
	Levocetirizine			C				Not Reported
	Prednisolone			C				Not Reported
	Biprofenid			C				Not Reported
	Lamaline (Acetaminophen\Caffeine\Opium)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14479139	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Disability; Drug Ineffective; Hypertension; Mobility Decreased; Nausea; Vomiting; Weight Increased	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Leucovorin			C				Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported
	Naproxen			C				Not Reported

Pantoprazole Magnesium	C		Not Reported
Vitamin D2	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Escitalopram Oxalate	C		Not Reported
Clobetasol Propionate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14549456	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000622		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14551493	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000611			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14555780	EXPEDITED (15-DAY)		DE, HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-000303		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556119	NON-EXPEDITED			US-AMGEN-USASP2018023441			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556140	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000642			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Drug Intolerance; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Mtx			C				Not Reported
	Folic Acid			C				Not Reported
	Enalapril			C				Not Reported
	Tylenol Arthritis			C				Not Reported
	Metoprolol			C				Not Reported
	Orencia			C				Not Reported
	Azathioprine			C				Not Reported
	Nuvigil			C				Not Reported
	Prednisone			C				Not Reported
	Pravastatin Sodium			C				Not Reported
	Aspirin			C				Not Reported
	Lasix			C				Not Reported
	Potassium Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556141	EXPEDITED (15-DAY)		DS	MT-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000644			Female	MLT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556142	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000647		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Musculoskeletal Stiffness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Maxeran			C				Not Reported
	Metoject			C				Not Reported
	Xeljanz			C				Not Reported
	Etanercept			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556143	EXPEDITED (15-DAY)		HO, LT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010617		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Decreased; Blood Calcium Decreased;	Hydroxychloroquine Tablet			S	Oral			Concordia

Blood Chloride Decreased; Blood Sodium Decreased; Dizziness; Dyspnoea; Electrolyte Imbalance; Erythema; Lethargy; Loss Of Consciousness; Palpitations; Rash; Skin Burning Sensation; Skin Exfoliation; Somnolence; Swelling; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556144	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010627		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis; Headache; Pneumonia; Psoriasis	Plaquenil Tablet			S	Unknown			Concordia
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556145	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14556146	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010633			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental			Concordia
	Gammagard			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14557509	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010621		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Pain; Facial Pain; Influenza; Lung Neoplasm Malignant; Lymphadenopathy; Nasopharyngitis; Ocular Toxicity; Pneumonia; Pneumonia; Productive Cough; Pulmonary Mass; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Incomplete; Vision Blurred	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin B6			C				Not Reported
	Vitamin D2			C				Not Reported
	Methotrexate			C				Not Reported
	Ondasetron			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14557510	EXPEDITED (15-DAY)		DE	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010622		38 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accidental Overdose; Pneumonia	Hydroxychloroquine		S	Unknown	Concordia
	Bupropion		S	Unknown	Not Reported
	Cyclobenzaprine		S		Not Reported
	Mirtazapine		S		Not Reported
	Pristiq		S		Not Reported
	Venlafaxine		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14557511	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010634		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Maternal Exposure Before Pregnancy; Placental Insufficiency; Premature Delivery	Hydroxychloroquine			S	Unknown			Concordia
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14557533	EXPEDITED (15-DAY)		OT	US-SA-2018SA027403		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity; Fatigue; Rheumatoid Arthritis; Treatment Failure; Visual Impairment; White Blood Cell Count Decreased	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14557918	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262158-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558097	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-18K-028-2263252-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial	Not Reported
	Ilaris	S	Unknown	Single-Use Vial	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558790	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263084-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported
	Synthroid	C		Not Reported
	Restasis	C		Not Reported
	Prednisone	C		Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558794	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262876-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558803	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263026-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558882	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263098-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Groin Pain; Investigation Abnormal; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not			Not Reported

Joint Swelling; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure					otherwise specified)					
	Plaquenil			S	Oral					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported
	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14559311	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263200-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14560007	EXPEDITED (15-DAY)		OT	CA-ROCHE-1747524			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra		S	Subcutaneous	Not Reported
	Rituxan		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Acetylsalicylic Acid		S	Unknown	Not Reported
	Gabapentin		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14560070	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2263202-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	13993562	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2105189-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14294544	NON-EXPEDITED			US-AMGEN-USASP2017185592		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Citracal			C	Unknown	Unk		Not Reported
	Mvi			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14528964	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000419			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Enbrel			S				Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral	0.7ml/7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14558099	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2248211-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560169	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263233-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Consciousness; Loss Of Personal Independence In	Humira			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Daily Activities; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Response Decreased	Plaquenil		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Prednisone		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560204	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2265598-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Terminal State; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Form-Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form-Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			C	Unknown	Form- Powder For Solution Subcutaneous Single Use Vial		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560375	NON-EXPEDITED			US-AMGEN-USASP2018023029			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560406	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-E2B_00010011		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer Stage Ii	Plaquenil			S	Oral			Concordia
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Alendronate Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560409	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000649		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiac Failure Congestive; Cardiomyopathy; Ejection Fraction Decreased; Intracardiac Thrombus; Toxicity To Various Agents; Ventricular	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			C				Not Reported

Dysfunction; Ventricular Hypertrophy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14560896	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2263206-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14561146	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262249-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Methotrexate	S	Unknown		Not Reported
	Rabeprazole Sodium	C			Not Reported
	Tramadol Hydrochloride	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14561316	NON-EXPEDITED			US-PFIZER INC-2018075130		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14561419	NON-EXPEDITED			US-PFIZER INC-2018075406		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Septra			S		Unk		Pfizer
	Calcium			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14563887	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine Generic			S				Not Reported
	Humira 40mg/0.8ml Abbvie			S	Subcutaneous			Abbvie

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2018	14563890	DIRECT					78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Product Dispensing Error; Wrong Product Administered	Hydroxychloroquine Sulfate 200mg Tablets, Usp			S	Oral			Not Reported
	Vitamin C			C				Not Reported
	Vitamin Dc			C				Not Reported
	Cranberry			C				Not Reported
	Coq10			C				Not Reported
	B12			C				Not Reported
	Vitamin E			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	12486072	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016291137		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Joint Swelling; Pain; Peripheral Swelling	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Sulfasalazine			S	Oral	Once Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Prednisone			S	Oral	5 Mg, Daily		Not Reported
	Plaquenil			S		Unk		Not Reported
	Apo-Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Acetylsalicylic Acid			C		81 Mg, Qd		Not Reported
	Amlodipine Besilate			C	Oral	5 Mg, Qd		Not Reported
	Pantoprazole Sodium			C	Oral	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	13395029	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002117		41 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Leukocytosis; Pruritus; Rash	Plaquenil			S	Oral			Concordia
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	13471111	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002544		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Pain; Facial Pain; Influenza; Lung Neoplasm Malignant; Lymphadenopathy; Nasopharyngitis; Ocular Toxicity; Pneumonia; Pneumonia; Productive Cough; Pulmonary Mass; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Incomplete; Vision Blurred	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported
	Vitamin B6			C				Not Reported
	Vitamin D2			C				Not Reported
	Folic Acid			C				Not Reported
	Ondansetron			C				Not Reported
	Dexamethasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14526762	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018018756			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Assistance Device User; Crohn'S Disease; Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	2000 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported

	Hydroxychloroquine		S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide		S	Oral	20 Mg, Qd		Not Reported
	Prednisone		C		Unk		Not Reported
	Citalopram		C		20 Mg, Qd		Not Reported
	Furosemide		C		40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14539671	EXPEDITED (15-DAY)		OT	IN-TORRENT-00001586		51 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus Inadequate Control; Neuropathy Peripheral; Off Label Use	Metformin Hydrochloride			S	Oral	3 Years Of Treatment		Unknown
	Glimepiride			S	Oral	For The Last 2 Year		Unknown
	Hydroxychloroquine Sulfate			S				Unknown
	Acarbose			S		For The Last 2 Year		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14546934	NON-EXPEDITED			US-PFIZER INC-2018065386		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565062	NON-EXPEDITED			US-AMGEN-USASP2018024297			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect	Enbrel			S	Unknown	Unk		Amgen

Incomplete	Methotrexate			S	Unknown	Unk	Not Reported
	Humira			S	Unknown	Unk	Not Reported
	Simponi			S	Unknown	Unk	Not Reported
	Remicade			S	Unknown	Unk	Not Reported
	Stelara			S	Unknown	Unk	Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Hcq			S	Unknown	Unk	Not Reported
	Otezla			S	Unknown	Unk	Not Reported
	Cyclosporine			S	Unknown	Unk	Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565095	NON-EXPEDITED			US-AMGEN-USASP2018024324			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			C		Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565114	NON-EXPEDITED			US-AMGEN-USASP2018024342			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Plaquenil	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565203	EXPEDITED (15-DAY)		HO, OT	US-ASTRAZENECA-2018SE21114		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Esomeprazole Magnesium			S	Oral			Astrazeneca
	Methotrexate Sodium			S	Subcutaneous	25 Mg, 4 Times Every Week		Not Reported
	Tofacitinib			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14565345	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018024287		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk Unk, Bid		Not Reported
	Toprol Xl			C		Unk		Not Reported
	Neurontin			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566126	NON-EXPEDITED			US-PFIZER INC-2018074409		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Plaquenil /00072602/			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566244	NON-EXPEDITED			US-PFIZER INC-2018072773		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14566252	NON-EXPEDITED			US-PFIZER INC-2018071438		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2018	14567983	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018073090			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pyoderma Gangrenosum	Methotrexate Sodium	S	Oral	15 Mg, Weekly		Pfizer
	Prednisolone	S		7.5 Mg, Daily		Not Reported
	Hydroxychloroquine	S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14505969	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-855746		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)			Teva
	Hydroxychloroquine			S	Oral	Four 200 Mg Tablets		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14569681	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000662			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14569682	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-			Female	USA

000664

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Ibuprofen			S				Not Reported
	Levaquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14569683	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000666			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychological Factor Affecting Medical Condition	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	13593177	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003175		48 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atonic Seizures	Hydroxychloroquine Tablet			S	Oral			Concordia
	Rivaroxaban			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	13995633	NON-EXPEDITED			US-PFIZER INC-2017405764		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

	Codeine	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Dilaudid	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14207413	NON-EXPEDITED			US-AMGEN-USASP2017172848			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14311547	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-E2B_00008957		51 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Psychotic Disorder	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia
	Prednisolone			S				Concordia

Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Prednisolone	S		Concordia
Hydroxychloroquine	S	Oral	Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
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Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Hydroxychloroquine	S		Concordia
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Azathioprine	S		Not Reported

Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
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Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Azathioprine	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Eltrombopag	S			Not Reported
Fingolimod	C			Not Reported
Fingolimod	C			Not Reported
Fingolimod	C			Not Reported
Ethinylestradiol, Levonorgestrel	C			Not Reported
Immunoglobulin (Ivig)	C	Intravenous (not otherwise specified)	(1g/Kg)	Not Reported
Immunoglobulin (Ivig)	C	Intravenous (not otherwise specified)		Not Reported
Immunoglobulin (Ivig)	C	Intravenous (not		Not Reported

							otherwise specified)			
			Immunoglobulin (Ivig)		C		Intravenous (not otherwise specified)			Not Reported
			Immunoglobulin (Ivig)		C		Intravenous (not otherwise specified)			Not Reported
			Immunoglobulin (Ivig)		C		Intravenous (not otherwise specified)			Not Reported
			Immunoglobulin (Ivig)		C		Intravenous (not otherwise specified)			Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported
			Romiplostim		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14561254	NON-EXPEDITED			US-PFIZER INC-2018069905		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14570409	EXPEDITED (15-DAY)		LT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000653		45 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Bundle Branch Block Right; Cardiac Failure; Cardiac Hypertrophy; Syncope	Plaquenil Tablet			S	Oral			Concordia
	Hizaar			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14570433	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0514			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Gastrooesophageal Reflux Disease; Infection; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14571628	NON-EXPEDITED			US-PFIZER INC-2018077583			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Cimzia			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14571752	NON-EXPEDITED			US-PFIZER INC-2018077224		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

	Endocet			S		Unk				Not Reported
	Imitrex			S		Unk				Not Reported
	Lortab			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14573337	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018078117			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Lyme Disease; Myocardial Infarction; Nervous System Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14574070	EXPEDITED (15-DAY)		OT	US-SA-2018SA040907		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Toxicity	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	13075048	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0971		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Joint Swelling; Pain; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Apo-Prednisone			S	Oral				Not Reported
		Acetylsalicylic Acid			C	Unknown				Not Reported
		Amlodipine Besilate			C	Unknown				Not Reported
		Pantoprazole Sodium			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	13448039	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1023156		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Complement Factor C4 Decreased; Double Stranded Dna Antibody Positive; Exposure During Pregnancy; Listeriosis; Platelet Count Decreased; Premature Delivery; Pyrexia	Prednisone			S	Oral	10 Mg, Qd		Not Reported
	Prednisone			S	Oral	25 Mg, Qd		Not Reported
	Prednisone			S	Oral	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Aspirin /00002701/			S	Oral	100 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	13939920	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005092			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14250745	NON-EXPEDITED			US-PFIZER INC-2017517269		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Cephalexin Monohydrate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14307447	NON-EXPEDITED			US-PFIZER INC-2017538967		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective	Sulfasalazine			S	Oral	Unk 4/Day		Pfizer
	Plaquenil			S	Oral	Unk, 2x/Day		Not Reported
	Leflunomide			S		Unk		Not Reported
	Cimzia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14538448	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018020790			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Cell Carcinoma	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14566136	NON-EXPEDITED			US-PFIZER INC-2018075091		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Therapeutic Product Effect Incomplete	Enbrel	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Skelaxin	S	Unk	Pfizer
	Cyclosporine	S	Unk	Not Reported
	Humira	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Otezla	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Simponi	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14574819	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000654		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Neuropathy Peripheral; Oral Pain; Pharyngeal Swelling; Swelling	Plaquenil 200 Mg Tablet			S				Concordia
	Clopidogrel			C				Not Reported
	Levothyroxine			C				Not Reported
	Duloxetine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576296	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000635			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tuberculosis	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576297	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000673		50 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Skin Disorder	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576298	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000674			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Injection Site Pain	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576299	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000675			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576301	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000678			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576302	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000679			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576303	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000680			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Atrophy	Hydroxychloroquine			S				Concordia
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576304	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000681			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576305	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000682			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Hyperhidrosis; Tachycardia	Hydroxychloroquine				S					Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576306	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000684			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576439	NON-EXPEDITED			US-PFIZER INC-2018079807		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14576979	NON-EXPEDITED		OT	US-AMGEN-USASP2018025872			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Interstitial Lung Disease	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2018	14579175	EXPEDITED (15-DAY)		OT	US-SA-2018SA042355		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	10334136	EXPEDITED (15-DAY)		OT	CA-ROCHE-1395719		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use;	Rituxan			S	Intravenous (not otherwise specified)	Dates Of Last Rituximab Infusion: 16/Dec/2013, 26/Jun/2014		Not Reported
	Metformin			S	Unknown			Not Reported
	Metformin			S				Not Reported
	Coumadin (Canada)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported

Pain; Thrombosis; Uterine Disorder; Weight Increased	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Methotrexate	C	Unknown	Stopping Due To Possible Reaction, Assessing If True Allergy		Not Reported
	Xarelto	C	Unknown			Not Reported
	Imuran	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14262670	NON-EXPEDITED		OT	US-PFIZER INC-2017522578		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14579868	NON-EXPEDITED			US-AMGEN-USASP2018026356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14579936	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS		59 YR	Female	USA

INC.-GSH201802-000693

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiac Failure; Cardiac Failure Congestive; Cardiomyopathy; Chronic Kidney Disease; Chronic Kidney Disease; Hepatic Fibrosis; Intracardiac Thrombus; Intraductal Proliferative Breast Lesion; Pneumonia	Hydroxychloroquine			S	Unknown			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Alendronate			C				Not Reported
	Allopurinol			C				Not Reported
	Metoprolol Er			C				Not Reported
	Nortriptyline			C				Not Reported
	Prednisone			C				Not Reported
	Prevacid			C				Not Reported
	Crestor			C				Not Reported
	Calcium With Vitamin D (Lekovit Ca)			C				Not Reported
	Coq10			C				Not Reported
	Magnesium (Aludrox)			C				Not Reported
	Vitamin B 12			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580237	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-TREX2018-0587			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyoderma Gangrenosum	Methotrexate			S	Oral			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580457	EXPEDITED (15-DAY)		HO, OT	PT-CONCORDIA PHARMACEUTICALS		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Product Use In Unapproved Indication; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown	15 Mg, Qd		Concordia
	Prednisolone			S	Unknown	25 Mg, Qd		Concordia
	Methylprednisolone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580459	EXPEDITED (15-DAY)		OT	FI-CONCORDIA PHARMACEUTICALS INC.-E2B_00010187		68 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Proteinuria; Unevaluable Event	Hydroxychloroquine			S	Unknown			Concordia
	Trexan			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Reumacon			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Myocrisin (Sodium Aurothiomalate)			S	Parenteral			Not Reported
	Ridaura			S	Unknown			Not Reported
	Prolia			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Calcium D			C	Unknown			Not Reported
	Thyroxin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580461	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000686			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580463	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000696			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580800	NON-EXPEDITED			US-AMGEN-USASP2018025945			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14580974	NON-EXPEDITED			US-PFIZER INC-2018081416		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		25 Mg, Weekly (Once A Week)		Pfizer

	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2018	14581028	NON-EXPEDITED			US-PFIZER INC-2018081047			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vomiting	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Orencia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14109673	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005903			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	50 Die		Not Reported
	Imuran			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14566978	EXPEDITED (15-DAY)		OT	AU-009507513-1705AUS007395		41 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapy Non-Responder	Betamethasone Dipropionate	S	Topical	Unk		Merck
	Prednisolone	S		Unk		Not Reported
	Tacrolimus	S		Unk		Not Reported
	Hydroxychloroquine Sulfate	S		Unk		Not Reported
	Methotrexate	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14576472	NON-EXPEDITED			US-PFIZER INC-2018078849		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Kineret			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585032	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000709			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Gastrooesophageal Reflux Disease; Hypersensitivity; Urticaria; Urticaria	Plaquenil			S				Concordia
	Hydroxychloroquine			S				Concordia
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585534	NON-EXPEDITED			US-PFIZER INC-2018085242		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Disorder; Joint Injury; Joint Swelling; Lip Erythema; Rash Macular; Visual Impairment; Weight Increased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Crestor			C		5 Mg, 1x/Day		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported
	Folic Acid			C		1 Mg, 1x/Day (Two Pills)		Not Reported
	Hydrocodone			C		Unk, 4x/Day (10-325 Mg, Four Times In Day, Take One Every Six Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585549	NON-EXPEDITED			US-PFIZER INC-2018083331		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14585660	EXPEDITED (15-DAY)		OT	CA-ROCHE-2077234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Celebrex			C						Not Reported
	Lyrica			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2018	14588793	EXPEDITED (15-DAY)		OT	IL-IMPAX LABORATORIES, INC-2018-IPXL-00499		45 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Type I Hypersensitivity	Doxycycline Hyclate Delayed Release			S	Unknown	Unk		Impax
	Doxycycline Hyclate Delayed Release			S	Intravenous (not otherwise specified)	Slow Iv Pushes In Escalating Concentartions		Impax
	Doxycycline Hyclate Delayed Release			S	Oral	100 Mg, 240 Min After Starting Escalating Dose Of Iv Pushes For Desensitization		Impax
	Doxycycline Hyclate Delayed Release			S	Unknown	Unk		Impax
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	13985718	NON-EXPEDITED			US-AMGEN-USASP2017140713		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Glucose-6-Phosphate Dehydrogenase Deficiency; Hepatic Enzyme Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported

Celebrex	C	Unk	Not Reported
Macrobid	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Bactrim	C	Unk	Not Reported
Crestor	C	Unk	Not Reported
Cleocin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14149614	NON-EXPEDITED		HO, OT	US-AMGEN-USASP2017164487		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Acute Generalised Exanthematous Pustulosis; Decreased Immune Responsiveness; Diarrhoea; Endodontic Procedure; Fatigue; Flatulence; Gastrointestinal Disorder; Injection Site Induration; Injection Site Pain; Injection Site Rash; Injection Site Swelling; Sleep Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14238261	EXPEDITED (15-DAY)		LT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006526		46 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suicidal Ideation	Hydroxychloroquine			S	Oral			Concordia

	Hydroxychloroquine			S	Oral					Concordia
	Zolpidem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14415191	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000257		74 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Fatigue; Headache; Visual Impairment	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14524896	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2018-005271		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Incorrect Dose Administered; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Aurobindo
	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram		Aurobindo
	Hydroxychloroquine			S		4 Df, Unk		Not Reported
	Activated Charcoal			C	Oral	50 Gram		Not Reported
	Hydroxychloroquine 200mg Tablet			S	Oral	In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14589810	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018026864			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer; Drug Ineffective; Rheumatoid Arthritis; Skin Cancer	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

			Prednisone		S	Unknown	Unk			Not Reported
			Plaquenil		S	Unknown				Not Reported
			Xeljanz Xr		C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14590161	NON-EXPEDITED			PHEH2018US008035			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking Sensation; Throat Irritation	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Novartis
	Losartan			C	Unknown			Not Reported
	Vitamins Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14592224	EXPEDITED (15-DAY)		OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18-01		71 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Infected Varicose Vein; Nocardiosis; Pneumonia; Varicose Ulceration	Methylprednisolone			S	Unknown			Hikma
	Methylprednisolone			S	Unknown			Hikma
	Methylprednisolone			S	Unknown			Hikma
	Methylprednisolone			S	Unknown			Hikma
	Methylprednisolone			S	Unknown			Hikma
	Methotrexate			S	Subcutaneous			Not Reported
	Salazopirina			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Plaquinol			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2018	14598059	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Kevzara Syringe 2 Pack 200mg/1.14ml Sarilumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Tabs 200mg Generic			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2018	13256110	EXPEDITED (15-DAY)		CA, OT	US-GLAXOSMITHKLINE-US2017GSK023447		2 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pyelocaliectasis; Congenital Spinal Cord Anomaly; Foetal Exposure During Pregnancy; Pyrexia; Viral Upper Respiratory Tract Infection	Belimumab			S	Transplacental	400 Mg, Cyc		Glaxosmithkline
	Lamictal			S	Transplacental	Unk, U		Glaxosmithkline
	Nicoderm			S	Transplacental	Unk, U		Glaxosmithkline
	Percocet			S	Transplacental	Unk, U		Not Reported
	Plaquenil			S	Transplacental	Unk, U		Not Reported
	Xanax			S	Transplacental	Unk, U		Not Reported
	Vyvanse			S	Transplacental	Unk, U		Not Reported
	Folate			C		Unk		Glaxosmithkline
	Methotrexate			C		Unk		Glaxosmithkline
	Penicillin (Benzylpenicillin)			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14005826	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005430			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Fatigue; Rheumatoid Arthritis; Visual Impairment; White Blood Cell Count Decreased	Plaquenil	S	Unknown		Concordia
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	C			Not Reported
	Meloxicam	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14574820	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Aleve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596485	EXPEDITED (15-DAY)		DE	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00010351		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Immunosuppression	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596487	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00010364		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported
	Chloroquine /00001002/			S	Unknown	200 Mg, Qd		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596494	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000718			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596496	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000727			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthritis; Discomfort; Drug Ineffective; Joint Effusion; Ligament Sprain; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596497	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000729		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rash Maculo-Papular	Plaquenil		S	Oral		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14596985	NON-EXPEDITED			US-AMGEN-USASP2018028128			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14597113	NON-EXPEDITED			US-AMGEN-USASP2018028077			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14597825	NON-EXPEDITED			US-PFIZER INC-2018085619			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Savella			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14597933	NON-EXPEDITED			US-PFIZER INC-2018085731		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14598204	EXPEDITED (15-DAY)		DE	GB-ORION CORPORATION ORION PHARMA-18_00003089		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Immunosuppression	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14599635	EXPEDITED (15-DAY)		DS	DK-SA-2018SA056654		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Diarrhoea	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14600349	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2018-FR-862974		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off	Paracetamol/Codeine Phosphate			S	Oral	6 Dosage Forms Daily; 2 Tab, Tid So Pain		Actavis

Label Use	Loxapac	S	Oral	1 Df, Unk 50 Drop (1/12 Millilitre)	Not Reported
	Theralene	S	Oral	1 Dosage Forms Daily; 1 Df, Qd 50 Drop (1/12 Millilitre)	Not Reported
	Noctamide	S	Oral	1 Dosage Forms Daily; 1 Tab, Qd	Not Reported
	Abilify	S	Oral	10 Milligram Daily; 10 Mg, Qd	Not Reported
	Dafalgan Codeine	S	Unknown	Unk, Tid	Not Reported
	Methotrexate	S	Oral	20 Mg, Qwk	Not Reported
	Lepticur	S	Oral	2 Dosage Forms Daily; 2 Tab, Qd	Not Reported
	Tranxene	S	Oral	1 Df, Unk	Not Reported
	Imeth	S	Oral	20 Mg, Qwk	Not Reported
	Plaquenil	S	Oral	400 Milligram Daily; 400 Mg, Qd	Not Reported
	Speciafoldine	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14391145	NON-EXPEDITED			US-PFIZER INC-2018018659		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14538848	NON-EXPEDITED			US-PFIZER INC-2018061990		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported

	Hydroxychloroquine	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Actemra	S	Unk	Not Reported
	Rituxan	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14575866	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0556		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14601835	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000731			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602028	EXPEDITED (15-DAY)		DE	DE-ROCHE-1888503		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pneumonia	Rituximab	S	Intravenous (not otherwise specified)	Subsequently Next Infusion Was Administered On /Sep/2012 And /Mar/2013.		Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602245	NON-EXPEDITED			US-AMGEN-USASP2018027504			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602444	NON-EXPEDITED			US-PFIZER INC-2018088090			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

	Mobic			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14602767	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14603472	EXPEDITED (15-DAY)		OT	US-SA-2018SA056610			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14603500	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010386		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anterograde Amnesia; Confusional State; Off Label Use	Plaquenil		S	Oral	400 Mg, Qd	Concordia
	Fluoxetine Hydrochloride		S	Oral	30 Mg, Qd	Not Reported
	Lepticur		S	Unknown	2 Tab, Qd	Not Reported
	Theralene		S	Oral	1 Df, Qd	Not Reported
	Fluoxetine Hydrochloride		S	Oral	30 Mg, Qd	Not Reported
	Methotrexate		S	Oral	20 Mg, Qwk	Not Reported
	Abilify		S	Oral	10 Mg, Qd	Not Reported
	Noctamide		S	Oral	1 Tab, Qd	Not Reported
	Paracetamol/Codeine Phosphate		S	Unknown	2 Tab, Tid	Not Reported
	Tranxene		S	Oral	1 Df, Unk	Not Reported
	Loxapac		S	Oral	1 Df, Unk	Not Reported
	Imeth		S	Oral	20 Mg, Qwk	Not Reported
	Dafalgan Codeine		S	Unknown	Unk, Tid	Not Reported
	Speciafoldine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2018	14603965	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010452		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine			S				Concordia
	Prednisone			S				Not Reported
	Aspirine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14017167	EXPEDITED (15-DAY)		OT	US-SA-2017SA180712		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Fatigue;	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Rheumatoid Arthritis; Visual Impairment; White Blood Cell Count Decreased	Methotrexate		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		C	Unknown	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14119226	EXPEDITED (15-DAY)		HO, LT, OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005978		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Genital Lesion; Off Label Use; Oral Disorder; Rash; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown			Concordia
	Omeprazole			S	Oral			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14127961	NON-EXPEDITED			US-PFIZER INC-2017459239		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14176955	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006317			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Systemic Lupus Erythematosus	Plaquenil 200 Mg Tablet	S	Oral	01/Jan/1996 To 01/Jan/2015		Concordia
	Plaquenil 200 Mg Tablet	S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14257305	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006563			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14306710	NON-EXPEDITED			US-AMGEN-USASP2017186874		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi Aria			S	Unknown	Unk		Not Reported
	Ana Lex			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14559531	NON-EXPEDITED			US-PFIZER INC-2017401558		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Glucose-6-Phosphate Dehydrogenase Abnormal; Hepatic Enzyme	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Increased; Treatment Failure	Humira	S	Subcutaneous	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Penicillin (Benzylpenicillin)	S		Unk		Not Reported
	Celebrex	C		Unk		Not Reported
	Macrobid	C		Unk		Not Reported
	Vancomycin	C		Unk		Not Reported
	Bactrim	C		Unk		Not Reported
	Crestor	C		Unk		Not Reported
	Cleocin	C		Unk		Not Reported
	Leflunomide	C		Unk		Not Reported
	Meloxicam	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14566192	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000626		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Chest Discomfort; Chest Pain; Dyspnoea; Ejection Fraction Decreased; Electrocardiogram St Segment Elevation; Intracardiac Thrombus; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14593203	NON-EXPEDITED			US-PFIZER INC-2018085260		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Xeljanz Xr			S		11 Mg, Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14601422	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000732			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Renal Impairment	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14606818	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000891		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiac Failure; Cardiac Failure Congestive; Cardiomyopathy; Chronic Kidney Disease; Chronic Kidney Disease; Hepatic Fibrosis; Intracardiac Thrombus; Intraductal Proliferative Breast Lesion; Pneumonia	Plaquenil			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lisinopril			S	Oral			Not Reported
	Alendronate			C				Not Reported
	Allopurinol			C				Not Reported
	Nortriptyline			C				Not Reported
	Prevacid			C				Not Reported
	Crestor			C				Not Reported
	Metoprolol			C				Not Reported
	Prednisone			C				Not Reported
	Lekovit Ca			C				Not Reported
	Coq10			C				Not Reported
	Aludrox			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin D2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14606835	NON-EXPEDITED			US-AMGEN-USASP2018029786			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607369	NON-EXPEDITED			US-PFIZER INC-2018092055		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Imuran			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14607427	NON-EXPEDITED			US-PFIZER INC-2018091913		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Prednisone			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14608560	NON-EXPEDITED			US-TEVA-2018-US-861957		273 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea	Hydroxychloroquine	S	Unknown	2mg/Kg/Day		Teva
	Cetirizine	C	Unknown			Not Reported
	Ranitidine	C	Unknown			Not Reported
	Montelukast	C	Unknown	4mg/Day		Not Reported
	Prednisolone	C	Unknown	0.65mg/Kg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14609196	EXPEDITED (15-DAY)		OT	GB-IMPAX LABORATORIES, INC-2018-IPXL-00645		13 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Ursodiol			S	Unknown	Unk		Impax
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14609957	DIRECT		OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Hypoaesthesia; Muscle Tightness; Muscular Weakness; Pain In Extremity; Paraesthesia; Product Substitution Issue; Tendon Disorder	Plaquenil			S	Oral	Quantity:180 Tablet(S);		Not Reported
	Hydroxychloroquine			C				Not Reported
	Marlissa			C				Not Reported
	Methotrexate			C				Not Reported
	Htz			C				Not Reported
	Verapamil			C				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported
	Singulair			C				Not Reported
	Levothyroxine			C				Not Reported
	Folic Acid			C				Not Reported
	Duloxetine			C				Not Reported
	Tizandine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14627866	EXPEDITED (15-DAY)		OT	CZ-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000736		64 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Swelling; Headache; Lip Swelling; Nausea; Oedema Peripheral; Tongue Oedema; Tremor	Plaquenil Tablet			S	Oral			Concordia
	Meloxicam			S	Oral			Not Reported
	Condrosulf			C				Not Reported
	Doreta			C				Not Reported
	Siofor			C				Not Reported
	Euthyrox			C				Not Reported
	Analergin			C				Not Reported
	Moduretic			C				Not Reported
	Atoris			C				Not Reported
	Atimos			C				Not Reported
	Latanoprost			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	13451334	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002467		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer Stage Ii	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alendronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	13928825	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004887			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Gastrointestinal Disorder; Pain; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Concordia
	Leflunomide			S	Unknown	Not Reported
	Methotrexate			C		Not Reported
	Enbrel			C		Not Reported
	Xeljanz			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14061259	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005638		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaphylactic Reaction; Anxiety Disorder; Appetite Disorder; Arthralgia; Arthritis; Atrophic Vulvovaginitis; Back Pain; Carotid Artery Disease; Carotid Artery Occlusion; Chronic Kidney Disease; Clostridium Difficile Infection; Clostridium Difficile Infection; Cognitive Disorder; Cough; Deafness; Depression; Diabetes Mellitus; Diabetic Ketoacidosis; Diabetic Neuropathy; Dizziness; Drug Dependence; Drug Ineffective; Drug Ineffective; Dry Eye; Dysphagia; Essential Hypertension; Extrapyramidal Disorder; Fall; Fatigue; Fibromyalgia; Gait Disturbance; Haemorrhagic Disorder;	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Tablet			S	Oral	2.5 Mg Tablet 6 Tablets By Mouth 1 Time A Week		Not Reported
	Codeine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Minocycline Hcl			S	Unknown			Not Reported
	Buspar Tablet			C				Not Reported
	Neostigmine Bromide			C				Not Reported
	Tresiba			C				Not Reported
	Pseudoephedrine			C				Not Reported
	Lyrica			C				Not Reported
	Reglan			C				Not Reported
	Robinul			C				Not Reported
	Claritin Tablet			C				Not Reported
	Neurontin Tablet			C				Not Reported
	Bentyl Capsule			C				Not Reported
	Lasix Tablet			C				Not Reported
	Benadryl Capsule			C				Not Reported

Hepatic Enzyme Increased; Hyperlipidaemia; Hypersensitivity Vasculitis; Hypoaesthesia; Impaired Gastric Emptying; Infection; Iron Deficiency Anaemia; Joint Arthroplasty; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Myalgia; Myopia; Nasal Congestion; Nausea; Neck Pain; Orthostatic Hypotension; Osteoarthritis; Osteopenia; Pain; Palpitations; Paraesthesia; Presbyopia; Purpura Non-Thrombocytopenic; Pyrexia; Radiculopathy; Rash; Restless Legs Syndrome; Retinal Degeneration; Rotator Cuff Syndrome; Spinal Osteoarthritis; Spinal Osteoarthritis; Spinal Osteoarthritis; Stomatitis; Stomatitis; Syncope; Synovitis; Systemic Lupus Erythematosus; Urinary Hesitation	Desyrel Tablet	C		Not Reported
	Novolog Injection	C		Not Reported
	Seroquel Tablet	C		Not Reported
	Lexapro Tablet	C		Not Reported
	Ativan Tablet	C		Not Reported
	Aquaphor Ointment	C		Not Reported
	Florastor Capsule	C		Not Reported
	Levothyroxine Tablet	C		Not Reported
	Zantac Tablet	C		Not Reported
	Aspirin Tablet	C		Not Reported
	Calcium Carbonate Tablet	C		Not Reported
	Prilosec Capsule	C		Not Reported
	Vitamin D3 Tablet	C		Not Reported
	Glucagen Injection	C		Not Reported
	Pravachol Tablet	C		Not Reported
	Lopressor Tablet	C		Not Reported
	Colchicine Tablet	C		Not Reported
	Tucks Ointment, 1-12.5 %	C	1-12.5 %	Not Reported
	Melatonin Tablet	C		Not Reported
	Anusol Ointment, 1-12.5 %	C	1-12.5 %	Not Reported
	Cefaclor	C		Not Reported
	Xeljanz Tablet	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14322315	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006691		73 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14330734	EXPEDITED (15-DAY)		HO, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006700		53 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain Upper; Acute Kidney Injury; Acute Kidney Injury; Blood Creatinine Increased; Chills; Constipation; Decreased Appetite; Drug Ineffective; Drug Specific Antibody; Gastrointestinal Disorder; Glucose Tolerance Impaired; Hypercalcaemia; Infection; Interstitial Lung Disease; Lacrimation Increased; Liver Disorder; Malaise; Nausea; Peripheral Venous Disease; Proteinuria; Pyrexia; Sinusitis; Sjogren'S Syndrome; Sleep Apnoea Syndrome; Spinal Pain; Supraventricular Tachycardia; Tendonitis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Spiricort			C				Not Reported
	Hydroxychloroquine Phosphate			C				Not Reported
	Buscopan			C				Not Reported
	Pantoprazol			C				Not Reported
	Lodotra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14346192	EXPEDITED (15-DAY)		HO, OT	FR-ELI_LILLY_AND_COMPANY-FR201712012383		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anterograde Amnesia; Confusional State; Off Label Use	Fluoxetine Hydrochloride		S	Oral	30 Mg, Daily	Eli Lilly And Co
	Fluoxetine Hydrochloride		S	Oral	30 Mg, Daily	Eli Lilly And Co
	Loxapac /00401801/		S	Oral	1 Df, Unknown	Not Reported
	Theralene		S	Oral	1 Df, Daily	Not Reported
	Paracetamol With Codeine Phosphate		S	Oral	6 Df, Daily	Not Reported
	Noctamide		S	Oral	1 Df, Unknown	Not Reported
	Abilify		S	Oral	10 Mg, Daily	Not Reported
	Dafalgan Codeine		S	Unknown		Not Reported
	Methotrexate		S	Oral	20 Mg, Weekly (1/W)	Not Reported
	Lepticur		S	Oral	2 Df, Unknown	Not Reported
	Tranxene		S	Oral	1 Df, Unknown	Not Reported
	Imeth /00113801/		S	Oral	20 Mg, Unknown	Not Reported
	Plaquenil /00072602/		S	Oral	400 Mg, Daily	Not Reported
	Speciafoldine		C	Oral	4 Df, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14379123	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000109		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Plaquenil			C				Not Reported

	Arava			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14422115	EXPEDITED (15-DAY)		OT	HR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000311		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Phospholipidosis; Proteinuria; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Concordia
	Azathioprine			C				Not Reported
	Prednisolone			C				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14607297	NON-EXPEDITED			US-PFIZER INC-2018091976		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610797	EXPEDITED (15-DAY)		DS	DK-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000909		65 YR	Male	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Incontinence; Diarrhoea	Plaquenil			S	Oral	200 Milligram(S);Daily		Concordia
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610873	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000741			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Fibrosis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610874	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000888		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocarditis	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610935	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000915			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14610969	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000728			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Tuberculosis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14611130	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000792		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumonia; Sinusitis	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14611131	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000820			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14611139	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000921		16 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Normal Tension Glaucoma	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	13661746	EXPEDITED (15-DAY)		OT	CA-SA-2017SA106179		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Cortisone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Form Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	13661836	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Cortisone			C				Not Reported

Product Effect Decreased; Therapeutic Product Effect Delayed

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14127568	EXPEDITED (15-DAY)		HO, LT, OT	AU-LUPIN PHARMACEUTICALS INC.-2017-06125		13 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Epiglottitis; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Lupin
	Prednisolone			C	Oral	High Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14406923	EXPEDITED (15-DAY)		OT	CA-SA-2018SA003541		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Form: Unknown Formulation		Not Reported
	Humira			S	Subcutaneous	40mg/0.8 Ml		Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14553221	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018065078		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Renal Cell Carcinoma	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14616282	NON-EXPEDITED			US-PFIZER INC-2018093510		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14616369	NON-EXPEDITED			US-PFIZER INC-2018095591		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Cellcept			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14617565	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031756			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Bupropion			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Irbesartan			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported

	Methotrexate			C	Oral	Unk				Not Reported
	Methotrexate			C	Parenteral	Unk				Not Reported
	Omeprazole			C		Unk				Not Reported
	Trazodone			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14618456	NON-EXPEDITED			US-AMGEN-USASP2018030518			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Myopathy; Rash; Sinus Disorder; Sinusitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2018	14619659	NON-EXPEDITED			US-AMGEN-USASP2018030605			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Infection; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2018	14621920	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-013071		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Exposure During Pregnancy	Prednisone		S	Unknown		Aurobindo
	Aspirine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2018	13967343	NON-EXPEDITED			US-AMGEN-USASP2017138326		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Dyspnoea; Tachycardia	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S				Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	12503511	EXPEDITED (15-DAY)		OT	CA-SA-2016SA114097		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Nausea; Retinitis; Treatment Failure	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

	Humira	S	Unknown			Not Reported
	Stelara	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown	More Than 20mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	12773750	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076755		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	13519598	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038058		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Arava		C	Unknown	Not Reported
					Codeine		C	Unknown	Not Reported
					Fentanyl		C	Unknown	Not Reported
					Gold		C	Unknown	Not Reported
					Levofloxacin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	13661878	EXPEDITED (15-DAY)		DS	CA-SA-2017SA105908		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Dizziness; Drug Ineffective; Eye Disorder; Headache; Inflammation; Joint Swelling; Ligament Sprain; Nausea; Orthosis User; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	13954117	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2078669-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Reaction; Drug Ineffective; Eye Disorder; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14373866	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-001231		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Codeine+Paracetamol			S	Oral	2 Tab, Tid Si Douleur		Aurobindo
	Fluoxetine			S	Oral	30 Mg, Od		Aurobindo
	Loxapac /00401801/			S	Oral	1 Df, Unk 50 Drop (1/12 Millilitre)		Not Reported
	Theralene			S	Oral	1 Df, Qd 50 Drop (1/12 Millilitre)		Not Reported
	Noctamide			S	Oral	1 Tab, Qd		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Dafalgan Codeine			S	Unknown	Unk, Tid ()		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Lepticur			S	Oral	2 Tab, Qd		Not Reported
	Tranxene			S	Oral	1 Df, Unk		Not Reported
	Imeth			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Speciafoldine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14529089	NON-EXPEDITED			US-PFIZER INC-2018061816		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14547144	NON-EXPEDITED			US-PFIZER INC-2018069047		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14623971	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018031380			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14624184	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031702		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Etanercept			S	Unknown	50 Mg, Qwk		Amgen
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Naprosyn			C	Unknown	500 Mg, Unk		Not Reported
	Losec			C	Unknown	20 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14624825	NON-EXPEDITED			US-PFIZER INC-2018098471			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Isoniazid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14625189	EXPEDITED (15-DAY)		OT	IE-GLENMARK PHARMACEUTICALS-2018GMK032961		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Leukopenia; Off Label Use; Skin Atrophy	Triamcinolone Acetonide			S	Unknown	Unk Unk, Unknown Freq.		Glenmark
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Tacrolimus			S	Topical	Unk Unk, Unknown Freq.		Not Reported
	Clobetasol Propionate			S	Topical	Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Oral	10 Mg, Unk		Not Reported
	Prednisolone			S	Oral	Unk, Unknown Freq. ()		Not Reported
	Fluconazole			C	Unknown	Unk, Unknown Freq. ()		Not Reported
	Co-Trimoxazole			C	Unknown	Unk, Unknown Freq. ()		Not Reported
	Efavirenz			C	Unknown	Unk, Unknown Freq.		Not Reported
	Lamivudine + Zidovudine			C	Unknown	Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14625813	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018031682			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Invasive Ductal Breast Carcinoma; Neuropathy Peripheral; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Neulasta			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627159	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031833		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Orencia			S	Unknown	250 Mg, Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Unk		Not Reported
	Methotrexate			C		25 Mg, Unk		Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627356	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2018100668		47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2018	14627691	EXPEDITED (15-DAY)		HO, LT	PHHY2018US040655		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Drug Reaction With Eosinophilia And	Hydroxychloroquine			S	Unknown	Unk		Novartis

Systemic Symptoms; Inflammation; Leukaemoid Reaction; Product Use In Unapproved Indication; Pustule; Pyrexia; Rash; Rash; Rash Erythematous; Rash Maculo-Papular; Supraventricular Tachycardia; Vasodilatation	Pilocarpine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	11228329	EXPEDITED (15-DAY)		OT	CA-SA-2015SA091041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C		Frequecy: Weekly		Not Reported
	Enbrel			C		Strength: Weekly		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	12492486	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel "Immunex"			S	Unknown	Solution Subcutaneous		Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Every 4 Week		Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Remicade			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	12911801	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091695		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Gastrointestinal Disorder; Headache; Hepatic Enzyme Increased; Joint Arthroplasty; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	13212508	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2015SA118692		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Enbrel	S	Unknown	Form- Solution Subcutaneous	Not Reported
Enbrel	S	Unknown	Form- Solution Subcutaneous	Not Reported
Humira	S	Unknown	Form- Solution Subcutaneous	Not Reported
Humira	S	Unknown	Form- Solution Subcutaneous	Not Reported
Ilaris	S	Unknown	Form- Powder For Solution Subcutaneous	Not Reported
Ilaris	S	Unknown	Form- Powder For Solution Subcutaneous	Not Reported
Ilaris	S	Unknown		Not Reported
Ilaris	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported

	Methotrexate Sodium			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	13519774	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038283		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	13661735	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA106077		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Spinal Disorder; Therapeutic Product Effect Incomplete	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	13661772	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105803		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug	Arava			S	Oral			Not Reported

Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Infection; Liver Function Test Increased; Rash; Syncope; Urticaria	Hydroxychloroquine	S	Oral			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Form:- Solution Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Form:- Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Form:- Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Form:- Solution Subcutaneous		Not Reported
	Xeljanz	C				Not Reported
	Prednisone	C	Unknown			Not Reported
	Prevacid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	13661818	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form:Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Frequency: Every 4 Weeks		Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14114384	NON-EXPEDITED			US-PFIZER INC-2017453156		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14198991	NON-EXPEDITED			US-PFIZER INC-2017491157		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14455575	EXPEDITED (15-DAY)		CA, HO, OT	PT-BAUSCH-BL-2018-001532		23 DAY	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Foetal Exposure During Pregnancy; Heart Block Congenital; Lung Infiltration; Lupus Pneumonitis; Respiratory Failure	Dexamethasone			S	Transplacental	Maternal Dose: 8 Mg/D On Week 26		Bausch And Lomb
	Prednisolone			S	Transplacental			Bausch And Lomb
	Salbutamol			S	Transplacental	Maternal Dose: 32mg/D On Week 26		Bausch And Lomb
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14496514	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007218			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cytopenia; Drug Intolerance	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1.5 G, Bid		Not Reported
	Tnf			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14629494	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038223		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Carpal Tunnel Syndrome; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hypertension; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	K20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14629694	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018031995			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Infection; Pain; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14630357	DIRECT		HO, OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dyspnoea; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Concordia
	Metro Gel			C				Not Reported
	Amytripline			C				Not Reported
	Raloxifen Hcl			C				Not Reported
	Lisinopril Hctz			C				Not Reported
	Aspirin			C				Not Reported
	Calcium W/ Vit D			C				Not Reported
	Flonase			C				Not Reported
	Zyrtec			C				Not Reported
	Vit D			C				Not Reported
	Mucinex			C				Not Reported
	Benedryl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14632806	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2018	14632989	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019941		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Pain	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous	50 Mg, Qmo			Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	13661724	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105937		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown	Form: Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	13661850	EXPEDITED (15-DAY)		HO	CA-SA-2017SA105879		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Eruption; Drug Ineffective;	Leflunomide			S	Oral			Not Reported

Fatigue; Femur Fracture; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Synovitis	Hydroxychloroquine	S	Oral			Not Reported
	Actemra	S	Unknown			Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Naproxen	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown			Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	13939557	NON-EXPEDITED			US-PFIZER INC-2017381829		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	1 Ml, Weekly		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14323895	EXPEDITED (15-DAY)		HO	PHHY2011NL128660		59 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease	Methotrexate			S	Oral	712 Mg, Qw		Novartis
	Hydroxychloroquine			S	Oral	2300 Mg, Unk		Not Reported
	Roactemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14454119	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018033993		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastroenteritis Viral; Limb Injury	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Tylenol /00020001/			S		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14511974	EXPEDITED (15-DAY)		DE, HO	DE-JNJFOC-20170202535		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pulmonary Fibrosis	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Roactemra			C	Intravenous (not otherwise specified)			Not Reported
	Mabthera			C	Unknown			Not Reported
	Mabthera			C	Unknown			Not Reported
	Mabthera			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

	Ass	C	Unknown			Not Reported
	Metoprolol Succinate	C	Unknown			Not Reported
	Ramipril	C	Unknown	5 Mg/25 Mg		Not Reported
	Prolia	C	Unknown			Not Reported
	Simvastatin	C	Unknown			Not Reported
	Omeprazole	C	Unknown			Not Reported
	Dekristol	C	Unknown			Not Reported
	Calcium Carbonate	C	Unknown			Not Reported
	Novaminsulfon	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14556685	NON-EXPEDITED			US-PFIZER INC-2018072556		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14633761	NON-EXPEDITED			US-AMGEN-USASP2018033840			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14633894	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION			Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tylenol 8 Hr			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14634433	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018033530			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	Unk Once Every Three Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14634763	NON-EXPEDITED			US-PFIZER INC-2018103359		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14634909	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qwk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1.0 G, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2018	14636596	EXPEDITED (15-DAY)		OT	CA-SA-2018SA071476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deep Vein Thrombosis; Depressed Mood; Emotional Distress; Foot Fracture; Gait Inability; Hypophagia; Loss Of Personal Independence In	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Orencia			C				Not Reported

Daily Activities; Osteoporosis; Pelvic Fracture; Quality Of Life Decreased; Rheumatoid Arthritis; Spinal Fracture; Therapeutic Product Effect Decreased	Otezla		C			Not Reported
	Dilaudid		C			Not Reported
	Vioxx		C			Not Reported
	Methotrexate		C	Unknown		Not Reported
	Warfarin		C	Unknown		Not Reported
	Prednisone		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	13661898	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105925		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Hypoaesthesia; Pharyngeal Oedema; Rash	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form: Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	13939313	NON-EXPEDITED		OT	US-AMGEN-USASP2017133933		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Bypass; Drug Intolerance; Injection Site Reaction	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Subcutaneous	50 Mg/2ml Solution 1ml, Qwk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14638770	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-000431		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Nephritis; Pulmonary Haemorrhage; Retinitis	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14638876	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000942		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14638909	NON-EXPEDITED			US-AMGEN-USASP2018034353			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastrointestinal Disorder	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14639196	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Penicillin G Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Silver			S	Oral			Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14642115	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018104391		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dizziness; Invasive Ductal Breast Carcinoma; Neuropathy Peripheral; Rheumatoid Arthritis	Enbrel			S		50 Mg, Qwk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Neulasta			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14642402	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP007290			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium			S		Df		Depomed
	Arava			S		Df		Not Reported
	Aspirin /00002701/			S		Df		Not Reported
	Enbrel			S	Subcutaneous	Df		Not Reported
	Gold			S		Df		Not Reported
	Humira			S	Subcutaneous	Df		Not Reported
	Methotrexate			S		Df		Not Reported
	Motrin			S		Df		Not Reported
	Naprosyn /00256201/			S		Df		Not Reported
	Plaquenil /00072602/			S		Df		Not Reported
	Tramadol			C		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14642445	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP007291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium			S		Df		Depomed
	Arava			S		Df		Not Reported
	Aspirin /00002701/			S		Df		Not Reported
	Enbrel			S	Subcutaneous	Df		Not Reported
	Humira			S	Subcutaneous	Df		Not Reported
	Hydroxychloroquine			S		Df		Not Reported
	Methotrexate			S		Df		Not Reported
	Motrin			S		Df		Not Reported
	Naprosyn /00256201/			S		Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14643337	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017523760		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ear Pain; Facial Paralysis; Insomnia; Nasopharyngitis; Pain In Jaw	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Cortisone			C		Unk		Not Reported
	Celebrex			C		Unk Unk, As Needed		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2018	14643804	NON-EXPEDITED		HO	US-TEVA-2018-US-869753		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	12936332	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP012750		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Decreased Appetite; Dizziness; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight	Diclofenac Potassium			S		Unk		Depomed
	Arava			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported

Decreased	Gold			S					Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Methotrexate Sodium			S		Unk			Not Reported
	Naprosyn			S		Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Plaquenil			S					Not Reported
	Plaquenil			S					Not Reported
	Plaquenil			S					Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk			Not Reported
	Tramadol Hydrochloride			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	12939752	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP012755		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium			S		Unk		Depomed
	Arava			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfamethoxazole And Trimethoprim			S		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	12939755	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP012754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium			S		Unk		Depomed
	Acetylsalicylic Acid			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Naprosyn			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	12939779	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP012749			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium			S		Unk		Depomed
	Diclofenac Potassium			S				Depomed
	Diclofenac Potassium			S				Depomed
	Diclofenac Potassium			S				Depomed
	Arava			S		Unk		Not Reported
	Aspirin /00002701/			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Naprosyn /00256201/			S		Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported

	Plaquenil /00072603/	S				Not Reported
	Plaquenil /00072603/	S				Not Reported
	Plaquenil /00072603/	S				Not Reported
	Tramadol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	12942619	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2016DEP012758			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium			S	Unknown	Unk		Depomed
	Acetylsalicylic Acid			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	13156439	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2017DEP000236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium			S		Unk		Depomed
	Acetylsalicylic Acid			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unk	Not Reported
	Methotrexate	S	Unk	Not Reported
	Motrin	S	Unk	Not Reported
	Naprosyn /00256201/	S	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	13162565	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2017DEP000259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium			S	Unknown	Unk		Depomed
	Arava			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Vitamin C Acid			S	Unknown	Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14144130	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-097833			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label	Orencia			S	Unknown			Bristol Myers Squibb

Use	Humira		S	Unknown				Not Reported
	Arava		S	Unknown	Unk			Not Reported
	Plaquenil /00072602/		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14601809	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0624		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hodgkin'S Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14636571	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017475498		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Drug Ineffective; Hepatic Enzyme Increased	Methotrexate Sodium			S		25 Mg, Per Week		Pfizer
	Sulfasalazine			S		500 Mg, Twice Daily		Pfizer
	Plaquenil /00072603/			S		400 Mg, 1x/Day		Not Reported
	Arava			S		10 Mg, Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14646335	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000955		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14646706	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14647004	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000962		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Dizziness; Myalgia; Pyrexia; Rhabdomyolysis	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Predonine			C				Not Reported
	Prednisolone			C				Not Reported
	Alfarol			C				Not Reported
	Feburic			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14650191	NON-EXPEDITED			US-TEVA-2018-US-862038		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Depressed Mood; Drug Ineffective; Feeling	Bupropion			S				Teva
	Bupropion			S				Teva

Abnormal; Irritability; Nervousness	Hydroxychloroquine		S	Unknown	Teva
	Escitalopram		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14651331	DIRECT	Y					Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Hydroxychloriquine 200mg Generic			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2018	14651444	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010605			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Jaw; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Nexium			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14246291	EXPEDITED (15-DAY)		OT	GB-ROCHE-2032429		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Danazol	C	Unknown	Not Reported
Danazol	C	Unknown	Not Reported
Dapsone	C	Unknown	Not Reported
Dapsone	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Lisinopril	C	Unknown	Not Reported
Lisinopril	C	Unknown	Not Reported
Bendroflumethiazide	C	Unknown	Not Reported
Bendroflumethiazide	C	Unknown	Not Reported
Vincristine	C	Unknown	Not Reported
Vincristine	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Cyclophosphamide	C	Unknown	Not Reported
Cyclophosphamide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14515720	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000524			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity; Pain In Extremity; Rheumatoid	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Synthroid			S	Oral			Not Reported

Arthritis; Unevaluable Event	Methotrexate	S	Oral		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14630795	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000939			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Rash Macular	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651896	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000979		39 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651898	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000961		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Headache; Tremor; Vasospasm	Plaquenil			S	Oral			Not Reported
	Endoxan			C				Not Reported
	Neoral			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651902	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000958		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Retinitis	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651903	EXPEDITED (15-DAY)		LT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000972		73 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Ulceration; Mouth Ulceration; Rash Papular; Stevens-Johnson Syndrome	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2018	14651905	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000980		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Lupus Enteritis; Nausea; Off Label Use; Product Use Issue; Rebound Effect; Vomiting; Weight Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14580790	NON-EXPEDITED			US-AMGEN-USASP2018026687			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Intolerance; Malaise; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported

	Humira			S	Unknown	40 Mg, Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14581874	EXPEDITED (15-DAY)		HO, OT	RO-SA-2018SA051602		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Intentional Product Misuse; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Diclofenac Salt Not Specified			S	Unknown			Not Reported
	Diclofenac Salt Not Specified			S	Unknown			Not Reported
	Clopidogrel Bisulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14628704	NON-EXPEDITED			US-AMGEN-USASP2018032572			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Hypersensitivity; Fatigue; Nausea; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported

	Codeine			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Vioxx			S	Unknown	Unk			Not Reported
	Celebrex			S	Unknown	Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14634055	NON-EXPEDITED			US-AMGEN-USASP2018033627			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14652962	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1664		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Malaise; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14652965	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-4091		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ear Pain; Facial Paralysis; Insomnia; Nasopharyngitis; Pain In Jaw	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14653033	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0814		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Losec			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14653492	EXPEDITED (15-DAY)		OT	IE-VELOXIS PHARMACEUTICALS-2044048		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Intentional Product Use Issue; Leukopenia; Skin Atrophy	Envarsus Xr			S				Veloxis Pharmaceuticals
	Hydroxychloroquine			S				Not Reported
	Fluconazole			C				Not Reported
	Efavirenz			C				Not Reported
	Triamcinolone			S				Not Reported
	Prednisolone			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Clobetasol Propionate			S				Not Reported
	Co-Trimoxazole			C				Not Reported
	Lamivudine + Zidovudine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14653912	NON-EXPEDITED			US-PFIZER INC-2018110395		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2018	14655051	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1016336			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Haemolysis	Hydroxychloroquine			S	Unknown	Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	12416161	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016276097		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Product Use In Unapproved Indication	Imeth			S	Oral	20 Mg, Weekly		Pfizer
	Fluoxetine Hydrochloride			S	Oral	30 Mg (1.5 Dosage Form), Daily (In Morning)		Not Reported
	Loxapac /00401801/			S	Oral	50 Drops 5 Times Daily,		Not Reported
	Theralene			S	Oral	50 Gtt, Daily (At Bedtime)		Not Reported
	Tranxene			S	Oral	1 Df, 4x/Day		Not Reported
	Noctamide			S	Oral	1 Df, Daily (Evening)		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Lepticur			S	Oral	2 Df, Daily (Morning)		Not Reported
	Dafalgan Codeine			S	Oral	2 Df, 3x/Day (Morning, Midday And Evening)		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Daily (200 Mg,2 In 1 D)		Not Reported
	Speciafoldine			C	Oral	4 Df, Weekly (On Wednesdays)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14333068	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2017544014		53 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain Upper; Acute Kidney Injury; Acute Kidney Injury; Blood Creatinine Increased; Chills; Constipation; Decreased Appetite; Drug Ineffective; Drug Specific Antibody; Gastrointestinal Disorder; Glucose Tolerance Impaired; Hypercalcaemia; Infection;	Xeljanz			S		1 Df, 2x/Day		Pfizer
	Simponi			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Spiricort			C				Not Reported
	Buscopan			C				Not Reported
	Pantoprazol			C				Not Reported
	Lodotra			C		1 Mg/Dl, Unk		Not Reported

Interstitial Lung Disease; Lacrimation Increased; Liver Disorder; Malaise; Nausea; Peripheral Venous Disease; Proteinuria; Pyrexia; Sinusitis; Sjogren'S Syndrome; Sleep Apnoea Syndrome; Spinal Pain; Supraventricular Tachycardia; Tendonitis; Therapeutic Product Effect Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14589081	NON-EXPEDITED			US-AMGEN-USASP2018027376			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14618809	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2018094462			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Azulfidine			S		Unk		Pfizer

	Methotrexate Sodium	S	Unk		Pfizer
	Enbrel	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported
	Humira	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Prednisone	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14630027	NON-EXPEDITED			US-PFIZER INC-2018097237		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14657368	NON-EXPEDITED			US-AMGEN-USASP2018036144			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mtx			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14657606	EXPEDITED (15-DAY)		OT	PHHY2018TR043893			Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14657628	NON-EXPEDITED			US-AMGEN-USASP2018037058			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14658442	NON-EXPEDITED			US-PFIZER INC-2018110377		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14658479	NON-EXPEDITED			US-PFIZER INC-2018112311		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14658548	NON-EXPEDITED			US-PFIZER INC-2018114863		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14658825	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000982			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14659770	EXPEDITED (15-DAY)		DE, HO, OT	AU-MYLANLABS-2018M1016721		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Thrombotic Thrombocytopenic Purpura	Hydroxychloroquine			S	Oral	200 Mg Daily		Not Reported
	Paracetamol			C	Unknown	Unk		Mylan
	Prednisolone			C	Unknown	Unk		Mylan
	Folic Acid			C	Unknown	Unk		Mylan

	Calcium	C	Unknown	Unk		Mylan
	Vitamin D /00107901/	C	Unknown	Unk		Mylan
	Aspirin /00002701/	C	Unknown	Unk		Mylan
	Metoprolol	C	Unknown	Unk		Mylan
	Medroxyprogesterone	C	Unknown	Unk		Mylan
	Oestradiol Valerate	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14665170	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panic Attack; Paraesthesia; Tinnitus	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2018	14666346	DIRECT		DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Enbrel			S	Subcutaneous	25mg/0.5ml Twice Weekly Subcutaneously		Amgen
	Alprazolam			C				Not Reported
	Gabapentin			C				Not Reported
	Scopolamine			C				Not Reported
	Synthroid			C				Not Reported
	Omeprazole			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13433315	EXPEDITED (15-DAY)		HO	IT-JNJFOC-20170411080		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer Stage Ii	Simponi			S	Subcutaneous			Not Reported

	Metotrexate			S	Oral				Not Reported
	Plaquenil			S	Oral				Not Reported
	Alendronate Sodium			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13676528	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003683		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13676529	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003709		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Eruption; Drug Ineffective; Fatigue; Femur Fracture; Loose Body In Joint;	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Osteoporosis; Osteoporotic Fracture; Pain; Rash; Synovitis	Adalimumab		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Naproxen		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S	Unknown	Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13677167	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003654		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Citalopram			C				Not Reported
	Folic Acid			C				Not Reported
	Losec			C				Not Reported
	Naprosyn			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13677168	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003714		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Joint Swelling;	Hydroxychloroquine			S	Oral	Daily		Concordia
	Arava			S	Oral			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous		Not Reported
	Methotrexate Sodium			S	Oral		Not Reported
	Prednisone			S	Oral		Not Reported
	Prednisone			S			Not Reported
	Simponi			S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13687629	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003752		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Spinal Disorder; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13692177	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003722		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Infection; Liver Function Test Increased; Rash; Syncope; Urticaria	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

					Remicade	S	Intravenous (not otherwise specified)		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Simponi	S	Subcutaneous		Not Reported
					Xeljanz	C			Not Reported
					Prednisone	C			Not Reported
					Prevacid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13692288	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003744		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Hypoaesthesia; Pharyngeal Oedema; Rash	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	Twice A Day		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	13692482	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003777		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported

Decreased	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Leflunomide	C			Not Reported
	Methotrexate	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14092931	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005820		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Macular; Rash Macular; Rash Pustular	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Alprazolam			C				Not Reported
	Paroxetine			C				Not Reported
	Repaglinide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14568220	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA023463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Localised Infection; Skin Discolouration; Skin Exfoliation; Soft Tissue Necrosis	Hydroxychloroquine			S	Oral	Dose And Frequency: 200/400mg		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14569444	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000648			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis	Hydroxychloroquine Tablet			S	Oral			Concordia
	Metex (Methotrexate Sodium)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14610798	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000911		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinal Injury; Retinopathy; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662035	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000983		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662037	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Plaquenil Tablet			S	Oral	Not Reported
	Arava			S	Oral	Not Reported
	Enbrel "Immunex"			S		Not Reported
	Humira			S		Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Remicade			S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662038	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000986		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Toxic Skin Eruption	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Colchicine			S	Oral			Not Reported
	Esidrex			C				Not Reported
	Loxen Lp			C				Not Reported
	Simvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14662788	EXPEDITED (15-DAY)		DE, OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-121489		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia	Abatacept			S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not	1000 Mg, Unk		Not Reported

					otherwise specified)				
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk			Not Reported
	Tocilizumab			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14663546	NON-EXPEDITED			US-PFIZER INC-2018116585		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Lortab			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14663556	NON-EXPEDITED			US-PFIZER INC-2018118350		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Azulfidine			S		Unk		Pfizer
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14663677	NON-EXPEDITED			US-PFIZER INC-2018114416			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil				S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14664319	NON-EXPEDITED			US-AMGEN-USASP2018037966			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14665407	NON-EXPEDITED			US-AMGEN-USASP2018037904			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stomatitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk, Injection		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14665569	EXPEDITED (15-DAY)		OT	PHHY2018GB039041			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14666279	EXPEDITED (15-DAY)		OT	PHHY2018GB039033			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Haemolysis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2018	14666547	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010522			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	13968432	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Eye Disorder; Musculoskeletal Stiffness; Peripheral Swelling; Pruritus; Rheumatoid Arthritis	Plaquenil		S	Oral	Concordia
	Hydroxychloroquine		S	Unknown	Concordia
	Sulfasalazine		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14564064	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018072109		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Localised Infection; Skin Discolouration; Skin Exfoliation; Skin Necrosis	Sulfasalazine			S	Oral	1500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine /00072603/			S		Unk, 200/400mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14585621	NON-EXPEDITED			US-PFIZER INC-2018083643		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14666678	EXPEDITED (15-DAY)		DE	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000998		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Urethral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14666798	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000996		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Limb; Muscle Disorder; Muscle Rupture; Musculoskeletal Disorder; Nodule; Pain In Extremity; Soft Tissue Infection; Synovitis	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667254	NON-EXPEDITED			US-AMGEN-USASP2018037537		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Intolerance; Injection Site	Enbrel			S	Unknown	Unk		Amgen

Reaction; Pain; Rash; Sinusitis; Vertigo	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667287	EXPEDITED (15-DAY)		DE	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00010620		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Subsequently Next Infusion Was Administered On /Sep/2012 And /Mar/2013.		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667490	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000852			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Concordia
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667620	NON-EXPEDITED			US-PFIZER INC-2018112229		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14667792	NON-EXPEDITED			US-PFIZER INC-2018118632		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14668952	EXPEDITED (15-DAY)		HO	US-JNJFOC-20180319142			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Abscess; Bacteraemia; Bacterial Infection; Cholecystitis Infective; Device Related Infection; Gastroenteritis; Necrotising Fasciitis; Off Label Use; Pneumonia; Product Use In Unapproved Indication; Pyelonephritis; Sepsis; Upper Respiratory Tract Infection; Urinary Tract Infection	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2018	14671276	EXPEDITED (15-DAY)		OT	PHHY2018AU039481		64 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Chills; Confusional State; Muscular Weakness; Pain; Pyrexia; Thrombocytopenic Purpura; Urine Output Decreased; Vomiting	Hydroxychloroquine			S	Oral	200 Mg, Qd		Novartis
	Paracetamol			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Medroxyprogesterone			C	Unknown			Not Reported
	Oestradiol Valerate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	13952127	NON-EXPEDITED			US-AMGEN-USASP2017136017		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hand Deformity; Therapeutic Product Effect Incomplete; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14287967	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-110516		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Furuncle; Herpes Zoster; Immunosuppression;	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported

Macular Degeneration; Pyrexia; Urinary Tract Infection	Xeljanz Xr	S	Unknown	11 Mg, Qd		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Medrol /00049601/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14422116	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000320			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Cataract; Contusion; Fall; Malaise	Plaquenil			S	Unknown			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14672557	NON-EXPEDITED			US-PFIZER INC-2018118590		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Prednisone			S		Unk		Not Reported
	Celestone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14672573	NON-EXPEDITED			US-PFIZER INC-2018118600		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14672598	NON-EXPEDITED			US-PFIZER INC-2018120696		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14673637	EXPEDITED (15-DAY)		OT	CA-BAXTER-2018BAX009183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Cellcept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14675814	EXPEDITED (15-DAY)		DE	PHHY2018US050605		74 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia; Product Use In Unapproved Indication	Prednisone			S	Unknown	60 Mg, Qd		Novartis
	Prednisone			S				Novartis
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14676511	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000953		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fall; Fatigue; Joint Swelling; Loss Of Consciousness; Musculoskeletal Pain; Weight Decreased	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14676513	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001014			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deep Vein Thrombosis; Depressed Mood; Emotional Distress; Foot Fracture; Gait Inability; Hypophagia; Loss Of Personal Independence In Daily Activities; Osteoporosis; Pelvic Fracture; Quality Of Life Decreased; Rheumatoid Arthritis; Spinal Fracture; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Otezla			C				Not Reported
	Dilaudid			C				Not Reported
	Vioxx			C				Not Reported
	Methotrexate			C				Not Reported
	Warfarin			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2018	13566517	EXPEDITED (15-DAY)		DE, HO, LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002964		63 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspiration; Bacterial Infection; Cytomegalovirus Infection; Nausea; Renal Impairment	Plaquenil			S	Oral			Concordia
	Imuran			C				Not Reported
	Prednisolone			C				Not Reported
	Fosrenol			C				Not Reported
	Furosemide			C				Not Reported
	Azosemide			C				Not Reported
	Sol-Melcort			C				Not Reported
	Lasix			C				Not Reported
	Mircera			C				Not Reported
	Predonine			C				Not Reported
	Lansoprazole			C				Not Reported
	Micardis			C				Not Reported
	Alfacalcidol			C				Not Reported
	Atorvastatin			C				Not Reported
	Benidipine			C				Not Reported
	Takecab			C				Not Reported
	Forteo			C				Not Reported
	Samtirel			C				Not Reported
	Warfarin			C				Not Reported
	Heparin Sodium			C				Not Reported
	Omeprazole			C				Not Reported
	Mosapride Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2018	14483978	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018014659			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Humira			S	Unknown	40 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2018	14524219	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000566		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cystitis Viral; Retinal Exudates; Vomiting	Plaquenil			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Cellcept			C				Not Reported
	Prograf			C				Not Reported
	Neoral			C				Not Reported
	Venoglobulin			C				Not Reported
	Januvia			C				Not Reported
	Surepost			C				Not Reported
	Zetia			C				Not Reported
	Crestor			C				Not Reported
	Lipitor			C				Not Reported
	Actonel			C				Not Reported
	Lotriga			C				Not Reported
	Micardis			C				Not Reported
	Diart			C				Not Reported
	Pariet			C				Not Reported
	Takecab			C				Not Reported
	Baktar			C				Not Reported
	Valixa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2018	14676549	NON-EXPEDITED			US-AMGEN-USASP2018039119			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Injection)		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14626101	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2105219-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous	Two Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14652522	NON-EXPEDITED			US-AMGEN-USASP2018036151			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14678395	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018040237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Advil			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Synthroid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14678616	NON-EXPEDITED			PHEH2018US011349		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cosentyx			S	Unknown			Not Reported
	Methotrexate Sandoz			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14679973	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1019511		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Mycobacterial Infection; Osteomyelitis	Prednisone			S	Oral	50 Mg/Day Dose Administered Initially Which Was Later Tapered		Not Reported

Hydroxychloroquine	S	Oral	To 5 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14680536	EXPEDITED (15-DAY)		OT	US-SA-2018SA075035		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Cystitis; Diarrhoea; Drug Intolerance; Insomnia; Osteopenia; Rash; Rheumatoid Arthritis; Stomatitis; Swelling; Visual Impairment	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Acthar			C	Unknown			Not Reported
	Latanoprost			C	Unknown			Not Reported
	Prednison			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14681591	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018006355		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Naproxen /00256202/			C		500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14682212	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1017484			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Prednisone			S	Transplacental	25 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	7.5 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2018	14686266	DIRECT		OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Disorder; Condition Aggravated; Drug Ineffective; Joint Swelling; Pain; Product Complaint; Product Substitution Issue; Seizure	Hydroxychloroquine 200mg Tab			S	Oral	Quantity:30 Tablet(S);		Sandoz
	Tylenol/Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14394458	EXPEDITED (15-DAY)		OT	CA-SA-2018SA010377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Form:Solution Subcutaneous		Not Reported

	Enbrel	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Form:Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Form:Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Form:Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14509798	NON-EXPEDITED			US-PFIZER INC-2018045863			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Leflunomide			S		10 Mg, 1x/Day		Not Reported
	Humira			S		40 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Xeljanz Xr			C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14517300	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000530		28 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Iridocyclitis; Vogt-Koyanagi-Harada Disease	Plaquenil Tablet	S	Oral		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14625117	NON-EXPEDITED			US-AMGEN-USASP2018031928			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hepatic Enzyme Increased; Injection Site Reaction; Rash	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14635115	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-004340			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Pelvic Pain; Pre-Existing Condition Improved; Systemic Lupus Erythematosus; Therapeutic Response Unexpected	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3.75 G, Bid		Jazz
	Hydroxychloroquine			S		Unknown Dose		Not Reported
	Albuterol Sulfate			C		Unk		Not Reported
	Acetaminophen W/Codeine			C		Unk		Not Reported
	Medrol Specific			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Claritin-D			C		Unk		Not Reported
	Veramyst			C		Unk		Not Reported
	Ibuprofen			C				Not Reported

	Omeprazole			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14682648	EXPEDITED (15-DAY)		HO	CA-ROCHE-2089239		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	2 Years		Not Reported
	Certolizumab Pegol			S	Subcutaneous	15 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous	1 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	2 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous	2 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	2 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Benadryl (Canada)			C				Not Reported
	Methotrexate			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14682761	NON-EXPEDITED			US-AMGEN-USASP2018040926			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683231	EXPEDITED (15-DAY)		OT	BE-ALKEM LABORATORIES LIMITED-IT-ALKEM-2018-01562		26 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome; Ocular Vasculitis; Proteinuria	Mycophenolate Mofetil			S	Unknown	500 Mg, 2 By 1 Co At W1, Up To 3 By 2 Co/Day At W3		Alkem
	Mycophenolate Mofetil			S	Unknown	500 Mg, Tid		Alkem
	Tacrolimus			S	Unknown	3 Mg More Than Or Equal To Therapeutic Drug Monitoring		Not Reported
	Tacrolimus			S	Unknown	6 Mg More Than Or Equal To Tdm		Not Reported
	Tacrolimus			S	Unknown	6 Mg, Unk		Not Reported
	Tacrolimus			S	Unknown	5 Mg, Unk		Not Reported
	Tacrolimus			S	Unknown	5.5 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg, Qd		Not Reported
	Prednisolone			S	Unknown	2-3 Mg/Day		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683492	NON-EXPEDITED			US-AMGEN-USASP2018039857			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14684056	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018GSK050584			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Depression	Benlysta Powder For Infusion			S	Intravenous (not otherwise specified)	10 Mg/Kg, Cyc		Glaxosmithkline
	Hydroxychloroquine			S				Not Reported
	Prednisone			S		30 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685202	EXPEDITED (15-DAY)		OT	CA-ROCHE-2094881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685374	EXPEDITED (15-DAY)		OT	CA-ROCHE-2094886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685388	EXPEDITED (15-DAY)		OT	AU-SA-2018SA082998		57 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Treatment Noncompliance	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Frequency: Once Every Four Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685503	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1019812		74 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685607	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1019824		43 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14685698	EXPEDITED (15-DAY)		OT	AU-SA-2018SA083343			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ranitidine			S	Unknown			Not Reported
	Montelukast			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14686999	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000992		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Recurrence; Pneumonia	Plaquenil Tablet	S	Oral		Not Reported
	Plaquenil Tablet	S	Oral		Not Reported
	Plaquenil Tablet	S	Oral		Not Reported
	Xeljanz 5mg	S	Oral	5mg Tablets-1 Tablet Taken By Mouth In The Morning, 1 Tablet Taken By Mouth At Night	Not Reported
	Xeljanz 5mg	S	Oral	5mg Tablets-1 Tablet Taken By Mouth In The Morning, 1 Tablet Taken By Mouth At Night	Not Reported
	Xeljanz 5mg	S	Oral	5mg Tablets-1 Tablet Taken By Mouth In The Morning, 1 Tablet Taken By Mouth At Night	Not Reported
	Methotrexate	S		Lcc Shot Into Her Stomach Once A Week	Not Reported
	Methotrexate	S		Lcc Shot Into Her Stomach Once A Week	Not Reported
	Methotrexate	S		Lcc Shot Into Her Stomach Once A Week	Not Reported
	Coreg	C	Oral	Maybe 100mg	Not Reported
	Hyzaar	C	Oral	Little Football Looking Pill Once By Mouth A Day	Not Reported
	Nexium	C	Oral	40mg Capsules Taken By Mouth 1-2 Times A Day Been Taking Once A Day For 40 Some Years, Since Her 20	Not Reported
	Folic Acid	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14689557	DIRECT		DS, OT			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Vertigo	Hydroxychloroquine	S	Oral		Not Reported
	Armour Thyroid	C			Not Reported
	Symbicort	C			Not Reported
	Olopatanase (Nasal Spray)	C			Not Reported
	Omeprezole	C			Not Reported
	Zyrtec-D	C			Not Reported
	Ibuprofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	13938800	NON-EXPEDITED			US-AMGEN-USASP2017134655		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Neurological Symptom	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Cosentyx			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	13988251	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166768		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Osteoarthritis; Pneumonia; Pruritus; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14147622	NON-EXPEDITED			US-BRISTOL-MYERS		67 YR	Male	USA

SQUIBB COMPANY-
BMS-2017-098396

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Headache; Nausea; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14372638	NON-EXPEDITED			US-AMGEN-USASP2018002382			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14475173	EXPEDITED (15-DAY)		OT	IE-ASTELLAS-2018US005582		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Leukopenia; Off Label Use; Skin Atrophy	Tacrolimus			S	Topical	Unk Unk, Unknown Freq.		Astellas
	Clobetasol Propionate			S	Topical	Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Oral	Unk, Unknown Freq.		Not Reported
	Triamcinolone			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Oral			Not Reported

		Fluconazole			C	Unknown	Unk, Unknown Freq.			Not Reported
		Co-Trimoxazole			C	Unknown	Unk, Unknown Freq.			Not Reported
		Efavirenz			C	Unknown	Unk, Unknown Freq.			Not Reported
		Lamivudine + Zidovudine			C	Unknown	Unk, Unknown Freq.			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14687502	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001047			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Rash Maculo-Papular; Toxic Skin Eruption	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688113	NON-EXPEDITED			US-PFIZER INC-2018126744		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688176	NON-EXPEDITED			US-PFIZER INC-2018126664		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688435	EXPEDITED (15-DAY)		HO, OT	DE-HORIZON-PRE-0130-2018		63 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenocarcinoma Of Colon	Azathioprine Tablet			S		100 Mg		Not Reported
	Azathioprine Tablet			S		100 Mg		Not Reported
	Azathioprine Tablet			S		Unk		Not Reported
	Azathioprine Tablet			S		200 Mg		Not Reported
	Azathioprine Tablets			S		150 Mg		Not Reported
	Azathioprine Tablet			S		150 Mg		Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Azathioprine Tablet			S		50 Mg		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Azathioprine Tablet			S		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14688647	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015375478		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Condition Aggravated; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	3000 Mg, Unk		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic (Every 2 Weeks)		Not Reported
	Cimzia			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2018	14689210	EXPEDITED (15-DAY)		OT	AU-SA-2018SA083294		30 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Deep Vein Thrombosis; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Histiocytic Necrotising Lymphadenitis; Lymphadenopathy; Placental Infarction; Placental Necrosis; Treatment Failure	Enoxaparin Sodium			S	Unknown			Not Reported
	Enoxaparin Sodium			S	Unknown	Dose Was Increased		Not Reported
	Enoxaparin Sodium			S	Unknown	Dose Was Increased		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Dose Was Weaned By 10 Mg Every Fortnightly To 20 Mg		Not Reported
	Prednisolone			S	Unknown	Dose Was Weaned By 10 Mg Every Fortnightly To 20 Mg		Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Immunoglobulin Human Normal			S	Unknown	1g/Kg		Not Reported
	Immunoglobulin Human Normal			S	Unknown	Dose Was Increased		Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14408891	NON-EXPEDITED			US-AMGEN-USASP2018006577			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk (30 For 30 Days)		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd (28 Tablets For 28 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14502196	NON-EXPEDITED			US-AMGEN-USASP2018016323			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	400 Mg, Qwk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	100 Mg, Bid		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14601836	EXPEDITED (15-DAY)		HO, OT	RO-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000746		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Intentional Product Misuse; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Diclofenac Salt Not Specified			S	Unknown			Not Reported
	Diclofenac Salt Not Specified			S				Not Reported

	Clopidogrel Bisulfate			S	Unknown					Not Reported
	Aspirin			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692301	NON-EXPEDITED			US-AMGEN-USASP2018041856			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692686	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018042122			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Consciousness; Pruritus	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Rituxan			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692743	EXPEDITED (15-DAY)		HO	ES-MEDAC PHARMA, INC.-2044744		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small Cell Lung Cancer	Metoject			S	Subcutaneous			Medac

	Prednisone	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S		Not Reported
	Simvastatin	C		Not Reported
	Risperidone	C		Not Reported
	Acetaminophen	C	Oral	Not Reported
	Tramadol	C	Oral	Not Reported
	Fosavance	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14692880	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2018-IN-000546		60 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restrictive Cardiomyopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14694376	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001059		71 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis Acute	Plaquenil			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14694638	EXPEDITED (15-DAY)		OT	PHHY2018CZ048590		35 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Abnormal; Cushingoid; Myopathy;	Prednisone			S	Unknown	120 Mg, Qd		Novartis

Osteoporosis; Spinal Cord Compression; Weight Increased	Prednisone		S	Unknown	10 Mg, Unk		Novartis
	Solumedrol		S	Unknown	Unk		Not Reported
	Solumedrol		S				Not Reported
	Imuran		S	Unknown	Unk		Not Reported
	Imuran		S				Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Plaquenil		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14695398	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-874853		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2018	14695923	EXPEDITED (15-DAY)		OT	US-SA-2018SA039653		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaphylactic Reaction; Anxiety Disorder; Appetite Disorder; Arthralgia; Arthritis; Atrophic Vulvovaginitis; Back Pain; Carotid Artery Disease; Carotid Artery Occlusion; Chronic Kidney Disease; Clostridium Difficile Infection; Clostridium Difficile Infection; Cognitive Disorder; Cough; Deafness; Depression; Diabetes Mellitus; Diabetic Ketoacidosis; Diabetic	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Buspar			C	Unknown			Not Reported
	Neostigmine Bromide			C				Not Reported

Neuropathy; Dizziness; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dry Eye; Dysphagia; Essential Hypertension; Extrapyramidal Disorder; Fall; Fatigue; Fibromyalgia; Gait Disturbance; Haemorrhagic Disorder; Hepatic Enzyme Increased; Hyperlipidaemia; Hypersensitivity Vasculitis; Hypoaesthesia; Impaired Gastric Emptying; Infection; Iron Deficiency Anaemia; Joint Arthroplasty; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Myalgia; Myopia; Nasal Congestion; Nausea; Neck Pain; Orthostatic Hypotension; Osteoarthritis; Osteopenia; Pain; Palpitations; Paraesthesia; Presbyopia; Purpura Non-Thrombocytopenic; Pyrexia; Radiculopathy; Rash; Restless Legs Syndrome; Retinal Degeneration; Rotator Cuff Syndrome; Spinal Osteoarthritis; Spinal Osteoarthritis; Spinal Osteoarthritis; Stomatitis;	Tresiba	C	Unknown		Not Reported
	Pseudoephedrine	C			Not Reported
	Lyrica	C			Not Reported
	Reglan	C			Not Reported
	Robinul	C			Not Reported
	Claritin	C	Unknown		Not Reported
	Neurontin	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Bentyl	C	Unknown		Not Reported
	Benadryl	C			Not Reported
	Desyrel	C	Unknown		Not Reported
	Novolog	C	Unknown		Not Reported
	Seroquel	C	Unknown		Not Reported
	Lexapro	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Aquaphor	C	Unknown		Not Reported
	Florastor	C	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Zantac	C			Not Reported
	Aspirin	C			Not Reported
	Calcium Carbonate	C			Not Reported
	Prilosec	C			Not Reported
	Vitamin D3	C			Not Reported
	Glucagen	C			Not Reported
	Pravachol	C			Not Reported
	Lopressor	C			Not Reported
	Colchicine	C			Not Reported
	Tucks	C			Not Reported
	Melatonin	C			Not Reported
	Anusol	C	Unknown	1-12.5	Not Reported
	Cefaclor	C			Not Reported
	Xeljanz	C			Not Reported

Stomatitis; Syncope; Synovitis; Systemic Lupus Erythematosus; Toothache; Urinary Hesitation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	13121184	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006087		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Amnesia; Arthralgia; C-Reactive Protein Increased; Disease Progression; Drug Dependence; Drug Ineffective; Dyspnoea; Fall; Hand Dermatitis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Loss Of Consciousness; Nausea; Palpitations; Product Dose Omission; Rheumatoid Arthritis; Stress; Upper Respiratory Tract Infection; Vomiting	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	Solution For Injection In Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cannabidiol			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14242412	NON-EXPEDITED			US-PFIZER INC-2017514660		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14309157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051037		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Olopatadine Hydrochloride			C				Not Reported
	Mavik			C				Not Reported
	Lyrica			C				Not Reported
	Amlodipine Besilate			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Esomeprazole Magnesium			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nexium			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14371188	NON-EXPEDITED			US-PFIZER INC-2018009768		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14596495	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000726			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Localised Infection; Skin Discolouration; Skin Exfoliation; Soft Tissue Necrosis	Hydroxychloroquine			S	Oral	200/400mg		Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14696365	NON-EXPEDITED			US-AMGEN-USASP2018041872			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Inflammatory Marker Increased; Mouth Ulceration; Rash	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698013	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2018012811		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Cimzia			S	Subcutaneous	Unk		Ucb
	Celebrex			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Neoral			S		Unk		Not Reported

		Plaquenil			S		Unk			Not Reported
		Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698023	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2018012676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Pain; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Ucb
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk, Once Daily (Qd)		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698167	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012698		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Cimzia			S		Unk		Ucb
	Actemra			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698301	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001000			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Not Reported

	Rocephin			S	Unknown					Not Reported
	Nimesulide			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698335	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001004			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity	Plaquenil			S				Not Reported
	Erythro			S				Not Reported
	Morphine			S				Not Reported
	Biaxin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698336	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001067			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sepsis	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698338	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001080			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancreatitis	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698349	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001006			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Lyme Disease; Myocardial Infarction; Nervous System Disorder	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698729	NON-EXPEDITED			US-PFIZER INC-2018125733		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nodule	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698840	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001024			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Not Reported
	Iodine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699153	NON-EXPEDITED			US-PFIZER INC-2018128381		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699155	NON-EXPEDITED			US-PFIZER INC-2018128453		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14700472	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001085		61 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microvascular Cranial Nerve Palsy; Sinusitis Fungal; Synovitis	Plaquenil			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2018	14193391	NON-EXPEDITED			US-AMGEN-USASP2017171397		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Injectable)		Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported
	Celebrex			C		200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2018	14702358	EXPEDITED (15-DAY)		OT	PHHY2018US050590		43 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pneumocystis Jirovecii Pneumonia	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Hydroxychloroquine			S				Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2018	14702366	EXPEDITED (15-DAY)		OT	PHHY2018TR051867		55 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Vomiting	Methotrexate			S	Unknown	15 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Prednisolone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2018	14702374	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA055440			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	13267953	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017007042			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Cimzia			S	Subcutaneous	200 Mg, Unk		Ucb
	Champix			S	Oral	1 Df, Once Daily (Qd)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Weekly (Qw)		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Plaquenil			S		400 Mg, Unk		Not Reported
	Enbrel			S		50 Mg,		Not Reported
	Valtrex			C				Not Reported
	Vimovo			C				Not Reported
	Crestor			C				Not Reported
	Oxycocet			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14065329	EXPEDITED (15-DAY)		OT	US-SA-2017SA191464		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaphylactic Reaction; Anxiety; Arthralgia; Arthritis; Atrophic Vulvovaginitis; Back Pain; Carotid Artery Disease; Carotid Artery Occlusion; Chronic Kidney Disease; Clostridium Difficile Infection; Cognitive Disorder; Cognitive Disorder; Cough; Deafness; Decreased Appetite; Depression; Diabetes Mellitus; Diabetic Ketoacidosis; Diabetic Neuropathy; Diarrhoea; Dizziness; Drug Dependence; Drug Ineffective; Dry Eye; Dysphagia; Essential Hypertension; Extrapyramidal Disorder; Fall; Fatigue; Fibromyalgia; Gait Disturbance; Haemorrhagic Disorder; Hepatic Enzyme Increased; Hyperlipidaemia; Hypersensitivity Vasculitis; Hypoaesthesia; Hypoaesthesia; Impaired Gastric Emptying;	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral	2.5 Mg Tablet 6 Tablets By Mouth 1 Time A Week (2.5 Mg)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Buspar			C	Unknown			Not Reported
	Tresiba			C	Unknown			Not Reported
	Claritin			C	Unknown			Not Reported
	Neurontin			C	Unknown			Not Reported
	Bentyl			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Desyrel			C	Unknown			Not Reported
	Novolog			C	Unknown			Not Reported
	Seroquel			C	Unknown			Not Reported
	Lexapro			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Florastor			C	Unknown			Not Reported

Infection; Iron Deficiency Anaemia; Joint Arthroplasty; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Myalgia; Myopia; Nasal Congestion; Nausea; Neck Pain; Orthostatic Hypotension; Osteoarthritis; Osteopenia; Palpitations; Paraesthesia; Paraesthesia; Presbyopia; Purpura; Pyrexia; Radiculopathy; Rash; Restless Legs Syndrome; Retinal Degeneration; Rheumatoid Arthritis; Rotator Cuff Syndrome; Spinal Osteoarthritis; Spinal Osteoarthritis; Stomatitis; Syncope; Synovitis; Systemic Lupus Erythematosus; Toothache; Treatment Failure; Urinary Hesitation	Levothyroxine	C	Unknown			Not Reported
	Zantac	C	Unknown			Not Reported
	Florastor	C	Unknown			Not Reported
	Aspirin	C	Unknown			Not Reported
	Calcium Carbonate	C	Unknown			Not Reported
	Prilosec	C	Unknown			Not Reported
	Vitamin D3	C	Unknown			Not Reported
	Pravachol	C	Unknown			Not Reported
	Lopressor	C	Unknown			Not Reported
	Tucks	C	Unknown			Not Reported
	Glucagen	C	Unknown			Not Reported
	Aquaphor	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Colchicine	C	Unknown			Not Reported
	Melatonin	C	Unknown			Not Reported
	Cefaclor	C				Not Reported
	Anusol	C	Unknown	Daily Dose: 1-12.5 %		Not Reported
	Neostigmine Bromide	C				Not Reported
	Tresiba	C	Unknown			Not Reported
	Pseudoephedrine	C				Not Reported
	Lyrica	C				Not Reported
	Reglan	C				Not Reported
	Robinul	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14380877	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000056		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Diarrhoea; Drug Ineffective; Drug	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral	50 Milligram(S); Every		Not Reported

Intolerance; Fatigue; Menorrhagia; Nausea; Tinnitus					Cycle	
	Apo-Leflunomide	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14688172	NON-EXPEDITED			US-PFIZER INC-2018126544		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14702581	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000952		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer	Hydroxychloroquine 200 Mg			S				Concordia
	Enbrel			S				Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14702774	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012685		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Retinal	Cimzia			S		Unk		Ucb
	Cimzia			S	Subcutaneous	Unk		Ucb

Disorder; Rheumatoid Arthritis	Humira		S		Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium		S		Unk	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Unk	Not Reported
	Plaquenil		S		Unk	Not Reported
	Plaquenil		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14703719	NON-EXPEDITED			US-PFIZER INC-2018128901		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Celestone /00008501/			S		Unk		Not Reported
	Otezla			S		Unk		Not Reported
	Kenalog			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14703728	NON-EXPEDITED			US-PFIZER INC-2018128738		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk, 2x/Day		Pfizer
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Kenalog			S	Intramuscular	80 Mg, Unk		Not Reported
	Hydroxychloroquine			S		Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14703742	NON-EXPEDITED			US-PFIZER INC-2018128653			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14703899	NON-EXPEDITED			US-PFIZER INC-2018130254		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704177	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1020266		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Supraventricular Tachycardia	Hydroxychloroquine			S	Unknown			Not Reported
	Pilocarpine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704190	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-055926			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Aspirin			S	Unknown			Bayer
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

White Blood Cell Count Decreased	Leflunomide	S	Oral	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Penicillin G	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Pregabalin	C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704191	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-055928			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Aspirin			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pregabalin			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704435	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-055934			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Aspirin			S	Unknown	Unk		Bayer

Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Penicillin G	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	Unk		Not Reported
	Pregabalin	C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704444	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-055948			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Aspirin			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Pregabalin			C		50 Mg, Qd		Not Reported
	Tylenol [Paracetamol]			C		650 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704716	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-055942		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive	Aleve			S	Unknown			Bayer

Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab	S	Unknown			Not Reported
	Tocilizumab	S				Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Naproxen	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported
	Methotrexate	C	Unknown	20 Mg, Unk		Not Reported
	Plaquenil	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704720	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-055945		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown			Bayer
	Tocilizumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported
	Folic Acid			C	Subcutaneous	Unk		Not Reported
	Leflunomide			C	Unknown	1 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14704750	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-055968		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown			Bayer
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2018	14705837	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2305309-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Complication; Drug Ineffective; Foot Deformity; Foot Deformity; Infection; Infection; Musculoskeletal Stiffness; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz			S	Unknown					Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14378545	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000070		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14409303	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pleural Effusion	Hydroxychloroquine			S				Concordia
	Prednisolone			S				Concordia
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14703929	NON-EXPEDITED			US-PFIZER INC-2018132455		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14709466	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001098			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Hypersensitivity; Urticaria	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Abatacept			C				Not Reported
	Enbrel			C				Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Lisinopril W Hydrochlorothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14709877	EXPEDITED (15-DAY)		OT	US-SA-2018SA093041			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Teratogenicity	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	12815118	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015036733			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow) (X3)		Ucb
	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 4 Weeks		Ucb
	Humira			S	Subcutaneous	40 Mg, Ev 2 Weeks(Qow)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	3000 Mg, Unk		Not Reported
	Tylenol			C				Not Reported
	Empracet			C				Not Reported
	Synvisc			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	13128603	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000467		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Amnesia; Arthralgia; C-Reactive Protein Increased;	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Disease Progression; Drug Dependence; Drug Ineffective; Dyspnoea; Fall; Hand Dermatitis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Loss Of Consciousness; Nausea; Palpitations; Product Dose Omission; Rheumatoid Arthritis; Stress; Upper Respiratory Tract Infection; Vomiting	Enbrel			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Cannabidiol			S	Unknown				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Folic Acid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14216127	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006457			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Acute Generalised Exanthematous Pustulosis; Decreased Immune Responsiveness; Diarrhoea; Endodontic Procedure; Fatigue; Flatulence; Gastrointestinal Disorder; Injection Site Induration; Injection Site Pain; Injection Site Rash; Injection Site Swelling; Sleep Disorder; Treatment Failure; Vomiting	Plaquenil			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported
	Xeljanz Xr Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14234847	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS			Female	USA

INC.-GSH201711-006514

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Acute Generalised Exanthematous Pustulosis; Decreased Immune Responsiveness; Diarrhoea; Endodontic Procedure; Fatigue; Flatulence; Gastrointestinal Disorder; Injection Site Induration; Injection Site Pain; Injection Site Rash; Injection Site Rash; Injection Site Swelling; Sleep Disorder; Treatment Failure; Vomiting	Plaquenil			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14491716	NON-EXPEDITED			US-PFIZER INC-2018050086		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk Unk, Weekly (Injection 1x Week)		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Orencia			S		Unk Unk, Monthly (Infused 1x Month)		Not Reported
	Actemra			S		600 Mg, Unk [600 Mg Infused 4 Times Weekly]		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported

	Arava	S		10 Mg, 1x/Day	Not Reported
	Plaquenil	S		300 Mg, 1x/Day	Not Reported
	Xeljanz Xr	C	Oral	11 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14552069	NON-EXPEDITED			US-PFIZER INC-2018071824		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Prednisone			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14630089	NON-EXPEDITED			US-PFIZER INC-2018098538		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14712211	EXPEDITED (15-DAY)		LT	NL-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-120808		25 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Toxicity To Various Agents; Vomiting	Hydroxychloroquine			S	Oral	Unk		Ipca
	Codeine			S	Oral	Unk		Ranbaxy
	Domperidone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14712956	NON-EXPEDITED			US-AMGEN-USASP2018042800			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14713056	NON-EXPEDITED			US-PFIZER INC-2018133862		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14713176	NON-EXPEDITED			US-PFIZER INC-2018135659		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14713343	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2018-018099			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Azithromycin	S	Unknown	Three Days Per Week		Aurobindo
	Hydroxychloroquine	S	Unknown			Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	Three Day Courses On A Monthly Base		Not Reported
	Methylprednisolone	S	Unknown	Systemic ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715037	EXPEDITED (15-DAY)		OT	RO-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001107		66 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Urinary Tract Infection	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Rituximab			C				Not Reported
	Alfacalcidol			C				Not Reported
	Metformin			C				Not Reported
	Insuman Rapid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715135	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001111			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Virus Infection; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Oral			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Atorvastatin			C				Not Reported
	Esomeprazole			C				Not Reported
	Perindopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715646	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-			Female	USA

001048

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			C				Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715653	EXPEDITED (15-DAY)		DS, OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001104		77 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Lung	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codalgin Forte			C				Not Reported
	Karvea			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14715654	EXPEDITED (15-DAY)		HO, OT	PK-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001120			Male	PAK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Chronic Lymphocytic Inflammation With Pontine Perivascular Enhancement Responsive	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Oral			Not Reported

To Steroids; Drug Ineffective; Erythema; Haemoglobin Decreased; Hepatic Enzyme Abnormal; Megakaryocytes Decreased; Myelodysplastic Syndrome; Neutropenic Sepsis; Neutrophil Count Decreased; Neutrophil Percentage Decreased; Nodule; Off Label Use; Pancytopenia; Papule; Platelet Count Decreased; Pyrexia; Rash; Skin Lesion; Skin Necrosis; Total Lung Capacity Decreased	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methylprednisolone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2018	14716342	EXPEDITED (15-DAY)		HO	PHHY2018US050980			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Chest Pain; Dyspnoea Exertional; Exercise Tolerance Decreased; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	12845032	EXPEDITED (15-DAY)		DE, HO, OT	DE-PFIZER INC-2016479161		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Respiratory Failure	Enbrel			S		50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Orencia			S	Unknown	750 Mg, Unk		Not Reported

Simponi	S	Unknown	50 Mg, Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
Tocilizumab	S	Unknown	680 Mg, Unk		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
Chloroquine	C		400 Mg, Daily		Not Reported
Prednisolone	C		Unk		Not Reported
Ass	C		Unk		Not Reported
Metoprolol	C		Unk		Not Reported
Ramipril	C		Unk		Not Reported
Prolia	C		Unk		Not Reported
Simvastatin	C		Unk		Not Reported
Folic Acid	C		Unk		Not Reported
Dekristol	C		Unk		Not Reported
Calcilac	C		Unk		Not Reported
Novaminsulfon	C		Unk		Not Reported
Omprazole	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	12995268	EXPEDITED (15-DAY)		OT	BR-ELI_LILLY_AND_COMPANY-BR201604003290		56 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arrhythmia; Asthma; Bone Disorder; Depression; Disorientation; Dizziness; Dry Mouth; Emphysema; Fall; Fall; Hypersensitivity; Hyperthyroidism; Injection Site Pain; Insomnia; Limb Injury; Malaise; Nausea; Pain; Pain In Extremity; Pneumonia; Product Dose	Forteo 250ug/Ml			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co
	Forteo 250ug/Ml			S		Unk Unk, Unknown		Eli Lilly And Co
	Caltrate /00944201/			S	Unknown	Unk, Unknown		Not Reported
	Doss /00454801/			S	Unknown	Unk, Unknown		Not Reported
	Reuquinol			S	Unknown	Unk, Unknown		Not Reported
	Serenata			C	Unknown	Unk, Unknown		Not Reported
	Omeprazol /00661201/			C	Unknown	Unk, Unknown		Not Reported

Omission; Product Dose Omission; Psychiatric Decompensation; Respiration Abnormal; Skin Burning Sensation; Skin Plaque; Spinal Deformity; Spinal Disorder; Spinal Fracture; Tremor; Weight Decreased	Zolpidem	C	Unknown	Unk, Unknown		Not Reported
	Nortriptylin	C	Unknown	Unk, Unknown		Not Reported
	Paracetamol	C	Unknown	Unk, Unknown		Not Reported
	Tibolene	C	Unknown	Unk, Unknown		Not Reported
	Chloroquine	C	Unknown	Unk, Unknown		Not Reported
	Prednisone	C	Unknown	Unk, Unknown		Not Reported
	Levoid	C	Unknown	Unk, Unknown		Not Reported
	Gabapentin	C	Unknown	Unk, Unknown		Not Reported
	Tramadol	C	Unknown	Unk, Unknown		Not Reported
	Vitamin D /00107901/	C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14177191	NON-EXPEDITED			US-PFIZER INC-2017482065		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Minocycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14228031	EXPEDITED (15-DAY)		HO, OT	US-SA-2017SA234699		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Acute Generalised Exanthematous Pustulosis; Decreased Immune Responsiveness; Diarrhoea; Endodontic Procedure; Fatigue; Flatulence; Gastrointestinal Disorder;	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

Injection Site Induration;
Injection Site Pain;
Injection Site Rash;
Injection Site Rash;
Injection Site Swelling;
Sleep Disorder; Treatment
Failure; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14442209	NON-EXPEDITED			US-PFIZER INC-2018034444		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Kineret			C		Unk		Not Reported
	Vioxx			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14523980	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018-0317971		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Haemorrhage	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead

Uterine; Confusional State; Dyspnoea; Female Sterilisation; Hysterectomy; Oxygen Saturation Decreased; Pneumonia; Protein Total Abnormal; Thrombosis	Adcirca	S	Unknown			Not Reported
	Uptravi	S	Unknown			Not Reported
	Zolpidem	S	Unknown			Not Reported
	Alprazolam	S	Unknown			Not Reported
	Levothyroxine	S	Unknown			Not Reported
	Zanaflex	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Oxycodone	S	Unknown			Not Reported
	Imitrex /01044801/	S	Unknown			Not Reported
	Lasix /00032601/	S	Unknown			Not Reported
	Ondansetron	S	Unknown			Not Reported
	Pantoprazole	S	Unknown			Not Reported
	Sumatriptan	S	Unknown	Unk		Not Reported
	Tizanidine	S	Unknown			Not Reported
	Furosemide	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Xarelto	C				Not Reported
	Belbuca	C				Not Reported
	Cyclobenzaprine	C				Not Reported
	Trintellix	C				Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14528991	NON-EXPEDITED			US-PFIZER INC-2018060158		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Erythrocin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14591892	NON-EXPEDITED		OT	PHEH2018US006866			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Chronic Spontaneous Urticaria; Headache; Lichen Planus; Pain In Extremity; Pruritus; Withdrawal Syndrome	Losartan Potassium			S	Unknown	Unk		Novartis
	Metoprolol			S	Unknown	Unk		Not Reported
	Verapamil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mirtazapine			S	Unknown	Unk		Not Reported
	Solu Medrol			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14610796	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000908		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Aspirine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14673352	NON-EXPEDITED			US-AMGEN-USASP2018039135			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	15 Mg, Qwk		Not Reported
	Remicaide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Arava			S	Unknown	20 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14682459	EXPEDITED (15-DAY)		OT	MY-BEH-2018089116			Unknown	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome	Human Immunoglobulin (Nc)			S	Transplacental			Not Reported
	Hydroxychloroquine /00072603/			S	Transplacental			Not Reported
	Cardiprin /00002701/			S	Transplacental			Not Reported
	Tinzaparin Sodium			S	Transplacental			Not Reported
	Methylprednisolone			S	Transplacental			Not Reported
	Tazocin Ef			S	Transplacental			Not Reported
	Meropenem /01250502/			S	Transplacental			Not Reported
	Imipenem			S	Transplacental			Not Reported
	Clarithromycin			S	Transplacental			Not Reported
	Ciprofloxacin /00697202/			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14719231	EXPEDITED (15-DAY)		OT	AU-ROCHE-2096434		31 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Lupus Nephritis; Off Label Use; Pleural Effusion; Pleuritic Pain	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14719521	NON-EXPEDITED			US-PFIZER INC-2018138058		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14719603	NON-EXPEDITED			US-PFIZER INC-2018137970		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14720363	NON-EXPEDITED			US-AMGEN-USASP2018044307			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Depression; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723050	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-877315		74 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown	Teva
	Methotrexate			S	Unknown	Barr
	Prednisone			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723054	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-877309		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Supraventricular Tachycardia	Hydroxychloroquine			S	Unknown			Teva
	Pilocarpine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723324	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-877733			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Hypotension; Pulmonary Hypertension; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723469	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-877333		43 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14723608	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1021523		71 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Infected Varicose Vein; Nocardiosis; Varicose Ulceration	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	8 Mg, Unk		Mylan
	Methylprednisolone			S	Unknown	6 Mg, Unk		Mylan
	Methylprednisolone			S	Unknown	8 Mg, Unk		Mylan
	Methylprednisolone			S	Unknown	12 Mg, Unk		Mylan
	Plaquinol			S	Unknown	Unk		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, Unk		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	480 Mg, Unk		Mylan
	Tocilizumab			S	Subcutaneous	162 Mg, Unk		Mylan
	Salazopirina			S	Unknown	2 G, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2018	14725417	EXPEDITED (15-DAY)		OT	PHHY2018US054037			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Syndrome	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14345048	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000011		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus	Plaquenil Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Rocaltrol			C				Not Reported

	Omepral			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14602371	NON-EXPEDITED			US-PFIZER INC-2018085550		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726077	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001128		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Plaquenil			S	Oral			Not Reported
	Valaciclovir			S	Oral			Not Reported
	Rovalcyte			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Bactrim			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726488	NON-EXPEDITED			US-PFIZER INC-2018139890			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726527	NON-EXPEDITED			US-PFIZER INC-2018139504			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726635	EXPEDITED (15-DAY)		HO	DK-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001133		24 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Plaquenil Tablet			S	Oral			Not Reported
	Frisium			C				Not Reported
	Topimax [Topiramate]			C				Not Reported
	Zonegran			C				Not Reported
	Apydan [Oxcarbazepine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726969	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-019624		74 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii	Hydroxychloroquine			S	Unknown			Zydus Pharm

Pneumonia	Prednisone		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14726971	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-019623		43 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14727516	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA059699			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Orencia		S	Unknown	Unk	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Remicade		S	Unknown	Unk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14727522	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA059681			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

					Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Plaquenil	S	Unknown	Unk	Not Reported
					Plaquenil	S			Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Remicade	S	Unknown	Unk	Not Reported
					Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan	S	Unknown	Unk	Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14727523	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA059691			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

				Hydroxychloroquine	S	Unknown			Not Reported
				Hydroxychloroquine	S				Not Reported
				Orencia	S	Intravenous (not otherwise specified)			Not Reported
				Orencia	S	Unknown	Unk		Not Reported
				Remicade	S	Intravenous (not otherwise specified)			Not Reported
				Remicade	S	Unknown	Unk		Not Reported
				Rituxan	S	Intravenous (not otherwise specified)			Not Reported
				Rituxan	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14727772	EXPEDITED (15-DAY)		HO, LT	PHHY2018CA059707			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Apo Hydroxychloroquine			S	Unknown			Not Reported
	Apo Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S			Not Reported
	Remicaid	S	Intravenous (not otherwise specified)		Not Reported
	Remicaid	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14728115	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-877194		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Mycobacterial Infection; Osteomyelitis; Osteomyelitis	Prednisone			S	Oral	50 Mg/Day Dose Administered Initially Which Was Later Tapered To 5 Mg/Day		Actavis
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2018	14728677	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA091862		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Acute Generalised Exanthematous Pustulosis; Decreased Immune Responsiveness; Diarrhoea; Endodontic Procedure; Fatigue; Flatulence; Gastrointestinal Disorder; Injection Site Induration; Injection Site Pain;	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

Injection Site Rash;
Injection Site Swelling;
Sleep Disorder; Treatment
Failure; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14708271	EXPEDITED (15-DAY)		OT	US-ROCHE-2093901			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tuberculin Test Positive	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2103908		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Frequency: Every 1 Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731384	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-			Female	JPN

001139

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731386	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001142		48 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Hydroxychloroquine Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731387	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001144		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rebound Effect; Sarcoidosis	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Azelastine Hydrochloride Fluticasone Propionate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731427	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001073			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731428	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001076			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731429	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001095		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Systemic Lupus Erythematosus; Treatment Noncompliance	Hydroxychloroquine			S				Not Reported
	Solumedrol			S				Not Reported
	Clindamycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731442	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001072			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Lisinopril			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2099493		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731462	EXPEDITED (15-DAY)		OT	CA-ROCHE-2103350		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 2.0		Not Reported

				Year(S)	
Methotrexate	S	Subcutaneous	Therapy Duration: 5.0 Month(S)		Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil	S	Unknown	Therapy Duration: 3.0 Year(S)		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 275.0 Nos		Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2018	14731729	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA060643			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Prefilled Syringe		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Remicade	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	12855840	EXPEDITED (15-DAY)		DE, HO, OT	DE-AMGEN-DEUNI2016142372		60 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Respiratory Failure	Etanercept			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Simponi			S	Unknown	50 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown	680 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Not Reported
	Chloroquine			C		400 Mg, Daily		Not Reported
	Prednisolone			C		Unk		Not Reported
	Ass			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Prolia			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

	Dekristol			C		Unk			Not Reported
	Calcilac			C		Unk			Not Reported
	Novaminsulfon			C		Unk			Not Reported
	Omprazole			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14559555	EXPEDITED (15-DAY)		OT	US-SA-2018SA045263			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Spinal Compression Fracture	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14629522	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2273360-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14643796	EXPEDITED (15-DAY)		DE	US-TEVA-2018-US-869752		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14688105	NON-EXPEDITED			US-PFIZER INC-2018126845			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14696314	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018042308		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Rash Pruritic	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14703947	NON-EXPEDITED			US-PFIZER INC-2018132359		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported

	Methotrexate			S	Oral	Unk			Not Reported
	Hydroxychloroquine			S		Unk			Not Reported
	Leflunomide			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732328	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00010937		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Maternal Exposure Timing Unspecified; Normal Newborn	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S		20 Mg, Qd		Not Reported
	Aspirin			S	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732630	EXPEDITED (15-DAY)		OT	CA-ROCHE-2102507		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732741	EXPEDITED (15-DAY)		OT	CA-ROCHE-2101985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732883	NON-EXPEDITED			US-PFIZER INC-2018141856			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733181	EXPEDITED (15-DAY)		OT	PHHY2018US054370		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Lymphopenia; Photosensitivity Reaction; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	Unk		Novartis
	Prednisone			S				Novartis
	Quinacrine			S	Unknown	Unk		Not Reported
	Quinacrine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733392	NON-EXPEDITED			US-AMGEN-USASP2018044533			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733713	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2018024417		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Haemorrhage Uterine; Confusional State; Dyspnoea; Female Sterilisation;	Ambrisentan			S	Unknown	10 Mg, Qd		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Furosemide			S	Unknown	Unk		Glaxosmithkline

Hysterectomy; Oxygen Saturation Decreased; Pneumonia; Protein Total Abnormal; Thrombosis	Sumatriptan	S	Unknown	Unk		Glaxosmithkline
	Adcirca	S	Unknown	Unk		Not Reported
	Uptravi	S	Unknown	Unk		Not Reported
	Zolpidem	S	Unknown	Unk		Not Reported
	Alprazolam	S	Unknown	Unk		Not Reported
	Levothyroxine	S	Unknown	Unk		Glaxosmithkline
	Zanaflex	S	Unknown	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Oxycodone	S	Unknown	Unk		Not Reported
	Imitrex	S	Unknown	Unk		Not Reported
	Lasix	S	Unknown	Unk		Not Reported
	Ondansetron	S	Unknown	Unk		Not Reported
	Trintellix	C		Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Xarelto	C		Unk		Not Reported
	Buprenorphine Hydrochloride	C		Unk		Not Reported
	Cyclobenzaprine	C		Unk		Not Reported
	Tizanidine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14735595	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098086		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Haemorrhage	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

		Methotrexate Sodium			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14735610	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098070		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Diarrhoea; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14735713	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098046		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Supeudol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14737532	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097836		19 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Depression; Gastrointestinal Disorder; Headache; Mental Disorder; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	Not Reported
	Plaquenil			S	Oral	Not Reported
	Apo-Prednisone			S	Unknown	Not Reported
	Celebrex			S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14737827	EXPEDITED (15-DAY)		OT	CA-ROCHE-2103378		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil			C				Not Reported
	Folic Acid			C				Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14738699	NON-EXPEDITED			US-PFIZER INC-2018141867			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	13201712	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Synthroid			C				Not Reported
	Restasis			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14216925	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017174281		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Oral	Unk ((1 In 1week))		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Xeljanz			C	Oral	10 Mg, Unk		Not Reported
	Prednisone			C	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14659612	NON-EXPEDITED			US-PFIZER INC-2018115527		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14708089	NON-EXPEDITED			US-PFIZER INC-2018134032		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14739662	EXPEDITED (15-DAY)		OT	CA-ROCHE-2102443		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14739695	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104045		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14739927	NON-EXPEDITED			US-PFIZER INC-2018143998		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	20 Mg, (Every Morning)		Not Reported

	Hydroxychloroquine /00072603/			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14739970	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2316035-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14741523	EXPEDITED (15-DAY)		HO	CA-ROCHE-2104665		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14742096	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018046651			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive	Enbrel			S	Unknown	Unk		Amgen

Pulmonary Disease; Drug Ineffective; Left Ventricular Dysfunction; Lung Disorder	Mtx			S	Oral	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Leflunomide			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Azathioprine			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14743791	NON-EXPEDITED			US-AMGEN-USASP2018046435			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14768537	DIRECT	Y				47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Gastrointestinal Disorder	Hydroxychloroquine 200mg			S	Oral	10/2018-01/2018		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14383962	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-003217			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Headache; Off Label Use; Rash	Orencia		S	Unknown	Unk	Bristol Myers Squibb
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14673338	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer	Hydroxychloroquine			S	Oral			Hikma
	Methotrexate			S	Oral			Westward
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14744328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2318103-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Hearing Aid User; Joint Swelling; Mobility Decreased; Pain; Pruritus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Penicillin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C		For 3 Years		Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14746420	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098068			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Arava		S	Oral		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Actemra		S	Subcutaneous		Not Reported
	Meloxicam		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Simponi		S	Unknown	Solution Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tylenol		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14746894	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097863		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown	Form:Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoprazole			C				Not Reported

		Pantoprazole Magnesium			C	Oral				Not Reported
		Tenofovir Disoproxil Zentiva			C	Oral				Not Reported
		Zopiclone			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14746898	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104671			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 240 Days		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 158 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14747209	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14747425	EXPEDITED (15-DAY)		OT	CA-SA-2018SA101614		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Unknown	2 Doses		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporin A			S	Unknown			Not Reported

	Naprosyn			S	Unknown					Not Reported
	Depo-Provera			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14747434	EXPEDITED (15-DAY)		OT	CA-SA-2018SA101620		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Calcium Salt Not Specified			S	Unknown			Not Reported
	Iron Polymaltose			S	Unknown			Not Reported
	Infliximab			S	Unknown	200-500 Mg		Not Reported
	Infliximab			S	Unknown	200-500 Mg		Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14833579	DIRECT	Y	HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	13253859	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894972		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 365.0 Nos		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 19.0 Year(S)		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14446262	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000345		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported

Failure	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	40mg/0.8ml		Not Reported
	Actemra	S	Unknown			Not Reported
	Methotrexate Sodium	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14561411	NON-EXPEDITED			US-PFIZER INC-2018075588		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14678942	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Sinusitis; Therapeutic Response Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14679208	NON-EXPEDITED			US-PFIZER INC-2018120106		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk	Unknown
	Sulfasalazine	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14750368	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-879643		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	600mg Daily Receiving From At Least 5 Years		Teva
	Hydroxychloroquine			S		Administered 8 Weeks After The Discontinuation Of The Previous Therapy		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14751110	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001116			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Vomiting	Plaquenil			S				Not Reported
	Methotrexate Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753106	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA100401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Hypersensitivity; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106225		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intramuscular	Therapy Duration: 5.0 Year(S)		Not Reported
	Methotrexate Sodium			S	Oral	Form Of Administration Injection		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 640.0 Nos		Not Reported
	Plaquenil			S	Oral	Therapy Duration: 5.0 Year(S)		Not Reported
	Naprosyn			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753242	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106220		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown	Form Of Administration: Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753349	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2105356		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Single Use		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S				Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753888	NON-EXPEDITED			US-SEBELA IRELAND LIMITED-2017SEB00329		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Pain; Therapeutic Product Effect Incomplete	Imuran			S		50 Mg, 1x/Day		Sebela
	Prednisone			S		5 Mg, 1x/Day		Not Reported
	Orencia			S	Subcutaneous	1 Dosage Units, 1x/Week		Not Reported
	Plaquenil			S	Oral	200 Mg, 1x/Day		Not Reported
	Percocet			C		1 Dosage Units, 3x/Day As Needed		Not Reported
	Zofran Odt			C	Oral	4-8 Mg, 3x/Day As Needed		Not Reported
	Lexapro			C		20 Mg, 1x/Day		Not Reported
	Vitamin D2			C	Oral	2000 U, 1x/Day		Not Reported
	Minoxidil			C		5 Mg, 2x/Day As Needed		Not Reported
	Carvedilol			C		25 Mg, 1x/Day		Not Reported
	Sodium Bicarbonate			C		1950 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14753893	NON-EXPEDITED			US-SEBELA IRELAND LIMITED-2017SEB00359			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma	Imuran			S				Sebela
	Enbrel			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2018	14754362	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018048427			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C		11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	13435389	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017158040		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer Stage Ii	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Daily		Not Reported
	Alendronate Sodium			C	Oral	70 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	13859719	NON-EXPEDITED			US-PFIZER INC-2017345222		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Arava			S		Unk		Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14158557	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006239			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Lupus Erythematosus	Plaquenil			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14334955	EXPEDITED (15-DAY)		HO, OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006713		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Product Use In Unapproved Indication; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Prednisolone			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14347733	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268436		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

	Enbrel	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Lyrica	C	Oral			Not Reported
	Methotrexate	C	Subcutaneous	1 Every 1 Week(S)		Not Reported
	Methotrexate	C	Oral	1 Every 1 Week(S)		Not Reported
	Naproxen	C	Unknown	1 Every 1 Day(S)		Not Reported
	Plaquenil	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14466131	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018010293		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Cystitis; Diarrhoea; Drug Intolerance; Insomnia; Osteopenia; Rash; Rheumatoid Arthritis; Stomatitis; Swelling; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Xeljanz Xr			S				Not Reported
	Xeljanz Xr			S				Not Reported
	Xeljanz Xr			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Acthar			C		80 Iu, Every Four Days		Not Reported
	Latanoprost			C	Ophthalmic	Unk, Qd		Not Reported
	Prednisone			C		12.5 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd (At Bedtime)		Not Reported

Prednisone	C	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14718729	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001119		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Diastolic Dysfunction; Dyspnoea Exertional; Endocardial Fibrosis; Exercise Tolerance Decreased; Left Ventricular End-Diastolic Pressure Increased; Myocardial Fibrosis; Pulmonary Arterial Wedge Pressure Increased; Pulmonary Hypertension; Restrictive Cardiomyopathy; Right Atrial Pressure Increased; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14754801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104621		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sodium Aurothiomalate				S	Unknown					Not Reported
	Sulfasalazine				S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14754838	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001127			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Not Reported
	Codeine			S				Not Reported
	Humira			S				Not Reported
	Vioxx			S				Not Reported
	Celebrex			S				Not Reported
	Isoniazid			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14754964	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001130			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash; Urticaria	Plaquenil			S				Not Reported
	Zithromax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14755417	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gonococcal Infection; Septic Shock; Treatment Noncompliance	Hydroxychloroquine			S	Unknown			Hikma
	Solumedrol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14756554	NON-EXPEDITED			US-PFIZER INC-2018150461		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Kenalog			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14758638	EXPEDITED (15-DAY)		HO	US-VALIDUS PHARMACEUTICALS LLC-US-2018VAL000619		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Haemorrhage Uterine; Confusional State; Dyspnoea; Oxygen Saturation Decreased; Pneumonia; Protein Total Abnormal; Thrombosis	Lasix			S	Unknown			Validus
	Furosemide			S	Unknown			Validus
	Ambrisentan			S	Unknown	10 Mg, Qd		Not Reported
	Adcirca			S	Unknown	Unk		Not Reported
	Uptravi			S	Unknown	Unk		Not Reported
	Zolpidem			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported
	Zanaflex			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Imitrex /01044801/			S	Unknown	Unk		Not Reported
	Ondansetron			S	Unknown	Unk		Not Reported

	Pantoprazole	S	Unknown	Unk		Not Reported
	Sumatriptan	S	Unknown	Unk		Not Reported
	Tizanidine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Xarelto	C				Not Reported
	Belbuca	C		Unk		Not Reported
	Cyclobenzaprine	C		Unk		Not Reported
	Trintellix	C		Unk		Not Reported
	Hydroxychloroquine Sulfate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14759072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106267		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

		Reactine (Canada)			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14759232	EXPEDITED (15-DAY)		HO	CA-ROCHE-2106276			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 210 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 15 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Injection, Therapy Duration: 15 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 15 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 15 Days		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 6 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14759293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106233		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Actemra		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Subcutaneous Solution	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Methotrexate		C			Not Reported
	Desoximetasone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14759319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106279		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported

		Remicade			S	Unknown				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Oral				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14759713	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106280		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2018	14760264	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2018GMK034324			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Arthralgia; Asthenia; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Glenmark
	Esomeprazole Magnesium			S	Oral	40 Mg, Qd		Not Reported
	Folic Acid			S	Unknown	1 Df, Unk, 2 Every 1 Week(S)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk, (1 Every 1 Week)		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk, (2 Every 1 Day)		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk,(1 Every 1 Day)		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk, (2 Every 1 Day)		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk, (2 Every 1 Day)		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk,5 Mg, Unk, (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	13989294	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005370		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Osteoarthritis; Pneumonia; Pruritus; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate Sodium			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14610636	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000904		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Maternal Exposure During Pregnancy; Missed Labour; Normal Newborn; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Aspirin			S	Unknown	100 Mg, Qd		Not Reported
	Enoxaparin			S		4000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760412	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001235			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760413	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001236			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Haemorrhage	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760414	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Glaucoma	Plaquenil			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760750	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105462		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760813	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2018	14760817	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20180407405		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Calcium Increased; Blood Creatinine Increased; Blood Urea Increased; Completed Suicide; Dehydration; Gastrointestinal Haemorrhage; Hepatomegaly; Hypotension; International Normalised Ratio Increased; Liver Function Test Increased; Nausea; Oxygen Saturation Decreased; Toxicity To Various Agents; Urine Output Decreased	Tylenol 8 Hour		Y	S	Oral			Not Reported
	Tylenol 8 Hour			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Vistaril			S	Unknown			Not Reported
	Ethanol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	13182650	EXPEDITED (15-DAY)		OT	CA-ROCHE-1747445		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 9 Months		Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Oral	On Hold		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14415897	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-005585			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14599748	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2018086882		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Progressive Multifocal	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Leukoencephalopathy	Azathioprine	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Thalidomide	S	Oral	Unk		Not Reported
	Cyclophosphamide	S	Unknown	Unk		Not Reported
	Immunoglobulin Human	C		1 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14637701	NON-EXPEDITED			US-PFIZER INC-2018105040		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Clinoril			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14652765	EXPEDITED (15-DAY)		HO	PT-ROCHE-2088903		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Off Label Use; Product Use In Unapproved Indication; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14745032	NON-EXPEDITED			US-PFIZER INC-2018146640		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Musculoskeletal Stiffness; Pain	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Kineret			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14761751	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001239		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C				Not Reported
	Folic Acid			C				Not Reported

		Pantoprazol Magnesium			C					Not Reported
		Tenofovir Disoproxil Fumarate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14761752	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001242		19 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Gastrointestinal Disorder; Headache; Mental Disorder; Rheumatoid Arthritis; Treatment Failure	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762088	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001263		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762089	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001265		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Hydroxychloroquine		S	Oral	Not Reported
	Leflunomide		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Supeudol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762287	NON-EXPEDITED			US-AMGEN-USASP2018048382			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypertension; Influenza; Rash; Treatment Failure	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Cosentyx			S	Unknown	150 Mg, Q4 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1 Tab Qd		Not Reported
	Azulfidine			S	Unknown	500 Mg, 1 Tab Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Voltaren			C		Unk		Not Reported
	Xeljanz Xr			C		11 Mg, 1 Tab Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762319	NON-EXPEDITED			US-AMGEN-USASP2018049443			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

	Sulfa			S	Unknown	Unk			Not Reported
	Ultram			S	Unknown	Unk			Not Reported
	Levaquin			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762376	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018049489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Drug Ineffective; Rash	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Oral	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762488	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762489	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001272			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Diarrhoea; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762490	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001273		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

		Pantoprazole			C						Not Reported
		Pantoprazole Magnesium			C						Not Reported
		Tenofovir Disoproxil Zentiva			C						Not Reported
		Zopiclone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762491	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Marijuana			C				Not Reported
	Risedronate			C				Not Reported
	Wellbutrin			C				Not Reported
	Celebrex			C				Not Reported
	Ergocalciferol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762492	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001278		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Haemorrhage	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

	Adalimumab			S	Subcutaneous				Not Reported
	Etanercept			S	Subcutaneous				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14762493	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001279			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14763410	NON-EXPEDITED			US-AMGEN-USASP2018048808			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Increased; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Mobic			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14763780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2106833		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14763969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104641		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14764459	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2018GMK034364			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypokinesia; Nerve Compression; Product Use In Unapproved Indication	Gabapentin			S	Unknown	300 Mg, Qd		Glenmark
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14764647	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107911		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituximab			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14765121	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

					otherwise specified)	Intravenous			
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14765271	NON-EXPEDITED			US-PFIZER INC-2018155095		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14765461	EXPEDITED (15-DAY)		HO	CA-ROCHE-2106953		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 210 Days		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 673 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14765662	EXPEDITED (15-DAY)		HO	US-ELI_LILLY_AND_COMPANY-US201804003113		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Haemorrhage	Adcirca			S	Unknown	Unk, Unknown		Eli Lilly And Co

Uterine; Confusional State; Dyspnoea; Oxygen Saturation Decreased; Pneumonia; Protein Total Abnormal; Thrombosis	Ambrisentan	S	Unknown	10 Mg, Daily		Not Reported
	Uptravi	S	Unknown	Unk, Unknown		Not Reported
	Zolpidem	S	Unknown	Unk, Unknown		Not Reported
	Alprazolam	S	Unknown	Unk, Unknown		Not Reported
	Levothyroxine	S	Unknown	Unk, Unknown		Not Reported
	Zanaflex	S	Unknown	Unk, Unknown		Not Reported
	Lyrica	S	Unknown	Unk, Unknown		Not Reported
	Oxycodone	S	Unknown	Unk, Unknown		Not Reported
	Imitrex /01044801/	S	Unknown	Unk, Unknown		Not Reported
	Lasix /00032601/	S	Unknown	Unk, Unknown		Not Reported
	Ondansetron	S	Unknown	Unk, Unknown		Not Reported
	Pantoprazol /01263201/	S	Unknown	Unk, Unknown		Not Reported
	Sumatriptan	S	Unknown	Unk, Unknown		Not Reported
	Tizanidine	S	Unknown	Unk, Unknown		Not Reported
	Furosemide	S	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Unknown		Not Reported
	Xarelto	C				Not Reported
	Belbuca	C				Not Reported
	Cyclobenzaprine	C				Not Reported
	Vortioxetine Hydrobromide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2018	14766382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107088			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira				S	Subcutaneous				Not Reported
	Plaquenil				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14261757	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3999		81 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dementia With Lewy Bodies; Fall; Hip Fracture; Movement Disorder; Parkinson'S Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14651904	EXPEDITED (15-DAY)		DS, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000970		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Maculopathy; Retinal Degeneration; Retinal Fovea Disorder; Retinal Fovea Disorder; Retinopathy; Visual Field Defect; Visual Impairment	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine (Salt Not Specified)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14674828	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR-APL-2018-015499		51 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Serotonin Syndrome; Vomiting	Fluoxetine			S	Oral	1 Dd		Aurobindo
	Fluoxetine			S	Oral	40 Milligram		Aurobindo

	Fluoxetine		S	Oral	Verhoging Van 1 X 1 Tabl Naar 1 X 2 Tab	Aurobindo
	Fluoxetine		S	Oral	20 Milligram	Aurobindo
	Plaquenil /00072602/		S	Oral	400 Milligram, Once A Day	Not Reported
	Celecoxib		C	Oral	200 Mg, Bid	Not Reported
	Zopiclon		C	Oral	7.5 Mg, Prn	Not Reported
	Nasacort		C	Nasal	1 Df, Daily	Not Reported
	Esomeprazol /01479301/		C	Oral	40 Mg, Bid	Not Reported
	Oxazepam		C	Oral	10 Mg, Prn	Not Reported
	Ethinylestradiol/Desogestrel		C	Oral	1 Df, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14766702	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Intolerance	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Salfasalazine			S	Unknown			Not Reported
	Tumor Necrosis Factor Receptor - Igg1			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14766703	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Calcium			C				Not Reported
	Lantus			C				Not Reported
	Lozide			C				Not Reported
	Metformin			C				Not Reported
	Naprosyn			C				Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported
	Vitamin D2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14766705	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767255	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767283	NON-EXPEDITED			US-AMGEN-USASP2018049250			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		2.5 Mg, Unk		Not Reported
	Methotrexate			C		20 Mg, Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14768002	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018050006			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cachexia; Fear Of Injection; Influenza; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Oral	20 Mg, Unk		Not Reported
	Mtx			S	Unknown	0.5 Mg, Injection		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14768891	EXPEDITED (15-DAY)		OT	CA-ROCHE-2103325		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 6.0 Year(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14769625	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2018GSK060007		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cervix Haemorrhage Uterine; Confusional State; Dyspnoea; Female Sterilisation; Hysterectomy; Oxygen Saturation Decreased; Pneumonia; Protein Total Abnormal; Thrombosis	Ambrisentan	S	Unknown	10 Mg, Qd	Glaxosmithkline
	Levothyroxine	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Furosemide	S	Unknown	Unk	Glaxosmithkline
	Sumatriptan	S	Unknown	Unk	Glaxosmithkline
	Imitrex	S	Unknown	Unk	Glaxosmithkline
	Adcirca	S	Unknown	Unk	Not Reported
	Uptravi	S	Unknown	Unk	Not Reported
	Zolpidem	S	Unknown	Unk	Not Reported
	Alprazolam	S	Unknown	Unk	Not Reported
	Zanaflex	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Lasix	S	Unknown	Unk	Not Reported
	Ondansetron	S	Unknown	Unk	Not Reported
	Tizanidine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported
	Buprenorphine Hydrochloride	C	Unknown	Unk	Not Reported
	Cyclobenzaprine	C	Unknown	Unk	Not Reported
	Trintellix	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14770083	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14838117	DIRECT	Y	OT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Ventricular Arrhythmia	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	12358201	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016059290		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14604112	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018056516		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Limb; Musculoskeletal Disorder; Nodule; Pain In Extremity; Soft Tissue Infection; Synovitis	Sulfasalazine			S	Oral	1 G, Daily		Pfizer
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported
	Leflunomide			C		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14676995	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001018			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Atrophy; Myasthenic Syndrome; Performance Status Decreased; Unevaluable Event	Hydroxychloroquine 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14739512	NON-EXPEDITED			US-AMGEN-USASP2018046672			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14761888	EXPEDITED (15-DAY)		OT	KZ-ROCHE-1547592		63 YR	Female	KAZ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Drug Ineffective; Pancreatitis Chronic	Mabthera	S	Intravenous (not otherwise specified)	Once Per 2 Weeks		Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	Once Per 2 Weeks		Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	Twice		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Medrol	S	Unknown			Not Reported
	Medrol	S	Unknown			Not Reported
	Medrol	S	Unknown			Not Reported
	Medrol	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Sandimmun	S	Unknown			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14772373	EXPEDITED (15-DAY)		HO	FR-CIPLA LTD.-2018FR15412			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Valacyclovir			S	Oral	Unk, Once Daily		Cipla
	Rovalcyte			S	Oral	450 Mg, Per Day		Not Reported
	Cellcept /01275102/			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported

	Prograf			S	Oral	5 Mg, Per Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773428	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107850		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Baclofen			C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773797	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis;	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773824	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001277		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pericarditis; Rebound Effect	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14773825	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gait Disturbance; Hypersensitivity; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Plaquenil			S	Oral	Not Reported
	Arava			S	Oral	Not Reported
	Methotrexate			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14774926	EXPEDITED (15-DAY)		HO	US-ACTELION-A-NJ2018-170550		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Haemorrhage Uterine; Confusional State; Dyspnoea; Female Sterilisation; Hysterectomy; Oxygen Saturation Decreased; Pneumonia; Protein Total Abnormal; Thrombosis	Uptravi			S	Oral			Actelion
	Ambrisentan			S	Unknown	10 Mg, Qd		Not Reported
	Adcirca			S	Unknown			Not Reported
	Zolpidem			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Zanaflex			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Imitrex			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Tizanidine			S	Unknown			Not Reported
	Sumatriptan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xarelto			C				Not Reported
	Belbuca			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Trintellix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14774959	EXPEDITED (15-DAY)		HO	DE-ELI_LILLY_AND_COMPANY-DE201804007668		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Olanzapine			S	Oral	2.5 Mg, 0-0-0.5-0		Eli Lilly And Co
	Tamoxifen			S	Oral	20 Mg, 0-0-1-0		Not Reported
	Quensyl			S	Oral	200 Mg, 0-0-1-0		Not Reported
	Pantoprazol /01263201/			C	Oral	20 Mg, Each Morning		Not Reported
	Prednisolon /00016201/			C	Oral	1 Mg, Bid		Not Reported
	Fentanyl			C	Transdermal	12 Ug, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14775139	EXPEDITED (15-DAY)		HO, OT	PHHY2018US060903		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy; Myopathy Toxic; Staphylococcal Infection; Systemic Lupus Erythematosus	Mycophenolate Mofetil			S	Unknown	250 Mg, Bid		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Prednisone			S	Unknown	30 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported
	Levetiracetam			C	Intravenous (not otherwise specified)	1500 Mg, Bid		Not Reported
	Methylprednisolone			C	Unknown	1000 Mg, Qd		Not Reported
	Acyclovir			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported

	Dapsone			C	Unknown					Not Reported
	Famotidine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14775438	EXPEDITED (15-DAY)		OT	BR-JNJFOC-20180415811			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Hepatitis	Simponi			S	Subcutaneous			Not Reported
	Reuquinol			S	Unknown			Not Reported
	Tecnomet			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14328174	EXPEDITED (15-DAY)		HO, OT	IT-BAYER-2017-244065		40 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Listeriosis; Maternal Exposure During Pregnancy; Platelet Count Decreased; Premature Delivery; Pyrexia	Aspirin			S		100 Mg, Unk		Bayer
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14776929	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Cellcept			S	Unknown	Dosing Info, Start Date And End Date Unknown		Not Reported

	Imuran		S	Unknown	Dosing Info, Start Date And End Date Unknown	Not Reported
	Myfortic		S	Unknown	Dosing Info, Start Date And End Date Unknown	Not Reported
	Methotrexate		S	Unknown	Dosing Info, Start Date And End Date Unknown	Not Reported
	Plaquenil		S	Unknown	Dosing Info, Start Date And End Date Unknown	Not Reported
	Prednisone		S	Oral	Dosing Information And Start Date Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14777490	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palindromic Rheumatism; Rheumatoid Arthritis; Vertigo	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Warfarin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14777593	NON-EXPEDITED			US-PFIZER INC-2018157826		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14777610	NON-EXPEDITED			US-PFIZER INC-2018159124		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Requip			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14778610	NON-EXPEDITED			US-PFIZER INC-2018161341		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14780696	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109102		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Tongue Ulceration; Tooth Infection	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

		Methotrexate Sodium			S	Unknown				Not Reported
		Sulphasalazine			S	Unknown				Not Reported
		Tramadol			C					Not Reported
		Prednison			C					Not Reported
		Indocine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14780908	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018066061			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Therapeutic Product Effect Delayed; Therapeutic Product Effect Incomplete	Benlysta Powder For Infusion			S		Unk Unk, Cyc		Glaxosmithkline
	Hydroxychloroquine			S		Unk Unk, U		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2018	14781433	NON-EXPEDITED			US-AMGEN-USASP2018052212			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14667481	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001005			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

		Ibuprofen			C						Not Reported
		Methotrexate			C						Not Reported
		Zostavax			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14781555	NON-EXPEDITED			US-AMGEN-USASP2018052282			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk Unk, Qwk (10 Tablets)		Not Reported
	Sulfasalazine			C		500 Mg, Bid		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14781572	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001207		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Right Ventricular Failure	Hydroxychloroquine			S				Concordia
	Ut-15c Sr/Placebo			S				Not Reported
	Ut-15c Sr/Placebo			S				Not Reported
	Letalrls			C				Not Reported
	Amlodipine			C				Not Reported
	Imuran			C				Not Reported
	Dok			C				Not Reported
	Ferric Carboxymaltose			C				Not Reported
	Furosemide			C				Not Reported
	Metolazone			C				Not Reported
	Bactrobani			C				Not Reported

	Prilosec			C						Not Reported
	Ondansetaron			C						Not Reported
	Spironolactone			C						Not Reported
	Prednisone			C						Not Reported
	Prochlorperazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782130	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2327648-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Rash; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Tuberculosis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782250	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109110		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Minocycline Hydrochloride		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Apo-Azathioprine		S	Unknown		Not Reported
	Amoxicillin/Clavulanate Potassium		C	Unknown		Not Reported
	Amoxil		C	Unknown		Not Reported
	Bacillus Calmette-Guerin (Bcg) Vaccine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782253	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109107		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782302	EXPEDITED (15-DAY)		HO	US-AMGEN-USASP2018050748			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Condition Aggravated; Drug Ineffective; Rash;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen

Toothache; Ulcer Haemorrhage	Methotrexate	S	Oral	17.5 Mg, Qwk	Not Reported
	Methotrexate	S	Oral	17.5 Mg, Qwk	Not Reported
	Methotrexate	S	Oral	17.5 Mg, Qwk	Not Reported
	Humira	S	Unknown	40 Mg, Q2wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q8wk	Not Reported
	Mtx	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782382	NON-EXPEDITED			US-PFIZER INC-2018161624		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782875	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001231			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14783142	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001233			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Headache; Herpes Zoster; Hypokalaemia; Intentional Product Misuse; Malaise; Nausea; Off Label Use; Otitis Media; Pain; Rash; Rheumatoid Arthritis; Syncope; Synovitis; Treatment Noncompliance	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S		Not Reported
	Arava	S		Not Reported
	Actemra	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Valsartan	S		Not Reported
	Xeljanz Xr	S		Not Reported
	Xeljanz Xr	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14783306	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001315		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Sensitivity To Weather Change	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Oral			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14783308	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001327		9 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Drug Ineffective; Muscular Weakness; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14784204	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-2018-DE-882331			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Microcephaly	Diclofenac			S	Transplacental	100mg As Needed		Actavis
	Paracetamol			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14785554	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-882767		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Concussion; Fall; Rib Fracture	Methotrexate			S				Barr
	Leucovorin Calcium			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Myrbetriq			S	Oral			Not Reported

	Doxycycline	S	Unknown	Not Reported
	Pantoprazol	C	Unknown	Not Reported
	Loratadine	C	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14785818	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109047		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14786309	EXPEDITED (15-DAY)		OT	US-SA-2018SA107625			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Tuberculosis	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

	Actemra			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14787045	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001247			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pruritus	Plaquenil			S				Not Reported
	Erythromycin			S				Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2018	14787201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109097		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Year(S)		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Therapy Duration: 5.0 Year(S)		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2018	14787423	EXPEDITED (15-DAY)		HO	CA-ROCHE-2109677		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Joint Swelling; Nausea; Platelet Count Increased; Vitamin D Decreased; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Betahistine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Vitamin C			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	12782794	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP012086		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Mycophenolate			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Prednisone		C	Intravenous (not otherwise specified)	7 Mg, Qd	Not Reported
	Humira		C	Subcutaneous	Unk	Not Reported
	Methotrexate		C	Unknown	1 Ml, Q.Wk.	Not Reported
	Celebrex		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13057258	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015775		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Nausea; Retinitis; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Stelara			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Unk, Q.Wk.		Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13057780	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP015710		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye	Apo-Leflunomide			S	Unknown	Unk		Apotex

Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13059020	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gait Disturbance; Impaired Work Ability; Insomnia; Joint Swelling; Meniere'S Disease; Pain; Peripheral Swelling; Therapeutic Response Decreased; Vertigo	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13059209	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015767			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide	S	Unknown			Apotex
	Apo-Hydroxyquine	S	Unknown	Unk		Apotex
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13896726	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP016734		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthritis; Back Pain; Bone Pain; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Joint Swelling; Kyphoscoliosis; Laboratory Test Abnormal; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Plantar Fasciitis; Sacroiliitis; Somnolence; Spinal Osteoarthritis; Spinal X-Ray Abnormal; Spondyloarthropathy	Apo-Meloxicam			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	15 Mg, Q.Wk.		Not Reported
	Naproxen			C	Unknown	500 Mg, Q.H.		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Unk		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13968222	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13968748	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018033		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Celebrex			S	Oral	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Humira			S	Unknown	40 Mg, 1 Every 2 Week		Not Reported
	Humira			S	Unknown	50 Unk, 1 Every 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Week		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported

	Methotrexate	S	Unknown	5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	125 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	125 Mg, One Every Two Weeks	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Altace	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Cipralex /01588501/	C	Unknown		Not Reported
	Citalopram	C	Unknown		Not Reported
	Conjugated Estrogens	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Estrace	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Shark Liver Oil	C	Unknown		Not Reported
	Tapentadol Hydrochloride	C	Unknown		Not Reported
	Taro-Mupirocin	C	Unknown		Not Reported
	Tramacet	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	13974176	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP017989			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex

Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Apo-Leflunomide	S				Apotex
	Actemra	S	Unknown	Unk		Not Reported
	Actemra	S				Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Anakinra	S				Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Ilaris	S	Subcutaneous	Unk		Not Reported
	Ilaris	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S				Not Reported
	Gold	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14218265	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015715		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Apo-Leflunomide			S	Unknown	20 Mg, One Every Two		Apotex

				Days		
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk		Apotex
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.I.W		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Tylenol /00020001/	C	Unknown			Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14235427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Q.I.W		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14236628	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021610		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Dysgeusia; Fluid Retention; Lower Respiratory Tract Infection; Musculoskeletal Pain; Pain In Extremity	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Meloxicam			S	Unknown	15 Mg, Qd		Apotex
	Apo Folic Acid			S	Unknown	1 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14400509	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005290		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown			Apotex
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S				Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14400610	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In	Diclofenac Potassium			S	Oral	75 Mg, Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Apotex

Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Methotrexate Sodium	S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Qd		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd		Not Reported
	Synthroid	S	Unknown	Unk		Not Reported
	Tecta	S	Oral	Unk		Not Reported
	Xeljanz	S	Unknown	Unk, Bid		Not Reported
	Depo-Medrol	C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14411605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005230		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14456428	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP006180		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	4 Df, Single		Not Reported
	Charcoal			C	Oral	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14468182	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14533616	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP006450		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis;	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin		S	Unknown	Unk		Not Reported
	Plaquenil /00072603/		S	Unknown	Unk		Not Reported
	Tramadol		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14535097	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006386		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown			Apotex
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14549482	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect	Amitriptyline			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	500 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

Incomplete	Pantoprazole			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14553142	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2018AP006636		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Ciprofloxacin			S	Unknown	Unk		Apotex
	Hydrocortisone			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14562120	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006750		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence; Pulmonary Hypertension; Tricuspid Valve Incompetence	Amlodipine			S	Oral	5 Mg, Bid		Apotex
	Bisoprolol			S	Oral	5 Mg, Bid		Not Reported
	Hydrochlorothiazide			S	Oral	12.5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Irbesartan			S	Oral	300 Mg, Qd		Apotex
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Oral	400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14597689	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cytopenia; Drug Intolerance	Azathioprine	S	Unknown			Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Qd		Apotex
	Leflunomide	S	Unknown			Apotex
	Sulfasalazine	S	Unknown	1.5 G, Bid		Not Reported
	Actemra	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Tnf (Norfloxacin\Tinidazole)	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14597696	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Myco[Phenolate			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14597702	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	10 Mg, 1 Every 2 Days		Apotex

Arthritis; Urinary Tract Obstruction	Leflunomide		S	Oral	10 Mg, 2 Every 1 Weeks	Apotex
	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14599578	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Adalimumab			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14630415	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007492			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14631484	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007494			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14663290	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007993		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	2.5 Mg, Qd		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, Qd		Not Reported
	Tenofovir Disoproxil			C	Unknown	Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14667273	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP008000		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Musculoskeletal Pain; Pancytopenia	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14672789	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007976		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Drug Hypersensitivity; Drug Ineffective; Hepatitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14740157	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009225		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Myco[Phenolate			S	Unknown	Unk		Apotex
	Belimumab			S	Unknown	528 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14741347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009188			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gastric Disorder; Leukopenia	Hydroxychloroquine		S	Oral			Apotex
	Leflunomide		S	Oral	Unk		Apotex
	Methotrexate		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14741348	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14746340	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009079		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14746344	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009075		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14750923	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009590			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Apotex
	Penicillin G /00000901/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14752372	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009506			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Hydroxychloroquine			S	Unknown			Apotex
	Myco[Phenolate			S	Unknown			Apotex
	Mycophenolate Sodium			S	Unknown			Apotex
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14752379	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009555			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Myco[Phenolate			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14752380	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009556			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex
	Myco[Phenolate			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14757584	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009588			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	10 Mg, B.I.Wk.		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14767363	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP010336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

		Desoximetasone			S	Oral	Unk			Not Reported
		Sulfasalazine			S	Unknown	500 Mg, Unk			Not Reported
		Reactine /00884302/			S	Unknown	Unk			Not Reported
		Humira			S	Subcutaneous	40 Mg, Unk			Not Reported
		Fosamax			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14778689	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Macular Degeneration	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Methotrexate			C	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	1000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2018	14788046	NON-EXPEDITED			US-AMGEN-USASP2018053091			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	13121161	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006070		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies;	Plaquenil			S	Unknown			Not Reported

Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Arava			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	13121328	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006086		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S		Solution Intra-Arterial		Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Rituxan			S		Solution Intravenous		Not Reported
	Simponi			S		Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Cellcept			S	Unknown					Not Reported
	Humira			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	13128792	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880373		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 190.0 Day(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported
	Gravol Ginger			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	13943463	NON-EXPEDITED		OT	US-AMGEN-USASP2017134674		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Infection;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen

Mouth Ulceration; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14347719	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268425		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form : Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form: Solution Intravenous		Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown	D5w 0.2 Mg/Ml		Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14479085	NON-EXPEDITED			US-AMGEN-USASP2018014038			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia Areata; Arthralgia; Drug Intolerance; Rotator Cuff Syndrome; Therapeutic Product Effect Incomplete	Enbrel		S	Unknown	Unk		Amgen
	Simponi		S	Unknown	Unk		Not Reported
	Humira		S	Unknown	Unk		Not Reported
	Cimzia		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Remicade		S	Unknown	Unk		Not Reported
	Xeljanz Xr		S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14635449	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2018101296		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Immunosuppression	Methotrexate Sodium			S	Oral	5 Mg, Weekly		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14767514	NON-EXPEDITED			US-PFIZER INC-2018140339		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14784738	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018156386		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S		200 Mg, 1x/Day		Not Reported
	Arava			C		20 Mg, 1x/Day		Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14788235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108819		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14788673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Treatment Failure; Vomiting	Apo-Hydroxyquine		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution	Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Simponi		S	Subcutaneous	Solution	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14789094	EXPEDITED (15-DAY)		OT	PHHY2018PT067989		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Progressive Multifocal Leukoencephalopathy	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Thalidomide Celgene			S	Oral	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14790643	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108799		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14790906	NON-EXPEDITED			US-AMGEN-USASP2018053149			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14794102	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1025480		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Mylan
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Mylan
	Chloroquine			S	Unknown	200 Mg, Qd		Mylan
	Tocilizumab			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2018	14794180	EXPEDITED (15-DAY)		OT	PHHY2018AU063702		36 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Paracetamol			S	Unknown	1 G, Prn		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg And 100 Mg Alternating Days		Not Reported
	Azathioprine			S	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	11398615	EXPEDITED (15-DAY)		OT	CA-SA-2015SA120299		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Frequency: Weekly		Not Reported
	Enbrel			S	Subcutaneous	Frequency: Weekly		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Dose: 4-8 Mg/Kg, Frequency: Monthly		Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Lozide			C	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	13147472	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840907			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	8x 2.5 Mg Tablets		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral	Therapy Duration: 370.0 Day(S)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	13339444	EXPEDITED (15-DAY)		OT	CA-SA-2017SA041301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Hepatitis; Rash	Leflunomide			S	Oral	Duration-For More Than 8 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14372952	EXPEDITED (15-DAY)		OT	CA-SA-2018SA001764		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14403437	EXPEDITED (15-DAY)		OT	CA-SA-2018SA012320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Desoximetasone			S	Cutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Form: Powder For Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Form: Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
Cortisone Acetate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14574477	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000658		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Headache; Infection; Malaise; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14766530	NON-EXPEDITED			US-AMGEN-USASP2018050714			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Headache;	Enbrel			S	Unknown	Unk		Amgen

Pain	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14797279	NON-EXPEDITED			US-AMGEN-USASP2018053641			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Inflammatory Marker Increased; Mouth Ulceration; Rash	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14797380	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018052953			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Liver Function Test Increased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14797487	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109906		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Minocycline Hydrochloride		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14797858	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1201		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Malaise	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14798723	NON-EXPEDITED			US-PFIZER INC-2018166288		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Daypro			S		Unk		Pfizer
	Metaxalone			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14799104	EXPEDITED (15-DAY)		OT	PHHY2018AU071536			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Paracetamol			S	Transplacental	Maternal Dose: 1 G As Needed		Not Reported
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg And 100 Mg Alternating Days		Not Reported
	Azathioprine			S	Transplacental	Maternal Dose: 50 Mg Daily		Not Reported
	Prednisolone			S	Transplacental	Maternal Dose: 5 Mg Daily		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14800761	EXPEDITED (15-DAY)		OT	CA-SA-2016SA186882		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous		Not Reported

	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2018	14801305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	13095555	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875132			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Ativan	C		Not Reported
	Benadryl & Dyclone Mouthrinse	C		Not Reported
	Codeine	C		Not Reported
	Cortisone	C		Not Reported
	Dexamethasone	C		Not Reported
	Dilaudid	C		Not Reported
	Enablex	C	Oral	Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog (Canada)	C		Not Reported
	Kineret	C		Not Reported
	Lasix	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoloc	C		Not Reported
	Restasis	C		Not Reported
	Rituxan	C		Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14192927	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017170336		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Clostridium Difficile Infection; Hypertension; Psychotic Disorder; Rheumatoid Arthritis; Sinus Disorder; Sinusitis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Q2wk		Not Reported

	Prednisone			C	Unknown	Unk			Not Reported
	Leflunomide			C	Oral	10 Mg, Qd			Not Reported
	Norco			C	Oral	5 Mg, As Necessary			Not Reported
	Zoloft			C		200 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14610875	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000896		81 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia With Lewy Bodies; Fall; Hip Fracture; Parkinson'S Disease; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14612792	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180306137		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hodgkin'S Disease Stage Ii	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown	Also Reported As 20 Mg Once Weekly		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14658029	EXPEDITED (15-DAY)		OT	US-ROCHE-2087483			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Asthenia; Clostridium Difficile	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Infection; Fatigue; Feeling Abnormal; Hypertension; Malaise; Psychotic Disorder; Rheumatoid Arthritis; Sinusitis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased	Enbrel	S	Unknown			Not Reported
	Xeljanz Xr	S	Oral	Therapy Start Date: 01/Jan/2018		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	C				Not Reported
	Norco	C	Unknown			Not Reported
	Zoloft	C	Unknown			Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803238	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2332565-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803616	EXPEDITED (15-DAY)		DE, HO	BR-ABBVIE-18K-020-2333972-00		83 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anaemia; Anaemia; Death; Limb Injury; Lung Disorder; Peripheral Swelling; Pneumonia; Skin Bacterial Infection	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Reuquinol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803835	NON-EXPEDITED			US-AMGEN-USASP2018053905			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapeutic	Enbrel			S	Unknown	Unk		Amgen

Product Effect Incomplete; Treatment Failure	Rituxan			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Methotrexate			C	Unknown	Unk			Not Reported
	Sulfasalazine			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110743			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14803894	NON-EXPEDITED			US-AMGEN-USASP2018055386			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Rash	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14804055	NON-EXPEDITED			US-PFIZER INC-2018166813		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14804209	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001296			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14804432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate Sodium		S	Oral	Not Reported
	Plaquenil		S	Oral	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Tofacitinib Citrate		C		Not Reported
	Abatacept		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14805283	EXPEDITED (15-DAY)		OT	CA-SA-2018SA001599		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14807007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Hydroxychloroquine		S	Unknown		Not Reported
					Imuran		S	Unknown		Not Reported
					Infliximab		S	Intravenous (not otherwise specified)		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14807466	EXPEDITED (15-DAY)		OT	US-ROCHE-2110448			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	Ongoing: Yes		Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Ongoing: Yes		Not Reported
	Plaquenil			S	Unknown	Ongoing: Yes		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2018	14807483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108987		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel	S	Unknown	Therapy Duration: 4.0 Month(S)	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 1.0 Month(S)	Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Orencia	S	Unknown	Therapy Duration: 10.0 Month(S)	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	13859120	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017119561		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Trazodone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14378543	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000064		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine		S	Oral	Concordia
	Leflunomide		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		C		Not Reported
	Wellbutrin		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14378552	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14379111	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14379112	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000063		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Methotrexate			C				Not Reported

		Naproxen				C							Not Reported
		Plaquenil				C							Not Reported
		Prednisone				C							Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14379118	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain; Peripheral Swelling; Stevens-Johnson Syndrome	Hydroxychloroquine			S	Oral			Concordia
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14380878	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000061		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Clonazepam			C				Not Reported
	Desipramine			C				Not Reported

		Gabapentin			C					Not Reported
		Nitroglycerin			C					Not Reported
		Rosuvastatin Calcium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14380879	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000086			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14576307	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000690		22 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Plaquenil Tablet			S	Oral			Concordia
	Psl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14692034	NON-EXPEDITED			US-AMGEN-USASP2018041430		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Infliximab			S	Unknown	Unk		Not Reported
	Promethazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14812906	NON-EXPEDITED			US-AMGEN-USASP2018055238			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14813179	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109805		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Orencia		S	Unknown	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Reactine (Canada)		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14813389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109841		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 3.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Months Therapy Duration: 331.0 Nos		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3.0 Months		Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 1.0 Month		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 8.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia			S	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14813842	NON-EXPEDITED			US-PFIZER INC-2018172643		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14813852	NON-EXPEDITED			US-PFIZER INC-2018170418		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14815367	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712238		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal	Actemra			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported

Stenosis; Synovitis	Hydroxychloroquine		S	Unknown	Therapy Duration: 2 Months	Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S)	Not Reported
	Xeljanz		C	Unknown		Not Reported
	Methotrexate Sodium		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14815457	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110624		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14815511	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110742		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint	Actemra			S	Unknown			Not Reported

Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14815519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S)		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Imuran	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2018	14816849	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-011513			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Toxic Epidermal Necrolysis	Dexamethasone			S	Unknown			Bausch And Lomb
	Ceftriaxone			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Doxycycline			C				Not Reported
	Prednisolone			C				Not Reported
	Augmentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14676992	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000960		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Decreased; Concussion; Contusion; Fall; Haematocrit Decreased; Haemoglobin Decreased; Prothrombin Time Prolonged; Red Blood Cell Count Decreased; Rib	Hydroxychloroquine			S	Oral			Not Reported
	Filgotinib Vs Placebo			S	Oral			Not Reported
	Filgotinib Vs Placebo			S	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Leucovorin Calcium			C	Oral			Not Reported

Fracture; Skin Laceration; Skin Laceration; Therapy Interrupted; Vertigo; White Blood Cell Count Increased	Hydroxychloroquine	C	Oral	Not Reported
	Myrbetriq	C	Oral	Not Reported
	Doxycycline	C	Oral	Not Reported
	Loratadine	C		Not Reported
	Meclizine	C		Not Reported
	Hydrocodone	C		Not Reported
	Atenolol	C		Not Reported
	Levothyroxine	C		Not Reported
	Amitriptyline	C		Not Reported
	Aspirin	C		Not Reported
	Estrace	C		Not Reported
	Naproxen	C		Not Reported
	Pantoprazole	C		Not Reported
	Acetaminophen	C		Not Reported
	Mag Al Plus Xs	C		Not Reported
	Bisacodyl	C		Not Reported
	Hydromorphone	C		Not Reported
	Ondansetron	C		Not Reported
	Oxycodone	C		Not Reported
	Simethicone	C		Not Reported
	Clindamycin	C		Not Reported
	Enoxaparin	C		Not Reported
	Ferrous Sulfate	C		Not Reported
	Dextrose	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14718728	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001118		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Hydroxychloroquine			S	Unknown	10-15 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14762765	NON-EXPEDITED			US-PFIZER INC-2018152891		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hepatic Enzyme Increased; Tongue Oedema	Doxycycline Hyclate			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Cyclosporin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14818430	NON-EXPEDITED			US-AMGEN-USASP2018055220			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14818887	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2018-021949		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Olanzapine Tablet			S	Oral	2.5 Milligram, 0-0-0.5-0, Tabletten		Aurobindo
	Tamoxifen			S	Oral	20 Mg, 0-0-1-0, Tabletten ()		Not Reported
	Quensyl			S	Oral	200 Mg, 0-0-1-0, Tabletten ()		Not Reported
	Pantoprazol /01263201/			C	Oral	20 Mg, 1-0-0-0, Tabletten ()		Not Reported
	Prednisolon /00016201/			C	Oral	1 Mg, 2-0-0-0, Tabletten ()		Not Reported
	Fentanyl			C	Transdermal	12 ?G / Tag, Schema, Pflaster Transdermal ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14821110	EXPEDITED (15-DAY)		OT	CA-SA-2018SA108231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cellulitis; Drug Ineffective; Erythema; Musculoskeletal Pain; Mycobacterium Tuberculosis Complex Test Positive; Pain; Psoriasis; Skin Mass; Skin Swelling	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14821951	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cellulitis; Drug Ineffective; Erythema; Musculoskeletal Pain;	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported

Mycobacterium Tuberculosis Complex Test Positive; Pain; Psoriasis; Skin Mass; Skin Swelling	Celebrex	C	Not Reported
	Isoniazid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14822783	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018113957		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Hydroxychloroquine			S		200 Mg, Twice A Day		Not Reported
	Leflunomide			S		10 Mg, Once A Day		Not Reported
	Sulfasalazine			C		1000 Mg, Twice A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14822798	NON-EXPEDITED			US-PFIZER INC-2018175563			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Inflammatory Marker Increased; Mouth Ulceration; Rash	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14400977	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000222		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug	Hydroxychloroquine			S	Oral			Concordia

Ineffective; Dysgeusia; Fluid Retention; Lower Respiratory Tract Infection; Musculoskeletal Pain; Pain In Extremity	Folic Acid		S	Unknown	Not Reported
	Meloxicam		S	Unknown	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14400984	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000230		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Pyoderma Gangrenosum	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14400985	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Therapy Partial Responder; Urinary Tract Infection	Plaquenil			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Dose Reduce		Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14400993	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000206		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Pulmonary Fibrosis	Hydroxychloroquine			S	Oral			Concordia
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14628706	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018032590			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Chronic Kidney Disease; Epistaxis; Fall; Joint Swelling; Leukopenia; Rash; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cholestyramine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14823867	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201610-005276		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Plaquenil Tablet	S	Oral		Concordia
	Plaquenil Tablet	S			Concordia
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2018	14902090	DIRECT		DS			36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Asthenia; Cold Sweat; Dark Circles Under Eyes; Dizziness; Dysuria; Epistaxis; Eye Colour Change; Feeling Hot; Headache; Photophobia; Skin Discolouration	Plaquenil			S	Oral	Quantity:2 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2018	14824715	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110616			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Not Reported
Desoximetasone	C	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	13865613	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017350025		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis; Synovitis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Sulfasalazine			S		1 G, Bid		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		200 Mg, Bid		Not Reported
	Trazodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14030749	NON-EXPEDITED			US-AMGEN-USASP2017147827		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Enbrel			S	Unknown	Unk		Amgen

Hypersensitivity; Fatigue; Hypoaesthesia; Joint Swelling; Neck Pain; Peripheral Swelling	Plaquenil	S	Unknown	Unk		Not Reported
	Mtx	C	Subcutaneous	Unk		Not Reported
	Methotrexate	C		Unk		Not Reported
	Humira	C		Unk		Not Reported
	Meloxicam	C		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14667555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP008036		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Pain; Pain In Jaw; Swelling; Therapeutic Response Decreased	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Nifedipine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride W/Perphenazine			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14774322	NON-EXPEDITED			US-PFIZER INC-2018157243		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

Orencia	S	Unk		Not Reported
Humira	S	Unk		Not Reported
Cimzia	S	Unk		Not Reported
Cymbalta	S	Unk		Not Reported
Simponi Aria	S	Unk		Not Reported
Plaquenil	S	Unk		Not Reported
Remicade	S	Unk		Not Reported
Rituxan	S	Unk		Not Reported
Actemra	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14824783	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001436		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antineutrophil Cytoplasmic Antibody Positive; Blood Creatinine Increased; Condition Aggravated; Drug Ineffective; Glomerulonephritis Rapidly Progressive; Lupus Nephritis; Proteinuria; Renal Failure; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825197	EXPEDITED (15-DAY)		OT	KR-IPCA LABORATORIES LIMITED-IPC-2018-KR-000969			Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Hydroxychloroquine			S	Oral	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825198	EXPEDITED (15-DAY)		OT	KR-IPCA LABORATORIES LIMITED-IPC-2018-KR-000971			Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Neuropathy	Hydroxychloroquine			S	Oral	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825210	EXPEDITED (15-DAY)		OT	KR-IPCA LABORATORIES LIMITED-IPC-2018-KR-000967			Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma	Hydroxychloroquine			S	Oral	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825660	EXPEDITED (15-DAY)		HO, OT	CA-BAUSCH-BL-2018-011810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Bausch And Lomb
	Vitamin C			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825774	EXPEDITED (15-DAY)		DE, HO, OT	AU-ORION CORPORATION ORION PHARMA-18_00003502			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Multiple Organ Dysfunction Syndrome; Pancytopenia	Methotrexate			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825777	EXPEDITED (15-DAY)		HO	DE-ORION CORPORATION ORION PHARMA-18_00003493		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	10-15 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825847	NON-EXPEDITED			US-PFIZER INC-2018170749		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Gabapentin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825857	NON-EXPEDITED			US-PFIZER INC-2018172429		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825901	NON-EXPEDITED			US-PFIZER INC-2018173361			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ampicillin Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14825938	NON-EXPEDITED			US-PFIZER INC-2018174807		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14826982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2115495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form Of Administration Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14828607	EXPEDITED (15-DAY)		OT	PHHY2018TR071781		40 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Butterfly Rash; Product Use In Unapproved Indication; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Coumadin			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2018	14831044	NON-EXPEDITED			US-AMGEN-USASP2001000030			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear; Infection; Injection Site Reaction; Liver Function Test Increased; Rash; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk, Lower Dose		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	13980442	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005130		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Retinal Detachment	Plaquenil Tablet			S	Oral	200 Mg (1 Tablet) Daily And 400 Mg (2 Tablets) Daily, Alternately		Concordia
	Predonine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14276609	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1076955		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Dexamethasone			C	Unknown	Unk		Mylan
	Ciclosporin			C	Unknown	Unk		Mylan
	Lisinopril			C	Unknown	Unk		Mylan
	Danazol			C	Unknown	Unk		Mylan
	Dapsone			C	Unknown	Unk		Mylan
	Cyclophosphamide			C	Unknown	Unk		Mylan
	Atenolol			C	Endocervical	Unk		Mylan
	Vincristine			C	Unknown	Unk		Mylan
	Prednisolone			C	Unknown	Unk		Mylan
	Bendroflumethiazide			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14355557	NON-EXPEDITED			US-PFIZER INC-2018003734		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14375839	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2018M1002347		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; C-Reactive Protein Increased; Confusional State; Creatinine Renal Clearance Decreased; Off Label Use; Prothrombin Time Shortened	Fluoxetine			S	Oral	30 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Codeine Phosphate/Paracetamol			S	Oral	2 Df, Tid		Not Reported
	Loxapac /00401801/			S	Oral	1 Df, Unk		Mylan
	Loxapac /00401801/			S		50 Drop (1/12 Ml)		Mylan
	Theralene			S	Oral	1 Df, Qd		Mylan
	Theralene			S		50drop (1/12ml)		Mylan
	Noctamide			S	Oral	1 Df, Qd		Mylan
	Noctamide			S		1 Tab Qd		Mylan
	Abilify			S	Oral	10 Mg, Qd		Mylan
	Lepticur			S	Oral	2 Df, Qd		Mylan
	Tranxene			S	Oral	1 Df, Unk		Mylan
	Imeth /00113801/			S	Oral	20 Mg, Qw		Mylan
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Mylan
	Dafalgan Codeine			S	Unknown	Unk Unk, Tid		Mylan

	Speciafoldine			C	Oral	4 Df, Unk			Mylan
	Speciafoldine			C	Unknown	Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14776938	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001276		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporin A			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Depo-Provera			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14776939	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001302		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour	Hydroxychloroquine			S	Unknown			Not Reported

Benign; Off Label Use	Acetazolamide			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Methotrexate			S					Not Reported
	Leflunomide			S	Unknown				Not Reported
	Leflunomide			S					Not Reported
	Alendronate Sodium			S	Unknown				Not Reported
	Calcium Salt Not Specified			S	Unknown				Not Reported
	Iron Polymaltose			S	Unknown				Not Reported
	Infliximab			S	Unknown				Not Reported
	Infliximab			S					Not Reported
	Cyclosporin			S	Unknown				Not Reported
	Cyclosporin			S					Not Reported
	Azathioprine			S	Unknown				Not Reported
	Azathioprine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14783309	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001304		85 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Presyncope; Torsade De Pointes	Hydroxychloroquine			S	Unknown			Not Reported
	Digoxin			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Warfarin			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Rabeprazole			C				Not Reported
	Prednisolone			C				Not Reported
	Folic Acid			C				Not Reported
	Calcium			C				Not Reported
	Co-Dydramol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14831103	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14831258	NON-EXPEDITED			US-AMGEN-USASP2018057281			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Injection)		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14831436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112282		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14831522	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-036203			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Treatment Failure	Orencia			S	Oral	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	5 Mg, Qd		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone /00044702/			S	Unknown	5 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14832023	EXPEDITED (15-DAY)		DE, OT	IT-BAYER-2018-079507		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Asa			S		Unk		Bayer
	Influenza Vaccine Inactivated			S		Unk		Not Reported
	Celecoxib			S		Unk		Not Reported
	Warfarin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Montelukast			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Lorazepam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2018	14833440	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111303		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	11993072	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703967		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 6.0 Year(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 731.0 Nos		Not Reported
	Plaquenil			S	Oral	Therapy Duration: 6.0 Year(S)		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Lozide (Canada)			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	12190923	EXPEDITED (15-DAY)		OT	CA-ROCHE-1728184		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Intolerance; Hypertensive	Actemra			S	Unknown			Not Reported

Crisis; Interstitial Lung Disease; Liver Disorder	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate Sodium			S	Unknown				Not Reported
	Voltaren			C					Not Reported
	Synthroid			C					Not Reported
	Nexium			C					Not Reported
	Rituxan			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	13129018	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007995			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	13316486	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808908			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14360317	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-E2B_00009336		38 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Pregnancy On Oral Contraceptive	Plaquenil			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14400987	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthritis Bacterial; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Gastric Disorder; Mobility Decreased; Neurological Procedural Complication; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			C				Not Reported
	Diclofenac			C				Not Reported
	Plaquenil			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14403083	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000220		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14780067	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA109613		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Herpes Zoster; Hypokalaemia; Intentional Product Misuse; Malaise; Nausea; Off Label Use; Otitis Media; Pain; Rash; Rheumatoid Arthritis; Syncope; Treatment Noncompliance	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Valsartan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Enbrel			S	Unknown	Dose: (50mg 1wk)		Not Reported
	Enbrel			S	Subcutaneous	Dose: (50mg 2in 1wk)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Dose: 14.2857 Mg (50mg, 2 In 1 Wk)		Not Reported
	Enbrel			S	Unknown	Dose: (50mg 1wk)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14798416	NON-EXPEDITED			US-PFIZER INC-2018165896		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14835241	NON-EXPEDITED			US-AMGEN-USASP2018058443			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14835438	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112197		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous	Therapy Duration: 8 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 4 Years		Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14835705	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0901		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14835922	NON-EXPEDITED			US-AMGEN-USASP2018057473		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Ethanol; Drug Ineffective; Gastrointestinal Toxicity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

	Humira			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Leflunomide			C		Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14836545	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001442			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalasine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14836547	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001444			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Lyme Disease; Myocardial Infarction; Nervous System Disorder	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14836548	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14837476	EXPEDITED (15-DAY)		OT	US-SA-2018SA119438			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Rash; Therapeutic Product Effect Incomplete; Tuberculosis	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14837715	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA119555		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Herpes Zoster; Hypokalaemia; Intentional Product Misuse; Nausea;	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Off Label Use; Otitis Media; Rash; Rheumatoid Arthritis; Syncope	Xeljanz	S	Unknown			Not Reported
	Valsartan	S	Unknown			Not Reported
	Actemra	S	Unknown	Stop Date 2017		Not Reported
	Simponi	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Mtx	S	Unknown			Not Reported
	Mtx	S	Oral			Not Reported
	Mtx	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14837961	EXPEDITED (15-DAY)		OT	CA-ROCHE-2113016		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Anakinra			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration 3.0 Month(S)		Not Reported

	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 8 Months		Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14838019	EXPEDITED (15-DAY)		OT	US-SA-2018SA118468		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Cystitis; Diarrhoea; Drug Intolerance; Insomnia; Osteopenia; Rash; Rheumatoid Arthritis; Stomatitis; Swelling; Visual Impairment	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acthar			C	Unknown			Not Reported
	Latanoprost			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14838022	EXPEDITED (15-DAY)		OT	CA-ROCHE-2113021		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2018	14838074	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112126			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen/Codeine Phosphate			C	Unknown			Not Reported

		Meloxicam			C	Unknown				Not Reported
		Methotrexate			C	Unknown				Not Reported
		Synthroid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13250592	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016186135		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Simponi			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	3 Mg Per Kg/Q 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	3 Mg, Every 7 Weeks		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	3 Mg, Every 6 Weeks		Not Reported
	Methotrexate			C	Unknown	20 Mg, Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Eurofolic			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13271296	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897151			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13538130	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002868		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Erythema; Pustule; Rash; Urticaria	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral	200/400mg On Alternate Days		Concordia
	Plaquenil			S				Concordia
	Famotidine D			C				Not Reported
	Benet			C				Not Reported
	Prednisolone			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13760955	EXPEDITED (15-DAY)		CA, OT	PHHY2017US101238			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anomalous Pulmonary Venous Connection; Atrial Septal Defect; Cardiac Murmur; Cardiomegaly; Foetal Exposure During Pregnancy; Intraventricular	Mycophenolate Mofetil			S	Transplacental	Maternal Dose: 1000 Mg, Bid		Novartis
	Mycophenolate Mofetil			S	Transplacental	Maternal Dose: 500 Mg, Bid		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported

Haemorrhage; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Right Ventricular Hypertrophy; Tricuspid Valve Incompetence	Hydroxychloroquine		S	Transplacental	Maternal Dose: 200 Mg, Qd	Not Reported
	Heparin		S	Transplacental	Maternal Dose: 65 Mg, Bid	Not Reported
	Acetylsalicylic Acid		S	Transplacental	Maternal Dose: 81 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13760962	EXPEDITED (15-DAY)		OT	PHHY2017US099845		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Labour	Prednisone			S	Unknown	10 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Not Reported
	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Heparin			S	Unknown	65 Mg, Bid		Not Reported
	Acetylsalicylic Acid			S	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	13915763	NON-EXPEDITED			US-AMGEN-USASP2017128762		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Rash	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14409304	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral			Concordia
	Desoximetasone			S	Cutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14578375	NON-EXPEDITED			US-TEVA-2018-US-855725			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Urticaria	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14639473	NON-EXPEDITED			US-AMGEN-USASP2018034761		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sciatica; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown	11 Mg, Qd		Not Reported
	Cimzia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14659846	NON-EXPEDITED			US-AMGEN-USASP2018036954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi Aria			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14693105	EXPEDITED (15-DAY)		HO, OT	RO-MACLEODS PHARMACEUTICALS US LTD-MAC2018011879			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina	Clopidogrel			S	Unknown	Unk		Macleods

Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Aspirin	S	Unknown			Not Reported
	Diclofenac	S	Unknown	150 Mg, Qd		Not Reported
	Diclofenac	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk		Not Reported
	Methotrexate	C	Unknown	30 Milligram, Q.W.		Not Reported
	Methotrexate	C	Unknown	5 Mg, Unk		Not Reported
	Prednisone	C	Unknown	10 Mg, Unk		Not Reported
	Prednisone	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14694440	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001065			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; White Blood Cell Count Decreased	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14750429	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001221			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Chronic Kidney Disease; Drug Eruption; Epistaxis; Fall; Joint Swelling; Leukopenia; Rash; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous	Strength: 40mg/0.8ml		Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Cholestyramine			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14760415	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001240		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Lip Erosion; Rash Macular	Plaquenil			S	Unknown	200-400 Mg Every Other Day For Few Days		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C		1 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14825927	NON-EXPEDITED			US-PFIZER INC-2018174019		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14829618	NON-EXPEDITED			US-PFIZER INC-2018175204		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate Sodium			S		5 Mg, Unk		Pfizer
	Plaquenil			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14839682	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001138		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Bundle Branch Block; Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Abnormal; Hypokalaemia; Overdose; Pco2 Increased; Ventricular Hypokinesia	Hydroxychloroquine			S	Oral			Not Reported
	Paracetamol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840012	NON-EXPEDITED			US-AMGEN-USASP2018058434			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840013	NON-EXPEDITED			US-AMGEN-USASP2018059606			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Humira	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	C		25 Mg, Qwk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840281	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-171507		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Olanzapine			S	Oral	2.5 Mg, 0-0-0.5-0, Tabletten ()		Sun
	Tamoxifen			S	Oral	20 Mg, 0-0-1-0, Tabletten ()		Not Reported
	Quensyl			S	Oral	200 Mg, 0-0-1-0, Tabletten ()		Not Reported
	Pantoprazol			C	Oral	20 Mg, 1-0-0-0, Tabletten ()		Not Reported
	Prednisolon			C	Oral	1 Mg, 2-0-0-0, Tabletten ()		Not Reported
	Fentanyl			C	Transdermal	12 Ug / Tag, Schema, Pflaster Transdermal ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14840664	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001466		74 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Pharyngeal Oedema; Unevaluable Event	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14841151	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2340501-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Cardiac Failure; Pulmonary Embolism; Weight Fluctuation	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	On Saturday		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Progesterone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Oral	Before Bed		Not Reported
	Atorvastatin			C	Oral	At Bedtime And Taking For At Least 6 Months		Not Reported
	Cardiazem			C	Oral	Taking For At Least 6 Months		Not Reported
	Cardiazem			C				Not Reported
	Carvedilol			C	Oral			Not Reported
	Cozaar			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Folic Acid			C	Oral	Every Day Except Saturday When She Takes Methotrexate And Taking Since Year Or Two		Not Reported
	Aldactone			C	Oral			Not Reported
	Hydrocodone			C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily		Not Reported

	Tramadol			C						Not Reported
	Bumex			C	Oral					Not Reported
	Gabapentin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14842716	EXPEDITED (15-DAY)		LT, OT	AU-GLAXOSMITHKLINE-AU2018GSK076908		26 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Lupus Nephritis; Product Complaint; Product Use In Unapproved Indication; Rash; Serositis; Systemic Lupus Erythematosus	Belimumab			S	Oral	Unk		Glaxosmithkline
	Mycophenolate Mofetil			S	Oral	Unk		Glaxosmithkline
	Tacrolimus			S	Oral	Unk		Glaxosmithkline
	Methotrexate			S	Oral	Unk		Glaxosmithkline
	Azathioprine			S	Oral	Unk		Glaxosmithkline
	Rituximab			S	Oral	Unk		Not Reported
	Cyclophosphamide			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14842766	EXPEDITED (15-DAY)		HO, OT	PHHY2017GB071111		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Haemorrhagic Leukoencephalitis; Aphasia; Aspergillus Infection; Brain Midline Shift; Brain Oedema; Cerebral Aspergillosis; Confusional State; Culture Tissue Specimen Positive; Hemiparesis; Intracranial	Methotrexate			S	Unknown	1 Ot (Ug/L), Qw		Novartis
	Hydroxychloroquine			S	Unknown	1 Ot (Ug/L), Qw		Not Reported
	Sulfasalazine			S	Unknown	1 Ot (Ug/L), Qw		Not Reported

Mass; Leukopenia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843274	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018179468			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Lyme Disease; Myocardial Infarction; Nervous System Disorder	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843433	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018139180		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Impaired Work Ability; Loss Of Personal Independence In Daily Activities	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2018	14843470	EXPEDITED (15-DAY)		OT	IL-MYLANLABS-2018M1027939			Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type Iv Hypersensitivity Reaction	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	For Desensitisation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	13889987	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1517		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Gastrointestinal Disorder; Irritability; Perioral Dermatitis; Product Use Issue; Pruritus; Rash; Rash; Urticaria	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cortizone			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14647419	NON-EXPEDITED			US-PFIZER INC-2018108180		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Xalatan			S		Unk		Pfizer
	Clindamycin Phosphate			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Propanolol Hcl			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Alphagan			S		Unk		Not Reported
	Cheratussin			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Zanaflex			S		Unk		Not Reported
	Restoril			S		Unk		Not Reported

	Benicar	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14701349	NON-EXPEDITED		OT	US-AMGEN-USASP2018042137			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Rash; Therapeutic Product Effect Incomplete; Tuberculosis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14762065	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-1070		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Knee Deformity; Loss Of Personal Independence In Daily Activities	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14828988	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018160692		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Fall; Gait Disturbance; Osteoarthritis; Post Procedural Infection; Spinal Fracture; Upper Limb Fracture	Celebrex			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil /00072603/			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14840798	NON-EXPEDITED			US-PFIZER INC-2018176425		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14845003	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001393			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Rash; Therapeutic Product Effect Incomplete; Tuberculosis	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexte			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Humira			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Arava			S	Oral					Not Reported
	Xeljanz Tablet			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14845090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112957		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Ketorolac			C				Not Reported
	Prednisone			C				Not Reported
	Advil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14845215	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114712		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Arava	C			Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Coversyl	C	Oral		Not Reported
	Enbrel	C			Not Reported
	Ergocalciferol	C			Not Reported
	Folic Acid	C	Oral		Not Reported
	Humira	C	Unknown		Not Reported
	Indapamide	C	Oral		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Pantoloc	C	Oral		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Tylenol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14845410	NON-EXPEDITED			US-AMGEN-USASP2018058062			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14846120	EXPEDITED (15-DAY)		HO, OT	PHHY2016FR186739		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Fluoxetine Hydrochloride			S	Oral	30 Mg, Qd		Novartis
	Lepticur			S	Unknown	2 Df, Qd		Not Reported
	Theralene			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Abilify			S	Oral	10 Mg, Qd		Not Reported
	Noctamide			S	Oral	1 Df, Qd		Not Reported
	Paracetamol/Codeine			S	Unknown	2 Df, Tid		Not Reported
	Tranxene			S	Oral	1 Df, Unk		Not Reported
	Loxapac			S	Oral	1 Df, Unk		Not Reported
	Imeth			S	Oral	20 Mg, Qw		Not Reported
	Dafalgan Codeine			S	Unknown	Unk Unk, Tid		Not Reported
	Speciafoldine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14846209	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-040190		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Triamcinolone Acetonide			S		Unk		Bristol Myers Squibb
	Clobetasol			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14846268	NON-EXPEDITED			US-TEVA-2018-US-888343		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Eruption; Erythema; Eye Swelling; Mouth Swelling; Rash Erythematous; Wrong Technique In Product Usage Process	Hydroxychloroquine Sulfate			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14846681	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-024115		43 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Prednisone			S	Unknown	20 Milligram Per Day		Aurobindo
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14847154	EXPEDITED (15-DAY)			US-SA-2018SA045273		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Intolerance; Exposure During Pregnancy; Eye Disorder; Nausea; Therapeutic Product Effect Decreased; Unevaluable Event	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14848004	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-024152		74 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Prednisone			S	Unknown	60 Milligram Per Day		Aurobindo

	Methotrexate			S	Unknown	20 Milligram Weekly			Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14849814	EXPEDITED (15-DAY)		OT	CA-ROCHE-2115536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous	Therapy Duration: 8 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 4 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14849865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114738		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2018	14850009	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018077541		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Bronchitis; Ocular Discomfort; Product Use In Unapproved Indication; Sinusitis; Vision Blurred	Benlysta			S	Intravenous (not otherwise specified)	650 Mg, Cyc		Glaxosmithkline
	Benlysta			S				Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Advair			C				Not Reported
	Albuterol Nebulizer			C				Not Reported
	Ambien			C				Not Reported
	Ativan			C				Not Reported
	Baclofen			C				Not Reported
	Celebrex			C				Not Reported
	Crestor			C				Not Reported
	Cymbalta			C				Not Reported
	Hydrocodone			C				Not Reported
	Hysingla			C				Not Reported
	Iron			C				Not Reported
	Larin Fe			C				Not Reported
	Lyrica			C				Not Reported
	Nexium			C				Not Reported
	Norvasc			C				Not Reported
	Proair (Salbutamol Sulfate)			C				Not Reported
	Ritalin			C				Not Reported
	Topamax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14340914	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000004		11 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased; Pancreatitis	Plaquenil Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14515770	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000507		11 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Plaquenil			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14750428	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001220		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Chest Discomfort; Chest Pain; Electrocardiogram Pr Prolongation; Palpitations; Sinus Tachycardia	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Tacrolimus			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Lansoprazole			C				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported
	Ezetimibe			C				Not Reported
	Warfarin			C				Not Reported
	Methyldopa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2018	14850186	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114629		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported

Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2018	14826428	EXPEDITED (15-DAY)		HO	PHHY2018AU072262		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Weight Increased	Ranitidine			S	Unknown	150 Mg, Bid		Novartis
	Loratadine			S	Unknown	10 Mg, Bid		Not Reported
	Phenergan			S	Unknown	25 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	25 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2018	14850619	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-040962			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	10 Tab, Qwk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	11444504	EXPEDITED (15-DAY)		OT	CA-ROCHE-1628710		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Fatigue; Injection Site Reaction; Limb Injury; Limb Injury; Skin Atrophy; Skin Laceration	Rituxan			S	Unknown	2014 Unknown Dose Start/Stop Date		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Cortisone			C				Not Reported
	Naprosyn			C				Not Reported
	Tylenol			C				Not Reported
	Folic Acid			C	Unknown	Except Tuesdays		Not Reported
	Coversyl			C	Oral			Not Reported
	Pantoloc			C	Oral			Not Reported
	Tylenol #3 (Canada)			C	Oral	At Night		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	13195791	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin/Neomycin Sulfate/Polymyxin B Sulfate			S	Unknown			Not Reported

Failure	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C	Intramuscular	Not Reported
	Prednisone	C	Intramuscular	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	13781168	NON-EXPEDITED			US-AMGEN-USASP2017108285		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	13989298	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005375		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Chills; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Pyrexia; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Arthrotec			C				Not Reported

	Ketorolac			C						Not Reported
	Naproxen			C						Not Reported
	Cortisone			C						Not Reported
	Xeljanz			C						Not Reported
	Tylenol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14445994	EXPEDITED (15-DAY)		HO	US-ABBVIE-17K-163-2099796-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Cardiac Failure; Drug Interaction; Joint Swelling; Pulmonary Embolism; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	2.5mg Nine Tablets By Mouth On Saturday Once A Week		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Oral	Before Bed		Not Reported
	Cymbalta			S	Unknown			Not Reported
	Progesterone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Atorvastatin			C	Oral	At Bedtime		Not Reported
	Cardiazem			C	Oral			Not Reported
	Cardiazem			C				Not Reported
	Carvedilol			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Pantoprazole			C	Oral			Not Reported
	Folic Acid			C	Oral	Six Days A Week		Not Reported
	Aldactone			C	Oral			Not Reported
	Tramadol			C				Not Reported
	Tramadol			C				Not Reported

	Bumex			C	Oral				Not Reported
	Progesterone			C					Not Reported
	Plaquenil			C					Not Reported
	Cozaar			C	Oral				Not Reported
	Hydrocodone			C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily			Not Reported
	Gabapentin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14551744	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2260655-00		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Cystitis; Diarrhoea; Drug Eruption; Drug Intolerance; Insomnia; Osteopenia; Rheumatoid Arthritis; Stomatitis; Swelling; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Acthar			C				Not Reported
	Latanoprost			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14565483	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018024301			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Treatment Failure	Enbrel		S	Unknown	Unk	Amgen
	Orencia		S	Oral	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Unknown	5 Mg, Qd	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	5 Mg, Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown		Not Reported
	Xeljanz Xr		C	Unknown	11 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14653975	NON-EXPEDITED			US-PFIZER INC-2018112399		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14682928	NON-EXPEDITED			US-AMGEN-USASP2018039106		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14755309	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001213		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Oxytocin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14851178	NON-EXPEDITED			US-AMGEN-USASP2018060082			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14851288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114774		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14851385	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001470		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Dyspnoea Exertional; Gravitational Oedema; Orthopnoea	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14851386	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001471		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Natriuretic Peptide Increased; Cardiomyopathy; Ejection	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

Fraction Decreased; Fibrosis; Heart Sounds Abnormal; Inflammatory Marker Increased; Left Ventricular Dilatation; Left Ventricular Hypertrophy; Right Ventricular Heave; Tachycardia; Troponin T Increased; Venous Pressure Jugular Increased	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14851387	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001478		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Atrioventricular Block Complete; Cardiac Failure Congestive; Cardiomyopathy; Ejection Fraction Decreased; Muscular Weakness; Oedema Peripheral	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14852017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2115425		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Anakinra	C	Subcutaneous		Not Reported
	Ativan	C			Not Reported
	Benadryl (Canada)	C			Not Reported
	Codeine	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Enablex	C	Unknown	Tablet (Extended Release)	Not Reported
	Hydromorphone	C			Not Reported
	Kadian	C	Unknown		Not Reported
	Kenalog (Canada)	C	Intra-articular		Not Reported
	Lasix	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C			Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoprazole Sodium	C			Not Reported
	Restasis	C	Unknown		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Synthroid	C			Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown		Not Reported
	Vagifem	C	Vaginal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14852424	NON-EXPEDITED			US-PFIZER INC-2018184925		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14852827	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA166785		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthritis; Chest Pain; Chills; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Pyrexia; Rheumatoid Arthritis; Vomiting	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C				Not Reported
	Cortisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14853123	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2346189-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Rash; Skin Lesion; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Oedema; Toothache;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mtx			S	Oral			Not Reported
	Mtx			S	Oral			Not Reported
	Mtx			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Ulcer Haemorrhage	Arava		S	Unknown		Not Reported
	Cyclosporin		S	Unknown		Not Reported
	Doxycycline		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14854601	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1029230		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Prednisone			S		15 Mg, Qd		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14854897	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1028262			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyoderma Gangrenosum	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2018	14854905	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1028248			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	13905232	NON-EXPEDITED			US-PFIZER INC-2017365427		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Rash	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	13997758	NON-EXPEDITED			US-PFIZER INC-2017402909			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ampicillin Sodium			S		Unk		Unknown
	Arthrotec			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Cipro			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14692502	NON-EXPEDITED		OT	US-PFIZER INC-2018126405		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Infection; Infection; Influenza Like Illness; Pneumonia; Upper Respiratory Tract	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

Infection; Urinary Tract Infection	Remicade			S		Unk				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14700836	EXPEDITED (15-DAY)		OT	PHHO2018US003995			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased	Gsk2118436			S	Oral	150 Mg, Bid		Novartis
	Gsk2118436			S	Oral	100 Mg, Bid		Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Trametinib			S	Oral	15 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Cellcept			S	Unknown	1500 And 1000 Mg, Qam		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14740158	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009251		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Haemorrhage	Hydroxychloroquine			S	Oral	400 Mg, Every One Day		Apotex
	Leflunomide			S	Oral	20 Mg, Every One Day		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Etanercept			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg, Cyclical		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14741346	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009168			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisone Acetate			C	Subcutaneous	Unk		Not Reported
	Diclofenac			C	Subcutaneous	100 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	10 Mg, Bid		Not Reported
	Desoximetasone			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14746073	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Synovitis	Methotrexate	S	Unknown	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14746074	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Eye Disorder; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Nodule	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14746347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009094		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Once In 14 Days		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Mg, Q.Wk.		Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported

	Xeljanz			C	Unknown				Not Reported
	Zopiclone			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14752378	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14788035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009567			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Pregabalin			C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14798099	NON-EXPEDITED			US-AMGEN-USASP2018054469			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Infection; Mouth Ulceration; Myalgia	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown	11 Mg, Qd		Not Reported
	Benlysta			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14849270	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018077605		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropod Bite; Cutaneous Lupus Erythematosus; Decreased Appetite; Dysgeusia; Endodontic Procedure; Lethargy; Malaise; Nasal Ulcer; Pain; Papule; Product Dose Omission; Product Use In Unapproved Indication; Pyrexia; Stomatitis; Stress; Systemic Lupus Erythematosus; Tooth Disorder	Benlysta			S		Unk Unk, Cyc		Glaxosmithkline
	Benlysta			S				Glaxosmithkline
	Sucralfate			S		1 G, Tid		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Biotin			C				Not Reported
	Folic Acid			C				Not Reported
	Gralise			C				Not Reported
	Lisinopril			C		20 Mg, Unk		Not Reported
	Medroxyprogesterone			C				Not Reported
	Norco			C				Not Reported
	Premarin			C				Not Reported
	Prilosec			C				Not Reported
	Promethazine			C				Not Reported

	Proventil			C						Not Reported
	Reglan			C						Not Reported
	Spiriva			C						Not Reported
	Vitamin D3			C						Not Reported
	Zofran			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14858141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2115493		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14858748	EXPEDITED (15-DAY)		OT	PHEH2018US016971			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Mass; Vein Disorder	Xolair			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Multivitamins			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14859349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2115549		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14859957	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2018M1029575		14 YR	Female	HRV

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis; Proteinuria; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	500 Mg, Qd		Not Reported
	Azathioprine			C	Unknown	2 X 50 Mg Daily		Mylan
	Levothyroxine			C	Other	Unk		Mylan
	Prednisolone			C	Unknown	10 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14860414	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2346098-00		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cachexia; Drug Ineffective; Exposure To Communicable Disease; Fatigue; Fear Of Injection; Malaise; Musculoskeletal	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Pain; Nausea; Osmophobia; Pain In Extremity; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra		S	Unknown			Not Reported
	Methotrexate		S	Oral			Not Reported
	Methotrexate		S	Unknown	Injection		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14861280	EXPEDITED (15-DAY)		OT	US-SA-2018SA118066		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Atrioventricular Block Complete; Cardiac Failure Congestive; Cardiomyopathy; Ejection Fraction Decreased; Muscular Weakness; Oedema Peripheral	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14861681	EXPEDITED (15-DAY)		OT	PHHY2018GB003385			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qw		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14862056	EXPEDITED (15-DAY)		OT	PHHY2018GB003387			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyoderma Gangrenosum	Methotrexate Sodium			S	Oral	15 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2018	14948082	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Pain; Treatment Failure	Hydroxychloroquine			S				Not Reported
	Tylenol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	13939437	NON-EXPEDITED			US-PFIZER INC-2017309949		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14328384	NON-EXPEDITED			US-PFIZER INC-2017548280		86 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported
	Miacalcin			S		Unk		Not Reported

	Actonel			S		Unk				Not Reported
	Colcrys			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14663657	NON-EXPEDITED		OT	US-PFIZER INC-2018114445		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Misuse; Rheumatoid Nodule; Sinusitis	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous			Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14696099	NON-EXPEDITED			US-AMGEN-USASP2018042140			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14707619	NON-EXPEDITED			US-AMGEN-USASP2018042778			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

	Leflunomide			C	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14739450	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14740527	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009471		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14740528	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP009465		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cosentyx			S	Unknown	Unk		Not Reported

Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14744581	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Mg, Qd		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14746072	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased;	Hydroxychloroquine			S	Unknown	Unk		Apotex

Pneumonia; Rheumatoid Arthritis	Leflunomide		S	Unknown	Unk	Apotex
	Actemra		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Unknown	40 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14746233	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown			Apotex
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14746235	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009451		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex

Methotrexate	C	Subcutaneous	20 Mg, Q.Wk.		Not Reported
Sulfasalazine	C	Oral	1.5 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14746236	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009458		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Cough; Drug Ineffective; Hypoaesthesia; Intraocular Pressure Test Abnormal; Malnutrition; Migraine; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Platelet Count Decreased; Vision Blurred; Visual Impairment; Weight Increased	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14751008	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, B.I.Wk.		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Methotrexate			C	Oral	20 Mg, Q.Wk.		Not Reported
	Tocilizumab			C	Subcutaneous	162 Mg, One Every Two Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14751157	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14751340	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009612		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Hyzaar			C	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14751341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009613		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Leflunomide	S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Apotex
	Actemra	S	Unknown	8 Mg, Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
	Orencia	S	Unknown	750 Mg, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14752180	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009598			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Cimzia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	9 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14752369	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

	Methotrexate			C	Unknown	Unk				Not Reported
	Sulfasalazine			C	Oral	2.5 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14752370	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Finger Deformity; Malaise; Pain; Pulmonary Fibrosis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral			Apotex
	Sulfasalazine			C	Oral	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14752371	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009492			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14752376	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown		Apotex
	Leflunomide	S	Unknown		Apotex
	Humira	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14756816	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009604			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14757586	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine		S	Unknown	Unk		Apotex
	Leflunomide		S	Unknown	Unk		Apotex
	Actemra		S	Unknown	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14773090	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009954		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Feeding; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, One Every Two Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, One Every Two Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14773112	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14778990	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP010051		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Hepatitis	Hydroxychloroquine			S	Unknown	400 Mg, Cyclical		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14841141	NON-EXPEDITED			US-AMGEN-USASP2018058639			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Oedema	Enbrel			S	Unknown	Unk		Amgen
	Simponi Aria			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14845671	NON-EXPEDITED			US-PFIZER INC-2018182723		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14867993	NON-EXPEDITED			US-AMGEN-USASP2018061415			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14868019	NON-EXPEDITED			PHEH2018US017500			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Anger; Swelling Face	Hydroxychloroquine	S	Unknown		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14868352	EXPEDITED (15-DAY)		DE, HO	AU-ACCORD-066665			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Pancytopenia	Methotrexate			S				Accord
	Acetylsalicylic Acid			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14868786	NON-EXPEDITED			US-PFIZER INC-2018188554		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Sulfur			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14870516	NON-EXPEDITED			US-AMGEN-USASP2018061437		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2018	14871987	EXPEDITED (15-DAY)		OT	CA-SA-2018SA114079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Neurontin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Buro-Sol			C	Unknown			Not Reported
	Atasol (Acetaminophen)			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	13876370	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017074701		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Dermatitis; Dizziness; Gastrointestinal Disorder; Headache; Irritability; Nausea; Rash; Urticaria	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported

	Chloroquine			S	Unknown	400 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qwk		Not Reported
	Cortizone			C				Not Reported
	Hydrocortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14816923	EXPEDITED (15-DAY)			AR-PFIZER INC-2018169241		45 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Meprednisona			S		8 Mg, 2x/Day		Not Reported
	Vitamina D3			S		100 Ul, Unk (100 Ul, Every 15 Days)		Not Reported
	Pilocarpina			C		Unk		Not Reported
	Metformine			C		Unk		Not Reported
	Topiramato			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14824054	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2018056826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Impaired Work Ability; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Q4wk		Not Reported
	Indocin			S	Oral	50 Mg, Tid		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Q8wk				Not Reported
	Gold			S	Unknown	Unk				Not Reported
	Methacin			C	Oral	50 Mg, Tid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14840763	NON-EXPEDITED			US-PFIZER INC-2018176393		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Humira			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14852478	NON-EXPEDITED			US-PFIZER INC-2018184588		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14872412	NON-EXPEDITED			US-AMGEN-USASP2018061657			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873115	EXPEDITED (15-DAY)		OT	PR-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001454			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Eye Swelling; Malaise; Nausea; Pain; Pain; Sensitivity To Weather Change	Plaquenil 200 Mg			S	Oral	Therapy Start From 6 Months Ago And Stop From 5 Months Ago.		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Neurontin			S	Oral	Therapy Start From 6 Months Ago		Not Reported
	Prednisone			C	Oral			Not Reported
	Naproxen Sodium			C	Oral			Not Reported
	Naproxen Sodium			C				Not Reported
	Losartan			C				Not Reported
	Metoprolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873116	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001468		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Bundle Branch Block Right; Cardiac Murmur; Cardiotoxicity; Chest Pain; Conduction Disorder; Ejection Fraction Decreased; Mitral Valve Incompetence;	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Midodrine			C				Not Reported
	Fludrocortisone			C				Not Reported
	Levothyroxine			C				Not Reported
	Valproic Acid			C				Not Reported

Presyncope; Sinus Bradycardia; Systolic Dysfunction; Toxicity To Various Agents; Troponin Increased; Ventricular Hypertrophy; Ventricular Hypokinesia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873117	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873118	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001499		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhage Intracranial; Lower Gastrointestinal Haemorrhage; Off Label Use; Subdural Haematoma	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Eltrombopag			S	Unknown			Not Reported
	Cyclosporine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873119	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001566		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Decreased; Nephrolithiasis; Somnolence	Plaquenil	S	Oral		Not Reported
	Flecaine	C			Not Reported
	Atenolol	C			Not Reported
	Temesta (Lorazepam)	C			Not Reported
	Levothyrox	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873181	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2018US021242		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Tacrolimus			S	Unknown	Unk Unk, Once Daily		Astellas
	Apo-Azathioprine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Apo Mycophenolate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Gold			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873285	NON-EXPEDITED			US-PFIZER INC-2018186632			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873331	NON-EXPEDITED		OT	US-PFIZER INC-2018191511		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Fatigue; Meningitis Aseptic; Pruritus; Rash; Weight Decreased	Methotrexate Sodium	S		Unk		Pfizer
	Prednisone	S		Unk		Not Reported
	Azathioprine	S		Unk		Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Mycophenolate	S		Unk		Not Reported
	Rituximab	S		Unk		Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14873342	NON-EXPEDITED			US-PFIZER INC-2018190646		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14874686	NON-EXPEDITED			US-AMGEN-USASP2018062251			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14875103	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-086816		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin 81 Mg			S					Bayer
	Arava			S	Unknown				Not Reported
	Diclofenac			S	Unknown				Not Reported
	Diclofenac Potassium			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Gold			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Motrin			S	Unknown				Not Reported
	Naprosyn			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Sodium Aurothiomalate			S	Unknown				Not Reported
	Tramadol Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14875361	EXPEDITED (15-DAY)		OT	US-SA-2018SA122118			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blast Cells; Gastrointestinal Disorder	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14875499	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-086822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain;	Aspirin			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported

Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14875704	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201817123			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Gammagard Liquid			S	Intravenous (not otherwise specified)	70 G, Unk		Shire
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day:Qd		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Mg, 2x/Day:Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Mg, 2x/Day:Bid		Not Reported
	Apo Triamcinolone Aq			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	5 Mg/Kg, 1x/Day:Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, 1x/Week		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, 1x A Month		Not Reported
	Sulfasalazine			S	Oral	250 Mg, 1x/Day:Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14875892	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-086821		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14876592	EXPEDITED (15-DAY)		OT	PHHY2018PT076945			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg Daily		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14876593	EXPEDITED (15-DAY)		OT	PHHY2018IL001270			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Product	Hydroxychloroquine			S	Oral			Novartis

Use In Unapproved Indication

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2018	14876594	EXPEDITED (15-DAY)		OT	PHHY2018IL001275			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	11881971	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-15K-028-1529788-00		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Back Injury; Bone Erosion; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fall; Headache; Muscular Weakness; Nausea; Product Label Confusion; Rheumatoid Factor Positive; Synovitis; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	11918497	EXPEDITED (15-DAY)		HO	CA-ABBVIE-16K-028-1537866-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14562267	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-012757			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis Fungal; Synovitis; Vith Nerve Paralysis	Orencia			S	Unknown	Unk, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Cyclosporin A			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14627865	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000725		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Hydroxychloroquine			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14674523	EXPEDITED (15-DAY)		OT	CA-SA-2018SA072898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Urticaria	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lisinopril W/Hydrochlorothiazide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14694797	EXPEDITED (15-DAY)		HO, LT, OT	-SA-2018SA051602		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Product Use Issue; Rheumatoid Arthritis; Vascular Stent Thrombosis	Aspirin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Diclofenac Salt Not Specified			S	Unknown			Not Reported
	Diclofenac Salt Not Specified			S	Unknown			Not Reported

	Clopidogrel Bisulfate			S	Unknown					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14726372	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001134		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema Multiforme	Hydroxychloroquine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14787046	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001318		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Off Label Use; Rebound Effect; Subacute Cutaneous Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ketoconazole			C				Not Reported
	Clotrimazole			C				Not Reported
	Hydrocortisone			C				Not Reported
	Terbinafine			C				Not Reported
	Doxycycline			C				Not Reported
	Fluocinonide			C				Not Reported
	Tacrolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14832241	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA019474			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported

Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Enbrel	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Oral	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Desoximetasone	C				Not Reported
	Methotrexate	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14838569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017225076		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Dizziness; Gastrointestinal Disorder; Headache; Irritability; Nausea; Perioral Dermatitis; Rash; Rash; Urticaria	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Pfizer
	Chloroquine			S	Unknown	400 Mg, Weekly		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qwk		Not Reported
	Cortizone			C		Unk		Not Reported
	Hydrocortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14840106	EXPEDITED (15-DAY)		DS, HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001455		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Cytomegalovirus Colitis; Cytomegalovirus Gastritis; Encephalopathy; Enterococcal Infection; Fatigue; Hypoaesthesia; Hypotension; Klebsiella Infection; Lumbar Vertebral Fracture; Movement Disorder; Muscular Weakness; Myopathy; Paraesthesia; Pneumonia; Sensory Disturbance; Streptococcus Test Positive; Urinary Tract Infection; Urinary Tract Infection; Walking Disability	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Cyclophosphamide	S	Unknown		Not Reported
	Nifedipine	C			Not Reported
	Levothyroxine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14878575	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018061702			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Steatosis; Squamous Cell Carcinoma	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14878651	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001475		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Eruption	Hydroxychloroquine	S	In Normal Amount	Not Reported
	Psl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14878652	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001476		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Hydroxychloroquine			S				Not Reported
	Psl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14879299	NON-EXPEDITED			US-PFIZER INC-2018157423		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Oral Candidiasis	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14879497	NON-EXPEDITED			US-PFIZER INC-2018192850		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14879636	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP013621		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Interaction	Cyclosporine			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Eltrombopag			S	Unknown	Unk		Not Reported
	Immunoglobulin /00025201/			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amicar			S	Unknown	Unk		Not Reported
	Novo-Seven			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14879701	EXPEDITED (15-DAY)		OT	IE-ORION CORPORATION ORION PHARMA-18_00003603		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Leukopenia; Product Use In Unapproved Indication; Skin Atrophy	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Clobetasol Propionate			S	Topical			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Protopic			S	Topical			Not Reported
	Fluconazole			C	Unknown			Not Reported
	Efavirenz			C	Unknown			Not Reported
	Co-Trimoxazole			C	Unknown			Not Reported
	Lamivudine + Zidovudine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14879736	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16P-028-1774643-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14880546	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2018079167		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Zelitrex			S	Oral	3 G, Qd		Glaxosmithkline
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14881398	NON-EXPEDITED			US-PFIZER INC-2018193161		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14881866	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2018	14881886	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Avara			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Sulfonamides	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Cetirizine Hydrochloride	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Dose Form: Powder For Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Dose Form: Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	11868391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1524163-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	12568992	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1675501-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	14657392	EXPEDITED (15-DAY)		HO	DE-ROCHE-2087459		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	10-15 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Dose: 10-15mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	14885792	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1535280-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Insomnia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naprosyn			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	14886061	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001527			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Joint Swelling; Liver Injury; Pain; Peripheral Swelling	Plaquenil			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

		Cortisone Acetate			C						Not Reported
		Tramadol Hydrochloride			C						Not Reported
		Prednisolone			C						Not Reported
		Endep			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	14886063	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001572			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2018	14886465	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001501		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiac Hypertrophy; Cardiotoxicity; Ejection Fraction Decreased; Restrictive Cardiomyopathy; Ventricular Hypokinesia	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2018	14888610	NON-EXPEDITED			US-AMGEN-USASP2018063133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective;	Enbrel			S	Unknown	Unk		Amgen

Dyspnoea	Humira	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	11642644	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-15K-028-1481596-00		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Balance Disorder; Bursitis; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dry Mouth; Fall; Hand Deformity; Hypoaesthesia; Intervertebral Disc Operation; Joint Range Of Motion Decreased; Malaise; Muscle Tightness; Musculoskeletal Pain; Nausea; Neck Deformity; Nerve Compression; Nocturnal Dyspnoea; Pain In Extremity; Pruritus; Respiratory Disorder; Skin Wound; Spinal Cord Compression; Swelling; Therapeutic Product Effect Incomplete; Tracheostomy; Wound Complication; Wound Infection Staphylococcal	Humira 10mg/0.2ml			S	Subcutaneous	Duration: More Than 6 Months		Not Reported
	Humira 10mg/0.2ml			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	11925905	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539509-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspnoea; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Hypoaesthesia; Hypoaesthesia; Injection Site Hypoaesthesia; Migraine; Nausea; Pharyngeal Oedema; Rheumatoid Factor Positive; Swelling Face; Synovitis; Uveitis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	11926045	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539432-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthralgia; Arthralgia; Arthropathy; Arthropathy; Drug Ineffective; Drug Ineffective; Groin Pain; Joint Injury; Joint Injury; Joint Noise; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Peripheral	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Apo Rabeprazole			C				Not Reported

Swelling; Retinal Toxicity; Swelling; Swelling	Tramadol Hcl	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	11929350	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1539504-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Decreased Appetite; Dizziness; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	12213632	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1531731-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Osteoarthritis; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Oral	Cumulative Dose To First Reaction: 60 Milligram		Not Reported
	Naproxen			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Naproxen		S	Unknown	Not Reported
	Plaquenil		C		Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	12569119	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1675514-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Humira Vial			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	12570457	EXPEDITED (15-DAY)		HO	CA-ABBVIE-16K-028-1676602-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported

Shoulder Arthroplasty; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Motrin			S	Unknown	Not Reported
	Naprosyn			S	Unknown	Not Reported
	Naproxen			C		Not Reported
	Tramadol			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	12920728	EXPEDITED (15-DAY)		HO	CA-ABBVIE-16K-028-1771782-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	13980791	NON-EXPEDITED			US-AMGEN-USASP2017140102			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Flexeril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14151711	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006167		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Pigmentation; Maculopathy; Retinal Toxicity	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Rosuvastatin			C				Not Reported
	Natispray			C				Not Reported
	Atenolol			C				Not Reported
	Exforge			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Kardegic			C				Not Reported
	Carbamazepine			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14570408	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000652		71 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abnormal Weight Gain; Decreased Appetite; Dysphagia; Dysphonia; Dyspnoea; Dyspnoea; Epistaxis; Eye Infection; Fatigue; Pollakiuria; Pruritus; Retching; Sinusitis; Thrombosis; Vision Blurred; Vomiting	Plaquenil			S	Oral			Concordia
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14672542	NON-EXPEDITED			US-PFIZER INC-2018118445		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S		Unk		Pfizer
	Plaquenil /00072602/	S		Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14745105	NON-EXPEDITED			US-AMGEN-USASP2018047373			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Nausea; Vision Blurred	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Injection)		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14889029	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1771101-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Joint Swelling; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sinusitis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Failure						otherwise specified)				
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14889415	NON-EXPEDITED			US-AMGEN-USASP2018063343			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14889574	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1773054-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Peripheral Swelling; Retinal Toxicity; Sleep Disorder; Swelling	Methotrexate Sodium	S	Unknown			Not Reported
	Arava	C				Not Reported
	Plaquenil	C				Not Reported
	Rabeprazole Sodium	C				Not Reported
	Tramadol Hydrochloride	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14890367	NON-EXPEDITED			US-PFIZER INC-2018195347		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xeljanz			S	Oral	11 Mg, 1x/Day		Pfizer
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14890556	NON-EXPEDITED			US-PFIZER INC-2018193183		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14891287	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-086817		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Aspirin			S	Unknown	Unk		Bayer

Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Arava		S	Unknown	Unk		Not Reported
	Diclofenac Potassium		S	Unknown	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported
	Gold		S	Unknown	Unk		Not Reported
	Humira		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Motrin		S	Unknown	Unk		Not Reported
	Naprosyn		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk		Not Reported
	Voltaren		S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14892725	NON-EXPEDITED			US-PFIZER INC-2018195555		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14893074	NON-EXPEDITED			US-AMGEN-USASP2018062589			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14893478	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201817125			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Gammagard Liquid			S	Unknown	70 G, Unk		Shire
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 1x/2wks		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Week		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, 1x/Day:Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, 1x/Week		Not Reported
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, 1x/Week		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, 1x A Month		Not Reported
	Prednisone			S	Oral	3 Mg, 2x/Day:Bid		Not Reported
	Prednisone			S	Oral	5 Mg, 2x/Day:Bid		Not Reported
	Sulfasalazine			S	Unknown	250 Mg, 1x/Day:Qd		Not Reported
	Tocilizumab			S		280 Mg, 1x/2wks		Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14894095	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1537920-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol	Humira			S	Subcutaneous			Not Reported

Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Enbrel		S	Subcutaneous	Dosage Form : Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Ativan		C			Not Reported
	Cortisone		C			Not Reported
	Darifenacin Hydrobromide		C			Not Reported
	Hydromorphone Hydrochloride		C			Not Reported
	Diphenhydramine Hydrochloride		C			Not Reported
	Furosemide		C			Not Reported
	Loperamide		C			Not Reported
	Norflex		C			Not Reported
	Omnaris		C			Not Reported
	Pantoprazole Sodium		C			Not Reported
	Synthroid		C			Not Reported
	Vagifem		C			Not Reported
	Anakinra		C			Not Reported
	Rituximab		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14894137	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1775211-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Minodronic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	11923334	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1537827-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	11929303	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1449508-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	12570564	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1675426-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	13060298	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015843		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling; Swelling	Hydroxychloroquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	13191550	EXPEDITED (15-DAY)		OT	NL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-006019		38 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Normal Newborn; Pregnancy On Oral Contraceptive	Orencia		S	Subcutaneous	Unk		Bristol Myers Squibb
	Mtx /00113801/		S	Unknown	Unk		Not Reported
	Plaquenil /00072603/		S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	13555336	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086188		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia; Viral Upper Respiratory Tract Infection	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14249108	EXPEDITED (15-DAY)		OT	CA-SA-2017SA231964		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrooesophageal Reflux	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Disease; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14249112	EXPEDITED (15-DAY)		OT	CA-SA-2017SA232046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14635448	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2283209-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Asthenia; Chronic Sinusitis; Clostridium Difficile Infection; Fatigue;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported

Hypertension; Malaise; Psychotic Disorder; Rheumatoid Arthritis; Sinus Disorder; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Xeljanz Xr	S	Oral	Not Reported
	Hcq	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Leflunomide	C		Not Reported
	Norco	C		Not Reported
	Zoloft	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14800756	EXPEDITED (15-DAY)		OT	CA-SA-2016SA064478		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14839837	NON-EXPEDITED			US-AMGEN-USASP2018056635			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dermatitis Allergic; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported

	Actemra			S	Unknown	Unk			Not Reported
	Methotrexate			S	Oral	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Azulfidine			S	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14873420	NON-EXPEDITED			US-PFIZER INC-2018191328		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Orencia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14892728	NON-EXPEDITED			US-PFIZER INC-2018190419		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14894935	NON-EXPEDITED			US-AMGEN-USASP2018064257			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895053	EXPEDITED (15-DAY)		OT	US-ROCHE-2119559			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cachexia; Exposure To Communicable Disease; Fear Of Injection; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895173	NON-EXPEDITED			US-PFIZER INC-2018194374		88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Rofecoxib			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895476	EXPEDITED (15-DAY)		OT	PHHY2018IL001280			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Hydroxychloroquine		S	Oral			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14895882	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP013729		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S				Apotex
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Levonorgestrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14896517	NON-EXPEDITED			US-CELLTRION INC.-2018US018861			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Promethazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid (30 Day Supply)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14896801	NON-EXPEDITED			PR-PFIZER INC-2018196714		53 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil /00072602/			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14897189	EXPEDITED (15-DAY)		OT	US-SA-2018SA131770			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Infection; Oral Candidiasis; Treatment Failure	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14898626	EXPEDITED (15-DAY)		HO	FR-009507513-1805FRA004379		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Cubicin			S	Intravenous (not otherwise specified)	700 Mg, Qod		Merck
	Cubicin			S	Intravenous (not otherwise specified)	500 Mg, Qod		Merck
	Amoxicillin			S	Intravenous bolus	8 G, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Pantoprazole			S	Oral	20 Mg, Qd		Not Reported
	Furosemide			S	Oral	Unk		Not Reported
	Bisoce			C	Oral			Not Reported
	Fluindione			C	Oral			Not Reported
	Amlor			C	Oral			Not Reported
	Fumafer			C	Oral			Not Reported
	Kardegic			C	Oral			Not Reported
	Diffu-K			C	Oral			Not Reported
	Rosuvastatine			C	Oral			Not Reported

	Eupressyl	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2018	14898998	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539187-00		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	12572716	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1675469-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported

	Naprosyn			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	12980551	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA211322		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Intolerance; Rheumatoid Arthritis; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14241112	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA231847		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Intolerance; Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14496717	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-BAUSCH-BL-2018-003140		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis; Drug Ineffective; Haemophagocytic Lymphohistiocytosis; Portal Vein Thrombosis; Systemic Lupus Erythematosus	Metronidazole	S	Unknown			Not Reported
	Hydrocortisone	S	Unknown			Not Reported
	Meropenem	S	Unknown			Not Reported
	Ciprofloxacin	S	Unknown	Salt Not Specified		Not Reported
	Vancomycin	S	Unknown			Not Reported
	Prednisone	S	Unknown	Low-Dose		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14604016	EXPEDITED (15-DAY)		OT	IE-LEO PHARMA-307607		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective For Unapproved Indication; Leukopenia; Product Use In Unapproved Indication; Skin Atrophy	Protopic			S	Topical			Leo Pharm
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Clobetasol Propionate			S	Topical			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Fluconazole			C	Unknown			Not Reported
	Efavirenz			C	Unknown			Not Reported
	Co-Trimoxazole			C	Unknown			Not Reported
	Lamivudine + Zidovudine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14638826	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018033536		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Remicade			S	Unknown	Unk		Not Reported
	Cortef			S	Oral	30 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Arava			C		20 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14739543	NON-EXPEDITED			US-AMGEN-USASL2018045881		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia; Fatigue; Product Dispensing Error; Vomiting	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Oral	400 Mg, Qd (200 Mg 2 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14838571	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018162522		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	No Subject Drug			S		No Dose Given		Not Reported
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		10-15 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S		1000 Mg, Unk		Not Reported
	Rituximab			S		1000 Mg, Unk		Not Reported
	Rituximab			S		1000 Mg, Unk		Not Reported
	Rituximab			S		1000 Mg, Unk		Not Reported
	Rituximab			S		1000 Mg, Unk		Not Reported

	Rituximab	S	1000 Mg, Unk		Not Reported
	Rituximab	S	1000 Mg, Unk		Not Reported
	Rituximab	S	1000 Mg, Unk		Not Reported
	Rituximab	S	1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14881420	EXPEDITED (15-DAY)		OT	US-SA-2018SA134509		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Rash Pruritic	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14899091	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1563334-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Candida Infection; Carpal Tunnel Syndrome; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Resistance; Inflammation; Mouth Ulceration; Pain; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure; Treatment Failure	Golimumab		S	Unknown		Not Reported
	Prednisone		C			Not Reported
	Indocin		C			Not Reported
	Tramadol		C			Not Reported
	Shingles Vaccine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14899324	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Pain	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Tylenol Extra-Strength			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14899667	EXPEDITED (15-DAY)		DE	GB-TEVA-2018-GB-893543		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Immunosuppression	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14899804	NON-EXPEDITED			US-AMGEN-USASP2018064908			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Enbrel	S	Unknown	Unk		Amgen
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14901877	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00011687		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Anaphylactic Reaction; Drug Ineffective; Laboratory Test Abnormal; Malaise; Rash; Therapeutic Product Effect Decreased; Tremor; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Benepali			S	Unknown			Not Reported
	Sulphasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14902355	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2018M1031863			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Microcephaly	Diclofenac			S	Transplacental	100 Mg, Prn		Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Paracetamol			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2018	14904191	EXPEDITED (15-DAY)		OT	RO-TEVA-2018-RO-892906		66 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Escherichia Urinary Tract Infection	Methotrexate	S	Intramuscular	7.5 Mg/Week		Barr
	Plaquenil	S	Unknown			Not Reported
	Rituximab	C	Unknown	X 2 Every 2 Weeks		Not Reported
	Alfacalcidol	C	Oral			Not Reported
	Metformin	C	Oral			Not Reported
	Insuman Rapid	C	Subcutaneous	100 Iu (International Unit) Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	11923519	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1538903-00		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	12576100	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1675943-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Drug Ineffective; Fatigue; Grip	Humira			S	Subcutaneous			Not Reported

Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	13519974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038553		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Contraindicated Product Administered; Drug Ineffective; Nodule; Pain	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Not Reported
	Enbrel			S	Parenteral	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	13903296	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2017-025085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Bausch And Lomb
	Ramipril			S	Oral			Not Reported

Arthritis; Sciatica	Folic Acid			S	Unknown				Not Reported
	Actemra			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Levothyroxine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Tylenol			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14689574	EXPEDITED (15-DAY)		OT	IE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007426		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Leukopenia; Product Use In Unapproved Indication; Skin Atrophy	Triamcinolone Acetonide			S	Unknown	Unk		Bristol Myers Squibb
	Clobetasol Propionate			S	Topical			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Prednisolone			S	Oral			Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Protopic			S	Topical			Not Reported
	Fluconazole			C	Unknown			Not Reported
	Co-Trimoxazole /00086101/			C	Unknown			Not Reported
	Efavirenz			C	Unknown			Not Reported
	Lamivudine + Zidovudine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14766761	NON-EXPEDITED			US-AMGEN-USASP2018050007			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14840893	NON-EXPEDITED			US-PFIZER INC-2018177661		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		3 G, Daily		Pfizer
	Plaquenil			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14904934	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001548			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Tinnitus	Plaquenil Tablet			S	Unknown			Not Reported
	Plaquenil Tablet			S		1 Tablet Per Day Or Every Other Day Total		Not Reported
	Humira			S	Subcutaneous	Strength: 40mg/0.8ml Start Date: Several Year Ago		Not Reported
	Fish Oil			C				Not Reported
	Magnesium			C				Not Reported
	Zyrtec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14904935	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001556			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Oral Candidiasis; Treatment	Plaquenil			S				Not Reported
	Methotrexate			S		4 Tab		Not Reported

Failure	Leflunomide			S						Not Reported
	Humira			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14904937	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001620			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Plaquenil Tablet			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906474	NON-EXPEDITED			US-AMGEN-USASP2018064114			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906503	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001622		63 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agranulocytosis	Plaquenil			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Furosemide			S	Oral			Not Reported
	Amoxicillin			S	Intravenous bolus			Not Reported
	Cubicin			S	Intravenous (not otherwise specified)			Not Reported
	Cubicin			S	Intravenous (not otherwise specified)			Not Reported
	Fluindione			C				Not Reported
	Bisoce			C				Not Reported
	Amlor			C				Not Reported
	Fumafer			C				Not Reported
	Kardegic			C				Not Reported
	Diffu K			C				Not Reported
	Rosuvastatin			C				Not Reported
	Eupressyl			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906505	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001633		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Nausea; Rheumatoid Arthritis; Vomiting	Plaquenil Tablet			S	Oral			Not Reported
	Plaquenil Tablet			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906506	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001634		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Hydroxychloroquine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906507	EXPEDITED (15-DAY)		LT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001635		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Self-Injury; Loss Of Consciousness	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906923	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906925	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001641		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Abdominal Pain Upper; Arthralgia; Blood Glucose Increased; Bronchitis; Burning Sensation; Diarrhoea; Erythema; Erythema; Erythema; Fatigue; Feeling Abnormal; Feeling Hot; Fracture; Headache; Headache; Infusion Related Reaction; Joint Stiffness; Oedema Peripheral; Oxygen Saturation Decreased; Pharyngeal Paraesthesia; Rash Erythematous; Sinusitis; Swelling; Throat Irritation; Urinary Tract Infection; Urine Odour Abnormal	Hydroxychloroquine		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen		C			Not Reported
	Actonel		C			Not Reported
	Diphenhydramine Hydrochloride		C			Not Reported
	Hydroxychloroquine		C			Not Reported
	Leucovorin		C			Not Reported
	Methotrexate		C			Not Reported
	Methylprednisolone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906939	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastric Disorder; Therapeutic Product Effect Decreased; Visual Field Defect	Plaquenil Tablet			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14906940	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001648		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Flatulence	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sertraline			C				Not Reported
	Naproxen			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14907104	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1564574-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Leflunomide 20		Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14907384	NON-EXPEDITED			US-AMGEN-USASP2018065513			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14908154	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001673			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Cimzia			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14908656	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001654			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14908901	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001649		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Plaquenil Tablet	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14908902	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001651		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Sarcoidosis; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			C				Not Reported
	Salazopyrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14908998	NON-EXPEDITED			US-PFIZER INC-2018200835		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2018	14992483	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Pruritus; Rash; Rash	Plaquenil			S				Abbvie

	Humira Pen 40mg/0.8ml Abbvie			S	Subcutaneous					Abbvie

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14595498	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000713		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Cystitis; Diarrhoea; Drug Intolerance; Insomnia; Osteopenia; Rash; Rheumatoid Arthritis; Stomatitis; Swelling; Visual Impairment	Plaquenil			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr Tablet			S	Oral			Not Reported
	Xeljanz Xr Tablet			S				Not Reported
	Xeljanz Xr Tablet			S				Not Reported
	Xeljanz Xr Tablet			S				Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Acthar			C				Not Reported
	Latanoprost			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14689201	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018039949			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Dizziness; Drug Ineffective; Rash; Surgery; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Humira			C	Unknown	Unk				Not Reported
	Orencia			C	Unknown	Unk				Not Reported
	Voltaren			C	Unknown	Unk				Not Reported
	Evoxac			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14732904	NON-EXPEDITED			US-PFIZER INC-2018141984		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14773034	NON-EXPEDITED			US-PFIZER INC-2018158348		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14805617	NON-EXPEDITED			US-PFIZER INC-2018170236			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Methotrexate Sodium	S		Unk (More Than 10 Years)	Unknown
	Methotrexate	S	Oral	Unk (More Than 10 Years)	Not Reported
	Plaquenil	S		Unk (More Than 10 Years)	Not Reported
	Imuran	S		Unk (More Than 10 Years)	Not Reported
	Orencia	S		Unk (More Than 10 Years)	Not Reported
	Humira	S		Unk (More Than 10 Years)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14903661	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2353510-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Chronic Kidney Disease; Epistaxis; Fall; Joint Swelling; Leukopenia; Rash; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Colestyramine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14911070	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001664			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Not Reported
	Avara			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfonamides	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14911071	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001666		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Asa			C				Not Reported
	Bisoprolol			C				Not Reported

		Candesartan			C						Not Reported
		Pantoprazole Magnesium			C						Not Reported
		Rosuvastatin Calcium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14911072	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001627		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Fatigue; Fatigue; Gastrooesophageal Reflux Disease; Nausea; Nausea; Occipital Neuralgia; Oxygen Saturation Decreased	Hydroxychloroquine			S	Oral			Not Reported
	Indometacin			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol			C				Not Reported
	Rosuvastatin			C				Not Reported
	Prednisone			C				Not Reported
	Pantoprazole			C				Not Reported
	Pantoloc			C				Not Reported
	Naproxen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Benadryl			C				Not Reported
	Elavil			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14911140	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported

	Methotrexate	S	Subcutaneous	20 Mg, Qwk		Not Reported
	Simponi	S	Subcutaneous	Unk, Q2mo		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14911836	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14912058	NON-EXPEDITED			US-PFIZER INC-2018201530		41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14912108	NON-EXPEDITED			US-PFIZER INC-2018201129		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14913582	EXPEDITED (15-DAY)		OT	CA-DEPOMED, INC.-CA-2018DEP001110		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Movement Disorder; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased	Diclofenac Potassium			S	Unknown	Unk		Depomed
	Amitriptyline			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn E			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Apo-Diclofen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14914978	NON-EXPEDITED			US-CELGENEUS-USA-20180503195			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Headache; Liver Function Test Abnormal; Malaise; Nausea; Palmoplantar Pustulosis	Otezla			S	Oral			Celgene
	Otezla			S				Celgene
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Arava			C	Unknown					Not Reported
	Enbrel			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14915050	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018068004			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	650 Mg, Bid		Not Reported
	Aleve			C	Unknown	Unk Unk, As Necessary		Not Reported
	Ramipril			C	Unknown	2.5 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2018	14985318	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2018	12572941	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1675522-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Retinal Toxicity; Swelling	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2018	14906946	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1679072-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Muscular Weakness; Nausea; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	12422813	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-041847		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Liver Function Test Increased;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Enbrel			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	12555749	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-16K-028-1673628-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Orencia			S				Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S		Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	12566423	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1675936-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	12568816	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1675945-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Femur Fracture; Hypermobility Syndrome; Osteoporosis; Pain; Rash; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

	Orencia	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Xeljanz	S	Oral	Cumulative Dose To First Reaction 60 Mg		Not Reported
	Actemra	S	Unknown			Not Reported
	Folic Acid	C				Not Reported
	Methotrexate	C		731 Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	12914278	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092827			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Physical Disability; Thrombocytosis	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	500 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	5 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	13166255	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004944		87 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Contraindicated Product Administered; Disease Recurrence; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arthrotec			S	Unknown	Unk		Not Reported

Ineffective; Heart Rate Increased; Joint Arthroplasty; Macular Degeneration; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk	Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Qwk	Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid	Not Reported
	Lucentis			C	Unknown	Unk, Qmo	Not Reported
	Arava			C	Oral	10 Mg, Bid	Not Reported
	Tylenol Arthritis Pain			C	Oral	3 Df, Qd	Not Reported
	Aspirin /00002701/			C	Unknown	81 Mg, Unk	Not Reported
	Acetylsalicylic Acid			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	13519924	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038070		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	13853138	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk; Cyclical		Bristol Myers Squibb
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q2wk; Cyclical		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk; Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk; Cyclical		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Coversyl /00790702/			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leucovorin /00566701/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14551916	NON-EXPEDITED			US-PFIZER INC-2018069387		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14659730	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018036142		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Full Blood Count Abnormal; Headache; Herpes Zoster; Hypokalaemia; Intentional Product Misuse; Linear Iga Disease; Malaise; Nausea; Off Label Use; Otitis Media; Rheumatoid Arthritis; Syncope	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Unknown	Unk Unk, Qwk	Amgen
	Enbrel	S	Subcutaneous	50 Mg, 2 Times/Wk	Amgen
	Enbrel	S	Unknown	50 Mg, Qwk	Amgen
	Mtx	S	Unknown	Unk	Not Reported
	Mtx	S	Oral	7.5 Mg, Qwk	Not Reported
	Mtx	S	Unknown	10 Mg, Qwk	Not Reported
	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
	Prednisone	S	Unknown	3 Mg, Qd	Not Reported
	Prednisone	S	Unknown	10 Mg, Qd	Not Reported
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hcq	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Valsartan	S	Unknown	Unk	Not Reported
	Xeljanz Xr	S	Unknown	Unk	Not Reported
	Xeljanz Xr	S	Oral	11 Mg, Qd	Not Reported
	Cefuroxime Axetil	C		500 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14795608	NON-EXPEDITED			US-AMGEN-USASP2018053912			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Xeljanz	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14892827	NON-EXPEDITED			US-PFIZER INC-2018196699		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Back Pain; Drug Ineffective; Faeces Pale; Injection Site Reaction	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14917166	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1602486-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Skin Erosion; Synovitis	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Unknown		Not Reported
	Methotrexate			S	Unknown	20 Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14917443	NON-EXPEDITED			US-AMGEN-USASP2018066791			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Azulfidine			S	Unknown	Unk				Not Reported
	Plaquenil			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14917532	NON-EXPEDITED			US-AMGEN-USASP2018066856			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14917678	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1602473-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Nausea; Osteoarthritis; Synovitis	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate Sodium			S	Oral	20-25mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14917710	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2017-02068		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Anaphylactic Reaction; Lethargy; Leukopenia; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14918180	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-025883		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Beta Haemolytic Streptococcal Infection; Central Obesity; Compression Fracture; Cushingoid; Cytomegalovirus Gastritis; Dysstasia; Encephalopathy; Fatigue; Gastrointestinal Haemorrhage; Hypoaesthesia; Hypotension; Intervertebral Discitis; Muscular Weakness; Myopathy; Paraesthesia; Seizure; Sinus Tachycardia; Urinary Tract Infection; Weight Increased	Prednisone			S	Oral	60 Milligram, Daily		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14918832	NON-EXPEDITED			US-PFIZER INC-2018205786		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14919215	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1676533-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Drug Ineffective; Drug Ineffective; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14919379	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1679062-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Arava	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14920663	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018203360		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Drug Interaction; Dyspnoea; Pulmonary Embolism; Weight Fluctuation	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Mg, 2 In 1 D)		Pfizer
	Cymbalta			S		Unk (2 Weeks)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lexapro			S	Oral	20 Mg, 1x/Day (20 Mg, 1 In 1 D)		Not Reported
	Methotrexate			S	Oral	9 Df, Weekly (1 In1 Wk)(On Saturday)		Not Reported
	Methotrexate			S	Oral	Unk, Weekly (1 In 1 Wk)		Not Reported
	Progesterone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remeron			S	Oral	15 Mg, 1x/Day (Before Bed (15 Mg, 1 In 1 D))		Not Reported
	Atorvastatin			C	Oral	20 Mg, 1x/Day (At Bed Time And Taking For Atleast 6 Months (20 Mg, 1 In 1 D))		Not Reported
	Cardiazem			C	Oral	240 Mg, 1x/Day (Taking For At Least 6 Months (240 Mg,1 In 1 D))		Not Reported
	Cardiazem			C				Not Reported

Carvedilol	C	Oral	6.25 Mg, 2x/Day (6.25 Mg, 2 In 1 D)	Not Reported
Cozaar	C	Oral	25 Mg, 1x/Day (25 Mg,1 In 1 D)	Not Reported
Potassium	C	Oral	Unk Unk, 2x/Day (2 In 1 D)	Not Reported
Potassium	C	Oral	10 Meq, 1x/Day (10 Milliequivalents,1 In 1 D)	Not Reported
Pantoprazole	C	Oral	40 Mg, 1x/Day (40 Mg,1 In 1 D)	Not Reported
Folic Acid	C	Oral	1 Mg, Unk (1 Mg, 6 In 1 Wk)	Not Reported
Aldactone	C	Oral	2 Df, 1x/Day (2 Dosage Forms, 1 In 1 D)	Not Reported
Hydrocodone Bitartrate And Acetaminophen	C	Oral	1 Df, Unk (Hydrocodone Bitartrate:10 Mg/Acetaminophen:325 Mg One Tablet By Mouth Two To Three Times)	Not Reported
Tramadol	C		Unk, As Needed (As Required)	Not Reported
Bumex	C	Oral	2 Mg, 1x/Day (2 Mg,1 In 1 D)	Not Reported
Gabapentin	C		400 Mg, 3x/Day (400 Mg,3 In 1 D)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2018	14920759	EXPEDITED (15-DAY)		OT	PHHY2017US203298			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	12265523	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1601244-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Lyophilized Powder		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	12568643	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1676924-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Impaired Healing; Joint Instability; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14581868	EXPEDITED (15-DAY)		OT	PHEH2018US007593			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Psoriasis; Rheumatoid Arthritis; Urticaria; Visual Field Defect	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Cosentyx			S				Novartis
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14585031	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Ear Infection; Eye Infection; Furuncle; Nasopharyngitis; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14781556	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018051592		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bipolar Disorder; Clostridium Difficile Infection; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fear Of Injection; Food Allergy; Hypersensitivity; Injection Site Infection;	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Otrexup			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

Mastocytosis; Nausea; Orthostatic Hypotension; Pain; Subcutaneous Abscess; Swollen Tongue; Treatment Failure; Vomiting	Cimzia			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14889975	NON-EXPEDITED			US-AMGEN-USASP2018063258			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921298	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1603016-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia			S	Intravenous (not otherwise specified)					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921300	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20.0 Mg, Unk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Oral	400.0 Mg, Qd		Not Reported
	Apo Hydroxyquine			S	Oral	200.0 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20.0 Mg, Qd		Not Reported
	Folic Acid			C	Oral	5.0 Mg, Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921345	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1602411-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cortisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044619			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921413	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk, Q2wk		Not Reported
	Methotrexate			S	Oral	15 Mg, Unk		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl /00790702/			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin /00566701/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921419	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1679165-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Sedimentation Rate Increased; Synovitis				otherwise specified)		
	Prednisone		S	Unknown		Not Reported
	Xeljanz		S	Oral		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Intra-arterial	25.0 Mg, Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1.0 G, Bid		Not Reported
	Reactine /00884302/			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported

	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921567	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044368		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921648	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043901		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Ibuprofen			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported

	Prednisone			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921684	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044737		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Body Height Below Normal; Bone Density Decreased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction; Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo Triamcinolone Aq			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	25 Mg, 2 Times/Wk		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, Unk		Not Reported
	Etanercept			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Methotrexate			S	Unknown	15.0 Mg/M2, Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, 2 Times/Wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921813	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-045243		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Ill-Defined Disorder; Joint Swelling; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	600 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14921892	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1678998-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922043	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044247			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Not Reported

Arthritis	Plaquenil /00072602/	S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922077	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044295		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	70 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown	1000 Mg, Bid		Not Reported
	Tocilizumab			S	Unknown	680 Mg, Q4wk		Not Reported
	Tocilizumab			S	Unknown	360 Mg, Qmo		Not Reported
	Ciclosporin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922141	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Pain; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922264	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922297	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00011749		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Dysuria; General Physical Health Deterioration; Headache; Pyrexia; Vomiting	Prednisolone			S	Oral	5 Mg, 1-0-0-0, Tabletten		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1-0-0-0, Tabletten		Not Reported
	L-Thyroxin 50			C	Oral	50 Microg, 1-0-0-0, Tabletten		Not Reported

Furosemid	C	Oral	125 Mg, 1-1-0-0, Tabletten	Not Reported
Apidra	C	Subcutaneous	Schema, Injektions-/Infusionslösung	Not Reported
Toujeo 300 Einheiten/Ml Injektionslösung In Fertigpen	C	Subcutaneous	Schema, Injektions-/Infusionslösung	Not Reported
Novalgin (Metamizole Sodium)	C	Oral	500 Mg, 1-1-1-1, Tabletten	Not Reported
Fentanyl	C	Transdermal	37.5 Microg, Schema, Pflaster Transdermal	Not Reported
Lyrica 25mg	C	Oral	25 Mg, 1-0-1-0, Kapseln	Not Reported
Allopurinol	C	Oral	100 Mg, 1-0-0-0, Tabletten	Not Reported
Simvastatin	C	Oral	20 Mg, 0-0-1-0, Tabletten	Not Reported
Perenterol Forte 250mg	C	Oral	250 Mg, Bedarf, Kapseln	Not Reported
Nebivolol	C	Oral	5 Mg, 0-0-1-0, Tabletten	Not Reported
Movicol	C	Oral	13.125|0.35|0.18|0.05 G, Bedarf, Beutel	Not Reported
Ramipril	C	Oral	2.5 Mg, 1-0-0-0, Tabletten	Not Reported
Pantozol	C	Oral	40 Mg, 1-0-1-0, Tabletten	Not Reported
Ecural Salbe	C	Transdermal	1-0-1-0, Salbe	Not Reported
Pipamperone	C	Oral	Bedarf, Saft	Not Reported
Dekristol 20000i.E.	C	Oral	20000 Ie / Woche, 1-0-0-0, Kapseln	Not Reported
Vomex A	C	Oral	Bedarf, Dragees	Not Reported
Hydrochlorothiazid	C	Oral	25 Mg, 1-0-0-0, Tabletten	Not Reported
Ass 100	C	Oral	100 Mg, 1-0-0-0, Tabletten	Not Reported
Magnetrans Forte 150mg	C	Oral	150 Mg, Bedarf, Kapseln	Not Reported
Iberogast N	C	Oral	Bedarf, Tropfen	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922526	NON-EXPEDITED			US-PFIZER INC-2018207656		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14922609	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001726			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Rheumatoid Arthritis; Unevaluable Event	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14923175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2126800		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Piroxicam			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14923927	NON-EXPEDITED			US-PFIZER INC-2018207239		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14923929	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1846652-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Product Dose Omission	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14924817	EXPEDITED (15-DAY)		OT	FR-BAYER-2018-092538		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Acetylsalicylic Acid(<=100 Mg)			S		100 Mg, Unk		Bayer
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Prednisone			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14925388	EXPEDITED (15-DAY)		OT	CN-MYLANLABS-2018M1033821		43 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Methotrexate			S	Unknown	17.5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	0.2 G, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	8 Mg/Kg, At Week 0, 4 And 8		Mylan
	Sulfasalazine			S	Unknown	2.25 G, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14925396	EXPEDITED (15-DAY)		OT	CN-MYLANLABS-2018M1033823		57 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	0.4 G, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	8 Mg/Kg, At Week 0, 4 And 8		Mylan
	Sulfasalazine			S	Unknown	1.5 G,Qd		Mylan
	Sulfasalazine			S	Unknown	2.25 G, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14925403	EXPEDITED (15-DAY)		OT	CN-MYLANLABS-2018M1033822		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine			S	Unknown	0.4 G,Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	8 Mg/Kg, At Week 0, 4 And 8		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14926030	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1851298-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Intolerance; Fatigue; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2018	14926040	NON-EXPEDITED			US-AMGEN-USASP2018068410			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Simponi			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Humira			S	Unknown	Unk			Not Reported
	Xeljanz Xr			C		11 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	12262217	EXPEDITED (15-DAY)		DS	CA-ABBVIE-16K-028-1600656-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous	Therapy Duration: 366		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 365		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine Sodium			C				Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	12422597	EXPEDITED (15-DAY)		OT	CA-ROCHE-1766629		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Psoriatic Arthropathy; Rash; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Lyrica		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Piroxicam		C		Not Reported
	Prednisone		C	Urethral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	13735014	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1959708		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral	(Never Weaned Or Discontinued)		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14499394	EXPEDITED (15-DAY)		OT	IE-BAUSCH-BL-2018-002757		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective For Unapproved Indication; Leukopenia; Off Label Use; Product Use In Unapproved Indication; Skin Atrophy	Prednisolone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Clobetasol Propionate			S	Topical			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Methotrexate			S	Oral	Weekly		Not Reported
	Protopic			S	Topical			Not Reported
	Fluconazole			C	Unknown			Not Reported
	Co-Trimoxazole			C	Unknown			Not Reported
	Efavirenz			C	Unknown			Not Reported
	Lamivudine + Zidovudine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14617238	EXPEDITED (15-DAY)		HO, LT, OT	RO-TORRENT-00000041		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Acetylsalicylic Acid			S	Unknown	Unk		Unknown
	Clopidogrel			S	Unknown			Unknown
	Diclofenac			S		150 Mg, Daily		Unknown
	Hydroxychloroquine			S				Unknown
	Methotrexate			S	Unknown			Unknown
	Prednisone			S				Unknown
	Sulfasalazine			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14634096	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-022864			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Eye Disorder; Infection; Mouth Ulceration; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14831539	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-036289			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Endocervical			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14886062	EXPEDITED (15-DAY)		DE	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001555			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Premature Separation Of Placenta	Hydroxychloroquine	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14918779	NON-EXPEDITED			US-PFIZER INC-2018148451		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14926312	EXPEDITED (15-DAY)		HO, OT	US-ALVOGEN-2018-ALVOGEN-095866		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bipolar Disorder; Clostridium Difficile Infection; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fear Of Injection; Food Allergy; Hypersensitivity; Injection Site Infection; Mastocytosis; Nausea; Orthostatic Hypotension; Pain; Subcutaneous Abscess; Swollen Tongue; Vomiting	Clindamycin			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S				Not Reported
	Otrexup			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Cimzia			S				Not Reported
	Amoxicillin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Plaquenil			S				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14926558	NON-EXPEDITED			US-AMGEN-USASP2018068122			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927052	NON-EXPEDITED			US-AMGEN-USASP2018068044			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk (Injection, Usp)		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927082	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001593			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Retinal Toxicity	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927095	NON-EXPEDITED			US-AMGEN-USASP2018068434			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Rash; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	200, Unk, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927368	NON-EXPEDITED			US-PFIZER INC-2018209743		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Otezla			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927413	NON-EXPEDITED			US-PFIZER INC-2018209723		37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927478	NON-EXPEDITED			US-PFIZER INC-2018209333			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Imuran			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927660	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2125931		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Procytox			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2018	14927760	NON-EXPEDITED			US-PFIZER INC-2018209705		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	11923563	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539322-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	12566509	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1675930-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Etanercept		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Parenteral	Not Reported
	Tofacitinib		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	12924318	EXPEDITED (15-DAY)			PHHY2016CA152379		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Cystitis; Dermal Cyst; Ear Infection; Malaise; Pain In Extremity; Pleurisy; Urinary Tract Infection	Cosentyx			S	Subcutaneous	300 Mg, Qw		Not Reported
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Not Reported
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Not Reported
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qw		Not Reported
	Ciclosporin			S	Subcutaneous			Novartis
	Plaquenil			S	Unknown	Unk Unk, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	13570716	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003024		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased;	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia; Viral Upper Respiratory Tract Infection	Orencia	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Naproxen	C			Not Reported
	Prednisone	C			Not Reported
	Advil	C			Not Reported
	Folic Acid	C			Not Reported
	Ketorolac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	13649563	EXPEDITED (15-DAY)		OT	CA-ROCHE-1947861		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

	Methotrexate Sodium			S	Unknown					Not Reported
	Piroxicam			C						Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14576201	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-018529			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Rash	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14610934	EXPEDITED (15-DAY)		DE	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000914		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Plaquenil Tablet			S	Oral			Concordia
	Predonine			C				Not Reported
	Micardis			C				Not Reported
	Zetia			C				Not Reported
	Baktar			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14899325	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001617			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported

		Sulfasalazine			C						Not Reported
		Azathioprine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14930932	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1678990-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Aspirin			C				Not Reported
	Cymbalta			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14931289	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1564		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Interstitial Lung Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Plaquenil			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Celebrex			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14932374	NON-EXPEDITED			PHEH2018US019397			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14932507	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001585			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Plaquenil			S				Not Reported
	Enbrel			S				Not Reported
	Rituxan			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933033	NON-EXPEDITED			US-PFIZER INC-2018211771		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933044	NON-EXPEDITED			US-PFIZER INC-2018212027		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933391	EXPEDITED (15-DAY)		OT	CA-ROCHE-2128038		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934759	NON-EXPEDITED			US-AMGEN-USASP2018069168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear Of Injection; Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14935419	EXPEDITED (15-DAY)		HO	US-ELI_LILLY_AND_COMPANY-US201805009292		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomegaly; Cerebral Disorder; Pain; Pulmonary Embolism; Sleep Apnoea Syndrome	Cymbalta			S		Unk		Eli Lilly And Co
	Humira			S	Unknown	Unk Unk, Unknown		Not Reported
	Methotrexate			S	Oral	On Saturday		Not Reported
	Xeljanz			S	Unknown	Unk, Unknown		Not Reported
	Progesterone			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Atorvastatin			C	Oral	20 Mg, Daily		Not Reported
	Cardiazem /00489701/			C	Ophthalmic	240 Mg, Daily		Not Reported
	Potassium			C	Unknown	10 Df, Daily		Not Reported
	Folic Acid			C	Unknown	Unk, Daily		Not Reported
	Gabapenin			C	Unknown	400 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	13759354	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Impaired Work Ability; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Imuran			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14236016	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006511		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Haemorrhage	Plaquenil Tablet			S	Oral			Concordia
	Imuran			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14236017	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006528		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Condition Aggravated; Drug Ineffective; Hypoacusis; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Folic Acid			S	Unknown			Not Reported
	Centrum			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

	Caltrate Plus		S	Unknown	Not Reported
	Actonel		S	Oral	Not Reported
	Sodium Aurothiomalate		S	Parenteral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14236018	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006529		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Rheumatoid Arthritis; Sleep Disorder	Plaquenil Tablet			S	Oral			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238240	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006500		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrogram Abnormal; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Rotator Cuff Syndrome; Shoulder Arthroplasty; Synovial Disorder; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238241	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006501		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Intolerance; Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238242	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006504		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Meningitis Viral	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cymbalta			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238243	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006505		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Hydroxychloroquine			S	Unknown			Concordia

Abnormal; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Not Reported
	Simponi			S	Unknown	Not Reported
	Lipitor			C		Not Reported
	Methotrexate			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238244	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006506		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Pain; Rheumatoid Arthritis; Sleep Disorder	Plaquenil Tablet			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate Sodium			C				Not Reported
	Sulfasalazine			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238245	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006508		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Pain; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238254	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006520		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; C-Reactive Protein Abnormal; Chronic Sinusitis; Drug Intolerance; Infection; Monocytosis; Nausea; Neutropenia; Pruritus; Psoriasis; Red Blood Cell Sedimentation Rate Abnormal; Sinusitis; Synovitis; Urinary Tract Infection	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238255	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006521		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Apo-Folic			S	Unknown			Not Reported
	Apo-Gabapentin			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

		Xeljanz			S	Oral					Not Reported
		Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238256	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006522		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Hypersensitivity; Drug Ineffective; Drug Use Disorder; Musculoskeletal Stiffness; Sleep Disorder; Sleep Disorder; Swelling	Hydroxychloroquine Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238260	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006525		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Liver Function Test Abnormal; Lupus-Like Syndrome; Mucosal Inflammation; Psoriasis	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

	Leflunomide			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238262	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006527		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Methotrexate			C				Not Reported
	Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14238267	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006543		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intracranial Pressure Increased; Meningitis; Meningitis Aseptic	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Salazopyrin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14551498	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hypertensive Urgency; Presyncope	Plaquenil		S	Oral	Concordia
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Rituximab		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Xeljanz		C		Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14918650	NON-EXPEDITED			US-PFIZER INC-2018204493		65 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14936727	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001753			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Conjunctival Hyperaemia; Drug Eruption; Erythema; Lymphadenopathy; Malaise; Systemic Lupus	Plaquenil			S	Oral			Concordia
	Prednisolone			C				Not Reported

Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14936788	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAXTER-2018BAX015092		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Baxter
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Rituxan			S				Not Reported
	Apo-Prednisone			S	Unknown	Dosage Form: Tablet		Not Reported
	Apo-Prednisone			S	Unknown	Dosage Form: Tablet		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablet		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Oral	Dosage Form: Not Specified		Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937090	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201804014523			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Increased; Burning Sensation; Erythema; Fall;	Humulin Nph			S	Subcutaneous	25 U, Each Morning		Eli Lilly And Co
	Humulin Nph			S	Subcutaneous	25 U, Each Evening		Eli Lilly And Co

Mouth Ulceration; Muscle Disorder; Oral Fungal Infection; Polymyositis; Scoliosis	Humulin Nph	S	Subcutaneous	25 U, Each Morning		Eli Lilly And Co
	Humulin Nph	S	Subcutaneous	25 U, Each Evening		Eli Lilly And Co
	Plaquenil /00072602/	S	Unknown	Unk, Unknown		Not Reported
	Glimepiride	C		2 Mg, Unk		Not Reported
	Glimepiride	C		4 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937813	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001750			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937922	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001397		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Rheumatoid Arthritis	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported
	Cortef	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported
	Arava	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14938139	EXPEDITED (15-DAY)		OT	PHHY2018CN003112		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine			S	Unknown	0.4 G, Qd		Novartis
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14938149	EXPEDITED (15-DAY)		OT	PHHY2018CN003115		57 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Methotrexate			S	Unknown	12.5 Mg, Qw (10-12.5 Mg)		Novartis
	Sulfasalazine			S	Unknown	2.25 G, Qd (1.5-2.25g)		Not Reported
	Hydroxychloroquine			S	Unknown	0.4 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14938868	EXPEDITED (15-DAY)		OT	PHHY2018CN003111		43 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatitis B	Methotrexate			S	Unknown	17.5 Mg, Qw		Novartis

Reactivation	Hydroxychloroquine	S	Unknown	0.2 G, Qd		Not Reported
	Sulfasalazine	S	Unknown	2.25 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14939559	EXPEDITED (15-DAY)		LT, OT	CA-APOTEX-2018AP013671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Minocycline			S	Unknown	Unk		Not Reported
	Mycophenolate Sodium			S	Unknown	Unk		Apotex
	Sulfasalazin			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Apo-Atorvastatin			C	Unknown	Unk		Not Reported
	Apo-Prednisone			C	Unknown	Unk		Not Reported
	Apo-Zopiclone			C	Unknown	Unk		Not Reported
	Lactaid			C	Unknown	Unk		Not Reported
	Lactulose			C	Unknown	Unk		Not Reported
	Levemir			C	Unknown	Unk		Not Reported
	Methadone			C	Unknown	Unk		Not Reported
	Nabilone			C	Unknown	Unk		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Pms-Cetirizine			C	Unknown	Unk		Not Reported
	Quinapril Hydrochloride			C	Unknown	Unk		Not Reported
	Vitamin E /00110501/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14941069	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018004400		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Posture Abnormal	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		400 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14238238	EXPEDITED (15-DAY)			CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006498		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Crying; Drug Ineffective; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine			S	Oral			Concordia
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14241893	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006534		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthritis; Bone Pain; Chest Pain; Chest Pain; Drug Ineffective; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Joint Swelling; Kyphoscoliosis; Laboratory Test Abnormal; Musculoskeletal Discomfort;	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Sulphasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

Musculoskeletal Stiffness; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Spinal X-Ray Abnormal; Therapeutic Product Effect Incomplete; Treatment Failure	Naproxen	C		Not Reported
	Pantoprazole	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14628429	NON-EXPEDITED		OT	US-AMGEN-USASL2018031892			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cachexia; Concussion; Dyspnoea; Fatigue; Head Injury; Inflammatory Bowel Disease; Influenza; Injection Site Mass; Injection Site Pruritus; Injection Site Swelling; Joint Effusion; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Pred Forte			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14941268	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001711			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity	Hydroxychloroquine			S				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14941269	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001760		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Septra			C				Not Reported
	Xeljanz			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14941540	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001702		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Foot Deformity; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Ergocalciferol			C				Not Reported
	Marijuana			C				Not Reported
	Risedronate			C				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14941542	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001396			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2018	14941563	EXPEDITED (15-DAY)		OT	CA-ROCHE-2127995		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2018	14941838	EXPEDITED (15-DAY)		HO	PHHY2018US007582		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blister; Herpes Zoster Cutaneous Disseminated; Pain; Rash; Rash; Skin Lesion	Etanercept			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Aciclovir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14922610	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001729		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Drug Ineffective; Haemophagocytic Lymphohistiocytosis; Portal Vein Thrombosis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Hydrocortisone			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported

	Ciprofloxacin Salt Not Specified	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Vancomycin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2018	14942975	NON-EXPEDITED			US-AMGEN-USASP2018071141			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Migraine; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk (More Than 3 Months)		Not Reported
	Remicade			S	Unknown	Unk (More Than 3 Months)		Not Reported
	Sulfasalazine			S	Unknown	Unk (More Than 3 Months)		Not Reported
	Plaquenil			S	Unknown	Unk (More Than 3 Months)		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Humira			C	Unknown	Unk (More Than 3 Months)		Not Reported
	Orencia			C	Unknown	Unk (More Than 3 Months)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	13680073	EXPEDITED (15-DAY)		OT	CA-SA-2017SA112802		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling;	Desoximetasone			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Folic Acid			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported

Systemic Lupus Erythematosus	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Fosamax	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg,Unk	Not Reported
	Orencia	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone	S	Unknown	Unk Unk,Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Sulfasalazine	S	Oral	1 G,Bid	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Leflunomide	C	Unknown	Unk Unk,Unk	Not Reported
	Xeljanz	C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	13687630	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling;	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S				Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Systemic Lupus Erythematosus	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Leflunomide	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14400982	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000227		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Drug Ineffective; Hepatitis; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14656671	EXPEDITED (15-DAY)			CA-PFIZER INC-2017534482		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Xeljanz			S	Oral	5 Mg, Twice A Day		Pfizer
	Plaquenil /00072602/			S	Oral	300 Mg, Once A Day		Not Reported
	Arava			S	Oral	20 Mg, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14913428	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-007954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure; Rhinorrhoea; Ulcer	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Methotrexate			S		Unknown Dose		Not Reported
	Hydroxychloroquine Phosphate			S		Unknown Dose		Not Reported
	Magnesium Malate			C		Unk		Not Reported
	Irbesartan			C		Unk		Not Reported
	Nystatin			C		Unk		Not Reported
	Ambien			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported
	Dymista			C		Unk		Not Reported
	Biotin			C		Unk		Not Reported
	Flax Seed Oil			C		Unk		Not Reported
	Magnesium Citrate			C		Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Tylenol With Codeine No.3			C		Unk		Not Reported

Cortisone	C	Unk	Not Reported
Diclofenac	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Tramadol Hcl	C	Unk	Not Reported
Oxycodone And Acetaminophen	C	Unk	Not Reported
Carvedilol	C	Unk	Not Reported
Esomeprazole Magnesium	C	Unk	Not Reported
Omeprazole	C	Unk	Not Reported
Tums E-X	C	Unk	Not Reported
Calcium Citrate With Vitamin D	C	Unk	Not Reported
Modafinil	C	Unk	Not Reported
Metoprolol Tartrate	C	Unk	Not Reported
Nuvigil	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Valsartan Hctz	C	Unk	Not Reported
Ropinirole Hcl	C	Unk	Not Reported
Pantoprazole Sodium	C	Unk	Not Reported
Prolia	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Neurontin	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Allertec	C	Unk	Not Reported
Guaifenesin	C	Unk	Not Reported
Metolazone	C	Unk	Not Reported
Potassium Cl	C	Unk	Not Reported
Vitamin B-12	C	Unk	Not Reported
Fluticasone Propionate	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported

	Allopurinol	C	Unk		Not Reported
	Torsemide	C	Unk		Not Reported
	Ascorbic Acid	C	Unk		Not Reported
	Zolpidem Tartrate	C	Unk		Not Reported
	Fluocinonide	C			Not Reported
	Folic Acid	C	Unk		Not Reported
	Ondansetron Hcl	C			Not Reported
	Osphena	C			Not Reported
	Pennsaid	C			Not Reported
	Sucralfate	C			Not Reported
	Super B Complex With C	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14934002	EXPEDITED (15-DAY)		HO	US-GILEAD-2018-0335572		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catheterisation Cardiac; Diarrhoea	Ambrisentan			S	Unknown	5 Mg, Qd		Gilead
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remodulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944502	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001732		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Blindness Unilateral; Bronchitis; Immunodeficiency; Ocular Discomfort; Product Use In Unapproved Indication; Sinusitis; Vision Blurred	Plaquenil			S				Not Reported
	Benlysta (Belimumab) Powder For Solution For Infusion			S		Route: Intravenous Inf		Not Reported
	Benlysta (Belimumab) Powder For Solution For Infusion			S				Not Reported
	Advair			C				Not Reported
	Albuterol Nebulizer			C				Not Reported
	Ambien			C				Not Reported
	Ativan			C				Not Reported
	Baclofen			C				Not Reported

	Celebrex			C						Not Reported
	Crestor			C						Not Reported
	Cymbalta			C						Not Reported
	Hydrocodone			C						Not Reported
	Hysingla			C						Not Reported
	Iron			C						Not Reported
	Larin Fe			C						Not Reported
	Lyrica			C						Not Reported
	Vitamin B			C						Not Reported
	Vitamin D Nos			C						Not Reported
	Nexium			C						Not Reported
	Norvasc			C						Not Reported
	Proair			C						Not Reported
	Ritalin			C						Not Reported
	Topamax			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944694	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001437		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Hydroxychloroquine			S	Oral			Concordia
	Olanzapine			S	Oral			Not Reported
	Tamoxifen			S	Oral			Not Reported
	Pantoprazol			C				Not Reported
	Prednisolon			C				Not Reported
	Fentanyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944695	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001435		61 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Cough	Hydroxychloroquine 200 Mg Tablet			S	Oral			Not Reported
	Euthyrox			C				Not Reported

	Tramadol			C						Not Reported
	Vigantoletten			C						Not Reported
	Formoterol			C						Not Reported
	Rocaltrol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944696	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001434		75 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Tachycardia	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported
	Almarytm			S	Oral			Not Reported
	Torvast			C				Not Reported
	Congescor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944697	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Disability; Drug Ineffective; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944698	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001405		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush; Hypertension; Polyuria; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Oral			Not Reported
	Methotrexate			S				Not Reported

	Humira			C						Not Reported
	Cortisone			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944822	NON-EXPEDITED			US-AMGEN-USASP2018071805			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Ultram			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfa /00076401/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944995	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001771		74 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Pharyngeal Swelling; Unevaluable Event	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945157	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0081		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Knee Deformity; Posture Abnormal; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945181	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018070178		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Herpes Zoster Disseminated	Etanercept			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Acyclovir			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945438	EXPEDITED (15-DAY)		CA, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-03346			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brachycephaly; Camptodactyly Congenital; Clinodactyly; Coloboma; Congenital Arterial Malformation; Dysmorphism; Exposure During Pregnancy; External Auditory Canal Atresia; Hypertelorism Of Orbit; Microtia; Oesophageal Atresia; Olfactory Nerve Agenesis; Retrognathia	Mycophenolate Mofetil			S	Unknown	0.75 G, Qd		Alkem
	Prednisone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Alendronate			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14946375	NON-EXPEDITED			US-SA-2018SA142817			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14946377	NON-EXPEDITED			US-SA-2018SA104592			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Headache; Nausea	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	11 Mg,Qd		Not Reported
	Imuran (Azathioprine Sodium)			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14949767	NON-EXPEDITED			US-AMGEN-USASP2018072901			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14702350	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown			Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14859573	NON-EXPEDITED			US-PFIZER INC-2018181315			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Tylox			S		Unk		Not Reported
	Avalox			S		Unk		Not Reported
	Omnisporin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14921229	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1537885-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14922535	NON-EXPEDITED			US-PFIZER INC-2018207412		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk (X10 Yrs)		Pfizer
	Methotrexate			S	Oral	Unk (10 Yrs)		Not Reported
	Hydroxychloroquine			S		Unk (10 Yrs)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14934860	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1827551US		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Pulmonary Embolism	Progesterone Unk			S	Unknown	Unk		Allergan
	Humira			S	Subcutaneous	Unk Unk, Single		Not Reported
	Methotrexate			S	Oral	9 Df, Q Week, On Saturday		Not Reported
	Methotrexate			S	Oral	1 Df, Q Week, On Saturday		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Oral	20 Mg, Qd		Not Reported
	Cardiazem			C	Oral	240 Mg, Qd		Not Reported
	Potassium			C	Oral	1 Df, Bid		Not Reported
	Potassium			C	Oral	10 Meq, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd Except On Saturdays		Not Reported
	Hydrocodone			C	Oral	1 Df, Prn (2 Or 3 Qd)		Not Reported
	Tramadol			C	Unknown	Unk Unk, Prn		Not Reported

	Bumex			C	Oral	2 Mg, Qd				Not Reported
	Gabapentin			C	Oral	400 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14939740	NON-EXPEDITED			US-PFIZER INC-2018191173		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950001	EXPEDITED (15-DAY)		DE, HO, OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001781		59 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Multiple Organ Dysfunction Syndrome; Necrotising Fasciitis; Pain; Septic Shock; Streptococcal Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950061	NON-EXPEDITED			US-AMGEN-USASP2018072643			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Infection	Enbrel			S	Unknown	Unk		Amgen

	Leflunomide			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Methotrexate			C		Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950063	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-168012		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Ejection Fraction Decreased; Hypokinesia; Left Ventricular Dilatation; Left Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2131646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14950950	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-04		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiotoxicity	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14952224	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2130978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Indocine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14952250	EXPEDITED (15-DAY)		DE, HO, OT	NL-ABBVIE-18P-114-2370799-00		59 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Multiple Organ Dysfunction Syndrome; Necrotising Fasciitis; Pain; Septic	Adalimumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Shock; Streptococcal Infection	Methotrexate		S	Unknown		Not Reported
	Etanercept		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14952345	NON-EXPEDITED			US-PFIZER INC-2018220101			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Ultram			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14952416	NON-EXPEDITED			US-PFIZER INC-2018215680		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2018	14953139	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018104985		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; White Blood	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer

Cell Count Decreased	Sulfasalazine	S	2000 Mg, Daily	Pfizer
	Plaquenil /00072602/	S	Unk	Not Reported
	Plaquenil /00072602/	S	300 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	13525728	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1966142-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14221971	EXPEDITED (15-DAY)		HO, OT	FR-AMGEN-FRASP2017175794		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Erythema; Oedema; Pruritus; Pyrexia; Rash; Rash Erythematous; Rash Morbilliform; Skin Lesion	Procoralan			S	Oral	5 Mg, Bid		Amgen
	Bactrim			S	Oral	2 Df (400 Mg), Qd		Not Reported
	Tavanic			S	Oral	2 Df(500 Mg), Qd		Not Reported

	Plaquenil	S	Oral	2 Df, (500 Mg), Qd	Not Reported
	Previscan (Fluindione)	S	Oral	15 Mg, Qd	Not Reported
	Aldactone	C	Oral	2 Df, Qd	Not Reported
	Speciafoldine	C	Oral	5 Mg, Unk	Not Reported
	Speciafoldine	C	Oral	Unk	Not Reported
	Speciafoldine	C	Oral	Unk	Not Reported
	Speciafoldine	C	Oral	Unk	Not Reported
	Cerazette (Desogestrel)	C		Unk	Not Reported
	Lasilix	C	Oral	20 Mg, Unk	Not Reported
	Triatec (Ramipril)	C	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14604395	NON-EXPEDITED			US-AMGEN-USASP2018028167			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Avalox			S	Unknown	Unk		Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown	Unk		Not Reported
	Tylox			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	17.5 Mg, Qwk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14782872	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2327605-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Off Label Use; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14939427	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2018070520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Eye Disorder; Hip Arthroplasty; Intracranial Aneurysm; Osteoporosis; Pneumonia; Post Procedural Pulmonary Embolism; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	2.5 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14948246	NON-EXPEDITED			US-PFIZER INC-2018218947		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer

	Methotrexate Sodium			S	Oral	Unk			Pfizer
	Leflunomide			S		Unk			Not Reported
	Hydroxychloroquine			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14955751	EXPEDITED (15-DAY)		OT	CA-ROCHE-2128003		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14956660	EXPEDITED (15-DAY)		OT	US-ROCHE-2130554			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Hepatic Steatosis; Squamous Cell Carcinoma	Rituxan		S	Unknown	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958053	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20180538194		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanoderma	Rilpivirine Hydrochloride			S	Oral			Not Reported
	Tenofovir Disoproxil			S	Oral			Not Reported
	Emtricitabine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958362	NON-EXPEDITED			US-MYLANLABS-2018M1032176		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Mucosal Discolouration; Swollen Tongue	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Mg, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958640	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2370444-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported

Incomplete; Therapeutic Product Effect Incomplete	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Imuran		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Xeljanz Xr		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14959508	EXPEDITED (15-DAY)		DE	US-MEDAC PHARMA, INC.-2048809		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Metastatic Malignant Melanoma	Methotrexate			S				Medac
	Etanercept			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14687656	NON-EXPEDITED			US-AMGEN-USASP2018040737			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Fatigue; Osteoarthritis; Ulcer; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		11 Mg, Unk		Not Reported
	Alprazolam			C		Unk		Not Reported
	Advair Hfa			C		Unk		Not Reported
	Tylenol With Codein #3			C		Unk		Not Reported

	Omeprazole	C		40 Mg, Unk	Not Reported
	Prednisone	C	Unknown	Unk, 10 Mg, 7.5 Mg, 5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14879423	NON-EXPEDITED			US-PFIZER INC-2018190741		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk (Treatment Length: 2-3 Years)		Pfizer
	Plaquenil			S		Unk (Treatment Length: 2-3 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14901572	EXPEDITED (15-DAY)		DE, OT	IT-BAUSCH-BL-2018-013600		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Lorazepam			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Influenza Vaccine			S	Unknown			Not Reported
	Montelukast			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14961345	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0832		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Marrow Failure; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14965105	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2018M1033816		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Hypoglycaemia	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Cellcept /01275102/			C	Unknown			Mylan
	Mycophenolate Mofetil			C	Unknown	500 Mg, Unk		Mylan
	Prednisolone			C	Unknown	10 Mg, Unk		Mylan
	Atenolol			C	Unknown	50 Mg, Unk		Mylan
	Furosemide			C	Unknown			Mylan
	Amlodipine			C	Unknown			Mylan
	Pantoprazole			C	Unknown			Mylan
	Alfacalcidol			C	Unknown			Mylan
	Calcium Carbonate			C	Unknown			Mylan
	Icodextrin			C	Unknown	1.5 Unk, Unk Dianeal 1.36% 5 L And 2.27% 5 L Over 9 Hour Each Fill 1.9 L		Mylan
	Dianeal			C	Unknown	Dianeal 1.36% 5 L And 2.27% 5 L Over 9 Hour Each Fill 1.9 L		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14965187	EXPEDITED (15-DAY)		OT	FR-GILEAD-2018-0341248		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanoderma	Tenofovir Disoproxil Fumarate			S	Oral			Gilead
	Emtriva			S	Oral			Gilead
	Rilpivirine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2018	14965196	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2018M1037085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatitis	Hydroxychloroquine			S		Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported
	Leflunomide			C		Unk		Mylan
	Simponi			C		Unk		Mylan
	Orencia			C		Unk		Mylan
	Nystatin			C		Unk		Mylan
	Enbrel			C				Mylan
	Methotrexate			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2018	13590707	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941545		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Enbrel			S	Subcutaneous					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Cimzia			C	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2018	14580462	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000687			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blindness; Drug Eruption; Drug Hypersensitivity; Macular Degeneration; Procedural Pain; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Humira			S	Subcutaneous	40mg/0.8ml, Approximately Start In 2012 Or 2013		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Mobic			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Tramadol			C				Not Reported
	Sucralfate			C				Not Reported
	Protonix			C				Not Reported
	Lipitor			C				Not Reported
	Forticol			C				Not Reported
	Diazepam			C				Not Reported
	Lunesta			C				Not Reported
	Aspirin			C				Not Reported
	Benadryl			C				Not Reported
	Paroxetine			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2018	14966044	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001431		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Wellbutrin			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2018	14966049	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001366			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Celebrex			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	13373701	NON-EXPEDITED			US-PFIZER INC-2017128206		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abscess Neck; Depression; Erythema;	Xeljanz Xr			S		11 Mg, Daily		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer

Eye Infection; Eye Pain; Fatigue; Nasal Congestion; Neck Mass; Rash; Rash Vesicular; Urinary Tract Infection	Xeljanz Xr	S	Oral	11 Mg, Daily		Pfizer
	Xeljanz Xr	S	Oral	11 Mg, Daily		Pfizer
	Hydroxychloroquine	S		Unk		Not Reported
	Bd Allergy Syringe	C		Unk		Not Reported
	Albuterol Sulfate	C		Unk		Not Reported
	Alprazolam Atb	C		1 Mg, Unk		Not Reported
	Amrix	C		30 Mg, Unk		Not Reported
	Diflucan Duo	C		200 Mg, Unk		Not Reported
	Duloxetine	C		60 Mg, Unk		Not Reported
	Gabapentin	C		600 Mg, Unk		Not Reported
	Glyxambi	C		Unk		Not Reported
	Trazodone Hcl	C		50 Mg, Unk		Not Reported
	Hydrocodone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14286124	EXPEDITED (15-DAY)		OT	GB-ACCORD-062065		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Off Label Use	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Danazol			C	Unknown			Not Reported
	Dapsone			C	Unknown			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C				Not Reported
	Atenolol/Atenolol Hydrochloride			C	Unknown			Not Reported

	Vincristine			C	Unknown				Not Reported
	Prednisolone			C	Unknown				Not Reported
	Bendroflumethiazide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14694429	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001064		76 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epiglottitis	Plaquenil 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14747475	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018145602		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bladder Prolapse; Cardiac Disorder; Localised Infection	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14937812	EXPEDITED (15-DAY)		DS	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001749		58 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Maculopathy; Maculopathy; Off Label Use; Overdose; Retinal Toxicity; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown	7.5 Mg/Kg Actual Bodyweight		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Fluticasone Salmeterol			C				Not Reported
	Tiotropium Bromide			C				Not Reported
	Telmisartan			C				Not Reported
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14938058	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001751		69 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Off Label Use; Optical Coherence Tomography Abnormal; Overdose; Retinal Toxicity; Vision Blurred; Visual Field Defect	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	11.4 Mg/Kg Actual Body Weight, Cumulative Dose More Than 440 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14966678	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001786		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Pulmonary Embolism; Weight Fluctuation	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	On Saturday		Not Reported
	Methotrexate			S	Oral	Dose Decreased		Not Reported
	Xeljanz			S	Oral			Not Reported
	Progesterone			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lexapro			S	Oral			Not Reported
	Remeron			S	Oral	Before Bed		Not Reported
	Gabapentin			C				Not Reported
	Atorvastatin			C	Oral			Not Reported
	Cardiaze			C	Oral	Taking For At Least 6 Months		Not Reported
	Cardiaze			C				Not Reported

Carvedilol	C	Oral			Not Reported
Cozaar	C	Oral			Not Reported
Potassium	C	Oral			Not Reported
Potassium	C	Oral			Not Reported
Pantoprazol	C	Oral			Not Reported
Folic Acid	C	Oral	Every Day Except Saturday When She Takes Methotrexate And Taking Since Year Or Two (1 Mg, 6 In 1 Wk)		Not Reported
Aldactone	C	Oral			Not Reported
Aldactone	C	Oral			Not Reported
Hydrocodone	C	Oral	10/325mg One Tablet By Mouth Two To Three Times Daily		Not Reported
Tramadol	C		As Required		Not Reported
Bumex	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14967008	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-174507		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Disseminated	Hydroxychloroquine			S	Unknown	Unk		Sun
	Etanercept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14967461	EXPEDITED (15-DAY)		OT	CA-ROCHE-2133190		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Cimzia			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Methotrexate Sodium			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968659	NON-EXPEDITED			US-AMGEN-USASP2018074646			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Palpitations	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Injection		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14968966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2133728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown	Frequency: Every 1 Day		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14969001	NON-EXPEDITED			US-SA-2018SA117535		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased; Treatment Failure	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S				Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S				Sanofi
	Prednisone			S	Unknown	10 Mg,Qd		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14969833	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1036395		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Herpes Zoster Cutaneous Disseminated	Hydroxychloroquine			S	Unknown			Not Reported
	Aciclovir			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14971596	NON-EXPEDITED			US-AMGEN-USASP2018074755			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Oral	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	14971703	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-174527		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Anastrozole			S	Unknown	Unk		Sun
	Docetaxel			S	Unknown	Four 21-Day Cycles		Sun
	Hydroxychloroquine			S	Unknown	400 Mg, Daily (7.01 Mg/Kg/Daily)		Sun
	Cyclophosphamide			S	Unknown	Four 21-Day Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2018	15056853	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Erythema; Petechiae; Pruritus; Rash; Urticaria	Hydroxychloroquine	S	Oral		Northstar
	Levothyroxine	C			Not Reported
	Verapamil	C			Not Reported
	Zyrtec	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14867880	NON-EXPEDITED			US-AMGEN-USASP2018060870			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Decreased Immune Responsiveness; Dizziness; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14874155	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018185914		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Delirium; Drug Ineffective; Fall; Insomnia; Seizure; Skin Disorder; Somnolence; Tinnitus	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14923636	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018204725		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported

Haemorrhage; Pharyngitis Streptococcal; Systemic Lupus Erythematosus; Thyroid Cancer	Prednisone	C		5 Mg, 1x/Day	Not Reported
	Celebrex	C		200 Mg, 2x/Day	Not Reported
	Leflunomide	C		20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14972614	NON-EXPEDITED			US-PFIZER INC-2018227132			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14972846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2131729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14973917	NON-EXPEDITED			US-SA-2018SA042414			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14974490	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-048559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Autoimmune Neuropathy; Cytopenia; Therapeutic Response Decreased	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14975000	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018222350		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Anaphylactic Reaction; Laboratory Test Abnormal; Malaise; Rash; Tremor; Vomiting	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulphasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14975503	EXPEDITED (15-DAY)		HO	PHHY2018DE015476		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Methotrexate			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	10 To 15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14975845	NON-EXPEDITED			US-ROCHE-2017639			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral	For 30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14975886	NON-EXPEDITED			US-ROCHE-2056837			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Injection Site Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14975986	NON-EXPEDITED			US-ROCHE-2067356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Rash	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976039	NON-EXPEDITED			US-ROCHE-2035725			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976231	NON-EXPEDITED			US-ROCHE-1995890			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral	Refills: 11, Interim Care: 11 Mg Xr Oral Once A Day, 5 Refills		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976254	NON-EXPEDITED			US-ROCHE-2053340		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Butterfly Rash; Drug Ineffective; Gastrointestinal Disorder; Mental Status Changes; Pruritus	Actemra			S	Unknown	Ongoing: Unknown		Not Reported
	Humira			S	Subcutaneous	Ongoing: Unknown		Not Reported
	Plaquenil			S	Unknown	Six Months		Not Reported
	Cimzia			S	Unknown	Ongoing:Unknown		Not Reported
	Methotrexate			S	Unknown	Ongoing: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976267	NON-EXPEDITED			US-ROCHE-2075103			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira			S					Not Reported
	Cimzia			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976321	NON-EXPEDITED			US-ROCHE-2058422			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2133768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine (Canada)	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2018	14976565	NON-EXPEDITED			US-SA-2018SA142855			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	12236982	EXPEDITED (15-DAY)		OT	BR-ROCHE-1335531		50 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Blindness; Burning Sensation; Cataract; Erythema; Fatigue; Gait Disturbance; Groin Pain; Localised Infection; Migraine; Pain; Pain In Extremity; Peripheral Swelling; Skin Discolouration; Therapeutic Product Effect Delayed; Tooth Disorder; Tooth Fracture; Vomiting	Actemra			S	Intravenous (not otherwise specified)	Date Of Most Recent Dose Of Tocilizumab: Mar/2014 Date Of Most Recent Dose Of Tocilizumab: 23/Mar/20		Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Reuquinol			S	Unknown			Not Reported
	Meticorten			S	Unknown			Not Reported
	Tecnomet			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	13409857	NON-EXPEDITED		OT	US-PFIZER INC-2017145337		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Malaise; Pneumonia; Upper Respiratory Tract Infection; Vitamin D Decreased	Xeljanz			S		5 Mg, Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	13926331	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017376020			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Therapy Change	Ramipril			S	Oral	Unk Unk, 1x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown	1 Df, 2x/Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	1 Df, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14751179	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1054		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bladder Prolapse; Cardiac	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Disorder; Localised Infection	Arava		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14977224	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001790		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea Haemorrhagic; Dyspepsia	Hydroxychloroquine Tablet			S	Oral	1.5 Tablet By Mouth Once Daily		Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole			S				Not Reported
	Xeljanz Xr			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14977290	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-049920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Steatosis; Squamous Cell Carcinoma	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14977441	NON-EXPEDITED			US-AMGEN-USASP2018075008			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk		Amgen
	Remicade	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Mtx	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14978242	NON-EXPEDITED			US-SA-2018SA149317			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14978908	EXPEDITED (15-DAY)		OT	CA-SA-2018SA144750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Lung Neoplasm Malignant; Pain; Pain In Extremity; Pulmonary Fibrosis; Pulmonary Mass; Swelling; Upper Limb Fracture	Plaquenil			S	Oral	300 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg		Not Reported
	Methotrexate			C	Oral	15 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14979233	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018075330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Knee Arthroplasty; Liver Disorder; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14979598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2135227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous				Not Reported
	Acetaminophen/Codeine Phosphate			C					Not Reported
	Meloxicam			C					Not Reported
	Methotrexate			C	Unknown				Not Reported
	Synthroid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14980034	NON-EXPEDITED			US-SA-2018SA142830			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Plaquenil			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14981455	EXPEDITED (15-DAY)		HO	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-174957		36 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Prednisone			S	Unknown			Mutual
	Hydroxychloroquine			S	Unknown			Sun
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	13112134	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Lupus Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	13931785	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2716			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Rheumatoid Arthritis; Sciatica	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Ramipril			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14530263	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2018JPN006113		63 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Proteinuria	Belimumab			S	Intravenous drip	10 Mg/Kg, Unk		Glaxosmithkline
	Loxonin Tablets			S	Oral	60 Mg, Bid, After Breakfast And Dinner		Not Reported
	Prograf			S	Oral	0.5 Mg, Qd, After Dinner		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd, After Breakfast		Not Reported
	Rinderon [Betamethasone]			C		0.5 Mg, 1d		Not Reported
	Rinderon [Betamethasone]			C		0.25 Mg, Qd, After Breakfast		Not Reported
	Celestamine Combination Tablets			C		1 Df, Qd, Before Bedtime		Not Reported
	Nipolazin Tablets			C		3 Mg, Bid, After Breakfast And Dinner		Not Reported
	Itorol			C		40 Mg, Bid, After Breakfast And Dinner		Not Reported
	Metgluco Tablets			C		250 Mg, Bid, After Breakfast And Dinner		Not Reported
	Coniel			C		4 Mg, Bid, After Breakfast And Dinner		Not Reported
	Constan [Alprazolam]			C		0.4 Mg, Tid,Morning, Evening, Before Bedtime		Not Reported
	Lixiana			C		60 Mg, Qd After Breakfast		Not Reported
	Fluitran			C		2 Mg, Qd, After Breakfast		Not Reported
	Furosemide Tablets			C		20 Mg, Bid, After Breakfast And Lunch		Not Reported
	Tramcet Combination Tablets			C		2 Df, Qid, After Breakfast, Lunch And Dinner, Before Bedtime		Not Reported

Triazolam Tablets	C	0.5 Mg, Qd, Before Bedtime	Not Reported
Brotizolam	C	0.25 Mg, Qd, Before Bedtime	Not Reported
Rohypnol Tablets	C	1 Mg, Qd, Before Bedtime	Not Reported
Bofutsushosan	C	2.5 G, Tid, After Breakfast, Lunch And Dinner	Not Reported
Grandaxin	C	50 Mg, Tid, After Breakfast, Lunch And Dinner	Not Reported
Mecobalamin	C	500 ?G, Tid, After Breakfast, Lunch And Dinner	Not Reported
Bayaspirin Tablets	C	100 Mg, Qd, After Morning	Not Reported
Ebrantil Capsules	C	30 Mg, Bid, After Breakfast And Dinner	Not Reported
Mexiletine Hydrochloride	C	50 Mg, Bid, After Breakfast And Dinner	Not Reported
Eperisone Hydrochloride	C	50 Mg, Qd, After Dinner	Not Reported
Maintate (Bisoprolol Fumarate)	C	5 Mg, Qd, After Dinner	Not Reported
Lansoprazole-Od Tablets	C	15 Mg, Qd, After Dinner	Not Reported
Magmitt Tablet	C	330 Mg, Tid, After Breakfast, Lunch And Dinner	Not Reported
Sumilu Stick	C	Unk, Bid	Not Reported
Paroxetine	C	20 Mg, Qd, After Dinner	Not Reported
Depakene-R Tablet	C	200 Mg, Bid,After Breakfast And Dinner	Not Reported
Isosorbide Dinitrate Tape	C	40 Mg, Qd, Morning	Not Reported
Kipres Tablets	C	10 Mg, Qd, After Dinner	Not Reported
Domperidone	C	5 Mg, Tid, After Breakfast, Lunch And Dinner	Not Reported
Shakuyakukanzoto	C	2.5 G, Prn	Not Reported

	Limaprost Alfadex	C	5 ?G, Tid, After Breakfast, Lunch And Dinner	Not Reported
	Symbicort	C	Unk	Not Reported
	Glycerin	C	Unk	Not Reported
	Antebate Ointment	C	Unk	Not Reported
	Fesin (Japan)	C	Unk	Not Reported
	Influenza Ha Vaccine	C		Not Reported
	Predonine	C	Unk	Not Reported
	Luprac	C	8 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14711895	NON-EXPEDITED			US-AMGEN-USASP2018042884			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Full Blood Count Decreased; Rash	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14878663	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1435		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Confusional State; Decreased Appetite; Delirium; Drug Ineffective; Fall; Insomnia; Seizure; Skin Disorder;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Somnolence; Tinnitus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14931716	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1547		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Pharyngitis Streptococcal; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14970638	EXPEDITED (15-DAY)		HO	TR-MYLANLABS-2018M1036921		36 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Cutaneous Disseminated	Hydroxychloroquine			S	Unknown	Interval: Periodically		Not Reported
	Prednisone			S	Unknown	Interval: Periodically		Not Reported
	Cyclophosphamide			S	Unknown	Interval: Periodically		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14981565	EXPEDITED (15-DAY)		HO	PHHY2018TR010791		36 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Generalised Oedema; Herpes Zoster; Pain	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14981717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2133136		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Cataract Operation; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 397 Days		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 6 Years		Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 560 Nos		Not Reported
	Orencia			S	Unknown	Therapy Duration: 471 Days		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 10 Years		Not Reported
	Remicade			S	Unknown	Therapy Duration: 471 Days		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14982054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2133207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14982344	NON-EXPEDITED			US-AMGEN-USASP2018075761			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14983494	EXPEDITED (15-DAY)		DE	PHHY2018GB016460		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Immunosuppression	Methotrexate			S	Oral	5 Mg, Qw		Novartis
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14984948	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018224492		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Gastrointestinal Disorder; Headache; Irritable Bowel Syndrome; Malaise	Methotrexate Sodium			S				Unknown
	Sulfasalazine			S				Pfizer
	Plaquenil /00072603/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14984969	NON-EXPEDITED			US-SA-2018SA042307		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14984998	NON-EXPEDITED			US-PFIZER INC-2018231659		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985537	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE016757		63 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenocarcinoma Of Colon	Azathioprine			S	Unknown	50 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	50 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	150 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	200 Mg, Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14986084	EXPEDITED (15-DAY)		DE	FR-ASTRAZENECA-2018SE72414		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Inexium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14767724	NON-EXPEDITED			US-AMGEN-USASP2018050028			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14946381	EXPEDITED (15-DAY)		OT	US-SA-2018SA142796		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Dysarthria; Facial Paralysis; Urticaria	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S		Unk		Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Cimzia			S				Not Reported
	Prozac			C				Not Reported
	Singulair			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14963952	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2018215190		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Avelumab			S	Intravenous (not otherwise specified)	Unk, Cyclic (D1, 15)		Pfizer
	Gemcitabine Hydrochloride			S	Intravenous (not otherwise specified)	Unk, Cyclic (Days 1, 8, 15)		Unknown
	Abraxane			S	Intravenous (not otherwise specified)	Unk, Cyclic (Days 1, 8, 15)		Not Reported
	Hydroxychloroquine			S	Oral	Unk Unk, Daily		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Eliquis			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14987126	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001516			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Dysarthria; Facial Paralysis; Urticaria	Plaquenil			S	Unknown			Not Reported
	Methotrexate Oral			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Humira (Solution For Injection)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Prozac			C				Not Reported
	Singulair			C				Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14987127	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001842			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Myofascial Pain Syndrome; Rash; Surgery; Swelling	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Voltaren			C				Not Reported
	Evoxac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14987132	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001969		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Coma; Feeling Jittery;	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported

Heart Rate Increased; Herpes Zoster; Lung Neoplasm Malignant; Visual Acuity Reduced	Topalgic (Tramadol Hydrochloride)	C	Not Reported
	Prednisone	C	Not Reported
	Cortancyl	C	Not Reported
	Isoptine	C	Not Reported
	Folic Acid	C	Not Reported
	Vitamine D	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14987224	NON-EXPEDITED			US-AMGEN-USASP2018075595			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastrointestinal Disorder; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14987498	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-029059		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanoderma	Tenofovir Disoproxil			S	Oral	Unk		Aurobindo
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Emtricitabine			S	Oral	Unk		Not Reported
	Rilpivirine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14988324	NON-EXPEDITED			US-SA-2018SA117555		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Arava	S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine	S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate	S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14988888	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010619		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Tinnitus; Visual Impairment	Hydroxychloroquine			S	Unknown			Concordia
	Asa			C				Not Reported
	Oxyneo			C				Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14989327	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018185680		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Lung Disorder	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Plaquenil /00072603/			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14990341	NON-EXPEDITED			US-ROCHE-2102830			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Fatigue; Pain; Rash; Tachyphylaxis	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14991163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2136829		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 9 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365 Nos		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14991190	EXPEDITED (15-DAY)		OT	CA-ROCHE-2136824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Methotrexate Sodium			S	Unknown				Not Reported
		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Prednisone			S	Unknown				Not Reported
		Reactine (Canada)			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Phthalylsulfathiazole			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14991213	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2135268			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo Celecoxib			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	15089420	DIRECT	Y	HO, LT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Antiphospholipid Syndrome; Bone Marrow Failure; Fall; Haematocrit Decreased; Haemoglobin Decreased; Hypercoagulation; Pain; Platelet Count Decreased; Psychotic Disorder; Red Blood Cell Count Decreased; Refusal Of Treatment By Patient; Thrombocytopenia	Plaquenil	S	Oral	1 YR	Not Reported
	Warfarin	C			Not Reported
	Lamotrigine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	12330313	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1750335		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Erythema; Granuloma Skin; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Ulcer	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2, Therapy Duration: 2 Years Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Therapy Duration: 10 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 20 Years		Not Reported
	Enbrel			S	Unknown			Not Reported

	Codeine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 20 Years	Not Reported
	Myochrysine	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	13583994	EXPEDITED (15-DAY)		OT	CA-ROCHE-1861323		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	14992359	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-903120		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Olanzapine			S	Oral	0-0-0.5-0,		Teva
	Tamoxifen			S	Oral	0-0-1-0,		Actavis
	Quensyl			S	Oral	0-0-1-0		Not Reported
	Pantoprazol			C	Oral	1-0-0-0		Not Reported
	Prednisolon			C	Oral	2-0-0-0		Not Reported
	Fentanyl			C	Transdermal	12 Microgram Daily; Pattern,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	14992430	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2018-029866		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Gabapentin			S	Oral	Unspecified		Aurobindo
	Mirtazapine			S	Oral	Unspecified		Aurobindo
	Zopiclone			S	Oral	Unspecified		Not Reported
	Morphine			S	Oral	Unspecified		Not Reported
	Hydroxychloroquine			S	Oral	Unspecified		Not Reported
	Ethanol			S	Oral	Unspecified		Not Reported
	Amitriptyline			S	Oral	Unspecified		Not Reported
	Oxazepam			S	Oral	Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jun-2018	15096212	DIRECT					1 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia	Hydroxychloroquine Sulfate			S	Oral	Quantity:2 Df Dosage Form;		Zydus Pharm
	Propranol			C				Not Reported
	Napronen			C				Not Reported
	Fluoxetine			C				Not Reported
	D 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2018	14993248	NON-EXPEDITED			US-AMGEN-USASP2018077058			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Pain	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14671940	NON-EXPEDITED			US-AMGEN-USASP2018039133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14719968	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-017694		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Valaciclovir Arrow			S	Oral	(1)		Aurobindo
	Rovalcyte			S	Oral	450 Milligram		Not Reported
	Cellcept /01275102/			S	Oral	()		Not Reported
	Plaquenil /00072602/			S	Oral	()		Not Reported
	Bactrim			S	Oral	()		Not Reported
	Prograf			S	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14920834	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1032511		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Haemophagocytic Lymphohistiocytosis; Herpes Zoster; Listeria Sepsis; Lymphopenia; Progressive Multifocal Leukoencephalopathy	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1 G		Mylan
	Cellcept /01275102/			S	Oral			Mylan
	Thalidomide Celgene			C	Oral	Unk		Mylan
	Thalidomide Celgene			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14973936	NON-EXPEDITED			US-SA-2018SA134735			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Nausea	Plaquenil	S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14993892	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001693			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hip Arthroplasty; Inflammation; Knee Arthroplasty; Musculoskeletal Pain	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14993894	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Fatigue; Gait Disturbance	Plaquenil			S	Unknown			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14993895	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Lung Neoplasm Malignant; Pain; Pain In Extremity; Pulmonary Fibrosis; Pulmonary Mass; Swelling; Upper Limb Fracture	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994187	EXPEDITED (15-DAY)		DS	CA-ROCHE-2136759		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14995292	NON-EXPEDITED			US-SA-2018SA048627			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14995433	NON-EXPEDITED		OT	US-SA-2018SA146356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Therapeutic Response Decreased; Therapy Non-Responder	Arava			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14996429	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-016352			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukoencephalopathy; Viral Infection	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Perindopril			C				Not Reported
	Esomeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14997411	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-016350			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death; Treatment Failure	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported

	Acetylsalicylic Acid	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enoxaparin	S	Unknown	Not Reported
	Immunoglobulin Human Normal	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	12535047	EXPEDITED (15-DAY)		OT	CA-ROCHE-1788584			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	Upto 25 Mg		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Discontinued		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Discontinued		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Celexa (Canada)			C	Unknown	Frequency: Every 1 Day		Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	12769617	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	13957004	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017387995		79 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Pressure Systolic Increased; Condition Aggravated; Hypoaesthesia	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tylenol Arthritis			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14551085	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2107516-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Anaemia; Arthropathy; Cataract; Contusion; Fall; Malaise	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14998633	EXPEDITED (15-DAY)		OT	CA-ROCHE-2133196		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14998955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2136781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

		Prednisone			S	Unknown				Not Reported
		Reactine (Canada)			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14998969	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-020432		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blister; Blood Creatinine Increased; Erythema; Herpes Zoster Cutaneous Disseminated; Pain; Rash; Skin Lesion	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Aciclovir			S	Intravenous (not otherwise specified)			Zydus Pharm
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14999177	EXPEDITED (15-DAY)		OT	AR-IPCA LABORATORIES LIMITED-IPC-2018-AR-001300			Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14999479	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1463		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate (Trade Name			S	Unknown			Not Reported

Intolerance; Hypersensitivity; Lung Disorder	Unknown) Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	14999516	EXPEDITED (15-DAY)		DE, OT	FR-IPCA LABORATORIES LIMITED-IPC-2018-FR-001246		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S	Oral	Unk		Ipca
	Gabapentin			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Zopiclone			S	Oral	Unk		Not Reported
	Morphine			S	Oral	Unk		Not Reported
	Alcool			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Oxazepam Ayerst			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	15001175	EXPEDITED (15-DAY)		DE	FR-009507513-1806FRA004440		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Toxicity To Various Agents	Mirtazapine			S	Oral	Unk		Merck
	Zopiclone			S	Oral	Unk		Not Reported
	Morphine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Not Reported
	Alcohol			S	Oral	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Oral	Unk		Not Reported
	Oxazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	15003094	EXPEDITED (15-DAY)		OT	CA-ROCHE-2135285			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2018	15116176	DIRECT	Y	HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Product Substitution Issue; Vomiting	Hydroxychloroquine S Tab			S	Oral			Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	Hydroxyz Hcl			C				Not Reported
	Promethazine			C				Not Reported
	Verapamil			C				Not Reported

	Eszopiclone	C	Not Reported
	Clopidogrel	C	Not Reported
	Doxepin	C	Not Reported
	Duloxetine	C	Not Reported
	Methotrexate	C	Not Reported
	Folic Acid	C	Not Reported
	Gabapentin	C	Not Reported
	Zonisamide	C	Not Reported
	Amitiza	C	Not Reported
	Topiramate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	12491786	EXPEDITED (15-DAY)		LT, OT	CA-SA-2016SA115212		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Drug Ineffective; Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Rituximab			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Tocilizumab			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	13534151	EXPEDITED (15-DAY)		OT	PHHY2017US066551		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Necrobiosis Lipoidica Diabeticorum	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Etanercept			S	Subcutaneous	50 Mg, Qw		Not Reported
	Diclofenac			C	Unknown	50 Mg, Tid		Not Reported
	Cephalexin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14667782	NON-EXPEDITED			US-PFIZER INC-2018118758		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14688462	NON-EXPEDITED			US-PFIZER INC-2018125034		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14781557	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018051590		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis Infective; Cellulitis; Drug Ineffective; Post Procedural Haemorrhage; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

		Remicade			S	Unknown	Unk			Not Reported
		Levofloxacin			C		750 Mg, Qd			Not Reported
		Leflunomide			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	14867937	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018061276		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Rectal Ulcer Haemorrhage	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Xeljanz Xr			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15003432	NON-EXPEDITED			US-AMGEN-USASP2018078158			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Mtx			C	Unknown	Unk		Not Reported
	Mtx			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15003691	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001917		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Off Label Use; Optical Coherence Tomography Abnormal; Retinal Fovea Disorder; Retinal Toxicity; Retinogram Abnormal; Retinopathy; Visual Acuity Reduced; Visual Field Tests Abnormal; Visual Impairment	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15004255	NON-EXPEDITED			US-PFIZER INC-2018237818		84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Norco			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15004267	NON-EXPEDITED			US-PFIZER INC-2018235977		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Otezla			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15004397	NON-EXPEDITED			US-PFIZER INC-2018239633		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15004731	NON-EXPEDITED			US-SA-2018SA156418		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15007038	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139011		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15007049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2018	15119457	DIRECT						Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	12688972	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Actemra		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Abatacept		S	Unknown	Not Reported
	Cortisone		C	Oral	Not Reported
	Desoximetasone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	13964095	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2833		79 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Pressure Systolic Increased; Hypoaesthesia	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Tylenol Arthritis			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	13973860	EXPEDITED (15-DAY)		HO	CA-ROCHE-1991494		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue;	Actemra			S	Unknown			Not Reported

Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Naproxen		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	14540356	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018006221		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Calcifications; Breast Mass; Drug Ineffective; Neoplasm Malignant; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Ramipril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	14666657	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000995		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Exposure During Pregnancy; Renal Impairment	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Predonine			C				Not Reported
	Prograf			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	14715382	EXPEDITED (15-DAY)		CA, OT	DE-GLAXOSMITHKLINE-DE2018056141			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Microcephaly	Diclofenac			S	Transplacental	100 Mg, As Needed, Geststional Week Of Exposure 0-19 + 4 ; As Necessary		Glaxosmithkline
	Paracetamol			S	Transplacental	Gestational Week Of Exposure- 17-21		Glaxosmithkline
	Sulfasalazine			S	Transplacental	Gestational Week Of Exposure- 0-17		Not Reported
	Hydroxychloroquine			S	Transplacental	Gestational Week Of Exposure- 0-13		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	14762487	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001270		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervix Haemorrhage Uterine; Exposure During Pregnancy; Premature Delivery	Plaquenil 200 Mg			S	Oral			Not Reported
	Bethamethasone			C				Not Reported
	Prograf			C				Not Reported
	Predonin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009410	EXPEDITED (15-DAY)		HO	CA-ROCHE-2136828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Treatment Failure; Vomiting	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cimzia	C	Subcutaneous	Not Reported
	Enbrel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009429	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001856		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Plaquenil 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009430	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001857		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catheterisation Cardiac; Diarrhoea	Plaquenil			S	Unknown			Concordia
	Ambrisentan			S	Unknown			Not Reported
	Remodulin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009432	EXPEDITED (15-DAY)		OT	KP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001977		68 YR	Female	PRK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cystoid Macular Oedema; Detachment Of Macular Retinal Pigment Epithelium; Maculopathy; Reading Disorder; Retinopathy; Visual Acuity Reduced	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009434	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002033		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Encephalopathy; Extradural Abscess; Mental Status Changes; Mycobacterium Avium Complex Infection; Osteomyelitis	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cefepime			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009439	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006255		51 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil 200 Mg			S	Oral	Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009440	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006590			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Plaquenil			S	Oral	Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15009959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139890		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15010008	NON-EXPEDITED			US-PFIZER INC-2018237747		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15010020	NON-EXPEDITED			US-PFIZER INC-2018238008			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15010507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138917			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15010530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15010548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139898		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15011181	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001950		182 DAY	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Plaquenil 200 Mg Tablet			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15011182	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001956		1 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Low Birth Weight Baby; Premature Baby	Plaquenil 200 Mg Tablet			S	Transplacental			Not Reported
	Predonine			C	Transplacental			Not Reported
	Prograf			C	Transplacental			Not Reported
	Amlodipine			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15011305	NON-EXPEDITED			US-SA-2018SA131767			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S				Sanofi
	Humira			S				Not Reported
	Remicade			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15012606	NON-EXPEDITED			PHEH2018US022857			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Diarrhoea	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Novartis
	Metoprolol			C	Unknown	0.5 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15012643	NON-EXPEDITED			US-AMGEN-USASP2018079294			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rash; Treatment Failure	Enbrel			S	Unknown	Unk			Amgen
	Humira			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Augmentin			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15012949	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-905506		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Herpes Zoster Cutaneous Disseminated	Hydroxychloroquine			S	Unknown			Teva
	Etanercept			S	Unknown			Not Reported
	Acyclovir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15014007	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1039499		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma	Prednisone			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2018	15125446	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Plaquenil Unknown Unknown			S				Not Reported
	Enbrel 50 Mg/Ml Amgen			S	Subcutaneous			Amgen

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	14524373	NON-EXPEDITED			US-PFIZER INC-2018060024		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	14978406	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001897		60 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Pancreatitis	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Dapsone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15001019	EXPEDITED (15-DAY)		HO, OT	PHEH2018US022864		40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15007633	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018237134		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15015120	NON-EXPEDITED			US-ELI_LILLY_AND_COMPANY-US201805007989		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Decreased; Bone Pain; Pain In Extremity	Forteo 250ug/Ml			S	Subcutaneous	Unk Unk, Daily		Eli Lilly And Co
	Forteo 250ug/Ml			S	Subcutaneous	Unk Unk, Daily		Eli Lilly And Co
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15015523	EXPEDITED (15-DAY)		DE, OT	DE-GLAXOSMITHKLINE-DE2018GSK106547			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Glaxosmithkline
	Ramipril			S	Transplacental	20 Mg, Unk		Glaxosmithkline
	Simvastatin			S	Transplacental			Glaxosmithkline
	Prednisolone			S	Transplacental			Glaxosmithkline
	Metamizole			S	Transplacental			Glaxosmithkline
	Salbutamol			S	Transplacental			Glaxosmithkline
	Acetylsalicylic Acid			S	Transplacental			Glaxosmithkline
	Pantoprazole			S	Transplacental			Glaxosmithkline
	Nicotine			S	Transplacental			Glaxosmithkline
	Ezetimibe			S	Transplacental			Not Reported
	Torasemide			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2018	15017084	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001861		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Therapy Partial Responder	Hydroxychloroquine			S	Unknown			Concordia
	Minoxidil			S				Not Reported
	Topical Steroids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2018	15019096	EXPEDITED (15-DAY)		HO	DE-DRREDDYS-GER/GER/18/0100412		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Olanzapine			S	Oral	2.5 Mg, 0-0-0.5-0, Tabletten		Not Reported
	Tamoxifen			S	Oral	20 Mg, 0-0-1-0, Tabletten		Not Reported
	Quensyl			S	Oral	200 Mg, 0-0-1-0, Tabletten		Not Reported
	Pantoprazole			C	Oral	20 Mg, 1-0-0-0, Tabletten		Not Reported
	Prednisolon			C	Oral	1 Mg, 2-0-0-0, Tabletten		Not Reported
	Fentanyl			C	Transdermal	12 Mcg / Day, Scheme, Patch Transdermal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2018	13948142	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004987		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Myalgia; Pyrexia; Rhabdomyolysis	Plaquenil Tablet			S	Oral			Concordia
	Predonine			C				Not Reported
	Omepral			C				Not Reported
	Bayaspirin			C				Not Reported
	Fluitran			C				Not Reported

	Tramcet			C						Not Reported
	Onetram			C						Not Reported
	Metolate			C						Not Reported
	Foliamin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2018	15019162	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001481			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Plaquenil			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2018	15019301	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001439			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Teratogenicity	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	12491816	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA115333		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	12492244	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA115244		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Lung Disorder; Pericardial Effusion; Pulmonary Oedema; Renal Disorder; Rheumatoid Arthritis	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	13655293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1947851			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	14931542	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0066		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Calcifications; Breast Mass; Drug Ineffective; Neoplasm Malignant; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	14936793	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-121739		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cystitis; Dysaesthesia; Herpes Zoster; Nausea	Orencia			S	Unknown			Bristol Myers Squibb
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Mabthera			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dose 20-25		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	14962626	NON-EXPEDITED			US-PFIZER INC-2018223383		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer

	Sulfasalazine	S		Unk		Pfizer
	Humira	S		Unk		Not Reported
	Remicade	S		Unk		Not Reported
	Plaquenil	S		Unk		Not Reported
	Actemra	S		Unk		Not Reported
	Otezla	S		Unk		Not Reported
	Arava	S		Unk		Not Reported
	Orencia	S		Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019729	EXPEDITED (15-DAY)		OT	CA-ROCHE-2140639		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Asa			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139035		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Celebrex	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019890	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0893		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent; Diarrhoea; Infection; Lip Discolouration; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported
	Progesterone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Letrozole			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported

	Synthroid			C	Unknown				Not Reported
	Vitamin D Nos			C	Unknown				Not Reported
	Aleve			C	Unknown	As Needed			Not Reported
	Glucosamine			C	Unknown				Not Reported
	Letrozole			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019920	NON-EXPEDITED			US-AMGEN-USASP2018080204			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15019995	NON-EXPEDITED			US-AMGEN-USASP2018081085			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020044	EXPEDITED (15-DAY)		OT	CA-ROCHE-2136788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

					Orencia	S	Intravenous (not otherwise specified)		Not Reported
					Prednisone	S	Intravenous (not otherwise specified)		Not Reported
					Remicade	S	Intravenous (not otherwise specified)		Not Reported
					Cetirizine Hydrochloride	S	Unknown		Not Reported
					Cortisone Acetate	S	Topical		Not Reported
					Phthalylsulfathiazole	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020377	EXPEDITED (15-DAY)		OT	US-ZYDUS-020493		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Minocycline			S	Unknown			Zydus Pharm
	Infliximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020540	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001991			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity	Hydroxychloroquine 200 Mg			S				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020541	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002059		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Plaquenil			S	Oral			Not Reported
	Exforge			S	Oral			Not Reported
	Inegy			S	Oral			Not Reported
	Visipaque			S	Intravenous (not otherwise specified)			Not Reported
	Tardyferon			S	Oral			Not Reported
	Amlodipine			C				Not Reported
	Diffu K			C				Not Reported
	Lormetazepam			C				Not Reported
	Movicol			C				Not Reported
	Trileptal			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020542	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002062		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15020543	EXPEDITED (15-DAY)		DE, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002063		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Plaquenil			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15021881	NON-EXPEDITED			US-SA-2018SA132028		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Nausea; Vomiting	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Parenteral	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Not Reported
	Orencia			S		Unk Unk, Unk		Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15023548	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-892355		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Dysuria; General Physical Health Deterioration; Headache; Pyrexia; Vomiting	Prednisolone			S	Oral	5 Milligram Daily; 1-0-0-0		Actavis
	Quensyl			S	Oral	200 Milligram Daily; 1-0-0-0		Not Reported
	L-Thyroxin 50			C				Not Reported
	Furosemid			C				Not Reported
	Apidra			C				Not Reported
	Toujeo 300 Einheiten/Ml Injektionsloesung In Fertigpen			C				Not Reported
	Novalgin (Metamizole Sodium)			C				Not Reported
	Fentanyl			C				Not Reported
	Lyrica 25mg			C				Not Reported
	Allopurinol			C				Not Reported
	Simvastatin			C				Not Reported
	Perenterol Forte 250mg			C				Not Reported
	Nebivolol			C				Not Reported
	Movicol			C				Not Reported
	Ramipril			C				Not Reported

	Pantozol	C		Not Reported
	Ecural Salbe	C		Not Reported
	Pipamperone	C		Not Reported
	Dekristol 20000i.E.	C		Not Reported
	Vomex A	C		Not Reported
	Hydrochlorothiazid	C		Not Reported
	Ass 100	C		Not Reported
	Magnetrans Forte 150mg	C		Not Reported
	Iberogast N	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15023794	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2139905		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Ascorbic Acid			C	Unknown			Not Reported
	Biotin			C				Not Reported

Ferrous Fumarate	C		Not Reported
Folic Acid	C		Not Reported
Vitamin C	C		Not Reported
Vitamin A	C		Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Nicotinamide	C		Not Reported
Retinol Palmitate	C		Not Reported
Riboflavin	C		Not Reported
Sodium Ascorbate	C		Not Reported
Thiamine Mononitrate	C		Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Nasonex	C	Nasal	Not Reported
Nortriptyline Hydrochloride	C	Oral	Not Reported
Omega 3	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Pyridoxine Hydrochloride	C		Not Reported
Thiamine Hydrochloride	C		Not Reported
Trazodone Hydrochloride	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported
Vitamin D3	C	Unknown	Not Reported
Vitamine B12 Roche	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15026675	NON-EXPEDITED			US-AMGEN-USASL2018081353		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15026709	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115256		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15026710	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115136			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Plaquenil			S	Unknown	200 Mg,Qd		Sanofi
	Arava			S	Unknown	20 Mg,Qd		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	200 Mg,Qm		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg,Qd		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2018	15026755	EXPEDITED (15-DAY)		DE	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-175734			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Abuse; Drug Abuse; Toxicity To Various Agents	Gabapentine		S	Oral	Non Renseignee	Ranbaxy
	Mirtazapine		S	Oral	Non Renseignee	Sun
	Zopiclone		S	Oral	Non Renseignee	Not Reported
	Alcool		S	Oral	Non Renseignee	Not Reported
	Amitriptyline		S	Oral	Non Renseignee	Not Reported
	Hydroxychloroquine (Sulfate D)		S	Oral	Nonr Renseignee	Not Reported
	Morphine		S	Oral	Non Renseignee	Not Reported
	Oxazepam Ayerst		S	Oral	Non Renseignee	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14770310	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018145955		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Ineffective; Hepatitis; Leukopenia; Liver Function Test Increased; Musculoskeletal Disorder; Musculoskeletal Disorder; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Toxicity To Various Agents; Treatment Failure	Enbrel			S		25 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Kineret			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Kevzara			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14857934	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2330777-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Drug Ineffective; Dysarthria; Facial Paralysis; Urticaria	Enbrel	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prozac	C			Not Reported
	Singulair	C			Not Reported
	Diclofenac	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	14978042	NON-EXPEDITED			US-PFIZER INC-2018229470		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer
	Plaquenil			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15014564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1787		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15026886	NON-EXPEDITED			US-AMGEN-USASP2018081217			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ocular Toxicity; Rash	Enbrel	S	Unknown	Unk	Amgen
	Plaquenil	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd	Not Reported
	Restasis	C		Unk Unk, Q12h (Ophthalmic Emulsion One Drop In Each Eye)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027021	EXPEDITED (15-DAY)		OT	CA-ROCHE-2135238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported

	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027066	NON-EXPEDITED			US-AMGEN-USASP2018081075			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027457	EXPEDITED (15-DAY)		OT	GB-FLAMINGO-001720		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S				Not Reported
	Bisoprolol			S				Not Reported
	Arthrotec			S				Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Ceclor			S				Not Reported
	Demerol			S				Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Pethidine			S				Not Reported
	Methotrexate			S				Not Reported
	Erythro Base			S				Not Reported
	Arava			S				Not Reported
	Lyrica			S				Not Reported
	Norfloxacin/Norfloxacin Hydrochloride			S				Not Reported
	Erythromycin			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027490	EXPEDITED (15-DAY)		OT	TR-IPCA LABORATORIES LIMITED-IPC-2018-TR-001266		50 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pityriasis Lichenoides Et Varioliformis Acuta	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027562	NON-EXPEDITED			US-AMGEN-USASP2018080715			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027651	EXPEDITED (15-DAY)		HO	FR-009507513-1806FRA004800		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Inegy			S	Oral	1 Df, Qd		Merck
	Exforge			S	Oral	1 Df, Qd		Not Reported
	Visipaque			S	Intravenous (not otherwise specified)	In Total		Not Reported
	Tardyferon			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Amlodipine			C		Unk		Not Reported
	Lormetazepam			C		Unk		Not Reported

		Pantoprazole			C		Unk			Not Reported
		Movicol			C		Unk			Not Reported
		Trileptal			C					Not Reported
		Diffu-K			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027714	NON-EXPEDITED			US-PFIZER INC-2018243618		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027761	NON-EXPEDITED			US-PFIZER INC-2018245606		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027767	NON-EXPEDITED			US-PFIZER INC-2018245877		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15027833	NON-EXPEDITED			US-PFIZER INC-2018247578		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15028625	EXPEDITED (15-DAY)		HO	CA-ROCHE-2141304		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Vaginal			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported

	Loperamide Hydrochloride	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Oral	Not Reported
	Omega-3 Fatty Acids	C	Unknown	Not Reported
	Oxycodone Terephthalate	C		Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Perphenazine	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15028698	NON-EXPEDITED			US-PFIZER INC-2018246472		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Tylenol			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15029326	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-04		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Hikma
	Anastrozole			S	Unknown			Westward
	Cyclophosphamide			S	Unknown			Westward
	Docetaxel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15029403	EXPEDITED (15-DAY)		OT	PHHY2018TR018487		50 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pityriasis Lichenoides Et Varioliformis Acuta; Product Use In Unapproved Indication; Pruritus; Rash	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2018	15032094	EXPEDITED (15-DAY)		OT	TR-MYLANLABS-2018M1042085		50 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pityriasis Lichenoides Et Varioliformis Acuta	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	11862970	EXPEDITED (15-DAY)		OT	CA-ROCHE-1602815		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 730 Nos		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

	Enbrel			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	12499068	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA115323		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Eye Disorder; Headache; Inflammation; Joint Swelling; Ligament Sprain; Nausea; Orthosis User; Rheumatoid Arthritis	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	13632963	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003355		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Lip Swelling; Lymphocyte Count Decreased; Pruritus; Pyrexia; Rash	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Imuran			C				Not Reported
	Zetia			C				Not Reported
	Predonine			C				Not Reported
	Hibon			C				Not Reported
	Opalmon			C				Not Reported
	Magnesium Oxide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	13735954	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001515		54 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Metformin			S	Unknown	500 Mg, Unk		Ipca

	Hydroxychloroquine Tablets			S	Unknown	300 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14550868	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018021118			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Defaecation Urgency; Diarrhoea; Gastrointestinal Disorder; Injection Site Reaction; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate			S	Subcutaneous	50 Mg/2ml, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14634497	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000941		58 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Discomfort; Drug Ineffective; Feeling Abnormal; Gastritis; Headache; Musculoskeletal Stiffness; Nausea; Pain; Paravenous Drug Administration; Photosensitivity Reaction; Pulpitis Dental; Rheumatoid Arthritis; Sensitivity To Weather Change	Hydroxychloroquine			S	Unknown			Concordia
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Simvastatin			C				Not Reported
	Ramipril			C				Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14662023	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000988		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Delayed	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Cortisone			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14662024	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010742		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Eye Disorder; Headache; Inflammation; Joint Swelling; Ligament Sprain; Nausea; Orthosis User; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14840688	NON-EXPEDITED			US-AMGEN-USASP2018059593		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Rash Macular; Skin Swelling; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	14936943	NON-EXPEDITED			US-AMGEN-USASP2018069619			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034229	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001740			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankylosing Spondylitis; Hyperthyroidism; Liver Function Test Increased; Psoriasis; Respiratory Rate Increased	Plaquenil	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Loperamide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034245	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002004		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Viral	Hydroxychloroquine			S				Not Reported
	Minoxidil			C				Not Reported
	Clobetasol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034249	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002091		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Hypertrophy	Plaquenil Tablet			S	Oral	1 Year 10 Months 5 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034318	NON-EXPEDITED			US-AMGEN-USASP2018082071		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034326	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010692		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Atrovent			C				Not Reported
	Benzatropine			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Folic Acid			C				Not Reported
	Methoprazine			C				Not Reported
	Pantoprazole			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Salbutamol			C		100 Ug		Not Reported
	Trifluoperazine			C				Not Reported
	Zopiclone			C				Not Reported
	Levomepromazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034327	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010693		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Plaquenil Tablet			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034328	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010694		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Nausea; Rheumatoid Arthritis	Plaquenil Tablet		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Intramuscular		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034333	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010696		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Intestinal; Post Procedural Complication	Plaquenil Tablet			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034334	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010698		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation; Joint Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Ineffective; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034335	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010699		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Lung Disorder; Pericardial Effusion; Pulmonary Oedema; Renal Disorder; Rheumatoid Arthritis	Plaquenil Tablet	S	Unknown	Not Reported
	Arava Film Coated Tablet	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034336	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010702		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Disorder	Plaquenil Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034338	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010709		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Plaquenil Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034431	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		56 YR	Female	CAN

INC.-MAPI_00010728

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Disability; Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Plaquenil			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034432	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010729		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Plaquenil Tablet			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034433	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	6 Months 5 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	1 Year 6 Months 16 Days			Not Reported
	Xeljanz			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034434	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010732		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034435	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010735		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Duration 3 Months		Not Reported
	Arava			S	Unknown	Duration 3 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Duration 5 Months		Not Reported
	Arava			S	Unknown	Duration 3 Years		Not Reported
	Arava			S	Unknown	Duration 3 Years		Not Reported
	Arava			S	Unknown	Duration 3 Months		Not Reported
	Arava			S	Unknown	Duration 3 Months		Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15034436	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010738		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Red Blood Cell Sedimentation Rate	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Folic Acid			S				Not Reported
	Methotrexate Sodium			S				Not Reported

Increased; Treatment Failure	Cortisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035185	NON-EXPEDITED			US-PFIZER INC-2018249132			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035255	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010737		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			C				Not Reported
	Bupropion Hydrochloride			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035256	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010741		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis	Plaquenil Tablet		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035309	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010712		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Therapeutic Product Effect Incomplete	Plaquenil			S				Not Reported
	Arava			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035310	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010713		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Rheumatoid Arthritis; Synovitis	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035342	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Hypophagia; Urinary Incontinence; Viral Infection	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Esomeprazole			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035384	EXPEDITED (15-DAY)		LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Plaquenil Tablet			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Indometacin			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035447	NON-EXPEDITED			US-PFIZER INC-2018249187		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Lyrica			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Skelaxin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Robaxin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported
	Allegra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15035748	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP015762		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Docetaxel			S	Unknown	Unk		Apotex
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg (7.01 Mg/Kg), Daily		Not Reported
	Anastrozole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15036518	NON-EXPEDITED			US-PFIZER INC-2018247348		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15036580	EXPEDITED (15-DAY)		HO	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-04		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Immunosuppression	Hydroxychloroquine			S	Unknown			Hikma
	Etanercept			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15037485	NON-EXPEDITED		OT	US-SA-2018SA122740			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Leukopenia; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15038527	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-910411		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Unmasking Of Previously Unidentified Disease	Prednisone			S	Unknown			Actavis
	Minocycline			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva

	Infliximab				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2018	15039700	NON-EXPEDITED			PHEH2018US024762			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	13057590	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015706		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Intentional Product Misuse; Product Use Issue; Rheumatoid Arthritis; Unevaluable Event	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Vitamin B12 /00056201/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	13058810	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015763		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Oral			Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Apo-Azathioprine			S	Unknown			Not Reported

	Anakinra	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran /00001501/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	13058820	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015802		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Amnesia; Arthralgia; C-Reactive Protein Increased; Disease Progression; Drug Dependence; Drug Ineffective; Dyspnoea; Fall; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Loss Of Consciousness; Nausea; Palpitations; Product Dose Omission; Stress; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Cannabidiol			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	13406185	EXPEDITED (15-DAY)		OT	CA-ROCHE-1914425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Mouth Ulceration; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate Sodium	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	14575623	NON-EXPEDITED			US-AMGEN-USASP2018025749			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastric Disorder; Hypertension; Joint Swelling	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	14868051	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2346209-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bipolar Disorder; Clostridium Difficile Infection; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fear Of Injection; Food Allergy; Hypersensitivity; Injection Site Infection; Mastocytosis; Nausea; Orthostatic Hypotension;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Otrexup			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported

Pain; Subcutaneous Abscess; Swollen Tongue; Vomiting	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Xeljanz Xr	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	14952374	NON-EXPEDITED			US-PFIZER INC-2018215457		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S	Oral	2 G, Daily		Pfizer
	Hydroxychloroquine			S	Oral	Unk, Daily (300)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	14978408	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001929		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Erythema; Rash; Rebound Effect; Skin Exfoliation; Systemic Lupus Erythematosus; Tenderness	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15020901	NON-EXPEDITED			US-PFIZER INC-2018245378		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15041721	EXPEDITED (15-DAY)		OT	CA-ROCHE-2141915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15041745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2142618		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042021	NON-EXPEDITED			US-PFIZER INC-2018247370		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042058	NON-EXPEDITED			US-PFIZER INC-2018247024		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15042619	EXPEDITED (15-DAY)		HO	US-CELGENEUS-USA-20180603877		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Abraxane			S	Intravenous drip			Not Reported
	Avelumab			S	Intravenous drip			Not Reported
	Gemcitabine Hydrochloride			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Ibuprofen	C	Unknown			Not Reported
Apixaban	C	Unknown			Not Reported
Aspirin	C	Unknown	81 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15044355	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018165196		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Intolerance; Nausea; Vomiting	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Plaquenil /00072603/			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15046530	EXPEDITED (15-DAY)		OT	PHHY2018US023034		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Encephalopathy; Leukocytosis; Osteomyelitis Bacterial	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2018	15165250	DIRECT	N				79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blister; Cataract Operation; Feeling Hot; Insomnia; Nightmare; Onychomadesis; Pain; Pruritus; Rash Erythematous; Scab; Scar; Skin Burning Sensation; Skin Exfoliation; Stevens-Johnson Syndrome;	Plaquenil			S				Not Reported
	Fluoxetine			C				Not Reported
	Ketorolac			C				Not Reported
	Levothyroxine			C				Not Reported
	Losartan-Hydrochlorothiazide			C				Not Reported
	Prednisolone Acetate			C				Not Reported
	Prednisone			C				Not Reported
	Refresh			C				Not Reported
	Tirosint			C				Not Reported

Tongue Blistering

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	12441101	EXPEDITED (15-DAY)		OT	CA-ROCHE-1768215		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Off Label Use; Osteoporosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Inflectra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	13059155	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain; Peripheral Swelling; Stevens-Johnson Syndrome	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Enbrel			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Adverse Event Reporting System
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14218522	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2017AP021438		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting	Apo-Hydroxyquine			S	Oral	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Every 1 Day		Not Reported
	Actonel			C	Unknown	135 Mg, Q.Wk.		Not Reported
	Advair			C	Unknown	500 Mg, Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Every 1 Day		Not Reported
	Calcium			C	Unknown	500 Mg, Bid		Not Reported
	Citalopram			C	Unknown	30 Mg, Every 1 Day		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	3000 Df, Every 1 Day		Not Reported
	Ferrous Gluconate			C	Oral	300 Mg, Every 1 Day		Not Reported
	Folic Acid			C	Oral	Unk, Every 1 Day		Not Reported
	Hydrochlorothiazide			C	Unknown	25 Mg, Every 1 Day		Not Reported
	Olmesartan Medoxomil			C	Unknown	40 Mg, Every 1 Day		Not Reported
	Oxybutynin			C	Unknown	2.5 Mg, Every 1 Day		Not Reported
	Prednisone			C	Unknown	9 Mg, Every 1 Day		Not Reported
	Rabeprazole			C	Unknown	20 Mg, Every 1 Day		Not Reported
	Senna Alexandrina			C	Unknown	Unk		Not Reported
	Tiotropium Bromide			C	Unknown	18 Mg, Qid		Not Reported
	Tylenol /00020001/			C	Unknown	Unk, Qid		Not Reported
	Vitamin B12 /00056201/			C	Sublingual	1500 Mg, Every 1 Day		Not Reported
	Vitamin C /00008001/			C	Unknown	100 Mg, Every 1 Day		Not Reported

	Zinc Gluconate	C	Unknown	25 Mg, Every 1 Day		Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Every 1 Day		Not Reported
	Coenzyme Q10	C	Unknown			Not Reported
	Copper Sulphate	C	Unknown			Not Reported
	D-Alpha Tocopherol	C	Unknown			Not Reported
	Dha	C	Unknown			Not Reported
	Docusate Sodium	C	Unknown			Not Reported
	Omega-3 Marine Triglycerides	C	Unknown			Not Reported
	Spiriva	C	Unknown			Not Reported
	Manganese Sulfate	C	Unknown			Not Reported
	Fish Oil W/Tocopheryl Acetate	C	Unknown			Not Reported
	Ascorbic Acid	C	Oral	1000 Mg, Qd		Not Reported
	Aspirin /00002701/	C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14243136	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021917		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14284745	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017183698		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Haemorrhage; Infection; Nausea; Pneumonia; Rash; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14314089	NON-EXPEDITED			US-PFIZER INC-2017542359		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14361397	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018001010		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen

	Remicade	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Medrol	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14514940	EXPEDITED (15-DAY)		OT	IE-CONCORDIA PHARMACEUTICALS INC.-E2B_00009781		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Drug Ineffective For Unapproved Indication; Leukopenia; Off Label Use; Product Use In Unapproved Indication; Skin Atrophy	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Prednisolone			S	Oral	Unk		Concordia
	Prednisolone			S				Concordia
	Methotrexate			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Clobetasol Propionate			S	Topical	Unk Unk, Unknown		Not Reported
	Protopic			S	Topical	Unk Unk, Unknown		Not Reported
	Triamcinolone			S	Unknown	Unk, Unknown		Not Reported
	Efavirenz			C	Unknown	Unk Unk, Unknown		Not Reported
	Fluconazole			C	Unknown	Unk Unk, Unknown		Not Reported
	Co-Trimoxazole			C	Unknown	Unk, Unknown		Not Reported
	Lamivudine + Zidovudine			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14713828	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001125		30 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cytopenia; Deep Vein Thrombosis; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Histiocytic Necrotising Lymphadenitis; Lymphadenopathy; Placental Infarction; Placental Necrosis; Treatment Failure	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisolone	S	Unknown			Not Reported
	Prednisolone	S	Unknown			Not Reported
	Prednisolone	S	Unknown			Not Reported
	Enoxaparin Sodium	S	Parenteral			Not Reported
	Enoxaparin Sodium	S	Parenteral	(Approximately 1 Mg/Kg) From 5 Weeks Gestation		Not Reported
	Enoxaparin Sodium	S	Parenteral			Not Reported
	Warfarin Sodium	S	Unknown			Not Reported
	Aspirin	S	Unknown			Not Reported
	Immunoglobulin Human Normal	S	Unknown			Not Reported
	Immunoglobulin Human Normal	S	Unknown	From 9 Week		Not Reported
	Azathioprine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	14993893	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001949		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Herpes Zoster Disseminated; Pain; Rash; Rash Erythematous; Skin Lesion	Hydroxychloroquine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15009431	EXPEDITED (15-DAY)		OT	IL-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001960		45 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Dyspnoea; Nausea;	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Hydroxychloroquine Tablet			S				Not Reported

Pneumonia Bacterial; Pruritus; Q Fever	Doxycycline	S		O Min	Not Reported
	Doxycycline	S		15 Min	Not Reported
	Doxycycline	S		30 Min	Not Reported
	Doxycycline	S		45 Min	Not Reported
	Doxycycline	S		60 Min	Not Reported
	Doxycycline	S		75 Min	Not Reported
	Doxycycline	S		90 Min	Not Reported
	Doxycycline	S		105 Min	Not Reported
	Doxycycline	S		120 Min	Not Reported
	Doxycycline	S		135 Min	Not Reported
	Doxycycline	S		150 Min	Not Reported
	Doxycycline	S		165 Min	Not Reported
	Doxycycline	S		180 Min	Not Reported
	Doxycycline	S		195 Min	Not Reported
	Doxycycline	S		210 Min	Not Reported
	Doxycycline	S	Oral	240 Min	Not Reported
	Clarithromycin	S	Unknown		Not Reported
	Clarithromycin	S			Not Reported
	Moxifloxacin Hydrochloride	S	Unknown		Not Reported
	Moxifloxacin Hydrochloride	S			Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15009433	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001978		40 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Macular Pigmentation; Retinopathy; Visual	Hydroxychloroquine			S		8.5 Mg/Kg Actual Body Weight		Not Reported

Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15027713	NON-EXPEDITED			US-PFIZER INC-2018243477		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Metoprolol Tartrate			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15027802	NON-EXPEDITED			US-PFIZER INC-2018245697		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Celebrex			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		10 Mg, Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15047942	EXPEDITED (15-DAY)		OT	CA-BAXTER-2018BAX017516			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Xeljanz	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Celebrex	S	Oral		Not Reported
Levofloxacin	S	Unknown		Not Reported
Azithromycin	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Imuran	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Demerol	S	Unknown		Not Reported
Benadryl	S	Unknown		Not Reported
Ezetrol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15048297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Treatment Noncompliance	Leflunomide			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15048733	NON-EXPEDITED			US-PFIZER INC-2018249253		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Humira	S	40 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15048881	EXPEDITED (15-DAY)		OT	CA-ROCHE-2141222		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15048929	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002069		60 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049021	EXPEDITED (15-DAY)		DE	PHHY2018NL023699			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Dehydration; Diarrhoea	Hydroxychloroquine			S	Unknown	200 Mg, Tid		Novartis
	Tetracycline			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015753			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Interstitial Lung Disease	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049256	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hidradenitis; Staphylococcal Infection	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Escitalopram Oxalate			C	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk, Qd		Not Reported
	Zantac			C	Unknown	40 Mg, Qd		Not Reported
	Zoledronic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049605	EXPEDITED (15-DAY)		DE, OT	DE-NODEN PHARMA DAC_NOD-2018-000052			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Aliskiren			S	Transplacental	Unk		Noden Pharma
	Rivaroxaban			S	Transplacental	Unk		Not Reported
	Ramipril			S	Transplacental	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental	Unk		Not Reported
	Torasemide			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk		Not Reported
	Metamizole			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049785	EXPEDITED (15-DAY)		HO	CA-ROCHE-2141880		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported

	Xeljanz			S	Oral				Not Reported
	Folic Acid			C	Subcutaneous				Not Reported
	Leflunomide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049819	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015745		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Joint Swelling; Macule; Mobility Decreased; Pain; Skin Cancer; Swelling	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15049826	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015832		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15050252	NON-EXPEDITED			US-SA-2018SA043612			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15050253	NON-EXPEDITED			US-SA-2018SA048316		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oedema Peripheral	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Abatacept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15050254	NON-EXPEDITED			US-SA-2018SA029242		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Arava			S	Oral	Unknown		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15052920	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018080813			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear Of Injection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Intramuscular	25 Unk, Qwk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Simponi Aria	S	Unknown	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Kevzara	C		Unk		Not Reported
Xeljanz Xr	C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2018	15053283	EXPEDITED (15-DAY)		HO, LT	NL-MYLANLABS-2018M1042440		51 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Fluoxetine			S		1 Dd		Not Reported
	Plaquenil /00072602/			S		2 Dd 200mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jun-2018	15056504	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Hip Arthroplasty; Rash; Retinal Deposits	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2018	15056919	NON-EXPEDITED			US-ASTRAZENECA-2018SE81793		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium 24 Hr			S	Oral			Astrazeneca
	Cortisol			S				Not Reported
	Naprosyn			S				Not Reported
	Phenergan			S				Not Reported
	Plaquenil			S				Not Reported
	Tramadol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	12572510	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1795825		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Actemra			S	Unknown	Therapy Duration: 8.0 Month(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Prednisone			S	Unknown	Therapy Duration: 549.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	13336972	NON-EXPEDITED			US-PFIZER INC-2017107012			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Medrol			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

	Orencia			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14160713	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006238		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14167707	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006312		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Joint Fluid Drainage; Large Intestinal Obstruction; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown	1 Year 4 Months 17 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14174004	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006293		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine	S	Unknown		Concordia
	Leflunomide	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Pregabalin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14199241	EXPEDITED (15-DAY)		HO, OT	PHHY2017PT168437		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Product Use In Unapproved Indication; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Prednisolone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14694062	EXPEDITED (15-DAY)		OT	PHHY2018FR047308		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Hellp Syndrome; Maternal Exposure During Pregnancy; Off Label Use;	Oxytocin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported

Pre-Eclampsia	Prednisone			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	14970829	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20180540879			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bipolar Disorder; Clostridium Difficile Infection; Contraindicated Product Administered; Drug Hypersensitivity; Injection Site Infection; Mastocytosis; Orthostatic Hypotension; Pain; Subcutaneous Abscess	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otrexup			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pencillin			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058078	NON-EXPEDITED			US-PFIZER INC-2018254816		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058080	NON-EXPEDITED			US-PFIZER INC-2018255535			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058145	EXPEDITED (15-DAY)		CA, OT	DE-AUROBINDO-AUR-APL-2018-032193		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Septal Defect	Citalopram			S	Transplacental	10 [Mg/D]		Aurobindo
	Quensyl			S	Transplacental	200 [Mg/D]		Not Reported
	Folic Acid			C	Transplacental	0.8 [Mg/D]		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058213	NON-EXPEDITED			US-PFIZER INC-2018253278		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Diclofenac Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15058341	NON-EXPEDITED			US-PFIZER INC-2018254759			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15059217	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-032536		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
T-Cell Lymphoma	Prednisone			S	Unknown	Unk		Aurobindo
	Minocycline			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15059552	NON-EXPEDITED			US-SA-2018SA044702		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Nausea	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15059553	NON-EXPEDITED			US-SA-2018SA123050			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Oral	11 Mg, Qd		Sanofi

	Plaquenil			S	Oral	Unk, Unk				Sanofi
	Methotrexate			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15060855	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1044260		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy; Extradural Abscess; Mycobacterium Avium Complex Infection; Osteomyelitis; Paraspinal Abscess	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Mylan
	Cefepime			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15061042	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2018253926		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Gabapentin			S	Oral	Unk		Pfizer
	Zopiclone			S	Oral	Unk		Not Reported
	Morphine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Mirtazapine			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Oxazepam Ayerst			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15061215	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-001305			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure;	Hydroxychloroquine Sulfate			S	Unknown	Half Of 200 Mg, Unk		Ipca

Medication Error; Treatment Noncompliance	200mg Tablets, Usp

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15061354	EXPEDITED (15-DAY)		DE	PHHY2018CA028952		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Mycophenolate Mofetil			S	Unknown			Novartis
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15061507	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1043904			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15061521	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1043902			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Haemolysis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2018	15062328	NON-EXPEDITED			US-AMGEN-USASP2018083972			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	13058991	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015722		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported

	Cymbalta	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Penicillin G /00000901/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	14803461	NON-EXPEDITED			US-AMGEN-USASP2018055249			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Pain; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	14900626	NON-EXPEDITED			US-PFIZER INC-2018196791			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Fatigue	Methotrexate Sodium			S	Subcutaneous	Unk (Injectable)		Unknown
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15010374	EXPEDITED (15-DAY)		HO	PHHY2018IT039508		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Back Pain; Mycobacterium Avium Complex Infection; Osteomyelitis Bacterial; Pyrexia	Prednisone			S	Oral	50 Mg, Qd		Novartis
	Prednisone			S	Oral	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065074	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1370		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Intolerance; Nausea; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065349	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-020659		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acid Fast Bacilli Infection; Back Pain; C-Reactive Protein Increased; Encephalopathy; Extradural Abscess; Leukocytosis; Mycobacterium Avium Complex Infection; Osteomyelitis; Paraspinal Abscess; Red Blood Cell Sedimentation Rate Increased	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Cyclophosphamide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065376	EXPEDITED (15-DAY)		HO	CA-ROCHE-2143857			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Naproxen	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin Nos	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065543	NON-EXPEDITED			PHEH2018US024359		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot	Promacta			S	Oral	50 Mg, Qd		Novartis
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065684	NON-EXPEDITED			US-PFIZER INC-2018257221		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Malaise	Methotrexate Sodium	S	Unk		Pfizer
	Hydroxychloroquine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15065862	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Kineret			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15066591	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0727		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Kineret	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S			Not Reported
	Warfarin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15066669	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015898		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	10 Mg, Every One Day		Not Reported
	Advil /00044201/			S	Oral	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15066689	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015945		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Diarrhoea; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Oral	1 G, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15067808	NON-EXPEDITED			US-SA-2018SA109469			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Urticaria	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2018	15070018	EXPEDITED (15-DAY)		HO, OT	CN-MYLANLABS-2018M1045468		47 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Listeriosis; Meningoencephalitis Bacterial; Pneumonia Cryptococcal	Prednisone			S	Oral	Started At Unknown Dose		Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Mylan
	Cyclophosphamide			S	Unknown			Mylan
	Methylprednisolone			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	11134325	EXPEDITED (15-DAY)		OT	CA-ROCHE-1581214		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Decreased; Diarrhoea; Feeding Disorder; Feeding Disorder; Urinary Incontinence; Viral Infection; Vomiting; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 01/May/2015, 15/May/2015		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Nexium			C				Not Reported

	Folic Acid	C			Not Reported
	Tylenol	C			Not Reported
	Crestor	C			Not Reported
	Oxybutynin	C			Not Reported
	Zopiclone	C			Not Reported
	Pramipexole	C			Not Reported
	Prednisone	C			Not Reported
	Imuran	C	Oral		Not Reported
	Tylenol #3 (Canada)	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	13111591	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877142		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	13947305	EXPEDITED (15-DAY)		OT	CA-ROCHE-1986498		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	14331478	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2204952-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Herpes Zoster; Herpes Zoster; Hypoacusis; Memory Impairment; Mobility Decreased; Muscular Weakness; Musculoskeletal Chest Pain; Pain; Rheumatoid Arthritis; Weight Bearing Difficulty	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	14688099	NON-EXPEDITED			US-PFIZER INC-2018126850			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15048834	NON-EXPEDITED			US-PFIZER INC-2018252858		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15072814	NON-EXPEDITED			US-AMGEN-USASP2018084854			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15072921	EXPEDITED (15-DAY)		OT	CH-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002159			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Toxic Skin Eruption	Plaquenil		S	Unknown		Not Reported
	Salazopyrine		C			Not Reported
	Corticosteroid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15072970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2141850		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073258	EXPEDITED (15-DAY)		OT	CA-ROCHE-2145229		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

Decreased	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15073470	NON-EXPEDITED			US-PFIZER INC-2018258973		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Tylenol			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Celestone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15075678	NON-EXPEDITED			US-SA-2018SA153808			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Enbrel			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15075745	NON-EXPEDITED			US-SA-2018SA164630		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Plaquenil Sulfate			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15075866	NON-EXPEDITED			US-SA-2018SA170220		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Urticaria	Arava			S				Sanofi
	Plaquenil			S				Sanofi
	Mtx [Methotrexate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076418	EXPEDITED (15-DAY)		OT	CA-ROCHE-2143198		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported

		Methotrexate			C	Oral					Not Reported
		Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076525	EXPEDITED (15-DAY)		HO	CA-APOTEX-2018AP015975		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Mobility Decreased; Nerve Compression	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported
	Gabapentin			C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15076570	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1045681		41 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2018	15077053	NON-EXPEDITED			US-PFIZER INC-2018258525		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15080265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2145231		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15080513	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002136			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage; Cerebral Infarction; Medication Error	Plaquenil 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15080533	EXPEDITED (15-DAY)		HO	CA-ROCHE-2143920		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tacrolimus			S	Unknown					Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15080787	EXPEDITED (15-DAY)		HO	CA-ROCHE-2145254		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	Therapy Duration: 214 Nos		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15080988	EXPEDITED (15-DAY)		DE	FR-TEVA-2018-FR-913740		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Toxicity To Various Agents	Zopiclone			S	Oral	Non Renseignée		Not Reported
	Gabapentin			S	Oral	Non Renseignée		Ivax
	Mirtazapine			S	Oral	Non Renseignée		Teva
	Morphine			S	Oral	Non Renseignée		Not Reported
	Hydroxychloroquine (Sulfate D')			S	Oral	Nonr Renseignée		Not Reported
	Alcool			S	Oral	Non Renseignée		Not Reported
	Amitriptyline			S	Oral	Non Renseignée		Not Reported
	Oxazepam Ayerst			S	Oral	Non Renseignée		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15081474	EXPEDITED (15-DAY)		HO, OT	PHHY2018CN024180		42 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Meningitis Cryptococcal; Pneumonia Cryptococcal; Somnolence	Prednisone			S	Unknown	1 Mg/Kg, Qd		Not Reported
	Prednisone			S	Unknown	0.5 Mg/Kg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Ciclosporin			S	Unknown	4 Mg/Kg, Unk		Not Reported
	Ciclosporin			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Methylprednisolone			S	Unknown	500 Mg, Qd		Not Reported
	Piperacillin/Tazobactam			C	Unknown	4.5 G, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15081866	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002095		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15081867	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002172		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gingival Hypertrophy	Plaquenil Tablet			S	Oral	1 Year 10 Months 5 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082063	EXPEDITED (15-DAY)		CA	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-176792		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Septal Defect	Citalopram			S	Transplacental	10 [Mg/D]		Sun
	Quensyl			S	Transplacental	200 [Mg/D]		Not Reported
	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Not Reported
	Cytotec			C	Transplacental	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082171	NON-EXPEDITED			US-PFIZER INC-2018260677		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082202	EXPEDITED (15-DAY)		OT	GB-WEST-WARD PHARMACEUTICALS CORP.-GB-H14001-18-05		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin Hemihydrate			S		()		Hikma
	Erythromycin			S		()		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Norfloxacin			S		()		Not Reported
	Demerol			S		()		Not Reported
	Metronidazole			S		()		Not Reported
	Meperidine Hydrochloride			S		()		Not Reported

	Leflunomide	S		()	Not Reported
	Bisoprolol Fumarate	S		()	Not Reported
	Arthrotec	S		()	Not Reported
	Plaquenil	S	Oral	400 Mg	Not Reported
	Methotrexate	S		()	Not Reported
	Arava	S		()	Not Reported
	Ceclor	S		()	Not Reported
	Prednisone	S		()	Not Reported
	Sulfasalazine	S		()	Not Reported
	Erythro Base	S		()	Not Reported
	Lyrica	S		()	Not Reported
	Humira	S	Subcutaneous	400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15082686	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015973		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction; Visual Impairment	Leflunomide			S	Oral	Unk		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15084600	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-913200		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanoderma	Tenofovir Disoproxil			S	Oral			Teva
	Plaquenil			S	Oral			Not Reported
	Emtricitabine			S	Oral			Not Reported

	Rilpivirine			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15084815	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2015-376640		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S	Unknown			Bayer
	Arava			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown			Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15084968	EXPEDITED (15-DAY)		OT	PHHY2018ES027839		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15084970	EXPEDITED (15-DAY)		OT	PHHY2018ES027829		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Congestive Cardiomyopathy	Hydroxychloroquine	S	Unknown	Unk		Novartis
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15084971	EXPEDITED (15-DAY)		OT	PHHY2018ES027836		41 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk (Cumulative Dose 36g)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2018	15085342	EXPEDITED (15-DAY)		CA	DE-ALLERGAN-1832663US		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Citalopram Hydrobromide - Bp			S	Transplacental	10 Mg, Unk		Allergan
	Quensyl			S	Transplacental	200 Mg, Unk		Not Reported
	Femibion Schwangerschaft			C	Transplacental	0.8 Mg, Qd		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	12386552	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-089591		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation;	Aspirin			S	Unknown			Bayer
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim	S			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	13058150	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015772		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Off Label Use; Rash; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Unknown			Apotex
	Methotrexate Sodium			S	Intramuscular	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	50 Mg, 1 Every 3 Week		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Mg One Every 3 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, Once Every Two Week		Not Reported
	Gold (198 Au) Colloidal			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Arthrotec			S	Oral	50 Mg, Bid		Not Reported
	Advil /00109201/			C	Oral	200 Mg, Prn		Not Reported
	Tylenol /00020001/			C	Unknown	650 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	13688418	EXPEDITED (15-DAY)		OT	CA-ROCHE-1952625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	14751064	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009670			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	14969591	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014925		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Myco[Phenolate			S	Unknown	720 Mg, Bid		Apotex
	Cellcept /01275102/			S	Oral	Unk, Qd		Not Reported
	Cellcept /01275102/			S				Not Reported
	Cyclophosphamide			S	Unknown	150 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	14978407	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001923			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Toxic Skin Eruption	Plaquenil 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15087643	NON-EXPEDITED			US-AMGEN-USASP2018086207			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ill-Defined Disorder	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15088184	NON-EXPEDITED			US-AMGEN-USASP2018086154			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Codeine			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15088379	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18S-028-2404796-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Synthroid			S	Unknown	Unk		Not Reported
	Apo-Folic Acid			S	Oral	5 Mg, Unk		Not Reported
	Apo-Diclofenac			S	Topical	75 Mg, Bid		Not Reported
	Apo-Diclofenac			S	Oral	75 Mg, Unk		Not Reported
	Apo-Lisinopril			S	Unknown	Unk		Not Reported
	Lisinopril Dihydrate			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Pantoprazole Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Voltaren Sr			S	Oral	75 Mg, Bid		Not Reported

	Voltaren Sr			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15088616	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-020704		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Infection; Induration; Osteomyelitis Chronic; Pain Of Skin; Peripheral Swelling; Skin Hyperpigmentation; Skin Mass; Skin Ulcer	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Dapsone			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15089234	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002117			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cachexia; Concussion; Dyspnoea; Fatigue; Head Injury; Inflammatory Bowel Disease; Influenza; Injection Site Mass; Injection Site Pruritus; Injection Site Swelling; Joint Effusion; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15089235	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002175			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Chest Pain; Palpitations	Hydroxychloroquine Tablet			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15093126	NON-EXPEDITED			US-AMGEN-USASP2018086555			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15093348	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-059960			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Dyspnoea	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15210172	DIRECT	Y	HO			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperammonaemic Encephalopathy; Renal Tubular Acidosis	Hydroxychloroquine			S	Oral		2 MTH	Not Reported
	Carbamazepine Er			C				Not Reported
	Lamotrigine			C				Not Reported
	Levetiracetam			C				Not Reported
	Horsetail Supplement			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2018	15210341	DIRECT	Y	HO			70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Diarrhoea; Knee Arthroplasty	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Amlodipine			S				Not Reported
	Trintrllis			C				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2018	14788986	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001325		63 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Asthma	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Medrol			C				Not Reported
	Mtx			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2018	14715647	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001053			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Tuberculosis	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	14691767	EXPEDITED (15-DAY)		OT	CA-ROCHE-1798129		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angioedema; Back Pain; Blood Pressure Systolic Increased; Contusion; Diarrhoea; Diplopia; Dizziness; Eye Swelling; Face Oedema; Inflammation; Lip Oedema; Nasopharyngitis; Papule; Pruritus; Rash; Skin Plaque; Swelling Face; Urticaria; Visual Impairment	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Aerius (Canada)			S	Unknown			Not Reported

	Reactine (Canada)			S	Unknown	Qhs (At Night)				Not Reported
	Plaquenil			S	Unknown					Not Reported
	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	14800242	NON-EXPEDITED			US-PFIZER INC-2018165678		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	14858138	NON-EXPEDITED			US-AMGEN-USASP2018060661			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	14889400	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001496		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maculopathy; Off Label Use; Retinal Toxicity; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown	(1500 G On Varying Doses) 200-400 Mg Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	14995437	NON-EXPEDITED		OT	US-SA-2018SA146357			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Therapeutic Product Effect Incomplete	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Imuran [Azathioprine Sodium]			S		Unk		Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15048932	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010740		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Plaquenil Tablet			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15059643	NON-EXPEDITED			US-SA-2018SA143683			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unknown		Sanofi
	Plaquenil Sulfate			S	Unknown	Unknown		Sanofi
	Methotrexate			C	Unknown	Unknown		Not Reported
	Sulfasalazine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15095552	EXPEDITED (15-DAY)		HO	US-APPCO PHARMA LLC-2051153		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Cutaneous Disseminated	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15095710	EXPEDITED (15-DAY)		HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-169137		22 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Reversible Encephalopathy Syndrome	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	1000 Mg, Qd		Not Reported
	Methylprednisolone			S				Not Reported
	Prednisone			S	Unknown	1 Mg/Kg, Daily		Mutual
	Prednisone			S				Mutual
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Sun
	Hydroxychloroquine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15095815	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2145202		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Cellcept	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Procytox	S	Intravenous (not otherwise specified)	Not Reported
	Procytox	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone Sodium Succinate	C	Unknown	Not Reported
	Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15096013	EXPEDITED (15-DAY)		OT	CN-APPCO PHARMA LLC-2051158		57 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15096175	EXPEDITED (15-DAY)		LT	PHHY2018US028504		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Chromaturia; Drug-Induced Liver Injury; Fatigue; Malaise; Nausea; Transaminases Increased	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15096681	EXPEDITED (15-DAY)		OT	CA-ROCHE-2143868		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Tocilizumab			S	Subcutaneous	Therapy Duration: 8 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15096715	EXPEDITED (15-DAY)		DS	FR-PFIZER INC-2018257675		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Pruritus; Urticaria	Amlor			S	Oral	10 Mg, 1x/Day		Pfizer
	Endoxan /00021101/			S	Intravenous (not otherwise specified)	500 Mg, Every 2 Weeks		Not Reported
	Mesna			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, 1x/Day		Not Reported
	Bactrim			S	Oral	3 Df, Weekly/400/80 Monday/Wednesday/Friday		Not Reported
	Aprovel			C		Unk		Not Reported
	Cortancyl			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported

	Xanax	C	Unk		Not Reported
	Calcidose Vitamine D	C	Unk		Not Reported
	Kardegic	C	Unk		Not Reported
	Clareal	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15097193	NON-EXPEDITED			US-AMGEN-USASP2018087695			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15097270	NON-EXPEDITED			US-SA-2018SA134489			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Arava			S	Oral	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15097296	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Mobility Decreased; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

	Zostavax			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15098142	NON-EXPEDITED			US-PFIZER INC-2017428651			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15099010	EXPEDITED (15-DAY)		OT	CA-SA-2018SA168747		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Hydroxychloroquine			S		200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Methotrexate Sodium			S	Oral	15 Mg, Qw		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15099642	NON-EXPEDITED			US-AMGEN-USASP2018088651			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stomatitis; Treatment Failure; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Tofacitinib			C		5 Mg, Unk		Not Reported
	Mupirocin			C		Unk		Not Reported

	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2018	15099813	NON-EXPEDITED			US-AMGEN-USASP2018087947			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rash; Upper Respiratory Tract Infection	Enbrel			S	Unknown			Amgen
	Mtx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15050497	EXPEDITED (15-DAY)		OT	ES-CELLTRION INC.-2018ES020841			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Dolquine			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15058187	NON-EXPEDITED			US-PFIZER INC-2018255515		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15093336	NON-EXPEDITED			US-PFIZER INC-2018262160		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Calcium Decreased; Joint Effusion; Joint Noise; Joint Stiffness; Joint Swelling; Pain; Synovitis; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15099930	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002188		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Colour Blindness; Dysmetropsia; Visual Impairment	Plaquenil 200 Mg			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15100626	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0718		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Celebrex			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported

	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Cimzia			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15100735	NON-EXPEDITED			US-AMGEN-USASP2018086961			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15100977	NON-EXPEDITED			US-PFIZER INC-2018266865		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15100988	NON-EXPEDITED			US-AMGEN-USASP2018088460			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Palpitations	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

	Methotrexate				C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15101225	NON-EXPEDITED			US-AMGEN-USASP2018088446			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Tramadol			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15101377	NON-EXPEDITED			US-AMGEN-USASP2018086562			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15101722	NON-EXPEDITED			US-PFIZER INC-2018266442		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

	Humira			S		Unk				Not Reported
	Plaquenil			S		Unk				Not Reported
	Minocycline			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15101748	EXPEDITED (15-DAY)		HO	TR-APPCO PHARMA LLC-2051232		36 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Cutaneous Disseminated	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15102073	NON-EXPEDITED			US-SA-2018SA174044		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15102989	EXPEDITED (15-DAY)		OT	CN-APPCO PHARMA LLC-2051239		43 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15103088	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1046487		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Infection; Osteomyelitis	Methotrexate			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Mylan
	Dapsone			S	Unknown			Mylan
	Remicade			S	Unknown			Mylan
	Cytoxan			S	Unknown			Mylan
	Enbrel			S	Unknown			Mylan
	Gentamicin			C	Unknown			Mylan
	Meropenem			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15103116	EXPEDITED (15-DAY)		OT	CN-APPCO PHARMA LLC-2051243		37 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15103374	NON-EXPEDITED			US-PFIZER INC-2018268529		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2018	15105102	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2401116-00		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biotin Deficiency; Blood Glucose Decreased; Device Issue; Dizziness; Dry Skin; Folate Deficiency; Gastrointestinal Scarring; Hypertension; Injection Site Pain; Oedema; Onychomadesis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Sensitivity To Weather Change; Skin Fissures; Skin Haemorrhage; Systemic Lupus Erythematosus; Vitamin B12 Deficiency; Vitamin D Deficiency	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Vitamin B12			C				Not Reported
	Biotin			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	11624910	EXPEDITED (15-DAY)		DS, HO, OT	US-ABBVIE-15K-163-1477390-00		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cellulitis; Complication Associated With Device; Complication Associated With Device; Disability; Fall; Femur Fracture; Knee Arthroplasty; Limb Asymmetry; Osteoarthritis; Pain In Extremity;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Venlafaxine			C				Not Reported
	Gabapentin			C				Not Reported
	Folic Acid			C				Not Reported

Secretion Discharge; Thrombosis; Venous Occlusion; Weight Decreased	Vitamin D Nos			C						Not Reported
	Calcium With Vitamin D			C						Not Reported
	Ranitidine			C						Not Reported
	Fish Oil			C						Not Reported
	Vitamin C			C						Not Reported
	Multivitamin			C						Not Reported
	Zinc			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	12809231	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cortisone			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15065251	EXPEDITED (15-DAY)		OT	ES-AMGEN-ESPSP2018085278			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Dolquine			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15081878	NON-EXPEDITED			US-PFIZER INC-2018260291		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15105458	NON-EXPEDITED			US-AMGEN-USASP2018089472			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Infection	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

Xeljanz	C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15105589	EXPEDITED (15-DAY)		HO	PL-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002282		62 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Transaminases Increased	Plaquenil			S	Unknown			Not Reported
	Nilotinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15106203	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2408253-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2018	15106820	NON-EXPEDITED			US-SA-2018SA177809		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Mouth Ulceration	Arava			S				Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Methotrexate			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported

	Enbrel			C						Not Reported
	Simponi			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14161744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2014675			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14198747	NON-EXPEDITED			US-PFIZER INC-2017488930		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14409305	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Neoplasm Malignant; Pneumonia; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14490512	NON-EXPEDITED		OT	US-AMGEN-USASP2018015228			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Grip Strength Decreased; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	200 Mg, Qd		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14726553	NON-EXPEDITED			US-PFIZER INC-2018140809		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Diazepam			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Nabumetone			S		Unk		Not Reported
	Sulindac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14844377	EXPEDITED (15-DAY)		OT	CA-INTERCEPT-PMOCA2018000675			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anal Incontinence; Back Pain; Constipation; Dyspepsia; Fatigue; Frequent Bowel Movements; Insomnia; Intentional Self-Injury; Muscle Spasms; Nausea; Proctalgia; Pruritus; Rash; Scab; Somnolence; Suicidal Ideation; Thinking Abnormal	Ocaliva			S	Oral	5 Mg, Qw		Not Reported
	Urso			S	Oral	750 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	14872976	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS			Female	USA

						INC.-GSH201805-001453			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blast Cells; Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15108419	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0728			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia	Kineret			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Vioxx			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15108572	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002185		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Erythema Multiforme; Oral Candidiasis	Plaquenil 200 Mg	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15108575	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002286		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Hydroxychloroquine			S	Unknown	1 Year 11 Months 11 Days		Not Reported
	Leflunomide			S	Unknown	1 Year 5 Months 22 Days		Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15108654	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018089296			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Skin Hyperpigmentation; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15110499	EXPEDITED (15-DAY)		HO	PHHY2018DE035576		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration;	Olanzapine			S	Oral	2.5 Mg, (000. 50)		Novartis
	Tamoxifen			S	Oral	20 Mg, Qd (0-0-1-0)		Not Reported

Pyrexia	Quensyl	S	Oral	200 Mg, Qd (0-0-1-0)		Not Reported
	Pantoprazol	C	Oral	20 Mg, Qd (1-0-0-0)		Not Reported
	Prednisolon	C	Oral	1 Mg, Unk		Not Reported
	Fentanyl	C	Transdermal	12 Ug, Qd (Schema, Pflaster Transdermal)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15112184	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201807544		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Infection; Osteomyelitis Chronic	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Cytoxan			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2018	15112200	EXPEDITED (15-DAY)		CA, HO	US-TEVA-2018-US-918952		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug-Induced Liver Injury; Porphyria Non-Acute	Hydroxychloroquine			S	Unknown	400 Mg/Day		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	12733274	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-E2B_00007832		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Neuropsychiatric Lupus; Visual Field Defect	Plaquenil 200 Mg	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	12809274	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016037641		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly (Qw)		Not Reported
	Leflunomide			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Leucovorin			S		Unk, Weekly (Qw)		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Plaquenil			S		200 Mg, Once Daily (Qd)		Not Reported
	Prednisone			S		2 Df, Ev 2 Days (Qod)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, Ev 4 Weeks		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Folic Acid			S		Unk, Weekly (Qw)		Not Reported
	Tofacitinib			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		1 Df, Weekly (Qw) (5mg Strength)		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Apo-Prednisone			S		2 Df, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Once Daily (Qd)		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	14228416	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006483		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Erythema; Oedema; Pruritus; Pyrexia; Rash Erythematous; Rash Erythematous; Rash Morbilliform; Skin Lesion	Plaquenil			S	Oral			Concordia
	Tavanic			S	Oral			Not Reported
	Bactrim			S	Oral			Not Reported
	Procoralan			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Cerazette (Desogestrel)			C				Not Reported
	Lasilix Faible			C				Not Reported
	Triatec (Ramipril)			C				Not Reported
	Aldactone			C				Not Reported
	Speciafoldine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15089232	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002113		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis Infective; Cellulitis; Drug Ineffective; Post Procedural Haemorrhage; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Levofloxacin			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15113398	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002191			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Rectal Ulcer Haemorrhage	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15113443	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018028960		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydromorphone			C				Not Reported
	Cymbalta			C		Unk		Not Reported
	Aspirin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15114147	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002298		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Melanoderma	Plaquenil		S	Oral		Not Reported
	Tenofovir Disoproxil		S	Oral		Not Reported
	Rilpivirine		S	Oral		Not Reported
	Emtricitabine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15114148	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Gait Disturbance; Inflammation; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Rogaine			C				Not Reported
	Clindamycin			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15114994	NON-EXPEDITED			US-PFIZER INC-2018274663		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Advil			S		Unk		Pfizer
	Ketorolac Tromethamine			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Kenalog			S		Unk		Not Reported
	Celestone			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Acthar			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

	Duexis			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15226378	DIRECT	Y	RI			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rash Pruritic	Hydroxychloroquine			S	Oral			Not Reported
	Clindamycin			S	Oral	Other Frequency:Other;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14169199	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210678		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Joint Fluid Drainage; Large Intestinal Obstruction; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14169263	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg,Unk		Sanofi
	Adalimumab			S	Unknown	Unk Unk,Unk		Not Reported
	Etanercept			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg,Qd		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported

	Acetaminophen			C						Not Reported
	Pregabalin			C	Oral	50 Mg,Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14190085	NON-EXPEDITED		OT	US-AMGEN-USASP2017170755		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14340912	EXPEDITED (15-DAY)		HO, LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000001		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Disseminated Intravascular Coagulation; Duodenitis; Nausea; Pancreatitis Acute	Plaquenil 200 Mg			S	Oral			Concordia
	Cortril			C				Not Reported
	Thyradin			C				Not Reported
	Warfarin			C				Not Reported
	Bayaspirin			C				Not Reported
	Nexium			C				Not Reported
	Edirol			C				Not Reported
	Bactramin			C				Not Reported
	Miya-Bm			C				Not Reported
	Promac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14484224	NON-EXPEDITED		OT	US-AMGEN-USASP2018014674			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Mg, Bid, 01 Year		Not Reported
	Humira			S	Subcutaneous	Unk, 9 Months		Not Reported
	Plaquenil			S	Oral	1 Df, Bid (01 Year)		Not Reported
	Remicade			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	14731782	EXPEDITED (15-DAY)		HO, OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001135		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Back Pain; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Movement Disorder; Mycobacterial Infection; Mycobacterium Avium Complex Infection; Osteomyelitis; Osteomyelitis; Osteomyelitis Bacterial; Pyrexia	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15041867	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002110		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chorioretinopathy	Plaquenil 200 Mg Tablet	S	Oral		Not Reported
	Plaquenil 200 Mg Tablet	S	Oral		Not Reported
	Predonine	C			Not Reported
	Rabeprazole Sodium	C			Not Reported
	Baktar	C			Not Reported
	K-Supply	C			Not Reported
	Edirol	C			Not Reported
	Recalbon [Minodronic Acid]	C			Not Reported
	Prednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15118685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2150792		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15118747	EXPEDITED (15-DAY)		OT	CA-ROCHE-2150854		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15119196	NON-EXPEDITED			US-AMGEN-USASP2018090992			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15119609	NON-EXPEDITED			US-PFIZER INC-2018276312		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15119614	EXPEDITED (15-DAY)		OT	CA-ROCHE-2150786		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15120689	NON-EXPEDITED			US-SA-2018SA048844			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk		Sanofi
	Plaquenil Sulfate			S	Unknown	Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S		11 Mg, Qd		Not Reported
	Orencia			S		Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15120702	NON-EXPEDITED			US-SA-2018SA042404			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance;	Arava			S	Oral	Unk Unk,Unk		Sanofi

Treatment Failure	Plaquenil			S	Unknown	Unk Unk,Unk			Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15121783	NON-EXPEDITED			US-MYLANLABS-2018M1045990			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2018	15236413	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Weight Decreased	Plaquenil Tab 200mg			S			1 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	14804129	NON-EXPEDITED			US-PFIZER INC-2018168443		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15004234	NON-EXPEDITED			US-PFIZER INC-2018235373		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Not Reported

						Macrobid		S	Unk		Not Reported
						Plaquenil		S	Unk		Not Reported
						Dicyclomine		C	Unk		Not Reported
						Omeprazole		C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15100982	NON-EXPEDITED			US-PFIZER INC-2018266310		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15123637	EXPEDITED (15-DAY)		OT	CA-ROCHE-2150832		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15124711	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002394		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Progression; Nail Pigmentation	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15125690	NON-EXPEDITED			US-PFIZER INC-2018278612		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15126435	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2018M1049493		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Received Total 9 Courses		Mylan
	Cyclophosphamide			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15126465	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2018M1049492		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Received Total Four Courses Of Rituximab		Mylan
	Sulfasalazine			S	Unknown	Unk		Mylan

	Etanercept			S	Unknown					Mylan
	Infliximab			S	Unknown					Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2018	15127572	NON-EXPEDITED			US-SA-2018SA123049			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypersensitivity	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Tamoxifen Citrate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15128532	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002359		72 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Hydroxychloroquine			S	Oral			Not Reported
	Nystatin			C				Not Reported
	Lansoprazole			C				Not Reported
	Enalapril			C				Not Reported
	Felodipine			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15128818	EXPEDITED (15-DAY)		OT	CA-ROCHE-2151567			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Vioxx	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Leflunomide	C	Unknown	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129209	NON-EXPEDITED			US-PFIZER INC-2018278318		50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Nausea; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129260	NON-EXPEDITED			US-PFIZER INC-2018280257		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129266	NON-EXPEDITED			US-PFIZER INC-2018280120		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Sulfasalazine	S	Unk	Pfizer
	Humira	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129442	EXPEDITED (15-DAY)		OT	CA-ROCHE-2151446			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15129558	NON-EXPEDITED			US-SA-2018SA048625			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Rash	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi

	Sulfasalazine		S	Unknown	Unk Unk,Unk			Not Reported
	Humira		C		Unk			Not Reported
	Methotrexate		C		Unk			Not Reported
	Xeljanz		C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2018	15241178	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection	Methotrexate 2.5mg			S	Oral			Not Reported
	Hydroxychloroquine 200mg			S	Oral			Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	13420234	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017049793			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	14126165	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017461046		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Ear Infection; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Heart Rate Irregular; Influenza; Nasopharyngitis; Sinusitis; Upper Respiratory Tract Infection; Urinary Tract Infection; Vertigo	Xeljanz Xr	S	11 Mg, Unk	Pfizer
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	14176106	EXPEDITED (15-DAY)		HO, OT	PHHO2017US015225		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Bacteraemia; Dehydration; Liver Function Test Increased; Pyrexia	Gsk2118436			S	Oral	Unk		Novartis
	Gsk2118436			S	Oral	2 Df (75mg), Qd		Novartis
	Gsk2118436			S	Oral	2 Df (75mg), Qd		Novartis
	Gsk2118436			S	Oral	75 Mg, Unk		Novartis
	Gsk1120212			S	Oral	Unk		Not Reported
	Gsk1120212			S	Oral	1 Df (2mg), Bid		Not Reported
	Gsk1120212			S	Oral	1.5 Mg, Bid		Not Reported
	Gsk1120212			S	Oral	1 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Unk		Not Reported
	Pembrolizumab			S	Unknown	Unk		Not Reported
	Benicar			C	Oral	2 Df (Tablet Of 5mg) Daily		Not Reported
	Ondansetron Hcl			C	Oral	1 Df (Tablet Of 8mg), Qid Prn		Not Reported
	Melatonin			C	Oral	1 Df (Tablet 1.5mg), As Directed		Not Reported

	Lorazepam	C	Oral	1 Df (0.5mg), As Directed	Not Reported
	Sertraline	C	Oral	1 Df (50mg Tablet), As Directed	Not Reported
	Probiotic	C	Oral	1 Df (Capsule), Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	14755116	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006685		63 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Alfacalcidol			C				Not Reported
	Bayaspirin			C				Not Reported
	Bredinin			C				Not Reported
	Takepron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15076053	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-913782		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extradural Abscess; Mycobacterium Avium Complex Infection; Osteomyelitis; Paraspinal Abscess	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Cyclophosphamide			S	Unknown			Not Reported
	Cefepime			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133279	EXPEDITED (15-DAY)		DE, OT	US-ZYDUS-020798		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Gait Inability; Loss Of Personal Independence In Daily Activities; Mental Disorder;	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Not Reported

Progressive Multifocal Leukoencephalopathy	Prednisone		S	Unknown	Not Reported
	Etodolac		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Methylprednisolone		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Rituximab		S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133280	EXPEDITED (15-DAY)		DE, OT	US-ZYDUS-020797		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown			Zydus Pharm
	Rituximab			S	Intravenous drip			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Mycophenolic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133294	EXPEDITED (15-DAY)		DE, OT	US-ZYDUS-020799		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Ataxia; Dysaesthesia; Immune Reconstitution	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Leflunomide			S	Unknown			Not Reported

Inflammatory Syndrome;	Prednisone	S	Unknown		Not Reported
Muscle Spasms;	Prednisone	S	Unknown		Not Reported
Progressive Multifocal Leukoencephalopathy	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133486	NON-EXPEDITED			US-PFIZER INC-2018279856		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Piroxicam			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133493	NON-EXPEDITED			US-PFIZER INC-2018280661		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133500	NON-EXPEDITED			US-PFIZER INC-2018280448			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15133504	NON-EXPEDITED			US-PFIZER INC-2018280117		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15134413	EXPEDITED (15-DAY)		HO, OT	US-NOVOPROD-609537		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Herpes Zoster; Osteoporosis; Spinal Fracture	Victoza			S	Subcutaneous	Unk		Novo Nordisk
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Famotidine			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Loperamide			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported
	Gabapentin			S		Unk		Not Reported
	Nexium /01479302/			S		Unk		Not Reported
	Imdur			S		Unk		Not Reported
	Plavix			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Potassium			S		Unk		Not Reported
	Nitroglycerin			S		Unk		Not Reported
	Effexor			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Trandolapril			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

		Hydroxychloroquine			S		Unk			Not Reported
		Flomax /01280302/			S		Unk			Not Reported
		Furosemide			S		Unk			Not Reported
		Metoclopramide			S		Unk			Not Reported
		Nifedipine			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15135660	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI-FK201807796		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136131	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018276070		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Intestinal Ulcer; Mouth Ulceration; Product Use In Unapproved Indication	Gabapentin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136145	NON-EXPEDITED		OT	US-SA-2018SA119554		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Rheumatoid Arthritis	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Hydrocortisone			S	Oral	30 Mg,Qd		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	Unk Unk,Unk		Not Reported
	Xeljanz			C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136154	NON-EXPEDITED			US-SA-2018SA048623		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136160	NON-EXPEDITED			US-SA-2018SA048314		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Prednisone			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136256	NON-EXPEDITED			US-SA-2018SA167101			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136637	EXPEDITED (15-DAY)		OT	CA-ROCHE-2152850		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C	Oral			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136653	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI-FK201807797		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136701	EXPEDITED (15-DAY)		HO	CA-MYLANLABS-2018M1050262		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Fungal Infection; Osteomyelitis; Systemic Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown	Initiated At High Dose, Later The Doses Tapering Was Initiated At 40mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15136749	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-921839		29 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Infection; Osteomyelitis; Ototoxicity; Ototoxicity	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Dapsone			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

					Cyclophosphamide		S	Intravenous (not otherwise specified)	Not Reported
					Remicade		S	Unknown	Not Reported
					Cytoxan		S	Unknown	Not Reported
					Enbrel		S	Unknown	Not Reported
					Gentamicin		S	Unknown	Not Reported
					Meropenem		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15137562	EXPEDITED (15-DAY)		HO	CA-ROCHE-2152209		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2018	15241703	DIRECT	Y	HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug-Induced Liver Injury	Hydroxychloroquine			S	Oral					Not Reported
	Hydroxychloroquine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	14214319	EXPEDITED (15-DAY)		DE, LT, OT	JP-ROCHE-2013642		33 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Atrophy; Disseminated Intravascular Coagulation; Gastrointestinal Necrosis; Hepatic Function Abnormal; Herpes Zoster Disseminated; Intestinal Haemorrhage; Uterine Leiomyoma; Ventricular Fibrillation	Mycophenolate Mofetil			S	Oral	Other Purposes: Lupus Intestinal Catarrh		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramcet			S	Unknown	Single Use		Not Reported
	Arasena-A			S	Unknown	Dosage Is Uncertain.		Not Reported
	Prograf			C	Unknown	Dosage Is Uncertain.		Not Reported
	Prograf			C	Unknown			Not Reported
	Prednisolone			C	Oral	The Fractionation Dose Frequency Is Uncertain. Dose Interval Uncertainty		Not Reported
	Prednisolone			C	Oral	The Fractionation Dose Frequency Is Uncertain. Dose Interval Uncertainty		Not Reported
	Prednisolone			C	Oral	The Fractionation Dose Frequency Is Uncertain. Dose Interval Uncertainty		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Dosage Is Uncertain.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15021879	NON-EXPEDITED			US-SA-2018SA132136		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hypersensitivity; Infection	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Codeine			S		Unk Unk, Unk		Not Reported

Xeljanz Xr	S	Oral	11 Mg, Bid		Not Reported
Methotrexate	S		Unk Unk, Unk		Not Reported
Enbrel	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15102631	NON-EXPEDITED			US-SA-2018SA170398			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil S			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138093	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002313		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Pulmonary Haemosiderosis; Pulmonary Hypertension	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138094	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002314		6 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Pulmonary Haemosiderosis	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138108	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS		4 YR	Female	FRA

						INC.-GSH201807-002305			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Pulmonary Haemosiderosis	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138114	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002463		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138362	NON-EXPEDITED			US-AMGEN-USASP2018093866			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nodule	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138481	NON-EXPEDITED			US-AMGEN-USASP2018094628			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15139320	NON-EXPEDITED			US-PFIZER INC-2018282559		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15139352	EXPEDITED (15-DAY)		OT	PHHY2018CA039381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

			Humira	S	Subcutaneous	Unk			Not Reported
			Hydroxychloroquine Sulfate	S	Unknown	Unk			Not Reported
			Orencia	S	Intravenous (not otherwise specified)	Unk			Not Reported
			Phthalylsulfathiazole	S	Unknown	Unk			Not Reported
			Prednisone	S	Unknown	Unk			Not Reported
			Rituxan	S	Intravenous (not otherwise specified)	Unk			Not Reported
			Simponi	S	Subcutaneous	Unk			Not Reported
			Remicade	S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15140088	EXPEDITED (15-DAY)		HO, LT	US-APPCO PHARMA LLC-2051942		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Porphyria Non-Acute; Subacute Cutaneous Lupus Erythematosus	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15140214	EXPEDITED (15-DAY)		OT	KR-APPCO PHARMA LLC-2051943		68 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Retinal Toxicity	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15140325	EXPEDITED (15-DAY)		OT	KR-APPCO PHARMA LLC-2051944		40 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema;	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

Retinal Toxicity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	14654041	EXPEDITED (15-DAY)		OT	PHHY2018IE041144			Unknown	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Leukopenia; Off Label Use; Product Use In Unapproved Indication; Skin Atrophy	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Clobetasol Propionate			S	Topical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Prednisolone			S	Oral	Unk		Novartis
	Triamcinolone			S	Unknown	Unk		Not Reported
	Triamcinolone			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Triamcinolone			S	Unknown	Unk, Unknown		Not Reported
	Protopic			S	Topical	Unk		Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported
	Fluconazole			C	Unknown	Unk Unk, Unknown		Not Reported
	Co-Trimoxazole			C	Unknown	Unk		Not Reported
	Co-Trimoxazole			C	Unknown	Unk, Unknown		Not Reported
	Efavirenz			C	Unknown	Unk		Not Reported
	Efavirenz			C	Unknown	Unk, Unknown Freq.		Not Reported
	Efavirenz			C	Unknown	Unk Unk, Unknown		Not Reported
	Lamivudine + Zidovudine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	14813159	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001399			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Eczema; Erythema; Pain; Pruritus; Urticaria	Plaquenil 200 Mg			S	Oral			Not Reported
	Nexium			C				Not Reported

	Lipitor	C			Not Reported
	Alfacalcidol	C			Not Reported
	Ulcerlmin	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C			Not Reported
	Predonine	C		The Dose Of Predonine Was Tapered Down Each Week From 30 Mg/Day To 25 Mg/Day, To 20 Mg/Day, And To 1	Not Reported
	Predonine	C			Not Reported
	Allegra Tablet 60mg	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	14901468	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2283308-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Defaecation Urgency; Diarrhoea; Gastric Disorder; Injection Site Reaction; Joint Swelling; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	50 Mg/2ml		Not Reported
	Methotrexate			S	Subcutaneous	50 Mg/2ml		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	14922608	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001725			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Famotidine			C				Not Reported
	Predonine			C				Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15022130	NON-EXPEDITED			US-SA-2018SA159986		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Azulfidine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15102727	NON-EXPEDITED			US-SA-2018SA177152		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate Sodium			S	Oral			Not Reported
	Humira			S				Not Reported
	Remicade			S				Not Reported
	Cimzia			S				Not Reported
	Orencia			S				Not Reported
	Rituxan			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15146811	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2017SP011378			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fat Necrosis; Mycobacterium Chelonae Infection; Off Label Use; Panniculitis Lobular; Papule; Pruritus; Purpura; Skin Exfoliation; Skin Hyperpigmentation; Skin Lesion; Skin Mass; Skin Plaque	Mycophenolate Mofetil			S	Unknown	Unknown		Strides
	Prednisolone			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15147651	NON-EXPEDITED			US-PFIZER INC-2018285290			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Methotrexate			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15149901	EXPEDITED (15-DAY)		HO	DE-TORRENT-00008882		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State; Dysuria; General Physical Health Deterioration; Pyrexia	Pantoprazol			C	Oral	20 Mg, 1-0-0-0		Unknown
	Olanzapin			S	Oral	2.5 Mg, 0-0-0.5-0		Unknown
	Tamoxifen			S	Oral	20 Mg, 0-0-1-0		Unknown
	Prednisolon			C	Oral	1 Mg, 2-0-0-0		Unknown
	Fentanyl			C	Transdermal	12 G / Tag, Pflaster Transdermal		Unknown
	Quensyl			S	Oral	200 Mg, 0-0-1-0		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15150592	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-019273			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis Fungal; Synovitis; Vith Nerve Paralysis	Prednisolone			S	Unknown			Bausch And Lomb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15150818	NON-EXPEDITED		OT	US-SA-2018SA044703			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S	Oral	Unk		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2018	15150834	NON-EXPEDITED		OT	US-SA-2018SA160529			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	10 Mg, Bid		Sanofi
	Plaquenil Sulfate			S	Oral	1 Df, Bid		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qow		Not Reported

	Enbrel			S	Subcutaneous	50 Unk		Not Reported
	Remicade			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	13341427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP007865		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Prednisone			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown			Apotex
	Elavil			S	Unknown			Apotex
	Amitriptyline			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	14085396	NON-EXPEDITED			US-PFIZER INC-2017439307		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	14672577	NON-EXPEDITED			US-PFIZER INC-2018120472		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	14966234	NON-EXPEDITED		OT	US-AMGEN-USASP2018074055			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15152073	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002512		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Diarrhoea; Fatigue; Headache; Hepatic Enzyme Increased; Hepatosplenomegaly; Hilar Lymphadenopathy; Histoplasmosis; Hypoxia; Lymphadenopathy Mediastinal; Nausea; Night Sweats; Pyrexia; Splenomegaly; Vomiting	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			C				Not Reported
	Doxycycline			C				Not Reported
	Metronidazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15152497	EXPEDITED (15-DAY)		DE	US-TEVA-2018-US-926535		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Rituximab			S	Intravenous drip	Received Total 9 Courses		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15152505	EXPEDITED (15-DAY)		DE	US-TEVA-2018-US-926536		58 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Rituximab			S	Intravenous drip	Received Total Four Courses Of Rituximab		Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153070	NON-EXPEDITED			US-PFIZER INC-2018285735		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported

	Arava			S		Unk				Not Reported
	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153086	NON-EXPEDITED			US-PFIZER INC-2018285767			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153087	NON-EXPEDITED			US-PFIZER INC-2018286179		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153705	NON-EXPEDITED			PHEH2018US029043		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Irritation; Urticaria	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15153745	EXPEDITED (15-DAY)		OT	PHHY2018GB046013		48 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate			S	Unknown	Unk		Novartis

Abdominal Distension; Anaphylactic Reaction; Drug Ineffective; Laboratory Test Abnormal; Malaise; Rash; Therapeutic Product Effect Decreased; Tremor; Vomiting	Rituximab	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Every 14 Days		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Sulphasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15154944	EXPEDITED (15-DAY)		HO	CA-TEVA-2018-CA-926553		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Fungal Infection; Osteomyelitis; Systemic Infection	Prednisone			S	Unknown	Initiated At High Dose, Later The Doses Tapering Was Initiated At 40mg Daily		Actavis
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15155265	EXPEDITED (15-DAY)		OT	PHHY2018IE047182		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective For Unapproved Indication; Leukopenia; Off Label Use; Product Use In Unapproved Indication; Skin Atrophy	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Prednisolone			S	Oral	Unk		Novartis
	Methotrexate			S	Oral	10 Mg, Weekly		Not Reported
	Clobetasol Propionate			S	Topical	Unk		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported
	Protopic			S	Topical	Unk		Not Reported
	Co-Trimoxazole			C	Unknown	Unk		Not Reported
	Efavirenz			C	Unknown	Unk Unk, Unknown		Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported

	Lamivudine + Zidovudine			C	Unknown	Unk			Not Reported
	Lamivudine + Zidovudine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15155609	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1050759		70 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Avium Complex Infection; Osteomyelitis Bacterial	Prednisone			S		50 Mg Daily		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2018	15155735	EXPEDITED (15-DAY)		OT	PHHY2018CA038885		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	40 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	12922824	EXPEDITED (15-DAY)		OT	CA-ROCHE-1849821		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous	Not Reported
	Lyrica			S	Oral	Not Reported
	Orencia			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Simponi			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Methotrexate Sodium			S	Intra-arterial	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Piroxicam			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	13103941	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-001078		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	14242022	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021926		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Rheumatoid Arthritis; Stomatitis; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd		Not Reported
	Folinic Acid			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15049252	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15049253	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015761		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Celebrex			S	Unknown	200 Mg, Bid		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Enbrel			S	Unknown	Unk				Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15050148	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021593		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Every 1 Day		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Bid		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	25 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, 1 Every 2 Weeks For 4 Months And 6 Months		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, 1 Every 1 Week		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, 1 Every 6 Weeks		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15059396	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neutropenia	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15103182	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Leflunomide			S	Other	20 Mg, Qd		Apotex
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15157332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2155675			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Enbrel			C	Unknown				Not Reported
	Methotrexate			C	Subcutaneous				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15157974	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-05		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis	Hydroxychloroquine			S	Unknown			Hikma
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15158462	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015758			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Ineffective	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral			Not Reported
	Methotrexate			C	Oral	25 Mg, Q.Wk.		Not Reported
	Morphine			C	Oral	5 Mg, Bid		Not Reported
	Pms Azithromycin			C	Unknown	250 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15158597	EXPEDITED (15-DAY)		DE, OT	PHHY2018IL043372			Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecchymosis; Foetal Exposure During Pregnancy; Generalised	Etanercept			S	Unknown	25 Mg, Unk (Once Every 3 Days)		Novartis

Oedema; Haemorrhage; Hydrops Foetalis; Hypertrophy; Intravascular Papillary Endothelial Hyperplasia; Multiple Organ Dysfunction Syndrome; Premature Baby; Purpura; Renal Impairment; Staphylococcal Sepsis	Prednisone	S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd		Not Reported
	Enoxaparin	S	Unknown	120 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15158639	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018281500		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Advil			S		Unk, As Needed		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil /00072603/			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15158717	NON-EXPEDITED			US-SA-2018SA143679			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15160316	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2017SP010738			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Strides

Delivery	Mycophenolate Mofetil	S	Unknown	500 Mg, Bid		Strides
	Prednisolone	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Unknown		Not Reported
	Aspirin	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15256028	DIRECT		DS			49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash; Skin Hypertrophy	Generic Form Of Plaquenil			S	Oral	Quantity:1 Tablet(S);		Unknown
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2018	15258824	DIRECT	N	DE			64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Tetrabenazine			S	Oral			Oceanside
	Gabapentin			C				Not Reported
	Arava			C				Not Reported
	Depakote			C				Not Reported
	Er			C				Not Reported
	Xenazine			C				Not Reported
	Ambien			C				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	14872181	NON-EXPEDITED			US-AMGEN-USASP2018061691			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15048259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015743			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rheumatoid Arthritis; Swelling	Leflunomide			S	Unknown	200 Mg, Unk		Apotex
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Acetaminophen			C	Unknown	650 Mg, Bid		Not Reported
	Arthrotec			C	Unknown	50 Mg, Bid		Not Reported
	Mefenamic Acid			C	Unknown	200 Mg, Unk		Not Reported
	Tylenol /00020001/			C	Unknown	650 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15050177	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015826			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15051115	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	20 Unk, Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15056503	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2018AP015834		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Actonel			C	Unknown	135 Mg, Q.Wk.		Not Reported
	Advair			C	Unknown	500 Mg, Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Qd		Not Reported
	Aspirin /00002701/			C	Unknown	81 G, Qd		Not Reported
	Calcium			C	Unknown	500 Mg, Bid		Not Reported
	Citalopram			C	Unknown	30 Mg, Qd		Not Reported
	Coenzyme Q10			C	Unknown			Not Reported
	Copper Sulfate			C	Unknown			Not Reported
	D-Alpha Tocopherol			C	Unknown			Not Reported

Dha	C	Unknown		Not Reported
Docusate Sodium	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
Ferrous Gluconate	C	Oral	300 Mg, Qd	Not Reported
Folic Acid	C	Oral	5 Mg, Qd	Not Reported
Hydrochlorothiazide	C	Unknown	25 Mg, Qd	Not Reported
Hydroxychloroquine Sulphate	C	Oral	Unk, Qd	Not Reported
Manganese Sulfate	C	Unknown		Not Reported
Olmesartan Medoxomil	C	Unknown	40 Mg, Qd	Not Reported
Omega-3 Marine Triglycerides	C	Unknown		Not Reported
Omega-3 /01866101/	C	Unknown		Not Reported
Oxybutynin	C	Unknown	2.5 Mg, Qd	Not Reported
Prednisone	C	Unknown	9 Mg, Qd	Not Reported
Rabeprazole	C	Unknown	20 Mg, Qd	Not Reported
Rabeprazole	C	Oral	20 Mg, Bid	Not Reported
Senna Alexandrina	C	Unknown		Not Reported
Spiriva	C	Unknown		Not Reported
Tiotropium Bromide	C	Unknown	18 Mg, Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk, Qid	Not Reported
Vitamin B12 /00056201/	C	Unknown	1500 Mg, Qd	Not Reported
Vitamin C /00008001/	C	Unknown		Not Reported
Zinc Gluconate	C	Unknown	25 Mg, Qd	Not Reported
Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15067530	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015912		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug	Leflunomide			S	Unknown	Unk		Apotex

Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15067532	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP015881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Erosion; Drug Ineffective; Drug Intolerance; Joint Swelling; Nausea; Osteoarthritis; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Thrombocytosis; Thrombosis; Weight Decreased	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Actonel			C	Oral	35 Mg, Q.Wk.		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Oral	2000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15088344	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016068			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint	Leflunomide			S	Unknown	20 Mg, Unk		Apotex

Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown	20 Mg, Unk	Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qid	Not Reported
	Acetaminophen			C	Unknown	500 Mg, Unk	Not Reported
	Aurothiomalate De Sodium			C	Unknown	Unk	Not Reported
	Hydrocortisone Valerate			C	Unknown		Not Reported
	Hydromorphone			C	Unknown		Not Reported
	Hydroxychloroquine			C	Unknown		Not Reported
	Lyderm /00280401/			C	Unknown		Not Reported
	Myocrisin			C	Unknown	1 Every 2 Weeks	Not Reported
	Naproxen			C	Unknown	250 Mg, Qd	Not Reported
	Naproxen			C	Unknown	Unk	Not Reported
	Prednisone			C	Unknown	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15090030	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016084		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Loperamide			C	Unknown	Unk		Not Reported

		Celebrex			C	Unknown	Unk			Not Reported
		Bifidobacterium Bifidum			C	Unknown	Unk			Not Reported
		Actemra			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15097305	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016178		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Nodule; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	1500 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15101763	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15163670	EXPEDITED (15-DAY)		DS	CA-ROCHE-2156412		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15164241	NON-EXPEDITED			US-PFIZER INC-2018290584			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15164272	NON-EXPEDITED			US-PFIZER INC-2018290270		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported
	Arava	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15164951	NON-EXPEDITED			US-AMGEN-USASP2018096860			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Rash	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	1 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	0.8 Cc, Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15167693	NON-EXPEDITED			US-PFIZER INC-2018286078			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2018	15168533	NON-EXPEDITED			US-AMGEN-USASP2018096914			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Skin Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Arava			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	14158560	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006267			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Pregabalin			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	14225927	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021579		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain; Treatment Failure	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported

	Simponi			S	Unknown	Unk			Not Reported
	Simponi			S					Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Arava			C	Unknown	Unk			Not Reported
	Plaquenil /00072602/			C	Unknown	Unk			Not Reported
	Methotrexate			C	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	14778690	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, 3 Every 1 Weeks		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Every 1 Weeks		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	14882254	NON-EXPEDITED			US-AMGEN-USASP2018062617			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colour Blindness; Drug Hypersensitivity; Hepatic Enzyme Increased; Therapeutic Product Effect	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Incomplete	Methotrexate		S	Unknown	Unk		Not Reported
	Xeljanz Xr		C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15042667	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015740		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cellulitis; Drug Ineffective; Drug Intolerance; Myalgia; Nausea; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15073687	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Asa			C	Unknown	Unk		Not Reported
	Coversyl /00790702/			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported
	Prevacid			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15088509	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018086572			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15100686	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016211		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Nodule; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	1500 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15108573	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002186		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Rash	Plaquenil 200 Mg			S	Oral			Not Reported
	Rinderon [Betamethasone]			C				Not Reported
	Atorvastatin			C				Not Reported
	Calfina			C				Not Reported

Lansoprazole				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15124709	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002384		41 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15124710	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002387		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy; Ejection Fraction Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15168725	NON-EXPEDITED			US-AMGEN-USASP2018097012			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diarrhoea; Gastrointestinal Disorder; Injection Site Reaction	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15168783	EXPEDITED (15-DAY)		OT	PT-ROCHE-2156882		47 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15168889	EXPEDITED (15-DAY)		HO	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002523		35 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Weight Increased	Plaquenil			S	Unknown	200 Mg, Bid		Concordia
	Prednisolone			S	Unknown	25 Mg		Concordia
	Loratadine			S	Unknown	10 Mg, Bid		Not Reported
	Phenergan			S	Unknown	25 Mg		Not Reported
	Ranitidine Hydrochloride			S	Unknown	150 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15168890	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002525		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Plaquenil			S	Oral	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15169360	EXPEDITED (15-DAY)		OT	US-ROCHE-2079496			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Diabetes Mellitus; Diarrhoea; Drug Ineffective; Fatigue; Grip Strength Decreased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Neutropenia; Quality Of Life Decreased; Tooth Infection; Treatment Failure; Urinary Tract Infection	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170077	NON-EXPEDITED			US-PFIZER INC-2018292044		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170409	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002535		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pustular	Plaquenil			S	Oral			Concordia
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170637	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-928204		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Small Cell Lung Cancer	Prednisona			S	Oral	5 Milligram Daily;		Actavis
	Orencia 125			S	Subcutaneous			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Dolquine			S	Oral	200 Milligram Daily;		Not Reported
	Tramadol			C	Oral			Not Reported
	Risperidona			C	Oral			Not Reported
	Simvastatina 20			C	Oral	20 Milligram Daily;		Not Reported
	Fosavance			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15170705	EXPEDITED (15-DAY)		OT	US-SA-2018SA194400			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Ineffective; Dyspnoea; Injection Site Reaction; Paralysis; Rash; Transaminases Increased	Kevzara			S		Unk		Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Rituxan			S				Not Reported
	Humira			S				Not Reported
	Cimzia			S				Not Reported
	Imuran (Azathioprine)			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15171295	EXPEDITED (15-DAY)		OT	SE-GLAXOSMITHKLINE-SE2018125153		41 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Intentional Product Use Issue; Off Label Use	Dexamethasone			S	Unknown			Glaxosmithkline
	Prednisolone			S	Unknown	5 Mg, Unk		Glaxosmithkline
	Belimumab			S	Intravenous (not otherwise specified)	As Maintenance Dose		Glaxosmithkline
	Mycophenolate Mofetil			S	Unknown	2000 Mg, Unk		Glaxosmithkline
	Rituximab			S	Intravenous (not otherwise specified)	Two Weeks Apart		Not Reported
	Bortezomib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Cyclophosphamide			S	Unknown	800 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15172705	EXPEDITED (15-DAY)		OT	US-JNJFOC-20180722964		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use Issue; Psoriasis	Ustekinumab			S	Subcutaneous			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15173094	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1053001		90 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Confusional State;	Olanzapine			S	Oral	2.5 Mg, 0-0-0.5-0, Tabletten		Not Reported

Dysuria; General Physical Health Deterioration; Pyrexia	Quensyl		S	Oral	200 Mg,0-0-1-0	Mylan
	Tamoxifen		S	Oral	20 Mg, 0-0-1-0	Mylan
	Pantoprazol Al		C	Oral	20 Mg, 1-0-0	Mylan
	Prednisolon /00016202/		C	Oral	1 Mg, 2-0-0-0	Mylan
	Fentanyl		C	Transdermal	12 Mug/Tag,Schema.Pflaster Transdermal	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15175582	EXPEDITED (15-DAY)		OT	SE-TAKEDA-2018MPI009698		41 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Intentional Product Use Issue; Off Label Use	Bortezomib			S	Unknown	Unk		Takeda
	Dexamethasone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	5 Mg, Unk		Not Reported
	Cyclophosphamide			S	Unknown	800 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	2000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2018	15175623	NON-EXPEDITED			US-SA-2018SA042658		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Phosphate			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	12809341	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Plaquenil Sulfate			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Prednisone			S	Oral	15 Mg, Once Daily (Qd)		Not Reported
	Gold			C		Onjection		Not Reported
	Tofacitinib			C	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Celebrex			C				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	14148757	NON-EXPEDITED		OT	US-AMGEN-USASP2017164421		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelinating Polyneuropathy; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Injectable		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Minocycline			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported
	Restasis			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	14368885	EXPEDITED (15-DAY)		OT	FI-BAUSCH-BL-2018-000052			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Prednisolone			S	Unknown			Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15035037	NON-EXPEDITED			US-PFIZER INC-2018245694			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15131639	EXPEDITED (15-DAY)		HO	PHHY2018DE037825		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Rituximab			S	Unknown	1000 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis

	Methotrexate			S	Unknown					Novartis
	Hydroxychloroquine Sulphate			S	Unknown	10-15 Mg				Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15157596	NON-EXPEDITED			PHEH2018US028233			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15179490	NON-EXPEDITED			US-AMGEN-USASP2018097926			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rash; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180089	NON-EXPEDITED			US-PFIZER INC-2018293584		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180146	NON-EXPEDITED			US-PFIZER INC-2018294068			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180155	NON-EXPEDITED			US-PFIZER INC-2018294326			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180413	EXPEDITED (15-DAY)		CA, OT	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00014334			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Hydroxychloroquine			S	Transplacental	Unknown		Concordia
	Prednisolone			S	Transplacental	Unknown		Concordia
	Ezetimibe			S	Transplacental	Unknown		Not Reported
	Torasemide			S	Transplacental	Unknown		Not Reported
	Enoxaparin			S	Transplacental	Unknown		Not Reported
	Ramipril			S	Transplacental	Maternal Dose 20 Mg, Unk		Not Reported
	Nicotine			S	Transplacental	Unknown		Not Reported
	Salbutamol			S	Transplacental	Unknown		Not Reported
	Rivaroxaban			S	Transplacental	Unknown		Not Reported
	Simvastatin			S	Transplacental	Unknown		Not Reported

	Acetylsalicylic Acid		S	Transplacental	Unknown		Not Reported
	Tacrolimus		S	Transplacental	Unknown		Not Reported
	Aliskiren		S	Transplacental	Unknown		Not Reported
	Pantoprazole		S	Transplacental	Unknown		Not Reported
	Metamizole		S	Transplacental	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15180500	NON-EXPEDITED			US-PFIZER INC-2018294698			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15181261	NON-EXPEDITED			US-SA-2018SA195186		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2018	15265491	DIRECT		DS			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy	Hydroxychloroquine			S	Oral	Quantity:2 Df Dosage Form;		Prasco
	Metropolol			C				Not Reported
	Simvastin			C				Not Reported

	Prednisone			C						Not Reported
	Azellastine			C						Not Reported
	Levothyroxine			C						Not Reported
	Lyrica			C						Not Reported
	Multiple Vitamins			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14156310	NON-EXPEDITED			US-PFIZER INC-2017469564		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Minocycline			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14516229	EXPEDITED (15-DAY)		OT	PHHY2017NL200804		38 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Pregnancy On Oral Contraceptive	Methotrexate			S	Unknown	Unk		Novartis
	Plaquenil			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14693923	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-027489			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Incomplete; Tuberculosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14789787	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2266926-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Mtx			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	14966680	EXPEDITED (15-DAY)		LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001888		57 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

Lansoprazole	C					Not Reported
Bayaspirin	C					Not Reported
Crestor	C					Not Reported
Prednisolone	C					Not Reported
Cellcept	C					Not Reported
Depakene	C					Not Reported
Daiphen	C					Not Reported
Metformin Hydrochloride	C					Not Reported
Novorapid	C					Not Reported
Insulin Glargine	C					Not Reported
Canalia	C	Oral	1 Tablet/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15027128	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002082		365 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15027129	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002090		5 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15027580	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002089		4 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Cyclophosphamide	S	Unknown		Not Reported
	Corticosteroids	C	Intravenous (not otherwise specified)		Not Reported
	Corticosteroids	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15041865	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002096		25 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Altered State Of Consciousness; Decreased Appetite; Headache; Hypoglycaemia	Hydroxychloroquine			S	Unknown	4 Years Ago		Not Reported
	Cellcept			C				Not Reported
	Alfacalcidol			C				Not Reported
	Amlodipine			C				Not Reported
	Pantoprazole			C				Not Reported
	Atenololol			C				Not Reported
	Prednisolone			C				Not Reported
	Furosemide			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Icodextrin			C				Not Reported
	Dianeal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15073195	EXPEDITED (15-DAY)		DE, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-053161		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Platelet Count Decreased; Product Administration Error; Pyrexia	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk		Not Reported

	Montelukast Sodium			S	Unknown	Unk				Not Reported
	Lorazepam			S	Unknown	Unk				Not Reported
	Hydroxychloroquine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15138095	EXPEDITED (15-DAY)			FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002315		5 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Product Use Issue	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15138096	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002316		6 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication; Pulmonary Haemosiderosis	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15159300	EXPEDITED (15-DAY)			GB-PFIZER INC-2018286526		15 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication	Methotrexate Sodium			S		Unk, Weekly (Injections)		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Methylprednisolone			S				Pfizer

	Cyclophosphamide	S		Unk		Not Reported
	Prednisolone	S	Intravenous (not otherwise specified)	Unk, 2x/Week (Fortnightly Three-Day Intravenous Pulses)		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported
	Mycophenolate Accord	S		Unk		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S				Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Hydroxychloroquine	S				Not Reported
	Rituximab	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15188673	NON-EXPEDITED			US-PFIZER INC-2018295724		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15188676	NON-EXPEDITED			US-PFIZER INC-2018295959		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15188690	NON-EXPEDITED			US-PFIZER INC-2018295870		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sertraline Hcl			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Codeine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15189648	NON-EXPEDITED		OT	US-SA-2018SA192777			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia	Arava			S	Oral	10 Mg, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Enbrel			C	Subcutaneous	50 Mg, Qow		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Qow		Not Reported
	Mtx [Methotrexate]			C		Unk		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Remicade			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2018	15190800	NON-EXPEDITED			US-PFIZER INC-2018295643			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Humira			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	12330645	NON-EXPEDITED			CA-AMGEN-CANSP2016053986		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	12835893	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016138833		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bone Pain; Drug Ineffective; Fibromyalgia; Immunodeficiency; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Sacroiliitis; Somnolence; Treatment Failure	Enbrel			S	Unknown	50 Mg, Once Weekly		Amgen
	Meloxicam			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	15 Mg, Qweekly		Not Reported
	Folic Acid			C	Unknown	5 Mg, Unk		Not Reported
	Naproxen			C	Unknown	500 Mg, Qd		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	12879211	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016146021		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Apo Hydroxychloroquine			S	Unknown	400 Mg, 5 Days Per Week		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Lipitor			C	Oral	20 Mg, Od		Not Reported
	Methotrexate			C		15 Mg, Qwk		Not Reported
	Methotrexate			C		15 Mg, Qweekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	13070988	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016175717		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibiotic Therapy; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Synovial Cyst; Tooth Infection	Enbrel			S	Unknown	50 Mg, Qwk (Saturday)		Amgen
	Methotrexate			S	Subcutaneous	15 Mg, Qwk (Saturday)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C		15 Mg, Qd		Not Reported
	Omeprazole			C	Unknown	20 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd ((24 Hours After Methotrexate))		Not Reported
	Atrovent			C	Unknown	3 Puffs, Qwk		Not Reported
	Flovent			C	Unknown	125 Mug, Unk		Not Reported
	Alendronate			C	Unknown	70 Mg, Qwk		Not Reported
	Naproxen			C	Unknown	500 Mg, Bid		Not Reported
	Apo-Hydroxyquine			C	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	13080012	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2016045750		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erythema; Extremity Contracture; Gastrointestinal Toxicity; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Stiffness; Joint Swelling; Ocular Toxicity; Paraesthesia; Rash; Scar; Treatment Failure	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Omega-3			C	Oral	1 Tab, Qd		Not Reported
	Diclofenac			C	Topical	As Directed		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	14665951	EXPEDITED (15-DAY)		OT	US-SA-2018SA043334		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Gastrointestinal Haemorrhage	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methocarbamol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	14683297	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018039793		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Pyrexia; Rheumatoid Arthritis; Tooth Disorder	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Azulfidine			S	Unknown	Unk		Not Reported
	Azulfidine			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Actemra	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S				Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Xeljanz Xr	S	Oral	11 Mg, Qd		Not Reported
Prednisone	C		Unk Unk, Qd		Not Reported
Orencia	C		Unk		Not Reported
Methotrexate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15120706	EXPEDITED (15-DAY)		OT	US-SA-2018SA119811			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Defaecation Urgency; Diarrhoea; Gastric Disorder; Injection Site Reaction; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15192707	EXPEDITED (15-DAY)		HO	CA-ROCHE-2157168		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

					Plaquenil		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Tacrolimus		S	Unknown		Not Reported
					Tacrolimus		S	Unknown		Not Reported
					Prednisone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15192735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159558		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15192920	NON-EXPEDITED			US-AMGEN-USASP2018100208			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193251	EXPEDITED (15-DAY)		CA, OT	DE-DRREDDYS-GER/GER/18/0102170		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Citalopram			S		10 Mg/D		Not Reported
	Quensyl			S		200 Mg/D		Not Reported
	Femibion Schwangerschaft 1			C		0.8 [Mg/D]		Not Reported
	Cytotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193782	EXPEDITED (15-DAY)		OT	US-SA-2018SA193647			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Defaecation Urgency; Diarrhoea; Gastrointestinal Disorder; Injection Site Reaction; Nausea;	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil Sulfate			S		Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira	S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz Xr	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15193793	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA194020		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Hypersensitivity; Drug Intolerance; Hypertension; Palpitations; Rheumatoid Arthritis; Rheumatoid Arthritis; Tachycardia; Tinnitus; Unevaluable Event	Arava			S		Unk		Sanofi
	Enbrel			S		Unk Unk, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Methotrexate			S		Unk		Not Reported
	Toprol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15195983	NON-EXPEDITED			US-PFIZER INC-2018299944		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Rasuvo			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15197327	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1961418-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Cyclosporin	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported
	Tylenol Arthritis	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	12650486	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014040881		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Finger Deformity; Hepatic Enzyme Increased; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Treatment Failure; Wrist Deformity	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Depo-Medrol			C	Intramuscular	80 Mg, Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Pariet			C	Unknown	Unk		Not Reported
	Actonel			C		Unk		Not Reported
	Apo-Meloxicam			C	Unknown	15 Mg, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported
	Risedronate Sodium			C	Unknown	35 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14718798	EXPEDITED (15-DAY)		HO	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-028319			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14836546	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001443			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Defaecation Urgency; Diarrhoea; Gastric Disorder; Injection Site Reaction; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	50mg/2ml		Not Reported
	Methotrexate			S	Subcutaneous	50mg/2ml		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C	Oral			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	14901265	NON-EXPEDITED			US-PFIZER INC-2018198661		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15084870	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018248803			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Remicade			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Dolquine			S		Unk		Not Reported
	Adalimumab			S		Unk		Not Reported
	Abatacept			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15128533	EXPEDITED (15-DAY)		OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002398		58 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Maculopathy; Optic Nerve Disorder; Visual Field Defect	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported
	Plaquenil 200 Mg Tablet			S		200mg Morning And Evening		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201496	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002299		38 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Dyspnoea; Oedema Peripheral; Pulmonary Oedema	Hydroxychloroquine		S	Unknown		Concordia
	Warfarin		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201712	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002518			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Ulcerative; Grip Strength Decreased; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15201717	EXPEDITED (15-DAY)		HO	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002570		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Chest Discomfort; Cough; Tinnitus; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral	2dd1		Not Reported
	Methotrexaat			C				Not Reported
	Foliumzuur			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15202392	NON-EXPEDITED			US-PFIZER INC-2018299675		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15203145	NON-EXPEDITED			US-PFIZER INC-2018300245		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15203168	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA163597		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis Infective; Cellulitis; Drug Ineffective; Post Procedural Haemorrhage; Rheumatoid Arthritis	Arava			S		Unk		Sanofi
	Enbrel			S		Unk		Not Reported
	Xeljanz Xr			S	Oral	Unk Unk, Qd		Not Reported
	Xeljanz Xr			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15203373	NON-EXPEDITED			US-SA-2018SA171513			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Joint Swelling; Musculoskeletal Stiffness; Synovitis; Therapeutic Product Effect Incomplete	Arava			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15203448	EXPEDITED (15-DAY)		DE	PHHY2018FR055946		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Drug Abuse; Toxicity To Various Agents	Zopiclone			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	Unk		Novartis
	Mirtazapine			S	Oral	Unk		Not Reported
	Morphine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Alcool			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Oxazepam			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15204665	EXPEDITED (15-DAY)		OT	CA-ROCHE-2160232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15204684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159728		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15205537	NON-EXPEDITED			US-AMGEN-USASP2018100484			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Drug Ineffective; Drug Intolerance; Skin Discolouration	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Orencia			C				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15205563	EXPEDITED (15-DAY)		OT	GB-ABBVIE-18K-167-2432145-00			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	11512293	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015094598		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Drug Ineffective; Hand Deformity; Lung Disorder; Pelvic Fracture;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	Unk, Up To 25 Mg Qweek		Not Reported

Pneumonitis; Rheumatoid Arthritis	Methotrexate		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	200 Mg, Q2wk	Not Reported
	Leflunomide		S	Unknown	10 Mg, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, Bid	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Arava		C		Unk	Not Reported
	Prednisone		C		Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	12365814	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016059801		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			C		200 Mg, Bid		Not Reported
	Vimovo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	12823554	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016135908		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Joint Fluid Drainage; Large Intestinal Obstruction;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Leflunomide			S	Oral	20 Mg, Die		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Oral	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	12909517	EXPEDITED (15-DAY)		CA, HO, OT	CA-AMGEN-CANSP2016152635		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Ineffective; Drug Intolerance; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		500 Mg, Bid		Not Reported
	Naprosyn			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	12962996	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016163557		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Carpal Tunnel Syndrome; Drug Hypersensitivity; Drug Ineffective; Hypertension; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	125 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

	Prednisone				C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	13059397	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016178121		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Salazopyrin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	13079467	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016166982		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Musculoskeletal Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Unevaluable Event	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Oral	300 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15168689	NON-EXPEDITED		OT	US-JNJFOC-20180703700			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Simponi Aria			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Methotrexate	S	Intramuscular	25 Unspecified Units		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Sarilumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15206133	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Disability; Fatigue; Inflammation; Pain In Extremity	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15206526	NON-EXPEDITED			US-PFIZER INC-2018298375		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Diclofenac Epolamine			S		Unk		Unknown
	Gabapentin			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15207309	EXPEDITED (15-DAY)		HO	GR-TEVA-2018-GR-931816		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Scleroderma Renal Crisis	Methotrexate			S	Unknown			Barr
	Alprazolam			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported
	Folate Sodium			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15208509	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016358546		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Finger Deformity; Hepatic Enzyme Increased; Mouth Ulceration; Treatment Failure; Wrist Deformity	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2x/Day		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day (Monday To Friday Only)		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Depo-Medrol			C	Intramuscular	80 Mg, Unk		Not Reported
	Actonel Once-A-Week			C		35 Mg (1 Tablet), Weekly		Not Reported
	Calcium Antacid			C		500 Mg, 1x/Day		Not Reported
	Vitamin D2			C		5 Df, Daily (400 Unit Tablet, 2000 Unit Per Day)		Not Reported

	Pariet	C	Unknown	20 Mg, 1x/Day		Not Reported
	Apo-Meloxicam	C	Unknown	15 Mg, Qd		Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	50 Mg, Qd		Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15209908	NON-EXPEDITED			US-PFIZER INC-2018304164		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15210092	EXPEDITED (15-DAY)		OT	PHHY2018US049356		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	62.5 Mg, Qd		Not Reported
	Cyclophosphamide			S	Unknown	2 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15210093	EXPEDITED (15-DAY)		OT	PHHY2018US049351		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii	Methotrexate Sandoz			S	Unknown	20 Mg, Qw		Not Reported

Pneumonia	Prednisone			S	Unknown	10 Mg, Qd				Not Reported
	Hydroxychloroquine			S	Unknown	600 Mg, Qd				Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15275300	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension	Methotrexate 2.5ml Generic			S	Oral			Not Reported
	Hydroxychloroquine 200mg			S	Oral			Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2018	15211647	EXPEDITED (15-DAY)		OT	PHHY2017DE199980		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Dysaesthesia; Herpes Zoster; Nausea	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20-25 (Unit Not Reported)		Novartis
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2018	15211828	EXPEDITED (15-DAY)		OT	PHHY2018US050446		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Histoplasmosis Disseminated	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

	Ruxolitinib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	13070797	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2792		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erythema; Extremity Contracture; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Stiffness; Joint Swelling; Paraesthesia; Rash; Scar; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxychloroquine			S	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Omega-3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	13130412	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015306698		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Condition Aggravated; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Pelvic Fracture; Pneumonitis	Enbrel			S		50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Up To 25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Up To 25 Mg, Weekly (Injections)		Unknown
	Cimzia			S		200 Mg, Cyclic (Every 2 Weeks)		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Arava			S		10 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	14476902	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018012711			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Grip Strength Decreased; Hand Deformity; Loss Of Personal Independence In Daily Activities; Poor Venous Access; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15022669	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018236911		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Macular Degeneration; Tuberculin Test Positive	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15100939	NON-EXPEDITED			US-PFIZER INC-2018266907		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15171096	EXPEDITED (15-DAY)		LT, OT	US-PFIZER INC-2018292545		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Histoplasmosis Disseminated	Methotrexate Sodium			S		Unk		Pfizer
	Infliximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15212045	EXPEDITED (15-DAY)		CA, DE, OT	DE-PAN-2018-000402			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death Neonatal; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S				Not Reported
	Prednisolone			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Torasemide			S				Not Reported
	Salbutamol			S				Not Reported
	Metamizole			S				Not Reported
	Ezetimibe			S				Not Reported
	Xarelto			S				Not Reported
	Aliskiren			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Ramipril			S				Not Reported
	Nicotine			S				Not Reported
	Pantoprazole			S				Not Reported
	Simvastatin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15212142	EXPEDITED (15-DAY)		CA, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002703		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate	Hydroxychloroquine			S	Transplacental			Not Reported
	Folsaeure			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15212980	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002677		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil			S	Oral			Not Reported
	Solupred (Prednisolone Sodium Metazoate)			C				Not Reported
	Bactrim			C				Not Reported
	Chronadalate			C				Not Reported
	Kardegic			C				Not Reported
	Calcidose [Calcium Carbonate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15213262	NON-EXPEDITED			US-PFIZER INC-2018305304		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Celebrex			S		Unk		Pfizer
	Advil			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15213302	EXPEDITED (15-DAY)		DE, HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002709		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Confusional	Hydroxychloroquine			S	Unknown			Not Reported

State; Eosinophilia; Pleural Effusion; Respiratory Failure; Strongyloidiasis	Prednisone	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15213617	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201206-001689		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Nausea; Pancytopenia; Vomiting	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	Increased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15214110	NON-EXPEDITED			US-SA-2018SA205969		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Pain; Lacrimation Increased; Ocular Hyperaemia	Hydroxychloroquine			S		Unk		Sanofi
	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15215414	EXPEDITED (15-DAY)		OT	ES-SA-2018SA176684			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Abatacept			S	Unknown	Unk Unk, Unkk		Not Reported
	Adalimumab			S	Unknown	Unk, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk, Unk		Not Reported

	Etanercept	S	Unknown	Unk, Unk		Not Reported
	Infliximab	S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk, Unk		Not Reported
	Remicade	S	Unknown	Unk Unk, Unk		Not Reported
	Pantoprazole	C		Unk Unk, Unk		Not Reported
	Paracetamol	C		Unk Unk, Unk		Not Reported
	Enbrel	C		50 Mg, Unk		Not Reported
	Lornoxicam	C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15216652	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201808307		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15217897	NON-EXPEDITED			US-AMGEN-USASP2018101504			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Allergic; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported
	Xeljanz			C		5 Mg, Qod		Not Reported
	Xeljanz			C		5 Mg, (Every Other Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15218087	NON-EXPEDITED			US-AMGEN-USASP2018102319			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15218143	NON-EXPEDITED			US-AMGEN-USASP2018102276			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pain; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Minocycline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15218286	NON-EXPEDITED			US-AMGEN-USASP2018101073			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2018	15279796	DIRECT	Y				60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia Pfs			S			15 MTH	Bristol Myers Squibb
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	13929700	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2702		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14114555	NON-EXPEDITED			US-PFIZER INC-2017454079		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Limb Discomfort; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect	Xeljanz Xr			S		11 Mg, Daily		Pfizer
	Plaquenil			S		Unk		Not Reported

Incomplete; Trigger Finger

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14167631	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14172662	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006284		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Pregabalin			C						Not Reported
	Acetaminophen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14202805	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006410		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hypokinesia; Nasopharyngitis; Pain In Extremity; Rheumatoid Arthritis; Swelling	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14329435	EXPEDITED (15-DAY)		HO	NL-TEVA-2017-NL-840185		59 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease	Methotrexate			S	Oral			Barr
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14760417	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001245		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Advil		S	Oral	Not Reported
	Mefenamic Acid		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14761753	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14761754	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001250		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)	
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14762086	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Bifidobacterium Bifidum/Enterococcus Faecium			C				Not Reported
	Loperamide			C				Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14762091	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001268		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Depression; Drug Hypersensitivity; Drug Ineffective; Drug	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Celebrex		C		Not Reported
	Hydroxychloroquine		C		Not Reported
	Prednisone		C		Not Reported
	Vitamin D2		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	14766704	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15003774	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bipolar Disorder; Clostridium Difficile Infection; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown			Not Reported
	Humira(Solution For Injection)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Intolerance; Fear Of Injection; Food Allergy; Hypersensitivity; Injection Site Infection; Mastocytosis; Nausea; Orthostatic Hypotension; Pain; Subcutaneous Abscess; Swollen Tongue; Treatment Failure; Vomiting	Methotrexate	S	Subcutaneous	Not Reported
	Remicade	S	Unknown	Not Reported
	Otrexup	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Clindamycin	S	Unknown	Not Reported
	Amoxicillin	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15075748	NON-EXPEDITED			US-SA-2018SA167063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Treatment Failure	Arava			S		Unk		Sanofi
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15172120	EXPEDITED (15-DAY)		DE, OT	GB-MYLANLABS-2018M1055576		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agranulocytosis; Contraindicated Product Administered; Malaise; White Blood Cell Count Decreased	Clozaril	S	Oral	Unk			Mylan
	Hydroxychloroquine	S		Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15201711	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002514			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15210085	EXPEDITED (15-DAY)		DE, OT	PHHY2018GB053812		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Contraindicated Product Administered; Malaise; White Blood Cell Count Decreased	Clozaril			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15219683	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002659			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Skin Hyperpigmentation;	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Therapeutic Product Effect Decreased	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz Xr		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220005	NON-EXPEDITED			US-PFIZER INC-2018302056		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220045	NON-EXPEDITED			US-PFIZER INC-2018302584		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220275	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2158553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220365	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-		68 YR	Male	CAN

2584

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Polyneuropathy; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Atorvastatin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15220878	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002368			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Plaquenil 200 Mg			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15221053	NON-EXPEDITED			US-PFIZER INC-2018302598		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer

	Arava	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Simponi	S	50 Mg, Unk		Not Reported
	Actemra	C	162 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15222081	NON-EXPEDITED			US-PFIZER INC-2018300028		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15222122	EXPEDITED (15-DAY)		DE, HO	PHHY2018US052378		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Eosinophilia; Respiratory Distress; Respiratory Failure; Strongyloidiasis	Prednisone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15222238	EXPEDITED (15-DAY)		DS, OT	PHHY2018CA061543		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment	Voltaren Sr			S	Oral	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Mg, Bid		Not Reported
	Lisinopril Dihydrate			S	Unknown	Unk		Novartis
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported

Failure	Pantoprazole Sodium Sandoz	S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Diclofenac	S	Oral	2 Df, Qd		Not Reported
	Diclofenac	S	Oral	1 Df, Unk		Not Reported
	Lisinopril	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	1 Df, Qd		Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd		Not Reported
	Synthroid	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	2 Df, Qd		Not Reported
	Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15222944	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2018-026666			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone Tablets 5mg			S	Unknown	5 Mg, Unknown		Vintage
	Plaquenil /00072602/			S	Unknown	200 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15223318	EXPEDITED (15-DAY)		OT	PHEH2018US030734			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Disorder; Bone Pain; Exostosis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2018	15223570	EXPEDITED (15-DAY)		OT	US-SA-2018SA203905			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities	Arava	S	Oral	10 Mg, Bid		Sanofi
	Plaquenil Sulfate	S	Oral	1 Df, Bid		Sanofi
	Enbrel	S	Subcutaneous	50 Mg		Not Reported
	Enbrel	S	Subcutaneous	50 Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Bid		Not Reported
	Methotrexate	S		Unk		Not Reported
	Remicade	C				Not Reported
	Xeljanz Xr	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	12872122	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016144351		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrogram Abnormal; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Rotator Cuff Syndrome; Shoulder Arthroplasty; Synovial Disorder; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	13133072	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0250		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Drug Ineffective; Drug Intolerance; Pelvic	Methotrexate (Trade Name Unknown)			S	Oral	Upto 25 Mg		Not Reported
	Methotrexate (Trade Name			S	Unknown	Upto 25 Mg		Not Reported

Fracture; Pneumonitis	Unknown)					
	Enbrel	S	Unknown			Not Reported
	Cimzia	S	Unknown	Cyclic		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14698337	EXPEDITED (15-DAY)		OT	RO-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001070		45 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erythema; Fatigue; Macule; Myalgia; Nausea; Petechiae; Pruritus; Skin Plaque; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Vomiting	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Amoxicillin (Salt Not Specified)			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methylprednisolone			C				Not Reported
	Methylprednisolone			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14735750	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097932			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi

	Leflunomide			S	Unknown	Unk Unk,Unk	Sanofi
	Actemra			S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk	Not Reported
	Remicade			S	Unknown	Unk Unk,Unk	Not Reported
	Simponi			S	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14735950	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097886		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombosis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Prednisone			S	Unknown	10 Mg,Qd		Not Reported
	Mefenamic Acid			S	Oral	Unk Unk,Unk		Not Reported
	Advil [Ibuprofen]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	14907774	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018065437		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Hypertension; Rheumatoid Arthritis; Unevaluable Event	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	2.5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	5 Mg, Qd		Not Reported
	Xeljanz			S	Unknown	11 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Toprol			C	Unknown	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15072920	EXPEDITED (15-DAY)		DE, OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002137		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Hydroxychloroquine			S	Unknown			Not Reported
	Influenza Vaccine			S	Unknown			Not Reported
	Montelukast Sodium			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15082706	EXPEDITED (15-DAY)		CA, DE, OT	DE-ASTELLAS-2018US029036			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Advagraf			S	Transplacental	Unk Unk, Unknown Freq.		Astellas
	Salbutamol			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Xarelto			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Delix /00885601/			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Quensyl			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Pantozol /01263204/			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Torem /01036501/			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Nicotine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Rasilez			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Ezetimibe Msd			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported

	Novaminsulfon	S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Simvastatin	S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Prednisolone	S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Heparin Lmw	S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Rituximab	S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Clexane	S	Transplacental	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15104390	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018039584		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Grip Strength Decreased; Hand Deformity; Loss Of Personal Independence In Daily Activities; Poor Venous Access; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Azulfidine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15108574	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002200		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sensory Level Abnormal	Plaquenil 200 Mg Tablet			S	Oral	1 Month 27 Days		Not Reported
	Predonine			C				Not Reported
	Alfarol			C				Not Reported
	Rabeprazole Na			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15195882	NON-EXPEDITED			US-PFIZER INC-2018298275		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Hcq			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225157	EXPEDITED (15-DAY)		OT	CA-ROCHE-2160238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown	Therapy Duration: 8 Years		Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225204	NON-EXPEDITED			US-AMGEN-USASP2018104067			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225252	EXPEDITED (15-DAY)		DE, HO	US-SAMSUNG BIOEPIS-SB-2018-09828		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Strongyloidiasis	Infliximab			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225711	EXPEDITED (15-DAY)		OT	AU-ASTELLAS-2018US034137			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Graft Versus Host Disease	Tacrolimus			S	Unknown	Unk, Unknown Freq.		Astellas
	Cyclosporin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Mycophenolate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Sirolimus			S	Unknown	Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Unknown	Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown Freq.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225822	NON-EXPEDITED			US-PFIZER INC-2018306410		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225844	NON-EXPEDITED			US-PFIZER INC-2018306072			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15225975	EXPEDITED (15-DAY)		OT	US-ZYDUS-020998		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Arteriosclerosis; Blood Fibrinogen Decreased; Cytopenia; Diarrhoea; Disseminated Intravascular Coagulation; Haemophagocytic Lymphohistiocytosis; Hepatic Function Abnormal; Hepatic Steatosis; Hyperbilirubinaemia; Hypoglycaemia; Lactic Acidosis; Mesenteric Artery Stenosis; Pyrexia; Serum Ferritin Increased; Thrombocytopenia; Transaminases Increased	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Infliximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15226821	EXPEDITED (15-DAY)		DS, OT	AU-SA-2018SA186282		57 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liquid Product Physical	Arava			S		10 Mg, Qd		Sanofi

Issue; Product Colour Issue; Psoriatic Arthropathy; Pustular Psoriasis; Rash	Plaquenil Sulfate	S		200 Mg, Unk		Sanofi
	Simponi	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Methotrexate	C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227406	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-068876			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Contraindicated Product Administered; Skin Hyperpigmentation	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15227543	EXPEDITED (15-DAY)		OT	US-SA-2018SA137724			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Liver Function Test Increased; Therapeutic Product Effect Incomplete	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Xeljanz Xr			C				Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15228674	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1056820		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic	Methotrexate			S	Unknown			Not Reported

Lymphohistiocytosis; Histoplasmosis Disseminated	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2018	15229091	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1837628US		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anal Incontinence; Back Pain; Constipation; Diarrhoea; Dyspepsia; Fatigue; Frequent Bowel Movements; Insomnia; Intentional Self-Injury; Muscle Spasms; Nausea; Proctalgia; Product Dose Omission; Pruritus; Rash; Scab; Somnolence; Suicidal Ideation; Thinking Abnormal	Urso (Ursodeoxycholic Acid)			S	Oral	750 Mg, Qd		Allergan
	Ocaliva			S	Oral	5 Mg, Q Week		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	12583412	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016352693			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Unknown	200 Mg, Bid		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported

Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Unknown	200 Mg, Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Cortisone	C		Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Enablex	C		Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C		Unk	Not Reported
Kenalog	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lasix	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Norflex	C	Unknown	Unk	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	Unk	Not Reported

	Vagifem			C	Unknown	Unk			Not Reported
	Pantoprazole Sodium			C	Unknown	Unk			Not Reported
	Morphine Sulfate			C	Unknown	Unk			Not Reported
	Desoximetasone			C	Unknown	Unk			Not Reported
	Furosemide			C	Unknown	Unk			Not Reported
	Darifenacin Hydrobromide			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	12916055	EXPEDITED (15-DAY)		CA, HO, OT	CA-PFIZER INC-2016515429		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Ineffective; Drug Intolerance; Infection; Rheumatoid Arthritis; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		500 Mg, Twice A Day		Not Reported
	Naprosyn			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15102178	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016188			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Rash; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	1 Df, Unk		Apotex
	Azathioprine			S	Unknown	1 Df, Unk		Apotex
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Df, Q.Wk.		Not Reported

	Methotrexate			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15119788	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-033708		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Encephalopathy; Extradural Abscess; Mycobacterium Avium Complex Infection; Osteomyelitis; Paraspinal Abscess	Prednisone			S	Unknown	20 Milligram, Daily		Aurobindo
	Vancomycin			S	Unknown			Aurobindo
	Cyclophosphamide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15201715	EXPEDITED (15-DAY)		OT	BR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002551		52 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Affective Disorder; Amnesia; Dysgeusia; Feeling Abnormal; Fibromyalgia; Hepatic Cirrhosis; Malaise; Memory Impairment; Mental Impairment; Nausea; Pain; Retching	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Adalimumab			C				Not Reported
	Amitriptyline			C				Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15203389	NON-EXPEDITED			US-PFIZER INC-2018300604		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15206131	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002569		56 YR	Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hyperkeratosis; Systemic Lupus Erythematosus Rash	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15229842	NON-EXPEDITED			US-AMGEN-USASP2018104597			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15229910	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002776			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate			S	Unknown					Not Reported
	Remicade			C						Not Reported
	Xeljanz Xr			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15229918	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002715		20 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade	Plaquenil 200 Mg Tablet			S	Oral	1 Month 12 Days		Not Reported
	Plaquenil 200 Mg Tablet			S	Oral	1 Month 12 Days		Not Reported
	Loxoprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15230078	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015058			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15230079	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Qwk		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15230772	NON-EXPEDITED			US-AMGEN-USASP2018104598			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15231210	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018NL058053		59 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Multiple Organ Dysfunction Syndrome; Necrotising Fasciitis; Pain; Septic Shock; Streptococcal Infection	Hydroxychloroquine			S	Unknown			Novartis
	Adalimumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Mg, Q4w		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15231860	NON-EXPEDITED			US-PFIZER INC-2018308511		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15233481	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245223		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Product Effect Incomplete	Remicade	S	Unknown	300 Mg, Qmo	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	200 Mg, Bid	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Benadryl	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported
	Enablex	C		Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Kadian	C		Unk	Not Reported
	Kenalog	C	Unknown	40 Mg, Unk	Not Reported
	Kineret	C	Unknown	100 Mg, Unk	Not Reported
	Lasix	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Norflex	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown	Unk	Not Reported
	Pantoloc	C	Unknown	Unk	Not Reported
	Restasis	C	Unknown	Unk	Not Reported
	Rituxan	C		Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Trimethoprim	C	Unknown	Unk	Not Reported

	Urispas	C	Unknown	200 Mg, Unk		Not Reported
	Vagifem	C	Unknown	Unk		Not Reported
	Omnaris	C	Unknown	Unk		Not Reported
	Ativan	C		Unk		Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Morphine Sulfate	C	Unknown			Not Reported
	Furosemide	C		Unk		Not Reported
	Pantoprazole Sodium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2018	15288878	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis	Hydrochloroquine			S	Oral			Unknown
	Orencia			S	Subcutaneous			Bristol Myers Squibb

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	13065509	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016597779		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Salazopyrin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	13827965	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2276		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Celebrex			S				Not Reported
	Fentanyl			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S				Not Reported
	Oxycontin			S				Not Reported
	Sulfasalazine			S				Not Reported
	Aclasta			C				Not Reported
	Actonel			C				Not Reported
	Diphenoxylate Hydrochloride			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Gabapentin			C				Not Reported
	Nasonex			C				Not Reported
	Nexium			C				Not Reported
	Nortriptyline Hydrochloride			C				Not Reported
	Omega 3			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone Hydrochloride			C				Not Reported
	Tylenol			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14170353	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015200			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, Qwk		Not Reported

Rheumatoid Arthritis	Enbrel		S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Ciclosporin		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	200 Mg, Qwk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Imuran /00001501/		S			Not Reported
	Actemra		S		640 Mg,Qwk	Not Reported
	Gold		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	300 Mg, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14636674	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA018553			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Simponi	S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Desoximetasone	C				Not Reported
	Methotrexate	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14736051	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097868		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Depression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg,Qw		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Celebrex			C	Unknown	200 Mg,Bid		Not Reported
	Hydroxychloroquine Phosphate			C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C		Tapering Dose		Not Reported
	Ergocalciferol			C	Unknown	4000 Iu,Qd		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14737595	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA097779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis;	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Sanofi

Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra	S	Unknown	Unk Unk,Unk		Not Reported
	Azathioprine	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine	S	Oral	1.5 G,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14789365	EXPEDITED (15-DAY)		OT	FI-ACCORD-065926			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	14882797	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA019711			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Kineret			S	Unknown	100 Mg Per Syringe		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported

	Apo-Hydroxyquine			S	Unknown					Not Reported
	Desoximetasone			C		Unk				Not Reported
	Methotrexate			C						Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15164709	NON-EXPEDITED			US-SA-2018SA195062			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Meloxicam			S				Not Reported
	Arava			S				Sanofi
	Levofloxacin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15208941	EXPEDITED (15-DAY)		OT	PHHY2018GB058203		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Bisoprolol Fumarate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Novartis
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Leflunomide Sandoz			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported
	Ceclor			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Erythro Base			S	Unknown			Not Reported

	Metronidazole	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Norfloxacin	S	Unknown			Not Reported
	Erythromycin	S	Unknown			Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234510	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002610		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Condition Aggravated; Nasopharyngitis; Pyrexia; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Plaquenil			S	Unknown			Not Reported
	Xeijanz			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234511	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002687			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Seizure	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	E Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234669	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015129			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug	Infliximab Pfizer (Unknown)			S	Intravenous (not	300 Mg, Qwk		Not Reported

Intolerance; Rheumatoid Arthritis			otherwise specified)			
	Enbrel	S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Actemra	S	Unknown	640 Mg,Qwk		Not Reported
	Arava	S	Unknown			Not Reported
	Ciclosporin	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Imuran /00001501/	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234670	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015236			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Apo-Hydroxyquine			C	Unknown				Not Reported
	Azathioprine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2163744		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15234961	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015156			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Inflectra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Anakinra			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Tocilizumab			S	Unknown				Not Reported
	Desoximetasone			C	Unknown	Unk			Not Reported
	Methotrexate			C	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15235007	NON-EXPEDITED			US-AMGEN-USASP2018105262		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nodule	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15235076	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002629		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile	Plaquenil			S	Unknown			Not Reported

Infection; Drug Ineffective; Upper Respiratory Tract Infection	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15235442	NON-EXPEDITED			US-PFIZER INC-2018311833		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15236458	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2018136794		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Oral	Unk		Glaxosmithkline
	Voltaren Sr			S	Oral	75 Mg, Bid		Glaxosmithkline
	Lisinopril Dihydrate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Glaxosmithkline
	Pantoprazole Sodium Sandoz			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Oral	2 Df, Qd		Glaxosmithkline
	Diclofenac			S	Oral	1 Df, Unk		Glaxosmithkline
	Lisinopril			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported

	Sulfasalazine		S	Oral	500 Mg, Qd		Not Reported
	Synthroid		S	Unknown	Unk		Not Reported
	Xeljanz		S	Oral	2 Df, Qd		Not Reported
	Gold		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15237006	NON-EXPEDITED			US-PFIZER INC-2018312512		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15239734	NON-EXPEDITED			US-SA-2018SA176649		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Pruritus; Rash; Therapeutic Product Effect Decreased	Leflunomide			S	Subcutaneous	Unk Unk, Unk		Sanofi
	Nifedipine			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Meloxicam			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Celebrex			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15239739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2164460			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2018	15239852	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2018-019576		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Prednisone Tablets 10mg			S	Oral	10 Mg, Once In The Morning		Vintage
	Revatio			S	Oral	1 Df, Bid		Not Reported
	Plaquenil			S	Oral	1 Df, Bid		Not Reported
	Plaquenil			S				Not Reported
	Mycophenolate Mofetil			S	Oral	250 Mg, Od, In The Morning		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Oxygen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2018	15177946	NON-EXPEDITED		OT	US-JNJFOC-20180707599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Medrol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2018	15240274	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-039014		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Prednisone			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Hydroxychloroquine			S	Unknown	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2018	15240331	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-039019		23 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumocystis Jirovecii Pneumonia	Prednisone			S	Unknown	62.5 Milligram, Once A Day		Aurobindo
	Cyclophosphamide			S	Unknown	2 Doses		Not Reported
	Hydroxychloroquine			S	Unknown	2 Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	14102012	EXPEDITED (15-DAY)		HO, LT, OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005863		51 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Drug Interaction; Serotonin	Plaquenil 200 Mg Tablet			S	Oral	200 Mg, Bid,11 Months 6 Days 12 Hrs		Concordia

Syndrome; Vomiting	Plaquenil 200 Mg Tablet	S	Unknown			Concordia
	Fluoxetine	S	Oral	20 Mg, Daily, 1 Dd		Not Reported
	Fluoxetine	S	Oral	1 Dd		Not Reported
	Fluoxetine	S	Oral	Verhoging Van 1 X 1 Tabl Naar 1 X 2 Tabl		Not Reported
	Fluoxetine	S	Oral	40 Mg, Daily		Not Reported
	Desogestrel, Ethinylestradiol	C	Oral	Ethinylestradiol/Desogestrel Tablet 30/150ug/ Ethinylestradiol / Desogestrel Tablet 30 / 150ug		Not Reported
	Nasacort	C	Nasal	1 Df, Daily; Nasal Spray 55mcg/ Do 120 Do		Not Reported
	Esomeprazol	C	Oral	20 Mg, Bid		Not Reported
	Oxazepam	C	Oral	10 Mg, Prn		Not Reported
	Zopiclon	C	Oral	7.5 Mg, Prn		Not Reported
	Celecoxib	C	Oral	100 Mg, Bid		Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	14666754	EXPEDITED (15-DAY)		OT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000997		78 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Hydroxychloroquine			S	Unknown	5 Years 9 Months 7 Days 12 Hrs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	14677000	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001019		54 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Csf Oligoclonal Band Present; Dysarthria; Eye Movement Disorder; Hemiparesis; Infarction; Ischaemic Stroke; Vasculitis	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydrocortisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2018	15241375	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002804			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Intestinal Ulcer; Mouth Ulceration	Plaquenil			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	13923401	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

					Hydroxychloroquine		S	Unknown		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Rituxan		S	Unknown		Not Reported
					Apo-Hydroxyquine		S	Unknown		Not Reported
					Apo-Prednisone		S	Unknown		Not Reported
					Atorvastatin		C	Unknown		Not Reported
					Pantoprazole Sodium		C	Unknown		Not Reported
					Plaquenil		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	14804335	EXPEDITED (15-DAY)		HO	CA-ROCHE-2113851			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	14860114	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC-2018184214		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Lung Neoplasm Malignant; Pneumonia; Product Use Issue; Pulmonary Embolism	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Weekly		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15242135	NON-EXPEDITED			US-AMGEN-USASP2018105306			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Iron Deficiency Anaemia; Rash	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15242524	NON-EXPEDITED			US-AMGEN-USASP2018104985			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Colchicine			C		Unk		Not Reported
	Prednisone			C		Unk (Intermittently)		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15242808	EXPEDITED (15-DAY)		HO	CA-ROCHE-2163629		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Prednisone	S	Unknown		Not Reported
	Warfarin	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Amitriptyline	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15243650	EXPEDITED (15-DAY)		HO	US-ALCAMI_CORPORATION-USA-POI0581201800004		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Azasan			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15243668	NON-EXPEDITED			US-SA-2018SA184216		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz			C	Unknown	Unk Unk, Unk		Not Reported
	Humira			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15243793	NON-EXPEDITED		OT	US-SA-2018SA209131			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15245698	EXPEDITED (15-DAY)		OT	PHHY2018GB060604			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate			S	Oral	Unk		Novartis
	Methotrexate			S	Subcutaneous	Unk		Novartis
	Humera			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2018	15246798	EXPEDITED (15-DAY)		HO	PHHY2018US059492		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Overdose; Sinus Tachycardia; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	36 G, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	12928125	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2199		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Ankle Deformity; Arthralgia; Delirium; Dislocation Of Vertebra; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Deformity; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Type 2 Diabetes Mellitus; Wound Infection	Orencia		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Apo-Hydroxyquin		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Naprosyn		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	13070838	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2815		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Salazopyrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	14987418	EXPEDITED (15-DAY)		CA	DE-BAUSCH-BL-2018-016174			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Microcephaly	Diclofenac Sodium			S	Transplacental	100 Mg, As Needed, Gestational Week Of Exposure 0-19 + 4		Not Reported
	Paracetamol			S	Transplacental	Gestational Week Of Exposure- 17-21		Not Reported

	Hydroxychloroquine			S	Transplacental	Gestational Week Of Exposure- 0-13		Not Reported
	Sulfasalazine			S	Transplacental	Gestational Week Of Exposure- 0-17		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15119260	NON-EXPEDITED		OT	US-AMGEN-USASP2018090957			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Intolerance; Injection Site Pain; Leukopenia; Mouth Ulceration; Retinal Disorder; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15247169	EXPEDITED (15-DAY)		OT	CA-ROCHE-2163690		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15247344	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002751		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Plaquenil			S	Oral			Not Reported
	Previscan (Fluindione)			S	Oral			Not Reported
	Inexium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15247649	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Unevaluable Event	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown	1 Month 14 Days		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Erelzi			S	Unknown	3 Months 24 Days		Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15247708	EXPEDITED (15-DAY)		CA	DE-DEXPHARM-20180550			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Microcephaly	Sulfasalazine			S	Transplacental	Gestational Week Of Exposure- 17		Not Reported
	Paracetamol			S	Transplacental	Gestational Week Of Exposure- 17-21		Not Reported
	Diclofenac			S	Transplacental	Gestational Week Of Exposure- 23 ; As		Not Reported

		Hydroxychloroquine			S	Transplacental	Necessary Gestational Week Of Exposure - 13			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15249636	EXPEDITED (15-DAY)		OT	US-SA-2018SA213920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Intestinal Ulcer; Mouth Ulceration	Plaquenil			S	Oral			Sanofi
	Methotrexate			S	Oral			Not Reported
	Arava			S	Oral			Sanofi
	Gabapentin			S	Oral			Not Reported
	Humira			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15249673	NON-EXPEDITED			US-PFIZER INC-2018314276		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15250396	NON-EXPEDITED			US-AMGEN-USASP2018106881			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen

	Humira			S	Unknown	Unk			Not Reported
	Humira			S					Not Reported
	Hcq			S	Unknown	Unk			Not Reported
	Hcq			S					Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Methotrexate			S					Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S					Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15251761	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2018-021316		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Aciclovir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15253211	NON-EXPEDITED			US-AMGEN-USASP2018107684			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15253282	EXPEDITED (15-DAY)		DE, OT	PHEH2018US031811		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Decreased; Cardio-Respiratory Arrest; Dyspnoea; Loss Of Consciousness; Pleural Effusion	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Novartis
	Lorazepam	S	Unknown	2 Mg, Qd	Not Reported
	Mycophenolate Mofetil	S	Unknown	2000 Mg, Qd	Not Reported
	Rizatriptan Benzoate	S	Unknown	5 Mg, Prn	Not Reported
	Prednisone	S	Unknown	20 Mg, Qd	Not Reported
	Prednisone	S	Unknown	50 Mg, Qd	Not Reported
	Prednisone	S	Unknown	45 Mg, Qd	Not Reported
	Nifedipine	S	Unknown	60 Mg, Qd	Not Reported
	Singulair	S	Unknown		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	1 Df, Qd	Not Reported
	Lasix	S	Unknown	20 Mg, Qod	Not Reported
	Lasix	S	Unknown	20 Mg, Qd	Not Reported
	Ferrous Sulfate	C	Unknown	Unk	Not Reported
	Omeprazole	C			Not Reported
	Ondansetron	C	Unknown	Unk	Not Reported
	Valacyclovir	C	Unknown	Unk	Not Reported
	Venlafaxine	C	Unknown	Unk	Not Reported
	Zolpidem	C	Unknown		Not Reported
	Brexpiprazole	C	Unknown		Not Reported
	Oxygen	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2018	15296395	DIRECT		HO			75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fall; Fibula Fracture; Tibia Fracture	Hydroxychloroquine			S	Oral			Prasco
	Vit D			C				Not Reported
	Probiotic			C				Not Reported
	Me-Coprolol			C				Not Reported

	Tartrate 50			C						Not Reported
	Acetaminophen Pm			C						Not Reported
	Aspirin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	13067695	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	13925652	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA011529			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Unknown	300 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, 1/Week		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Prednisone			S		5 Mg, Daily		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S		400 Mg, Qd; Unknown		Not Reported
	Atorvastatin Calcium Anhydrous			C		Unk		Not Reported
	Pantoloc /01263201/			C				Not Reported
	Pantoprazole Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	14648194	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA018572			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Unknown	300 Mg, Qd		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Atorvastatin			C				Not Reported
	Pantoloc /01263201/			C				Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	14945582	NON-EXPEDITED		OT	US-AMGEN-USASP2018071322			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Aspartate Aminotransferase Increased; Blood Potassium Decreased; Drug Ineffective; Hair Growth Abnormal; Nasal Ulcer; Pneumonia	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15007053	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg/ 0.8 Ml		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15217926	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018101515			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Meloxicam			S	Unknown	15 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15224981	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002733			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Pantoprazole			C				Not Reported
	Paracetamol			C				Not Reported
	Enbrel			C				Not Reported

	Lornoxicam			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15241384	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002779		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Hyperinsulinaemic Hypoglycaemia; Off Label Use; Presyncope; Tremor	Hydroxychloroquine			S				Not Reported
	Diazoxide			S				Not Reported
	Prednisone			C				Not Reported
	Steroid			C		Steroid Taper		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15242159	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15248967	NON-EXPEDITED			US-PFIZER INC-2018312363		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15253553	EXPEDITED (15-DAY)		LT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002534		8 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rhabdomyolysis	Plaquenil			S	Oral	200 Mg/ Jour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15253708	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002541			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Unknown	Duration: 1 Year 10 Months 3 Days		Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15254496	EXPEDITED (15-DAY)		OT	CA-SA-2018SA208423			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Plaquenil			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sulfasalazine			C		200 Mg, Qd		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15255440	EXPEDITED (15-DAY)		OT	GB-ABBVIE-18K-167-2443696-00		60 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Metronidazole	S	Unknown	Not Reported
	Metronidazole	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Demerol	S	Unknown	Not Reported
	Demerol	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported
	Celebrex	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Ceclor	S	Unknown	Not Reported
	Ceclor	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Bisoprolol Fumarate	S	Unknown	Not Reported
	Bisoprolol Fumarate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Erythromycin	S	Unknown	Not Reported
	Erythromycin	S	Unknown	Not Reported
	Leflunomide Sandoz	S	Unknown	Not Reported
	Leflunomide Sandoz	S	Unknown	Not Reported
	Erythro Base	S	Unknown	Not Reported
	Erythro Base	S	Unknown	Not Reported
	Pethidine Hydrochloride	S	Unknown	Not Reported

		Pethidine Hydrochloride			S	Unknown				Not Reported
		Arthrotec			S	Unknown				Not Reported
		Arthrotec			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15255893	EXPEDITED (15-DAY)		OT	PHHY2018SA064967			Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Rheumatoid Arthritis	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Alendronate			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Vitamin D2			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15256681	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA064014		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported

	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S				Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15256736	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA064016			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2018	15257725	EXPEDITED (15-DAY)		OT	PHHY2018CA065088			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg, Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	11991071	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703185		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cortisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	13067408	EXPEDITED (15-DAY)		OT	CA-ROCHE-1871510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	Therapy Duration: 11		Not Reported

				Months	
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Reactine (Canada)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Methotrexate	S	Oral	Therapy Duration: 11 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Leflunomide	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	13890842	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)					
	Methotrexate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	14202801	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006380		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Osteonecrosis; Pruritus; Vitreous Floaters	Plaquenil 200 Mg Tablet			S	Oral	Dose Of 200 Mg/Day And 400 Mg/Day, Alternately 3 Months 6 Days 12 Hrs		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Dose Of 200 Mg/Day And 400 Mg/Day, Alternately 3 Months 6 Days 12 Hrs		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Dose Of 200 Mg/Day And 400 Mg/Day, Alternately,3 Months 6 Days 12 Hrs		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Dose Of 200 Mg/Day And 400 Mg/Day, Alternately,3 Months 6 Days 12 Hrs		Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral	4 Months 24 Days		Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia

	Prograf	S	Oral		Not Reported
	Cellcept	S	Oral		Not Reported
	Cellcept	S	Oral		Not Reported
	Cellcept	S	Oral		Not Reported
	Azanin	C			Not Reported
	Locoid	C			Not Reported
	Antebate	C			Not Reported
	Hirudoid	C			Not Reported
	Calcium Lactate	C			Not Reported
	Alfacalcidol	C			Not Reported
	Takepron	C			Not Reported
	Baktar	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	14658464	NON-EXPEDITED			PR-PFIZER INC-2018109486		56 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	14750390	EXPEDITED (15-DAY)		OT	CA-ROCHE-2103410		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15218192	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-069326		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nodule	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15258601	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002919			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15258630	NON-EXPEDITED			US-TEVA-2018-US-938871			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error	Hydroxychloroquine			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15260270	EXPEDITED (15-DAY)		HO	CA-ROCHE-2164477		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15260271	EXPEDITED (15-DAY)		OT	CA-ROCHE-2164498		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Methotrexate Sodium			S	Unknown				Not Reported
		Methotrexate Sodium			S	Oral				Not Reported
		Orencia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	11878110	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1685291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Muscular Weakness; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous Form		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	14340913	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000002		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Gait Inability; Muscular Weakness; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Enbrel			C				Not Reported
	Morphine			C				Not Reported

	Tylenol			C						Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15129562	NON-EXPEDITED			US-SA-2018SA187056			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Plaquenil			S				Sanofi
	Simponi			S				Not Reported
	Leflunomide			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15138112	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002360		82 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Prednisolone 5mg			S	Oral			Not Reported
	Edirol			C				Not Reported
	Bonviva			C				Not Reported
	Pravastatin Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15263439	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2164530		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	C	Subcutaneous	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15264600	EXPEDITED (15-DAY)		OT	PHHY2018US064922		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Hyperinsulinaemic Hypoglycaemia; Hypoglycaemia; Presyncope; Tremor	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15264712	EXPEDITED (15-DAY)		OT	CA-SA-2018SA213450			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Plaquenil			S		300 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Cimzia			S				Not Reported
	Methotrexate			C				Not Reported
	Esomeprazole Magnesium			C	Oral	40 Mg		Not Reported
	Lorazepam			C	Oral	1 Mg, Hs		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Alendronate Sodium			C	Oral	70 Mg,Q		Not Reported

	Atenolol	C		3 Df	Not Reported
	Trimebutine	C		1 Df, Bid	Not Reported
	Hydrochlorothiazide	C	Oral	25 Mg, Qd	Not Reported
	Chlordiazepoxide;Clidinium Bromide	C	Oral	5mg-2.5mg	Not Reported
	Certolizumab Pegol	C	Subcutaneous	400 Mg/2 Ml Q Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15264981	NON-EXPEDITED			US-MYLANLABS-2018M1057226			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus Allergic	Amlodipine			S	Topical			Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15266517	EXPEDITED (15-DAY)		OT	PHHY2018CA065197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Neoral			S	Oral	20 Mg, Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15266520	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA065301		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis;	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased; Upper Limb Fracture	Celebrex			S	Unknown	Unk			Not Reported
	Cimzia			S	Subcutaneous	Unk			Not Reported
	Enbrel			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Imuran			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15266530	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA065245		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2018	15305140	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Intraocular Pressure Increased	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2018	14361956	EXPEDITED (15-DAY)		OT	US-ROCHE-2039506			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelinating Polyneuropathy; Neuropathy Peripheral; Neutropenia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported
	Restasis			C	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2018	15267418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2167320		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2018	12859898	EXPEDITED (15-DAY)		OT	CA-ROCHE-1695809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration 4 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Orencia			S	Unknown	Therapy Duration: 10.0 Month(S)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	11923333	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539178-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Urinary Tract Infection			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	S	Oral		Not Reported
	Plaquenil Sulfate	S	Oral		Not Reported
	Gold	C			Not Reported
	Celebrex	C			Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	12251812	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1600389-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Duration: 3 Months		Not Reported
	Arava			S	Oral	Duration: 3 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Duration: 3 Months		Not Reported
	Arava			S	Unknown	5 Months		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown	Duration: 10 Months		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	12856089	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Discontinued Due To A Side Effect		Not Reported
	Humira			S	Subcutaneous	Discontinued Due To A Side Effect For 2 Years		Not Reported
	Arava			S	Unknown	Discontinued Due To A Side Effect		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Discontinued Due To Developing Cancer		Not Reported
	Plaquenil			S	Unknown	Taken For 2 Years, Stopped Working		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Stopped Working Therapy Duration: 730 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Clavulin			C				Not Reported
	Amoxil			C				Not Reported
	Adalimumab			C				Not Reported
	Bacillus Calmette-Guerin (Bcg) Vaccine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	13741989	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1999955-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Abatacept	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	13921654	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA011445			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Xeljanz			S	Unknown			Not Reported

	Arava	S		20 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Prednisone	S		5 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S			Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd;	Not Reported
	Atorvastatin	C			Not Reported
	Pantoprazole Sodium	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14236230	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA016389			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14313937	EXPEDITED (15-DAY)		OT	GB-TEVA-2017-GB-835362		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Danazol			C	Unknown			Not Reported
	Dapsone			C	Unknown			Not Reported
	Cyclophosphamide			C	Unknown			Not Reported
	Atenolol			C	Unknown			Not Reported
	Vincristine			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Bendroflumethiazide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	14495734	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000482		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastric Disorder; Gastroenteritis Viral; Gastroenteritis Viral; Joint Swelling; Pyrexia	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15004710	EXPEDITED (15-DAY)		OT	US-SA-2018SA146361			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Dysarthria; Facial Paralysis; Urticaria	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Singulair			C	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Prozac			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15059563	NON-EXPEDITED			US-SA-2018SA123052		44 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Enbrel			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15066052	NON-EXPEDITED			US-PFIZER INC-2018256808		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Azulfidine	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15268908	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167475		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide (Canada)			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15268927	EXPEDITED (15-DAY)		OT	CA-ROCHE-2166771		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15268954	EXPEDITED (15-DAY)		HO	CA-ROCHE-2168145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15269002	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002502		8 DAY	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Foetal Exposure During Pregnancy; Hypoglycaemia	Plaquenil			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15269251	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PAN-2018-000425			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ramipril			S				Not Reported
	Simvastatin			S				Not Reported
	Pantoprazole Sodium			S				Not Reported
	Dipyrone			S				Not Reported
	Nicotine			S				Not Reported
	Aliskiren			S				Not Reported
	Torasemide			S				Not Reported
	Salbutamol Sulfate			S				Not Reported
	Rivaroxaban			S				Not Reported
	Heparin			S				Not Reported
	Ezetimibe			S				Not Reported
	Prednisolone			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15269452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Infliximab	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported
Methotrexate	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15269678	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-05595		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperinsulinaemic Hypoglycaemia	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Lupin
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15270040	NON-EXPEDITED			US-PFIZER INC-2018321192		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Bystolic			C		Unk		Not Reported
	Lasix			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15270804	NON-EXPEDITED			US-SA-2018SA219387			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Prednisone			S				Not Reported
	Humira			S				Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271455	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-BOEHRINGER INGELHEIM GMBH, GERMANY-2016-BI-1337			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez			S	Transplacental	300 Mg, Qd		Noden Pharma
	Advagraf			S	Transplacental	6 Mg, Qd		Not Reported
	Advagraf			S	Transplacental	Unk		Not Reported
	Advagraf			S				Not Reported
	Simvastatin			S	Transplacental	Unknown		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unknown, Prn		Not Reported
	Metamizole Sodium			S	Transplacental	Unknown		Not Reported
	Heparin Lmw			S	Transplacental	Unknown		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Xarelto			S	Transplacental	Unknown		Not Reported
	Rituximab			S	Transplacental	Unk		Not Reported
	Torem /01036501/			S	Transplacental	100 Mg, Qd		Not Reported
	Torem /01036501/			S	Transplacental	Unk		Not Reported

	Pantozol /01263204/	S	Transplacental	40 Mg, Qd	Not Reported
	Nicotine	S	Transplacental	Unknown	Not Reported
	Nicotine	S	Transplacental	Unk	Not Reported
	Novaminsulfon	S	Transplacental	Unknown	Not Reported
	Delix /00885601/	S	Transplacental	20 Mg, Qd	Not Reported
	Quensyl	S	Transplacental	400 Mg, Qd	Not Reported
	Quensyl	S	Transplacental	Unk	Not Reported
	Prednisolon /00016201/	S	Transplacental	10 Mg, Qd	Not Reported
	Clexane	S	Transplacental	200 Mg, Qd	Not Reported
	Ezetimibe Msd	S	Transplacental	Unknown	Not Reported
	Mifegyne	C	Transplacental	Unk	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Cyclophosphamide	C	Transplacental	3000 Mg, Cumulative	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271564	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA065573		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271570	EXPEDITED (15-DAY)		OT	PHHY2018CA065255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg, Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271726	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15271785	EXPEDITED (15-DAY)		HO	CA-ROCHE-2167463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15272082	EXPEDITED (15-DAY)		HO	US-GENUS_LIFESCIENCES-USA-POI0580201800103			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram U-Wave Abnormality; Hypotension; Overdose; Somnolence; Ventricular Fibrillation	Oxycodone Hcl Capsules			S				Genus Lifesciences
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15272593	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA065555		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15272758	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-147222		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Aspirin			S	Unknown			Bayer
	Arava			S	Unknown			Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15272801	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-147342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia;	Aspirin			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Gold			S	Unknown	Unk			Not Reported
	Humira			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Motrin			S	Unknown	Unk			Not Reported
	Naprosyn			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Tramadol			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2018	15272822	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-147354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Aspirin			S	Unknown			Bayer
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	13132261	EXPEDITED (15-DAY)		OT	CA-ROCHE-1619414		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Hernia; Herpes Zoster;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Nasopharyngitis; Therapeutic Product Effect Decreased	Cimzia		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate Sodium		S	Oral		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Xeljanz		C	Oral	On Hold	Not Reported
	Xeljanz		C	Oral		Not Reported
	Lyrica		C	Oral		Not Reported
	Prednisone		C	Oral		Not Reported
	Arava		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	13288113	EXPEDITED (15-DAY)		DS	CA-ROCHE-1900638		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	13894679	EXPEDITED (15-DAY)		OT	CA-ROCHE-1979998		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Hyperaesthesia; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Folic Acid			C	Unknown	Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	13989718	EXPEDITED (15-DAY)		OT	CA-ROCHE-1993170		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported

	Estrogel			C	Unknown				Not Reported
	Furosemide			C					Not Reported
	Potassium Chloride			C					Not Reported
	Valsartan			C					Not Reported
	Xalatan			C	Ophthalmic				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	14845379	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018058843		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Coronary Artery Bypass; Depression; Drug Ineffective; Dyspnoea; Osteomyelitis; Paraesthesia; Toe Operation	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15076555	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PFIZER INC-2018258171			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cardiovascular Anomaly; Maternal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	Unk		Pfizer
	Prednisolone			S	Transplacental	Unk		Pfizer
	Ramipril			S	Transplacental	20 Mg, Unk (During 0-13+6 Weeks Of Gestation)		Pfizer
	Simvastatin			S	Transplacental	Unk		Not Reported

	Acetylsalicylic Acid		S	Transplacental	Unk		Not Reported
	Rivaroxaban		S	Transplacental	Unk		Not Reported
	Hydroxychloroquine		S	Transplacental	Unk		Not Reported
	Torasemide		S	Transplacental	Unk		Not Reported
	Tacrolimus		S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate		S	Transplacental	Unk		Not Reported
	Nicotine		S	Transplacental	Unk		Not Reported
	Aliskiren		S	Transplacental	Unk		Not Reported
	Ezetimibe		S	Transplacental	Unk		Not Reported
	Dipyrone		S	Transplacental	Unk		Not Reported
	Enalapril		S	Transplacental	Unk		Not Reported
	Lisinopril		S	Transplacental	Unk		Not Reported
	Heparin		S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274035	EXPEDITED (15-DAY)		OT	GB-ABBVIE-18K-167-2447081-00		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274398	EXPEDITED (15-DAY)		OT	CA-ROCHE-2166780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Personal Independence In Daily Activities; Pain; Peripheral Swelling	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Prednisone		S	Oral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167884			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274733	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-940003		78 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Methotrexate Sodium			S	Unknown			Barr
	Abatacept			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Chloroquine /00001002/			S	Unknown	200 Milligram Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274776	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167405		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15274837	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009257		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported

Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	20 Mg, Unk			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid			Not Reported
	Infliximab			S	Unknown	300 Mg, Qd			Not Reported
	Infliximab			S					Not Reported
	Arava			S	Oral	20 Mg, Qd			Not Reported
	Arava			S					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd			Not Reported
	Atorvastatin			C	Unknown				Not Reported
	Pantoloc /01263201/			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275579	EXPEDITED (15-DAY)			US-CELLTRION INC.-2018US019856			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Inflectra			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Duloxetine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275630	EXPEDITED (15-DAY)		HO	US-ZYDUS-021155		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypoglycaemia	Hydroxychloroquine		S	Unknown	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275639	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-021158		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Confusional State; Hyperinsulinaemic Hypoglycaemia; Presyncope; Tremor	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275743	EXPEDITED (15-DAY)		DE, HO	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-068		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Immunodeficiency; Parasitic Pneumonia; Strongyloidiasis	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			S	Unknown			Westward
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275796	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-068		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinomycotic Pulmonary Infection; Immunodeficiency; Respiratory Moniliasis	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Amoxicillin-Clavulanate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15275955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167429		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15276379	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168131		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Plaquenil	S	Oral	Not Reported
Asa	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Lantus	C	Subcutaneous	Not Reported
Lozide (Canada)	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Naprosyn	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15276571	EXPEDITED (15-DAY)		HO, OT	CA-ALKEM LABORATORIES LIMITED-CA-ALKEM-2018-06193		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Polyomavirus Test Positive; Pneumonia Aspiration; Progressive Multifocal Leukoencephalopathy	Mycophenolate Mofetil			S	Unknown	500 Mg, Qd		Alkem
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15276579	EXPEDITED (15-DAY)		HO, OT	CN-ALKEM LABORATORIES LIMITED-CN-ALKEM-2018-05528		39 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lymphoma; Diffuse Large B-Cell Lymphoma; Epstein-Barr Virus Test Positive	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Alkem
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277437	EXPEDITED (15-DAY)		OT	PHHY2018CA065579			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg, Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277614	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-943506		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2018	15277630	EXPEDITED (15-DAY)		HO	CA-ROCHE-2167415		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Plaquenil	C			Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	10173260	NON-EXPEDITED			US-PFIZER INC-2014130482			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Methotrexate			S		Unk		Pfizer
	Toviaz			S		Unk		Pfizer
	Requip			S		Unk		Not Reported
	Vytorin			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Omeprazole			S		20 Mg, Daily		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	13132234	EXPEDITED (15-DAY)		OT	CA-ROCHE-1776837		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Transaminases Increased	Actemra			S	Intravenous (not otherwise specified)	Form Of Admin Text: Not Specified Therapy Duration: 12.0 Months		Not Reported
	Sulfasalazine			S	Oral	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Oral	10-20mg/Day For Many Years But Currently On 30mg/Day Dosage Form		Not Reported

					Not Specified	
	Simponi	S	Intravenous (not otherwise specified)	Form Of Admin Text: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate Sodium	S	Oral	Weekly Therapy Duration Was 4 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14165935	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA210554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Leflunomide			S				Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Cimzia			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14165953	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210569		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	10 Mg,Qd		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14166196	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210628		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg,Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Pregabalin			C	Oral	50 Mg,Qd		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14169194	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210668			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg,Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			C	Oral	50 Mg,Qd		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14261036	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA178049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight;	Voltaren			S	Unknown			Novartis
	Diclofenac			S	Unknown			Novartis

Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Methotrexate	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Aspirin	S	Unknown	Unk		Not Reported
	Arava	S	Unknown			Not Reported
	Naprosyn	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Motrin	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid	S	Unknown			Not Reported
	Diclofenac Potassium	S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14786470	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA108335		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Full Blood Count Abnormal; Headache; Herpes Zoster; Hypokalaemia; Intentional Product Misuse; Malaise; Nausea; Off Label Use; Otitis Media; Pain; Rash; Rheumatoid Arthritis; Syncope; Synovitis; Treatment Noncompliance	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk, Unk		Sanofi
	Xeljanz			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Valsartan			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	5 Mg,Qd		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Qw		Not Reported

	Enbrel			S	Subcutaneous	50 Mg,Biw		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Cefuroxime Axetil			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14946734	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018071704			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gingival Bleeding; Intervertebral Disc Degeneration; Joint Stiffness; Ligament Laxity; Myalgia; Osteoarthritis; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qwk, Injectable		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	14966885	EXPEDITED (15-DAY)		OT	CA-ROCHE-2130966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Desoximetasone			C					Not Reported
	Methotrexate			C	Oral				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15271812	NON-EXPEDITED			US-PFIZER INC-2018323658		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15276619	NON-EXPEDITED			US-PFIZER INC-2018326302		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Gold			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15277586	NON-EXPEDITED			US-SA-2018SA224131			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Plaquenil			S				Sanofi
	Arava			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Xeljanz Xr			C	Oral	5 Mg, Bid		Not Reported
	Rituxan			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15279560	NON-EXPEDITED			US-PFIZER INC-2018325917		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Nabumetone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15280181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Subcutaneous		Not Reported
					Reactine (Canada)		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15280198	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15280199	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001601			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pyrexia;	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Azulfidine			S	Unknown			Not Reported
	Azulfidine			S				Not Reported

Rheumatoid Arthritis; Tooth Disorder	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Xeljanz	S	Oral		Not Reported
	Prednisone	C			Not Reported
	Orencia	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15280326	NON-EXPEDITED			US-AMGEN-USASP2018111130			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	0.5 Ml, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15280410	EXPEDITED (15-DAY)		OT	GB-GLAXOSMITHKLINE-GB2018143821		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown	Unk		Glaxosmithkline
	Arthrotec			S	Unknown	Unk		Glaxosmithkline
	Norfloxacin			S	Unknown	Unk		Glaxosmithkline
	Levofloxacin Hemihydrate			S	Unknown	Unk		Glaxosmithkline
	Erythromycin			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Glaxosmithkline

	Pethidine Hydrochloride		S	Unknown			Not Reported
	Erythromycin		S	Unknown	Unk		Not Reported
	Lyrica		S	Unknown			Not Reported
	Leflunomide Sandoz		S	Unknown			Not Reported
	Arava		S	Unknown	Unk		Not Reported
	Plaquenil		S	Oral	400 Mg, Unk		Not Reported
	Bisoprolol Fumarate		S	Unknown	Unk		Not Reported
	Humira		S	Subcutaneous	400 Mg, Unk		Not Reported
	Celebrex		S	Oral	200 Mg, Qd		Not Reported
	Ceclor		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Prednisone		S	Unknown	Unk		Not Reported
	Demerol		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2018	15282152	NON-EXPEDITED			US-AMGEN-USASP2018111702			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	13271290	EXPEDITED (15-DAY)		DS	CA-ROCHE-1898441			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)		Not Reported
	Arava			S	Unknown		Not Reported
	Celecoxib			S	Unknown		Not Reported
	Enbrel			S	Unknown		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Methotrexate Sodium			S	Oral		Not Reported
	Orencia			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate			S	Oral		Not Reported
	Prednisone			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	14032948	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005587		41 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Intentional Product Use Issue; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S	Unknown			Concordia
	Dexamethasone			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Bortezomib			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Two Weeks Apart		Not Reported
	Belimumab			S	Intravenous (not	As Maintenance Dose		Not Reported

						otherwise specified)				
		Immune Globulin Nos			C	Intravenous (not otherwise specified)				Not Reported
		Corticosteroids			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	14731385	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001141			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Haemolysis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15002227	EXPEDITED (15-DAY)		OT	PHEH2018US021874			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Erythema; Petechiae; Pruritus; Rash; Urticaria	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Bid		Novartis
	Levothyroxine			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Linum Usitatissimum Seed			C	Unknown	Unk		Not Reported
	Baby Aspirin			C	Unknown	Unk		Not Reported
	Zyrtec			C	Unknown	Unk		Not Reported
	Pepcid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15066093	EXPEDITED (15-DAY)		OT	US-GILEAD-2018-0347020		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Erythema; Muscle Tightness;	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead

Nausea; Peripheral Swelling; Scleroderma	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remodulin			C				Not Reported
	Adcirca			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15201718	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002601		46 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Inflammation; Nausea; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15208426	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2018GSK134352		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Premature Delivery	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Glaxosmithkline
	Prednisolone			S	Unknown	Unk, 0-14 Gw		Glaxosmithkline
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Glaxosmithkline
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Glaxosmithkline
	Ramipril			S	Unknown	20 Mg, Unk, Unknown Frequency (0-13+6 Gw)		Glaxosmithkline
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14		Glaxosmithkline

				Gw)	
	Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Metamizole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Salbutamol Sulfate	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Ezetimibe	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Torasemide	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Enoxaparin Sodium	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15230067	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA011522			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, 1/Week		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, 1/Week		Not Reported
	Humira			S	Subcutaneous	400 Mg, 1/Week		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Imuran /00001501/	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Azathioprine	S	Unknown			Not Reported
Humira	S	Unknown	40 Mg, Weekly (Unit=Prefilled Syringe)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15239741	NON-EXPEDITED			US-SA-2018SA183520		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Pain In Extremity; Unevaluable Event	Kevzara			S				Sanofi
	Arava			S				Sanofi
	Prednisone			S				Not Reported
	Plaquenil			S				Sanofi
	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S				Not Reported
	Simponi Aria			S				Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15258600	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002859		43 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S		After 2 Months Of Gradual Loading Of Mmf (Up To 1,250 Mg Twice Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283099	NON-EXPEDITED			US-AMGEN-USASP2018112076			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168869		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283350	NON-EXPEDITED			US-PFIZER INC-2018326385		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283358	NON-EXPEDITED			US-PFIZER INC-2018327733		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283461	NON-EXPEDITED			US-PFIZER INC-2018328354		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283540	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Esomeprazole Magnesium			C				Not Reported
	Lorazepam			C				Not Reported
	Sulfasalazine			C				Not Reported

	Alendronate Sodium			C					Not Reported
	Atenolol			C					Not Reported
	Trimebutine			C					Not Reported
	Hydrochlorothiazide			C					Not Reported
	Chlordiazepoxide;Clidinium Bromide			C					Not Reported
	Certolizumab Pegol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15283917	NON-EXPEDITED			US-AMGEN-USASP2018111803			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15285098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2170220		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

						otherwise specified)				
	Xeljanz				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15285294	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2166725		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15285484	EXPEDITED (15-DAY)		DS	CA-SA-2017SA190187			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Oral Herpes; Pain In Extremity;	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Bid		Sanofi
	Myochrysine			S				Not Reported
	Methotrexate			S		Unk		Not Reported

Rheumatoid Nodule; Skin Papilloma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15285714	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115269		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sinusitis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg,Qw		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2018	15286971	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002920		71 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	12308696	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	13057961	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1869629			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Anakinra	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Ilaris	S	Subcutaneous	Single Use Vial	Not Reported
Ilaris	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	14222196	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP007826		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Apo-Prednisone			S	Unknown	7 Mg, Qd		Apotex
	Apo-Celecoxib			S	Unknown	Capsule, Capsule Hard		Apotex
	Apo-Celecoxib			S				Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Ml, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	14300765	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-113748			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Treatment Failure	Orencia		S	Unknown		Bristol Myers Squibb
	Enbrel		S	Subcutaneous	50 Mg, Qwk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Minocycline		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown		Not Reported
	Restasis		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	14351652	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268415		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Prednisone			S	Unknown	20 Mg,Unk		Not Reported
	Prednisone			S	Unknown	40 Mg,Qd		Not Reported
	Sulfasalazine			S	Oral	2 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk,Qw		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	14474748	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180131896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)		
Humira	S	Subcutaneous		Not Reported
Arava	S	Oral	3 Months	Not Reported
Arava	S	Oral	3 Years	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral	3 Months	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	8 Years	Not Reported
Methotrexate Sodium	S	Unknown	4 Yeras	Not Reported
Methotrexate Sodium	S	Unknown	4 Yeras	Not Reported
Methotrexate Sodium	S	Unknown	4 Yeras	Not Reported
Methotrexate Sodium	S	Subcutaneous	2 Years	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Unknown	3 Month	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Intramuscular		Not Reported
Methotrexate	S	Intramuscular	3 Month	Not Reported
Methotrexate	S	Subcutaneous	3 Month	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15019896	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-055908			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Orencia	S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15190595	EXPEDITED (15-DAY)		OT	DE-SA-2018SA191114		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Premature Delivery	Prednisolone			S		0-14 Gw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Sanofi
	Metamizole Salt Not Specified			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Sanofi
	Salbutamol Sulfate			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Ramipril			S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)		Sanofi
	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Torasemide			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Enoxaparin Sodium			S	Unknown	Unk Unk, Unknown Freq. (0-14 Gw)		Sanofi
	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14		Not Reported

						Gw)			
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)			Not Reported
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15281064	NON-EXPEDITED			US-PFIZER INC-2018325812		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Otezla			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15287961	NON-EXPEDITED			US-PFIZER INC-2018328419			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metronidazole			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Phenazopyridine			S		Unk		Not Reported
	Propoxyphene			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15288506	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP005311			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Infection; Oedema Peripheral;	Tacrolimus			S	Unknown	Unk		Strides

Osteomyelitis Chronic; Skin Hyperpigmentation; Tenderness; Ulcer	Enbrel			S	Unknown	Unk			Not Reported
	Cytoxan Lyophilized			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Cytoxan Lyophilized			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Dapsone			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Etanercept			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15288641	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-075378		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15288861	EXPEDITED (15-DAY)		HO, LT	PHHY2018CA073927			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290266	EXPEDITED (15-DAY)		HO	CA-BAYER-2018-149815		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S				Bayer
	Enbrel			S				Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium [Methotrexate]			S				Not Reported

	Orencia			S					Not Reported
	Prednisone Acetate			S					Not Reported
	Prednisone			S					Not Reported
	Naproxen			C					Not Reported
	Folic Acid			C					Not Reported
	Plaquenil Sulfate			C					Not Reported
	Tocilizumab			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15290866	EXPEDITED (15-DAY)		OT	US-SA-2018SA034704		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelinating Polyneuropathy; Treatment Failure	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Arabloc			S	Unknown	Unk		Sanofi
	Minocycline			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			C		Unk		Not Reported
	Restasis			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15291663	NON-EXPEDITED			PHEH2018US032966			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2018	15318467	DIRECT		LT, OT			22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Hydroxychloroquine, Plaquenil			S	Oral	Quantity:2 Tablet(S);		Not Reported
	Dulera			C				Not Reported
	Singulair			C				Not Reported
	Xyzal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	14976255	EXPEDITED (15-DAY)		OT	US-ROCHE-2103598		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Pyrexia; Rheumatoid Arthritis; Tooth Disorder	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Azulfidine			S	Unknown			Not Reported
	Azulfidine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15230053	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2016CA013954			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, 1/Week		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg,		Not Reported

Infliximab Pfizer (Unknown)	S		Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Sulfasalazine Gf	S	Unknown		Not Reported
Actemra	S	Unknown	640 Mg, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	640 Mg, Qwk	Not Reported
Actemra	S		640 Mg	Not Reported
Actemra	S		640 Mg Weekly	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Ciclosporin	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	200 Mg, Qwk	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Qwk	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
Hydroxychloroquine	S			Not Reported
Imuran /00001501/	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Qwk;	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous	400 Mg, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15292335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2169537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2018	15292505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2170721		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Sodium Aurothiomalate			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	13320164	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902791		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	13989300	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005382		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone			S	Oral					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14203511	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3697		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14346895	NON-EXPEDITED			US-PFIZER INC-2017556117		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hair Colour Changes; Nausea; Thyroid Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Once A Day		Pfizer
	Methotrexate Sodium			S		20 Mg, 2x/Week		Pfizer
	Methotrexate Sodium			S		10 Mg, 1x/Day		Pfizer
	Plaquenil			S		400 Mg, Once A Day		Not Reported

Plaquenil	S	200 Mg, Once A Day	Not Reported
Plaquenil	S	10 Mg, Unk	Not Reported
Prednisone	S	Unk (7x Days)	Not Reported
Prednisone	S		Not Reported
Diclofenac Na	C	75 Mg, Twice A Day	Not Reported
Valacyclovir	C	20 Mg, 1x/Day	Not Reported
Lopressor	C	25 Mg, 1x/Day	Not Reported
Lopressor	C	50 Mg, Unk	Not Reported
Lopressor	C	75 Mg, Unk	Not Reported
Pantoprazole	C	40 Mg, 2x/Day	Not Reported
Pantoprazole	C	Unk, As Needed (Prn-Occasional)	Not Reported
Qvar	C	80 Ug, Daily [40 Ug 2 Puff Daily]	Not Reported
Lutein	C	25 Mg, 1x/Day	Not Reported
Edarbi	C	40 Mg, 1x/Day	Not Reported
Restasis	C	Unk	Not Reported
Cortisone	C	Unk	Not Reported
Sildenafil	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14365800	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000006		15 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myelodysplastic Syndrome; Normocytic Anaemia	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Imurel			S	Unknown			Not Reported
	Vitamin D3			C				Not Reported
	Diffu K			C				Not Reported
	Cortancyl			C				Not Reported

	Calcium Carbonate				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14446261	EXPEDITED (15-DAY)		DE	IL-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000342		54 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Salmonellosis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14502119	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000475		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Plaquenil			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Macrobid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	14744006	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018045922		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hair Colour Changes; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Plaquenil			S				Not Reported

Incomplete; Thyroid Disorder	Methotrexate Sodium	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, 2 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Qd	Not Reported
	Abatacept	S	Unknown	125 Unk, Qwk	Not Reported
	Hydroxychloroquine	C		400 Mg, Qd	Not Reported
	Hydroxychloroquine	C		200 Mg, Qd	Not Reported
	Valacyclovir	C		20 Mg, Qd	Not Reported
	Lopressor	C		25 Mg, Qd	Not Reported
	Lopressor	C		50 Mg, Qd	Not Reported
	Lopressor	C		75 Mg, Qd	Not Reported
	Pantoprazol	C		40 Mg, Bid	Not Reported
	Qvar	C		40 Mug, Qd (2 Puff Daily)	Not Reported
	Lutein	C		25 Mg, Qd	Not Reported
	Edarbi	C		40 Mg, Qd	Not Reported
	Restasis	C		Unk	Not Reported
	Diclofenac Na	C		75 Mg, Bid	Not Reported
	Prednisone	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Sildenafil	C		50 Mg, Tid	Not Reported
	Sildenafil	C		50 Mg, Bid	Not Reported
	Sildenafil	C		50 Mg, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15132118	NON-EXPEDITED		OT	DE-BAUSCH-BL-2018-018929		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Premature Delivery	Salbutamol Sulfate			S	Unknown	Unknown Freq. (0-14 Gw)		Bausch And Lomb
	Ramipril			S	Unknown	20 Mg, Unknown Freq. (0-13 Plus 6 Gw)		Not Reported

	Prednisolone	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Tacrolimus	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Ezetimibe	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Pantoprazole	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Metamizole	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Simvastatin	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Rivaroxaban	S	Unknown	Unknown Freq. (0-5 Gw)	Not Reported
	Torasemide	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Nicotine	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Acetylsalicylic Acid	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported
	Enoxaparin Sodium	S	Unknown	Unknown Freq. (0-14 Gw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15206167	NON-EXPEDITED			US-AMGEN-USASP2018100975			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Blood Glucose Increased; Drug Hypersensitivity; Drug Interaction; Eye Disorder; Migraine; Nausea; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15290643	EXPEDITED (15-DAY)		OT	FI-TEVA-2018-FI-941065			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Prednisolone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15293838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2170181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15295029	NON-EXPEDITED			US-PFIZER INC-2018330991			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium			S		Unk				Pfizer
	Plaquenil			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15295112	NON-EXPEDITED			US-PFIZER INC-2018331207		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15295119	NON-EXPEDITED			US-PFIZER INC-2018332845		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15295125	NON-EXPEDITED			US-PFIZER INC-2018332655		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15295668	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018GSK146649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration	Benlysta			S	Intravenous (not otherwise specified)	870 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15295794	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2017203988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Glaxosmithkline
	Aspirin			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Acetylsalicylic Acid			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Trimethoprim And Sulfamethoxazole			S	Unknown	Unk		Not Reported

	Tramadol Hydrochloride			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298037	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298280	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1840632US		52 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradypnoea; Intentional Overdose; Miosis	Escitalopram Oxalate - Bp			S	Oral	280 Mg, Unk		Allergan
	Plaquenil			S	Oral	3 G, Unk		Not Reported
	Doliprane			S	Oral	6 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2018	15298751	NON-EXPEDITED			PHEH2018US033438			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Pruritus	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Unk		Novartis
	Prednisone	C	Unknown	Unk		Not Reported
	Warfarin	C	Unknown	Unk		Not Reported
	Temazepam	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	13319538	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902898		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	14136561	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017449522		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Condition Aggravated; Diarrhoea; Dizziness; Fall; Fatigue; Feeding Disorder; Nausea; Pain; Sensitivity To Weather Change; Tooth Fracture; Vomiting	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported

Prednisone	C	Oral	1 Mg, Weekly As Needed	Not Reported		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15048931	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002116		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Plaquenil 200 Mg Tablet			S	Oral	6 Months 13 Days		Not Reported
	Plaquenil 200 Mg Tablet			S	Oral	6 Months 13 Days		Not Reported
	Plaquenil 200 Mg Tablet			S	Oral	6 Months 13 Days		Not Reported
	Atorvastatin			C				Not Reported
	Bonalon			C				Not Reported
	Atelec			C				Not Reported
	Lansoprazole			C				Not Reported
	Alfacalcidol			C				Not Reported
	Predonine			C				Not Reported
	Predonine			C				Not Reported
	Cellcept			C				Not Reported
	Cellcept			C				Not Reported
	Valsartan			C				Not Reported
	Valsartan			C				Not Reported
	Gasmotin			C				Not Reported
	Daiphen			C				Not Reported
	Bonviva			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15083310	EXPEDITED (15-DAY)		OT	DE-ASTELLAS-2018US029492		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Astellas
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Xarelto			S	Unknown	Unk, Unknown Freq. (0-5		Not Reported

			Gw)	
Ramipril	S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)	Not Reported
Hydroxychloroquine	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Acetylsalicylic Acid	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Pantoprazole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Torasemide	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Nicotine	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
Ezetimibe	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Metamizole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Simvastatin	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Prednisolone	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Dalteparin Sodium	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
Rituximab	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
Clexane	S	Unknown	Unk Unk, Unknown Freq. (0-14 Gw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15099932	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00013151		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced;	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14		Concordia

Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery				Gw)	
	Prednisolone	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Concordia
	Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Ramipril	S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)	Not Reported
	Acetylsalicylic Acid	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Pantoprazole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Torasemide	S	Unknown	Unk, Unknown Freq. (0-14 Gw); Unknown	Not Reported
	Torasemide	S		Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Tacrolimus	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Salbutamol	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Nicotine	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Ezetimibe	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Metamizole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Simvastatin	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Enoxaparin	S	Unknown	Unk Unk, Unknown Freq. (0-14 Gw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15158732	NON-EXPEDITED			US-SA-2018SA032606		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fear Of Injection; Headache; Rash	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	11 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15233170	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-934798		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arteriosclerosis; Cytopenia; Disseminated Intravascular Coagulation; Haemophagocytic Lymphohistiocytosis; Hepatic Steatosis; Histoplasmosis Disseminated; Hypoglycaemia; Lactic Acidosis; Mesenteric Artery Stenosis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15299064	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2018016395			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin			S	Unknown	Unknown		Macleods
	Arava			S	Unknown	Unknown		Not Reported
	Arthrotec			S	Unknown	Unknown		Not Reported
	Bisoprolol Fumarate			S	Oral	Unknown		Not Reported
	Ceclor			S	Unknown	Unknown		Not Reported

	Celebrex	S	Oral	200 Mg, Qd		Not Reported
	Demerol	S	Unknown	Unknown		Not Reported
	Erythro Base	S	Unknown	Unknown		Not Reported
	Erythromycin	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
	Leflunomide Sandoz	S	Unknown	Unknown		Not Reported
	Lyrica	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Metronidazole	S	Unknown	Unknown		Not Reported
	Norfloxacin	S	Unknown	Unknown		Not Reported
	Pethidine Hydrochloride	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Oral	400 Mg, Unk		Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15299673	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002991		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15299675	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003003		45 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tonic Clonic Movements	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15299677	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003021		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Deafness Neurosensory	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15300857	NON-EXPEDITED			PHEH2018US032946			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Petechiae; Pruritus; Rash; Urticaria	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2018	15301764	EXPEDITED (15-DAY)		OT	CA-ROCHE-2171328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	13989297	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005374		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	14357018	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA268182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Contusion; Disability; Drug Ineffective; Fatigue; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling; Swelling	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	14570460	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-		60 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercholesterolaemia; Low Density Lipoprotein Increased; Platelet Count Decreased; Visual Field Defect	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Baktar			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported
	Cellcept			C				Not Reported
	Onealfa			C				Not Reported
	Bonalon			C				Not Reported
	Calblock			C				Not Reported
	Avapro			C				Not Reported

	Carvedilol			C						Not Reported
	Natrix			C						Not Reported
	Nexium			C						Not Reported
	Famotidine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15305133	EXPEDITED (15-DAY)		DE, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002989		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Contraindicated Product Administered; Malaise; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Clozapine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306007	EXPEDITED (15-DAY)		OT	CN-IPCA LABORATORIES LIMITED-IPC-2018-CN-001758			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythrodermic Psoriasis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Ipca
	Prednisone			C	Unknown	30 Mg, Qd		Not Reported
	Prednisone			C	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306035	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-1970304		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Cystitis; Deep Vein Thrombosis; Dysaesthesia; Helicobacter Gastritis; Herpes Zoster; Nausea	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown	20-25 (Unit Not Reported)	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Salazosulfapyridine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306720	EXPEDITED (15-DAY)		OT	PHHY2018DE075563		34 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Death; Maternal Exposure During Pregnancy; Pre-Eclampsia	Prednisolone			S	Oral	5 Mg, Qd		Novartis
	Prednisolone			S	Oral	30 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Mometasone Furoate			S	Topical	Unk		Not Reported
	Prednicarbate			S	Topical	Unk		Not Reported
	Dalteparin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306727	EXPEDITED (15-DAY)		OT	PHHY2017SE204582		41 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Intentional Product Use Issue; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk (Two Weeks Apart)		Not Reported
	Mycophenolate Mofetil			S	Unknown	2000 Mg, Unk		Not Reported
	Bortezomib			S	Unknown	Unk		Not Reported

	Dexamethasone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Prednisolone	S	Unknown	5 Mg, Unk	Novartis
	Cyclophosphamide	S	Unknown	800 Mg, Unk	Not Reported
	Belimumab	S	Intravenous (not otherwise specified)	800 Mg, Unk (As Maintenance Dose)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306822	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP018993		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Gastrointestinal Disorder; Intentional Product Misuse; Malaise; Sjogren'S Syndrome; Weight Decreased; White Blood Cell Count Decreased	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	10 Mg, Q.Wk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Once Every Two Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307444	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-946495		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperinsulinaemic Hypoglycaemia	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307719	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307728	NON-EXPEDITED		OT	PHEH2018US034202			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Petechiae; Pruritus; Rash; Urticaria	Hydroxychloroquine Sulphate			S	Unknown	2 Df, Unk		Novartis
	Hydroxychloroquine Sulphate			S	Unknown	2 Df, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15307807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2171289			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15325122	DIRECT		OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Reaction To Excipient; Gingival Discomfort; Gingival Swelling; Headache; Noninfective Gingivitis	Plaquenil	Y	Y	S				Doterra International
	On Guard Toothpaste (Fluoride-Free)			S				Not Reported
	Cosmetics			S				Not Reported
	Synthroid			C				Not Reported
	Cytomel			C				Not Reported
	Mobic			C				Not Reported
	Restasis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14142755	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2017162570			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Abnormal; Body Height Decreased; Cardiac Failure Congestive; Cataract; Chest Pain; Constipation; Depression; Drug Ineffective; Fibromyalgia; Glaucoma; Hair Texture Abnormal; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mood Altered; Muscle Tightness;	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Zoloft			S	Unknown	Unk		Not Reported
	Savella			S	Unknown	5mg Titration Pack		Not Reported
	Aspirin			C	Oral	81 Mg, Qd		Not Reported

Myalgia; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Weight Increased	Vitamin D3		C	Oral	1000 Unit, Qd	Not Reported
	Vitamin D2		C		Unk	Not Reported
	Clonidine		C	Oral	0.1 Mg, Qd	Not Reported
	Torsemide		C	Oral	20 Mg, Qd	Not Reported
	Fish Oil		C	Oral	1000 Mg, Qd	Not Reported
	Prilosec		C	Oral	10 Mg, Qd	Not Reported
	Hydrocodone		C	Oral	5 Mg, Qid	Not Reported
	Hydrocodone		C	Oral	7.5 Mg, Qid	Not Reported
	Hydrocodone		C	Oral	2 Mg, Qid	Not Reported
	Potassium Chloride		C	Oral	10 Meq, Unk	Not Reported
	Docusate W/Senna		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14147343	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3286		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Dizziness; Fall; Fatigue; Feeding Disorder; Nausea; Pain; Rheumatoid Arthritis; Sensitivity To Weather Change; Tooth Fracture; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Prednisone			C	Oral	Weekly, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14378550	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000078		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Drug Hypersensitivity; Drug Ineffective	Hydroxychloroquine	S	Oral	200 Mg, 1x/ Day On Tuesday, Thursday,Saturday And Sunday		Concordia
	Hydroxychloroquine	S	Oral	200 Mg, 2x/ Day On Monday, Wednesday And Friday		Concordia
	Leflunomide	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Remicade	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Methotrexate	S	Oral	9 Tablets,Weekly		Not Reported
	Folic Acid	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14379115	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000082		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pneumonitis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral	Up To 25 Mg,		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg Daily 1 Every 2 Weekx 3 Doses;		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg Daily 1 Every 2 Week 2 Months 10 Days		Not Reported
	Tofacitinib Citrate			C				Not Reported
	Prednisone			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14379126	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Contusion; Disability; Drug Ineffective; Fatigue; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling; Swelling	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14379127	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000118		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14391353	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Mobility Decreased; Pain; Rheumatoid Arthritis	Plaquenil Tablet	S	Oral			Concordia
	Humira	S	Subcutaneous			Not Reported
	Cimzia	S	Subcutaneous	Duration 2 Months 28 Days		Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14391361	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000140		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xebanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14391364	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000170		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Panic Attack; Tinnitus	Hydroxychloroquine			S	Oral			Concordia
	Allopurinol			C				Not Reported
	Reactine (Cetirizine Hydrochloride)			C				Not Reported
	Tecta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14391369	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000219		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Certolizumab Pegol			S	Subcutaneous	4 Months 13 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400780	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000193		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400781	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cystitis; Drug Ineffective; Ear Infection; Rheumatoid Arthritis	Plaquenil 200 Mg Tablet		S	Oral	Concordia
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Celebrex		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400785	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000199		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Osteoarthritis; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400787	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Sodium Aurothiomalate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400790	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Hypersensitivity; Hypersensitivity; Hypersensitivity; Hypersensitivity; Hypersensitivity; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Avelox			S	Oral			Not Reported
	Amoxicillin Trihydrate Clavulanate Potassium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400791	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Amlodipine			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400792	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400793	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000141		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Plaquenil Tablet			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400794	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000142		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	2 Years 1 Day		Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400795	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000144		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Plaquenil Tablet			S	Oral			Concordia
	Naproxen Sodium			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Depo-Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400796	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000152			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400799	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400802	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Amoxil			C				Not Reported
	Clavulin			C				Not Reported
	Adalimumab			C				Not Reported
	Bcg Vaccine			C	Intradermal	Bcg Vaccine Live Intradermal		Not Reported
	Gold			C	Intradermal	Bcg Vaccine Live Intradermal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400804	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000192		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug	Plaquenil Tablet			S	Unknown			Concordia

Ineffective; Drug Intolerance; Rheumatoid Arthritis	Plaquenil Tablet		S	Unknown	Concordia
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Methotrexate		C		Not Reported
	Prednisolone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400989	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000202		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400990	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000203		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Oral			Concordia
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz Xr			C					Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14400992	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000205		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Nausea; Synovitis; Tachycardia	Hydroxychloroquine			S	Oral			Concordia
	Actemra			S	Intravenous (not otherwise specified)	6 Months 26 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Ug/Kg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Year 10 Months 2 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14403082	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000217		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Amlodipine Besilate	C		Not Reported
	Esomeprazole Magnesium Trihydrate	C		Not Reported
	Folic Acid	C		Not Reported
	Lyrica	C		Not Reported
	Mavik	C		Not Reported
	Esomeprazole	C		Not Reported
	Olopatadine Hydrochloride	C		Not Reported
	Prednisone	C		Not Reported
	Hydrochlorothiazide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14403086	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000212		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Stress; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14797811	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-170733			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Microcephaly	Diclofenac			S	Transplacental			Sun
	Hydroxychloroquine			S	Transplacental			Not Reported

	Sulfasalazine	S	Transplacental		Not Reported
	Paracetamol	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	14982110	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-903041		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown	Dose _ 10-15mg		Teva
	Hydroxychloroquine			S	Unknown			Teva
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15145663	EXPEDITED (15-DAY)		DE, HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00013368		15 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Drug Ineffective For Unapproved Indication; Interstitial Lung Disease; Off Label Use; Septic Arthritis Staphylococcal	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisolone			S	Intravenous (not otherwise specified)	High Dose, Bi Weekly		Concordia
	Prednisolone			S	Intravenous (not otherwise specified)			Concordia

	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Cyclophosphamide	S			Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Human Immunoglobulin Iv (Inn)	S	Intravenous (not otherwise specified)		Not Reported
	Human Immunoglobulin Iv (Inn)	S			Not Reported
	Rituximab	S			Not Reported
	Methyl Prednisolone	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15256474	NON-EXPEDITED			US-PFIZER INC-2018315019			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15308979	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172087			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Tocilizumab			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown	1.0 Dosage Forms Nos		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown	1.0 Dosage Forms Every 1 Day(S) Nos		Not Reported

	Methotrexate	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Ramipril	S	Oral	Every 1 Day(S) Nos		Not Reported
	Tylenol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15309872	EXPEDITED (15-DAY)		HO	CA-ROCHE-2172686		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	1.0 Dosage Forms		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Loperamide Hydrochloride			C	Unknown			Not Reported

	Nasonex		C	Unknown		Not Reported
	Omega 3		C	Unknown		Not Reported
	Oxycodone Terephthalate		C			Not Reported
	Pantoprazole Magnesium		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Trazodone Hydrochloride		C	Oral		Not Reported
	Tylenol		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15310012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172133		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15310349	EXPEDITED (15-DAY)		DE	FR-ACCORD-070967		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Toxicity To Various Agents	Amitriptyline			S	Oral			Accord
	Zopiclone			S	Oral			Not Reported
	Morphine			S	Oral	Unspecified		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Gabapentin			S	Oral				Not Reported
	Mirtazapine			S	Oral				Not Reported
	Oxazepam Ayerst			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15311774	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-04			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15312468	NON-EXPEDITED		OT	US-SA-2018SA119553			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	200 Mg,Unk		Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	5 Mg,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Xeljanz			C	Oral	5 Mg,Qd		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Oral	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

	Hydroxychloroquine			C	Unknown	Unk Unk,Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15312635	EXPEDITED (15-DAY)		OT	CA-SA-2018SA001556		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Plaquenil			S	Unknown	400 Mg,Unk		Sanofi
	Arava			S				Sanofi
	Apo-Azathioprine			S	Unknown	100 Mg,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg,Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg,Bid		Not Reported
	Hydroxychloroquine			C		400 Mg		Not Reported
	Amoxil [Amoxicillin Trihydrate]			C				Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			C				Not Reported
	Adalimumab			C				Not Reported
	Bcg Vaccine [Bcg Vaccine Live Intradermal]			C				Not Reported
	Gold (198 Au)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15313369	NON-EXPEDITED			US-TEVA-2018-US-945214			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper;	Hydroxyctab-A (Hydroxychloroquine)			S	Unknown			Teva

Blood Thyroid Stimulating Hormone Increased; Constipation; Flatulence; Hepatic Enzyme Increased; Lichen Planus; Pain; Rash; Vision Blurred

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	13868289	EXPEDITED (15-DAY)		DS	CA-ROCHE-1975848		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Lock; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Physical Disability; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14296309	EXPEDITED (15-DAY)		OT	PHHY2017FI186340			Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14391357	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		61 YR	Female	CAN

INC.-GSH201801-000136

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Pain; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure; Treatment Failure	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Asa			C				Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14391360	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000139		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Lymphopenia; Rash; Renal Impairment; Thrombocytopenia; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Duration: 2 Years 6 Months 18 Days		Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14400800	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000174		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Hypersensitivity;	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia

Musculoskeletal Pain; Rash; Rheumatoid Arthritis; Unevaluable Event	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14400973	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000214		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Condition Aggravated; Pyrexia; Synovitis	Hydroxychloroquine Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14400974	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000216		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	For 94 Weeks		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14400976	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000221		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Oral Mucosal Erythema; Rash; Skin Discolouration; Skin Exfoliation	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14422117	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000321			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Carpal Tunnel Syndrome; Cataract; Glycosylated Haemoglobin Increased; Hypoaesthesia; Influenza; Mass; Neck Mass; Nerve Injury; Neuropathy Peripheral; Nodule; Pain In Extremity; Pain In Extremity; Rash Pustular; Rheumatoid Arthritis; Skin Discolouration; Skin Mass; Staphylococcal Skin Infection; Staphylococcal Skin Infection	Plaquenil Tablet			S	Oral			Concordia
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14558242	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2262319-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Humira			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Codeine	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Myochrysine	S	Parenteral			Not Reported
	Prednisone	C				Not Reported
	Ciclosporin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14881733	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA126709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon	Myochrysine			S	Intramuscular	50 Mg, Qw		Not Reported
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Celebrex			S	Oral	Unk Unk,Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported

Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Isoniazid		C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14911078	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Hydroxychloroquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Isoniazid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	14967663	EXPEDITED (15-DAY)		DE, OT	IT-MACLEODS PHARMACEUTICALS US LTD-MAC2018014143			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Celecoxib			S	Unknown	Unk		Macleods
	Celecoxib			S	Unknown	Unk		Macleods
	Montelukast			S	Unknown	Unk		Macleods
	Aspirin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk, Regimen 1		Not Reported
	Montelukast			C	Unknown	Unk		Macleods
	Aspirin			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Macleods

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15107003	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002290			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic	Plaquenil			S	Unknown	For More Than 20 Years		Not Reported

Seizure; Optic Nerve Disorder; Seizure; Visual Field Defect	Sabril	S	Oral	From 8-9 Years.		Not Reported
	Sabril	S				Not Reported
	Sabril	S				Not Reported
	Onfi	C				Not Reported
	Keppra	C				Not Reported
	Prednisone	C		0.5 To 1 Mg		Not Reported
	Lorazepam	C		0.5 To 1 Mg		Not Reported
	Fluticasone	C				Not Reported
	Sumatriptan	C				Not Reported
	Cetrizine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15212006	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002668		60 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Diarrhoea; Drug Interaction; Nausea; Tachyarrhythmia	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15313580	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003010		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15313581	EXPEDITED (15-DAY)		CA, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003038			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spina Bifida	Hydroxychloroquine			S	Transplacental	0 - 20.5 Gestational Week,		Not Reported

							4 Months 25 Days			
	Cytotec			C						Not Reported
	Folio Forte			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314040	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174697		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174716		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174723		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314622	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172132		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15315362	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172784		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	2 Every 1 Day(S)		Not Reported
	Ergocalciferol			C	Unknown	1 Every 1 Week(S)		Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15315630	EXPEDITED (15-DAY)		OT	CN-MYLANLABS-2018M1062937		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Erythrodermic Psoriasis	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15315636	EXPEDITED (15-DAY)		OT	PHHY2018CZ048985		38 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Azathioprine			S	Unknown			Not Reported

Pancytopenia; Product Use In Unapproved Indication; Toxicity To Various Agents; Vasculitis Necrotising	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172731		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172675			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316315	EXPEDITED (15-DAY)		OT	GB-FRESENIUS KABI-FK201808831		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin (Manufacturer Unknown)			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Leflunomide Sandoz			S	Unknown	Unk		Not Reported
	Erythro Base			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Ceclor			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Erythromycin			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pethidine Hydrochloride			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316601	NON-EXPEDITED			US-AMGEN-USASP2018115672			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Infection; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Oral	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15317460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15317464	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172622		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Treatment Failure	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2018	14603972	EXPEDITED (15-DAY)			GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00010465			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Concordia
	Prednisolone			S	Unknown	7.5 Mg, Daily		Concordia
	Prednisolone			S	Unknown			Concordia
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported
	Tacrolimus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2018	15273701	NON-EXPEDITED			US-AMGEN-USASP2018110210		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	14552500	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2260737-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Grip Strength Decreased; Hand Deformity; Loss Of Personal Independence In Daily Activities; Poor Venous Access; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Azulfidine		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Xeljanz Xr		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	14875701	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126397		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis	Arava			S	Unknown	20 Mg,Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	14881564	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126723		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	300 Mg,Qd		Sanofi
	Actonel			S	Unknown	35 Mg,Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	1 G, Cyclical			Not Reported
	Hydroxychloroquine			C	Unknown	300 Mg,Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	14904316	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2018-025691		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Celecoxib			S	Unknown	Unk		Aurobindo
	Lorazepam			S	Unknown	Unk		Aurobindo
	Montelukast			S	Unknown	Unk		Aurobindo
	Asa			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Warfarin			S				Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk		Not Reported
	Influenza Vaccine Inactivated			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15153599	EXPEDITED (15-DAY)		HO	PHHY2018GR042310		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy	Prednisolone			S	Unknown	10 Mg, Qd		Novartis
	Prednisolone			S	Unknown	7.5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk, Unknown		Not Reported

Non-Responder; Weight Decreased	Etanercept		S	Unknown	Not Reported
	Citalopram		C	Unknown	Not Reported
	Citalopram		C		Not Reported
	Adalimumab		C	Unknown	Not Reported
	Alprazolam		C	Unknown	Not Reported
	Alprazolam		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15315852	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2016DE187187			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Nicotine			S	Transplacental			Not Reported
	Ramipril			S	Transplacental	20 Mg, Qd		Not Reported
	Pantoprazole Sodium			S	Transplacental	Unk		Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Metamizole Sodium			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Torasemide			S	Unknown	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	Unk		Novartis
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Aliskiren			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319270	EXPEDITED (15-DAY)		DS, OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002791		57 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liquid Product Physical Issue; Product Colour Issue; Psoriatic Arthropathy; Pustular Psoriasis; Rash	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319778	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003051		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anaemia; Diarrhoea; Disseminated Intravascular Coagulation; Haemophagocytic Lymphohistiocytosis; Hepatic Steatosis; Histoplasmosis Disseminated; Hyperbilirubinaemia; Hypoglycaemia; Lactic Acidosis; Pyrexia; Thrombocytopenia	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319808	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174778		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174107		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Form Of Admin: Not Specified		Not Reported
	Prednisone			S	Unknown	Form Of Admin: Not Specified		Not Reported
	Cimzia			C	Subcutaneous	Form: Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15319951	EXPEDITED (15-DAY)		OT	US-ROCHE-2174127		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Sciatica	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Orencia			C	Unknown					Not Reported
	Simponi			C	Subcutaneous					Not Reported
	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15320002	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174758			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15320068	NON-EXPEDITED			US-PFIZER INC-2018338401		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15320081	EXPEDITED (15-DAY)		HO	CA-ROCHE-2174744		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

		Vitamin D2		C	Unknown	Unk				Not Reported
		Montelukast		C	Unknown	Unk				Not Reported
		Zyrtec		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15320579	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174743			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15320735	EXPEDITED (15-DAY)		OT	PHHY2018CN077891		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dermatitis Exfoliative Generalised; Erythema; Erythrodermic Psoriasis; Hyperkeratosis; Leukocytosis; Skin Exfoliation	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Prednisone			C	Unknown	30 Mg, Qd		Not Reported
	Prednisone			C	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15321928	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018335852		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15322034	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15322063	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Arthritis			otherwise specified)		
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15322263	EXPEDITED (15-DAY)		OT	PHHY2018FR079918		6 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication; Pulmonary Haemosiderosis	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15322829	EXPEDITED (15-DAY)		OT	ES-IPCA LABORATORIES LIMITED-IPC-2018-ES-001759			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Lupus Erythematosus	Hydroxychloroquine			S	Transplacental	200 Mg, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15322930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174731		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Aspirin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15323271	EXPEDITED (15-DAY)		OT	PHHY2018GB080202		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate			S	Oral	Unk		Novartis
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2018	15323319	NON-EXPEDITED			US-PFIZER INC-2018338532		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Sulfasalazine	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13931007	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017295		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pelvic Fracture; Pneumonitis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Certolizumab Pegol			S	Subcutaneous	200 Mg, One Every Two Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, One Every Two Weeks		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, 1 Every 2 Week		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13959347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Enbrel			S	Unknown	Unk				Not Reported
	Methotrexate			S	Unknown	Unk				Not Reported
	Acetaminophen			C	Unknown	Unk				Not Reported
	Pregabalin			C	Oral	50 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	13965420	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017881		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Celebrex			S	Oral	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	1 Ml, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Mg, 1 Eveery 1 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Humira			S	Unknown	40 Unk, Cyclical		Not Reported
	Humira			S	Unknown	50 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, 1 Every 2 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, 1 Every 2 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown	5 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	7.5 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, 1 Every 2 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown	5 Mg, 1 Every 2 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown	7.5 Mg, 1 Every 2 Weeks		Not Reported

Orencia	S	Unknown	125 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	12.5 Mg, 1 Every 2 Weeks	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Altace	C	Unknown	5 Mg, Unk	Not Reported
Altace	C	Unknown	10 Mg, Unk	Not Reported
Apo-Gabapentin	C	Oral	100 Mg, Unk	Not Reported
Apo-Gabapentin	C	Unknown	300 Mg, Unk	Not Reported
Apo-Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	C	Oral	15 Mg, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, 2 Every One Week	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, 1 Every 2 Week	Not Reported
Cipralex /01588501/	C	Unknown	10 Mg, Unk	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Mg, Unk	Not Reported
Conjugated Estrogens	C	Oral	0.625 Mg, Unk	Not Reported
Cymbalta	C	Unknown	30 Mg, Qid	Not Reported
Cymbalta	C	Unknown	120 Mg, Qd	Not Reported
Cymbalta	C	Unknown	60 Mg, Unk	Not Reported
Escitalopram	C	Unknown	10 Mg, Unk	Not Reported
Estrace	C	Unknown	0.5 Mg, Unk	Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Unk	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Mg, Bid	Not Reported
Pantoloc /01263204/	C	Unknown	20 Mg, Qd	Not Reported
Pantoloc /01263204/	C			Not Reported
Ratio-Emtec	C	Unknown	Unk	Not Reported
Shark Liver Oil	C	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Mg, Unk	Not Reported
Taro-Mupirocin	C	Unknown	2 %, Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported

	Tramadol	C	Oral	50 Mg, Unk		Not Reported
	Gabapentin	C	Oral	100 Mg, Unk		Not Reported
	Gabapentin	C	Unknown	300 Mg, Unk		Not Reported
	Prednisone	C	Oral	5 Mg, Unk		Not Reported
	Prednisone	C	Oral	5 Mg, Tid		Not Reported
	Prednisone	C	Unknown	15 Mg, Qd		Not Reported
	Mupirocin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15042251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006898		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Apotex
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15043276	EXPEDITED (15-DAY)		HO	US-ABBVIE-18K-163-2251459-00		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Allergic Oedema; Arthralgia; Drug Hypersensitivity; Drug Level Decreased; Pruritus; Rash; Rheumatoid Arthritis; Swelling	Humira 40mg/0.8ml	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prozac	C			Not Reported
	Buspiron [Hyoscine Butylbromide;Metamizole Sodium Monohydrate]	C			Not Reported
	Equetro	C			Not Reported
	Premarin	C			Not Reported
	Vitamin B12	C			Not Reported
	Folic Acid	C			Not Reported
	Vitamin C	C			Not Reported
	Omega 3	C			Not Reported
	Vitamin E	C			Not Reported
	Turmeric	C			Not Reported
	Fioricet	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15089233	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002115			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Aspartate Aminotransferase Increased; Blood Potassium Decreased; Drug Ineffective; Hair Growth Abnormal; Nasal Ulcer; Pneumonia	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Xeljanz			S				Not Reported
	Prednisone			C				Not Reported
	Xeljanz Xr			C		Prolonged-Release Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15147763	NON-EXPEDITED			US-PFIZER INC-2018284613		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Sulfasalazine	S	Unk		Pfizer
	Plaquenil	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15193072	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2426221-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Pain; Injection Site Pain; Leukopenia; Mouth Ulceration; Retinal Disorder; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Limited The Use Of The Medication Hydroxychloroquine		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Enbrel Sureclick		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15299676	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003014			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported
	Xeljanz			C				Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15323751	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003096		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Chest Pain; Cough; Diffuse Alveolar Damage; Dyspnoea; Empyema; Lung Infiltration; Lymphocytic Infiltration; Pneumonia Bacterial	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15323971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174750		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C				Not Reported
	Leucovorin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15324219	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rheumatoid Arthritis	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15324506	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174734		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil (Canada)			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported

	Imitrex			C	Unknown				Not Reported
	Lyrica			C	Unknown				Not Reported
	Premarin			C	Unknown				Not Reported
	Tenormin			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15324611	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175279		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 245.0 Nos		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15324789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15325209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174781		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15325233	NON-EXPEDITED			US-PFIZER INC-2018342597		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15325657	EXPEDITED (15-DAY)		HO, OT	PHHY2017SE204634		40 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Intentional Product Use Issue; Off Label Use	Mycophenolate Mofetil			S	Unknown	2000 Mg,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg,Unk		Not Reported
	Prednisolone			S	Unknown	5 Mg,Unk		Novartis
	Bortezomib			C	Unknown	Unk Unk,Unk		Not Reported
	Dexamethasone			C	Unknown	Unk Unk,Unk		Not Reported
	Belimumab			C	Intravenous (not otherwise specified)	800 Mg,Unk		Not Reported
	Cyclophosphamide			C	Unknown	800 Mg,Unk		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15325849	NON-EXPEDITED			US-PFIZER INC-2018339591		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327082	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018343624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate Sodium			S	Unknown	25 Millicuries, Weekly		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327464	NON-EXPEDITED			US-ALLERGAN-1823979US		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Lexapro			S	Oral	20 Mg, Unk		Allergan
	Remeron			S		15 Mg, Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Oral	9 Df, Q Week		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cymbalta			S				Not Reported
	Atorvastatin			C				Not Reported
	Atorvastatin			C				Not Reported

	Atorvastatin	C			Not Reported
	Atorvastatin	C			Not Reported
	Cardiazem	C		240 Mg, Qd	Not Reported
	Carvedilol	C	Oral	12.5 Mg, Qd	Not Reported
	Cozaar	C	Oral	25 Mg, Qd	Not Reported
	Potassium	C	Oral	10 Meq, Qd	Not Reported
	Pantoprazole	C			Not Reported
	Folic Acid	C	Oral	1 Mg, Unk	Not Reported
	Aldactone	C	Oral	2 Df, Qd	Not Reported
	Hydrocodone	C	Oral	1 Df, Unk	Not Reported
	Tramadol	C		Unk Unk, Prn	Not Reported
	Bumex	C	Oral	2 Mg, Qd	Not Reported
	Gabapentin	C		400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327686	NON-EXPEDITED			US-SA-2018SA231559			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Rash	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			C		Unk		Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327770	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175349		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

					Methotrexate		S	Unknown	Not Reported
					Orencia		S	Unknown	Not Reported
					Dorzolamide Hydrochloride/Timolol Maleate		C	Unknown	Not Reported
					Ergocalciferol		C	Unknown	Not Reported
					Estradiol		C	Unknown	Not Reported
					Estrogel		C	Unknown	Not Reported
					Furosemide		C	Unknown	Not Reported
					Gravol		C	Unknown	Not Reported
					Potassium Chloride		C	Unknown	Not Reported
					Valsartan		C	Unknown	Not Reported
					Xalatan		C	Unknown	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
28-Aug-2018	15327945	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175366		49 YR	Female	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Actemra			S	Unknown			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Anakinra			C	Unknown			Not Reported	
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
28-Aug-2018	15327948	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175947		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327950	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175333		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175876			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15327955	EXPEDITED (15-DAY)		DS	CA-ROCHE-2175979		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2018	15328064	NON-EXPEDITED			PHEH2018US034935			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cosentyx			S	Unknown	Unk		Novartis
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	14911721	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001446			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Grip Strength Decreased; Hand Deformity; Loss Of Personal Independence In Daily Activities; Poor Venous Access; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	14981539	EXPEDITED (15-DAY)		OT	PR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-049979			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Therapeutic Product Effect	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported

Incomplete	Methotrexate		S	Unknown	Unk		Not Reported
	Humira		S	Subcutaneous			Not Reported
	Prednisone		S	Unknown			Not Reported
	Plaquenil /00072602/		S	Unknown			Not Reported
	Leflunomide		S	Unknown			Not Reported
	Imuran /00001501/		S	Unknown			Not Reported
	Xeljanz Xr		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	14987128	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001845			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Hypertension; Rheumatoid Arthritis; Unevaluable Event	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Leflunomide			C				Not Reported
	Toprol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	14987129	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001848			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Imuran			S	Unknown				Not Reported
	Xeljanz Xr			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15094883	NON-EXPEDITED			US-AMGEN-USASP2018087809			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15101962	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016191		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Haemoptysis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Pneumonia; Productive Cough; Seizure	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd, Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15219681	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002648			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Hospitalisation; Off Label Use; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			C				Not Reported
	Xeljanz Xr			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15319771	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001560			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hair Colour Changes; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Thyroid Disorder	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Prednisone			S	Oral	7×Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Valacyclovir			C				Not Reported
	Lopressor			C				Not Reported
	Lopressor			C				Not Reported
	Lopressor			C				Not Reported
	Pantoprazol			C				Not Reported
	Qvar			C		80 Ug,Daily (40 Ug 2puff Daily)		Not Reported

	Lutein			C					Not Reported
	Edarbi			C					Not Reported
	Restasis			C					Not Reported
	Diclofenac Na			C					Not Reported
	Thyroxin			C					Not Reported
	Prednisone			C					Not Reported
	Sildenafil			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15320164	NON-EXPEDITED			US-PFIZER INC-2018339742			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328242	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174114		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175373		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328379	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175984		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328487	EXPEDITED (15-DAY)		DE	FR-ROCHE-2175281			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Sepsis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328497	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Atorvastatin			C	Unknown					Not Reported
	Pantoprazole Sodium			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328888	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003103		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15328913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175436		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15329401	EXPEDITED (15-DAY)		CA, OT	DE-TORRENT-00009641		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Citalopram			S	Transplacental	10 [Mg/D]		Unknown
	Femibion Schwangerschaft 1			C	Transplacental	0.8 [Mg/D]		Unknown
	Quensyl			S	Transplacental	200 [Mg/D]		Unknown

	Cytotec			C	Transplacental	Unknown				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15329536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15329577	EXPEDITED (15-DAY)		HO	CA-ROCHE-2175238		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cellcept	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15329612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15329716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176657		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil (Amitriptyline Hydrochloride)			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tenormin			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15329885	NON-EXPEDITED			US-PFIZER INC-2018342916		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15330279	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Hepatic Enzyme Increased; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Urticaria	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Prednisone			C	Unknown	15 Mg, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported
	Prednisone			C	Unknown	Unk Unk, Qd		Not Reported
	Prednisone			C	Unknown	12 Mg, Unk		Not Reported
	Prednisone			C	Unknown	17 Mg, Unk		Not Reported
	Prednisone			C	Unknown	11 Mg, Unk		Not Reported
	Prednisone			C	Unknown	20 Mg, Unk		Not Reported
	Prednisone			C	Unknown	13 Mg, Unk		Not Reported
	Synthroid			C	Unknown	130 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Tums /00193601/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15330286	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019413			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15330288	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019418		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Swelling	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Naproxen			S	Unknown	Unk, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15330291	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Retinopathy	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Actemra			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15330642	EXPEDITED (15-DAY)		DE, OT	PHHY2018DE080588			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	Unk		Novartis
	Prednisolone			S				Novartis
	Mometasone Furoate			S	Transplacental			Not Reported
	Mometasone Furoate			S				Not Reported
	Prednicarbate			S	Transplacental			Not Reported
	Prednicarbate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331096	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176613		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176633			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Drug Ineffective;	Actemra			S	Unknown			Not Reported

Drug Intolerance; Intestinal Polyp; Leukopenia; Nephrolithiasis; Product Dose Omission; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Hydroxyquine			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331128	EXPEDITED (15-DAY)		HO	CA-ROCHE-2175958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported

	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2018	15331158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176740		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Infection; Liver Function Test Increased; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	13057585	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015698		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported

	Plaquenil /00072602/		S	Unknown	200 Mg, Bid		Not Reported
	Citalopram		C	Unknown	20 Mg, Qd		Not Reported
	Folic Acid		C	Unknown	5 Mg, Qd		Not Reported
	Losec /00661201/		C	Unknown	20 Mg, Qd		Not Reported
	Naprosyn /00256201/		C	Unknown	500 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	13057660	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015709		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Xalatan			C	Unknown	Unk		Not Reported
	Baclofen			C	Unknown	Unk		Not Reported
	Levaquin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	13111870	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Unknown Dose And Frequency.		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Every Week		Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rho(D) Immune Globulin			S	Unknown			Not Reported
	Humira			S	Subcutaneous	4 Years		Not Reported
	Xeljanz			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported
	Celebrex			C	Oral			Not Reported
	Lipitor			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	13224857	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastric Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400mg/200mg		Concordia
	Leflunomide			S	Oral			Not Reported
	Diclofenac			C				Not Reported

	Methotrexate			C						Not Reported
	Xeljanz			C						Not Reported
	Enbrel			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	13861983	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Frequency: Every Week		Not Reported
	Celebrex			C	Unknown	Ongoing		Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	13962979	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017777		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk, Prn		Not Reported
	Pregabalin			C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	14238494	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021655		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	14756806	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009614		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Kidney Infection; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	9 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15050168	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015755		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis;	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported

Swelling; Weight Decreased	Enbrel			S	Unknown	20 Mg, Qd				Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.				Not Reported
	Plaquenil /00072602/			S	Unknown	250 Mg, Qd				Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15082341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016094		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Unknown	40 Mg, Unk, One Every Two Weeks		Not Reported
	Humira			S	Unknown	40 Unk, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	40 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported
	Orencia			C	Unknown	125 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15269314	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002933			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure;	Plaquenil			S	Unknown			Not Reported

Drug Ineffective; Ocular Toxicity	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Sulfasalazine		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15313582	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003048		81 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased	Plaquenil			S	Oral			Not Reported
	Alfuzosin Hydrochloride			C				Not Reported
	Bisoprolol			C				Not Reported
	Prednisone			C				Not Reported
	Norset			C				Not Reported
	Lansoprazole			C				Not Reported
	Cordarone			C				Not Reported
	Previscan (Fluindione)			C				Not Reported
	Novonorm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332572	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175375		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332606	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176023			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332621	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176720		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332637	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176664		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Viral Upper Respiratory Tract Infection	Rituxan			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332646	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown	1 Every 24 Hour(S)		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Sulfasalazine			S	Oral					Not Reported
	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332698	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175370		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332750	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176675		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332808	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175435		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332859	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175446		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332920	EXPEDITED (15-DAY)		DS	CA-ROCHE-2175908		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15332940	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Celebrex			C	Unknown					Not Reported
	Leflunomide			C	Unknown					Not Reported
	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333003	NON-EXPEDITED			US-AMGEN-USASP2018118253		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclobenzaprin			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333114	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175396			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood	Tocilizumab			S	Unknown			Not Reported

Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Benadryl (Canada)	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C		Not Reported
	Darifenacin Hydrobromide	C		Not Reported
	Desoximetasone	C		Not Reported
	Dexamethasone	C		Not Reported
	Dilaudid	C		Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Kenalog (Canada)	C		Not Reported
	Kineret	C		Not Reported
	Loperamide	C		Not Reported
	Morphine Sulfate	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoloc	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Restasis	C		Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15333456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176673		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334229	NON-EXPEDITED			US-PFIZER INC-2018346301		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334480	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Hepatotoxicity; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex

	Methotrexate			S	Unknown	15 Mg, Q.Wk.				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.				Not Reported
	Sulfasalazine			C	Unknown	2 G, Qd				Not Reported
	Sulfasalazine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	13381976	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015817		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Apotex
	Actemra			S	Unknown	Unk Unk, Unknown		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk, Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G,		Not Reported
	Rituxan			S	Unknown	1 G,		Not Reported
	Actonel			S	Unknown	35 Mg, Q.Wk.		Not Reported
	Hydroxychloroquine			C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	13455667	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006912			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rheumatoid Arthritis; Swelling	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Gold			S	Other	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Arthrotec			C	Unknown	50 Mg, Bid		Not Reported
	Arthrotec			C	Unknown	100 Mg, Qd		Not Reported
	Mefenamic Acid			C	Unknown	200 Mg, Unk		Not Reported
	Tylenol /00020001/			C	Unknown	650 Mg, Bid		Not Reported
	Tylenol /00020001/			C	Unknown	1300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14167700	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006271			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Oxycodone			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14167708	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006316		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Urine Present; Cystitis; Drug Ineffective; Drug Intolerance; Genital Pain; Nephrolithiasis; Unevaluable Event; Uterine Disorder; Uterine Leiomyoma	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported
	Metoprolol Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14239391	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021685		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pneumonitis; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Certolizumab Pegol			S	Subcutaneous	400 Mg, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Cyclical		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

	Arava		C	Unknown	Unk				Not Reported
	Prednisone		C	Unknown	Unk				Not Reported
	Tofacitinib Citrate		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14580993	NON-EXPEDITED			US-PFIZER INC-2018081742		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	14908866	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001656		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15058160	EXPEDITED (15-DAY)		DE	GB-BEH-2018091946		15 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Privigen			S	Intravenous (not otherwise specified)	20 G, Unk		Csl Behring
	Privigen			S	Intravenous (not otherwise specified)	20 G, Unk		Csl Behring
	Privigen			S	Intravenous (not	10 G, Unk		Csl Behring

		otherwise specified)		
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	5 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	5 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	5 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	10 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	10 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	10 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Csl Behring
Hydroxychloroquine	S	Unknown		Not Reported

	Hydroxychloroquine	S				Not Reported
	Methotrexate /00113802/	S	Unknown	Unk, Qw		Not Reported
	Methotrexate /00113802/	S				Not Reported
	Prednisolone	S	Unknown			Not Reported
	Prednisolone	S	Unknown	Unk, Bi Weekly		Not Reported
	Mycophenolate Accord	S	Unknown			Not Reported
	Cyclophosphamide	S				Not Reported
	Rituximab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15209410	NON-EXPEDITED			US-SA-2018SA194616		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Palpitations	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15315217	NON-EXPEDITED			US-PFIZER INC-2018341578		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15330728	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018117785			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Enbrel			S	Unknown	Unk		Amgen

	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Prednisone	C		5 Mg, Bid		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15336808	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177485		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15336904	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2464673-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug-Induced Liver Injury	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337054	EXPEDITED (15-DAY)		HO	CA-ROCHE-2173411		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown	Tablet (Extendedrelease)		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Trazodone Hydrochloride			C	Oral			Not Reported
	Tylenol			C	Oral			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Nasonex			C	Unknown	2.0 Dosage Forms		Not Reported
	Omega 3			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337062	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003135		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Age-Related Macular Degeneration; Drug Intolerance	Hydroxychloroquine	S	Unknown	3 Months 1 Day, 400 Mg Die		Not Reported
	Methotrexate	C				Not Reported
	Adalimumab	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337065	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pantoloc			C				Not Reported
	Zopiclone			C				Not Reported
	Folic Acid			C				Not Reported
	Crestor			C				Not Reported
	Tylenol			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337066	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002922			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Respiratory Tract Infection; Sinusitis; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sst			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337124	EXPEDITED (15-DAY)		OT	CA-ROCHE-2173459		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337126	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175956		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Mobicox			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337255	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178187		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337303	EXPEDITED (15-DAY)		DS	CA-ROCHE-2178171		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Naproxen			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

		Folic Acid			C	Unknown				Not Reported
		Esomeprazole			C	Unknown				Not Reported
		Bupropion			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337339	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019551		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Diarrhoea; Dizziness; Drug Intolerance; Hypersensitivity; Lung Disorder; Malaise; Pulmonary Toxicity; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown	80 Mg, Total		Not Reported
	Diclofenac			C	Unknown	50 Mg, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Tecta			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337479	NON-EXPEDITED			US-PFIZER INC-2018351784		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	400 Mg, Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported
	Cyclobenzaprin			S	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337485	NON-EXPEDITED			US-PFIZER INC-2018346831		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15337990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177377		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Actemra			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Simponi			S	Unknown	Not Reported
	Ergocalciferol			C	Unknown	Not Reported
	Leucovorin			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338043	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178161		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Leucovorin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338044	EXPEDITED (15-DAY)		DS	CA-ROCHE-2175423		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea;	Rituxan			S	Intravenous (not			Not Reported

Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance				otherwise specified)		
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177479		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178181		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

					Azathioprine		S	Unknown		Not Reported
					Enbrel		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Minocycline		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338367	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177429			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15338404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176719			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15339715	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018315015		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Tylenol Arthritis			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15340189	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-950325		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy	Hydroxychloroquine			S	Unknown	The Woman Had Been Receiving		Teva

Hydroxychloroquine
Approximately 5.3mg/Kg
From 10 Years

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15340740	NON-EXPEDITED			US-SA-2018SA228943			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2018	15340827	NON-EXPEDITED			US-SA-2018SA240679			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Corticosteroid Nos			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2018	15341444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178226			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective;	Actemra			S	Unknown			Not Reported

Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Acetaminophen/Caffeine/Codeine Phosphate/Meprobamate	C	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2018	13339953	EXPEDITED (15-DAY)		CA, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001710		2 DAY	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Pyelocaliectasis; Congenital Spinal Cord Anomaly; Foetal Exposure During Pregnancy; Pyrexia; Viral Upper Respiratory Tract Infection	Plaquenil			S	Transplacental			Concordia
	Belimumab			S	Transplacental	400 Mg. Cyc		Not Reported
	Lamictal			S	Transplacental			Not Reported
	Nicoderm			S	Transplacental			Not Reported
	Percocet			S	Transplacental			Not Reported
	Xanax			S	Transplacental			Not Reported
	Vyvanse			S	Transplacental			Not Reported
	Penicillin			C				Not Reported
	Folate			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2018	14233164	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-076991		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Balance Disorder; Blood Pressure Decreased; Cough; Dizziness; Dyspnoea; Erythema; Fall; Fine Motor Skill Dysfunction; Gastric Disorder; Headache; Hyperhidrosis; Joint Swelling; Loss Of Consciousness; Malaise; Migraine; Mobility Decreased; Movement Disorder; Musculoskeletal Chest Pain; Nausea; Pain; Pain In Extremity; Pneumonia; Poor Venous Access; Productive Cough; Rash; Respiratory Symptom; Rib Fracture; Skin Disorder; Spinal Cord Oedema; Vision Blurred; Weight Increased	Abatacept			S	Intravenous (not otherwise specified)	1000 Mg, Q4wk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Cortisone			C	Unknown	Unk		Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Dilaudid			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported
	Zmax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2018	14400996	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000209		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Ptosis; Ocular Discomfort; Retinopathy; Uveitis; Visual Impairment	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S				Concordia

	Plaquenil Tablet	S			Concordia
	Corticosteroid Nos	C			Not Reported
	Hydrocortisone	C			Not Reported
	Paroxetine	C			Not Reported
	Lysanxia	C			Not Reported
	Tetrazepam	C			Not Reported
	Mepronizine	C			Not Reported
	Ogast	C			Not Reported
	Zocor	C			Not Reported
	Efferalgan Codeine	C			Not Reported
	Calciprat	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2018	14611133	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000906		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Rash Macular	Plaquenil			S		Afternoons		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2018	15342413	EXPEDITED (15-DAY)		HO	PHHY2018DE086955		75 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Wound	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Biw		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	14773827	EXPEDITED (15-DAY)		HO, OT	CL-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001280		31 YR	Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Tendonitis; Toxic Skin Eruption	Plaquenil			S	Oral			Not Reported
	Corticoids			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	14911074	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001658		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	14941555	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001607			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Liver Function Test Increased; Therapeutic Product Effect Incomplete	Plaquenil			S				Not Reported
	Enbrel			S				Not Reported
	Arava			S				Not Reported
	Remicade			S				Not Reported
	Methotrexate			C				Not Reported

	Xeljanz Xr			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	14987137	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001510			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapy Non-Responder	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15013075	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018218828		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Herpes Zoster; Malaise; Pain; Spinal Fracture	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15072922	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002173		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Hydroxychloroquine			S				Not Reported

Increased; Aspartate Aminotransferase Increased; Chills; Chromaturia; Drug-Induced Liver Injury; Fatigue; Hepatic Cirrhosis; Malaise; Nausea	Hydroxychloroquine	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15100658	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-061914			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Respiratory Tract Infection; Sinusitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sst			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15241847	NON-EXPEDITED			US-AMGEN-USASP2018105300			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Vancomycin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15298688	NON-EXPEDITED			US-AMGEN-USASP2018113022			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Injection Site Urticaria; Liver Function Test Increased; Treatment Failure; Urticaria	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Plaquenil			S	Unknown	200 G, Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Zocor			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15330466	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175401		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15342633	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010701		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sinusitis	Plaquenil Tablet			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous	4 Months 16 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15342634	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002741			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Dysarthria; Facial Paralysis; Urticaria	Plaquenil Tablet			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			C				Not Reported
	Methotrexate			C				Not Reported
	Singulair			C				Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C				Not Reported
	Prozac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15342641	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176750		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Amlodipine Besilate		C	Unknown		Not Reported
					Gabapentin		C	Unknown		Not Reported
					Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15342730	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178225		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15343031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178204		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	M-Eslon	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Venlafaxine Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15344061	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177451		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2018	15345137	EXPEDITED (15-DAY)		OT	PHHY2018DE087235		71 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Hydroxychloroquine			S	Unknown			Novartis
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	14868018	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-039726			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Rash; Therapeutic Product Effect Incomplete; Tuberculosis	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15231852	NON-EXPEDITED			US-PFIZER INC-2018308078		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk (High Dose)		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15316018	EXPEDITED (15-DAY)		CA, DE, OT	DE-GLAXOSMITHKLINE-DE2018GSK152004			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus	Ramipril			S	Transplacental	20 Mg, Unk (Exposure Duration 0-13+6 Weeks)		Glaxosmithkline
	Acetylsalicylic Acid			S	Transplacental	Unk		Glaxosmithkline
	Nicotine			S	Transplacental	Unk		Glaxosmithkline

Persistent; Ventricular Septal Defect	Pantoprazole		S	Transplacental	Unk	Glaxosmithkline
	Prednisolone		S	Transplacental	Unk	Glaxosmithkline
	Simvastatin		S	Transplacental	Unk	Glaxosmithkline
	Ezetimibe		S	Transplacental	Unk	Not Reported
	Hydroxychloroquine		S	Transplacental	Unk	Not Reported
	Metamizole		S	Transplacental	Unk	Not Reported
	Salbutamol Sulfate		S	Transplacental	Unk	Not Reported
	Torasemide		S	Transplacental	Unk	Not Reported
	Aliskiren		S	Transplacental	Unk	Not Reported
	Tacrolimus		S	Transplacental	Unk	Not Reported
	Rivaroxaban		S	Transplacental	Unk	Not Reported
	Enoxaparin		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15337274	NON-EXPEDITED			US-AMGEN-USASP2018119971			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Infection	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15345784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177440		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15345859	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178238		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

		Prednisone			S	Unknown				Not Reported
		Reactine (Canada)			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346038	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2583			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Anaphylactic Reaction; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346239	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2178216			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep	Rituxan			S	Intravenous (not			Not Reported

Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure			otherwise specified)		
	Rituxan	S			Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Unknown	Prefilled Syringe - Solution For Injection	Not Reported
	Humira	S	Subcutaneous	Prefilled Syringe - Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Unknown	Single-Use Vial, Powder For Solution Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Powder For Injection	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Unknown	Powder For Solution For Injection	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346282	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178154		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346283	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2018-044039			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Sepsis	Prednisone			S	Unknown	20 Mg, Qd		Aurobindo
	Hydroxychloroquine			S	Unknown	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2179237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

					Enbrel		S	Subcutaneous		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Leflunomide		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178153		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346343	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177410			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Rituxan			S	Intravenous (not			Not Reported

Enzyme Increased; Pneumonia; Rheumatoid Arthritis					otherwise specified)				
	Actemra			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177396			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346360	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177359		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346610	EXPEDITED (15-DAY)		HO	CA-ROCHE-2179241			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

	Remicade				S	otherwise specified) Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346736	EXPEDITED (15-DAY)		CA, OT	FR-IPCA LABORATORIES LIMITED-IPC-2018-FR-001812			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Nephrocalcinosis; Placental Insufficiency; Pneumoperitoneum; Premature Baby; Volvulus Of Small Bowel	Hydroxychloroquine			S	Transplacental	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15346794	EXPEDITED (15-DAY)		CA, OT	FR-IPCA LABORATORIES LIMITED-IPC-2018-FR-001889			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ileal Atresia; Low Birth Weight Baby; Placental Hypertrophy; Placental Insufficiency; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15347242	NON-EXPEDITED			US-SA-2018SA238087			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Urticaria	Arava	S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine	S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate	S	Unknown	Unk Unk, Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unk		Not Reported
	Simponi	S	Unknown	Unk Unk, Unk		Not Reported
	Actemra	C	Subcutaneous	Unk Unk, Unk		Not Reported
	Xeljanz	C	Oral	1 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15349437	EXPEDITED (15-DAY)		CA, OT	FR-MYLANLABS-2018M1064652			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Intestinal Malformation; Foetal Exposure During Pregnancy; Volvulus	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15349487	EXPEDITED (15-DAY)		CA, OT	FR-MYLANLABS-2018M1065107			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Intestinal Atresia	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15349688	NON-EXPEDITED			US-SA-2018SA247641			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2018	15350057	NON-EXPEDITED			US-AMGEN-USASP2018121644			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	14072022	NON-EXPEDITED			US-PFIZER INC-2017437375		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		2.5 Mg, Unk (6 A Week)		Pfizer
	Xeljanz Xr			S		11 Mg, Daily		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	14892448	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018192419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Liver Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Pantoprazole			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15317063	EXPEDITED (15-DAY)		DE	GR-PFIZER INC-2018341522		57 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Doxycycline Monohydrate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15317067	EXPEDITED (15-DAY)		DE	GR-PFIZER INC-2018341501		50 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Doxycycline Monohydrate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Moxifloxacin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ciprofloxacin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350696	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350725	EXPEDITED (15-DAY)		HO, OT	MX-LUPIN PHARMACEUTICALS INC.-2018-06152		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Mg, Qid		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Amiodarone			S	Intravenous bolus	300 Mg, Qd		Not Reported
	Amiodarone			S	Intravenous bolus	900 Mg, Qd		Not Reported
	Amiodarone			S	Unknown	200 Mg, Qid		Not Reported
	Amiodarone			S	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	20 Mg, Qid		Not Reported
	Warfarine			C	Unknown	2.5 Mg, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350864	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013388		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Four Every One Week		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2179238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15350897	EXPEDITED (15-DAY)		HO, OT	MX-IPCA LABORATORIES LIMITED-IPC-2018-MX-001841			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Long Qt Syndrome	Hydroxychloroquine			S	Unknown	200 Mg, Qid		Ipca
	Hydroxychloroquine			S				Ipca
	Amiodarone			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	900 Mg, Unk		Not Reported
	Amiodarone			S	Unknown	200 Mg, Qid		Not Reported

	Furosemide			C	Unknown	20 Mg, Qid				Not Reported
	Warfarine			C	Unknown	2.5 Mg, Qid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351059	EXPEDITED (15-DAY)		OT	SG-BAUSCH-BL-2018-024060		55 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Interstitial Lung Disease	Prednisolone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mometasone Furoate			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351093	NON-EXPEDITED			US-AMGEN-USASP2018120192			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Pain	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351174	NON-EXPEDITED			US-AMGEN-USASP2018121784			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351176	NON-EXPEDITED			US-AMGEN-USASP2018121462			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Diarrhoea; Drug Hypersensitivity; Injection Site Reaction; Oedema Peripheral; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351316	NON-EXPEDITED			US-PFIZER INC-2018352573		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15351530	NON-EXPEDITED			US-PFIZER INC-2018354821		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15353358	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018120144		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Product Dose Omission; Wrong Technique In Product Usage Process	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	12098241	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Dose Reduced		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Frequency: Every 1 Day; Therapy Duration: 4 Months, Stopped Due To Nausea,Vomiting, Intolerance		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	13233237	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893773		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	13966976	EXPEDITED (15-DAY)		OT	CA-ROCHE-1992036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 245.0 Nos		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Other			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	13968431	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005235		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported
	Adalimumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15134688	EXPEDITED (15-DAY)		OT	DE-LEO PHARMA-309838		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication; Renal Vein Thrombosis; Vena Cava Thrombosis	Protopic			S	Unknown	Unk, Unknown Freq. Gestational Week 0-14		Leo Pharm
	Protopic			S				Leo Pharm
	Simvastatin			S	Unknown	Unk, Unknown Freq. Gestational Week 0-14		Not Reported

Hydroxychloroquine	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Prednisolone	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Ramipril	S	Unknown	20 Mg, Gestational Week 0-13+6	Not Reported
Torasemide	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Ezetimibe	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Acetylsalicylic Acid Sandoz	S	Unknown	Unk, Unknown Freq Gestational Week 0-14	Not Reported
Acetylsalicylic Acid Sandoz	S			Not Reported
Salbutamol	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Metamizole	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Aliskiren	S	Unknown	Unk, Unknown Freq. Gestational Week 0-5	Not Reported
Rituximab	S			Not Reported
Cyclophosphamide	S			Not Reported
Pantoprazole	S	Unknown	Unk, Unknown Freq. Gestational Week 0-14	Not Reported
Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
Nicotine	S	Unknown	Gestational Week 0-14	Not Reported
Enoxaparin	C		Gestational Week 0-14	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15302441	EXPEDITED (15-DAY)		CA, DE, OT	DE-SA-2018SA192203			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Exposure During Pregnancy; Low Birth	Ramipril			S	Transplacental	20 Mg Exposure Duration: 0-13+6 Weeks		Sanofi

Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Acetylsalicylic Acid	S	Transplacental	Unk		Not Reported
	Ezetimibe	S	Transplacental	Unk		Not Reported
	Hydroxychloroquine	S	Transplacental	Unk		Sanofi
	Metamizole Salt Not Specified	S	Transplacental	Unk		Not Reported
	Nicotine	S	Transplacental	Unk		Sanofi
	Pantoprazole	S	Transplacental	Unk		Not Reported
	Prednisolone	S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk		Not Reported
	Simvastatin	S	Transplacental	Unk		Not Reported
	Torasemide	S	Transplacental	Unk		Not Reported
	Aliskiren	S	Transplacental	Unk		Not Reported
	Tacrolimus	S	Transplacental	Unk		Not Reported
	Rivaroxaban	S	Transplacental	Unk		Not Reported
	Enoxaparin	C	Transplacental	Exposure Duration: 0-14 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15340326	NON-EXPEDITED			PHEH2018US035679			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Petechiae; Pruritus	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15354182	EXPEDITED (15-DAY)		DE, OT	PHHY2016FR187230			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Sepsis	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15354262	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2178176			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15354459	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2180401			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15354466	EXPEDITED (15-DAY)		HO	CA-ROCHE-2180423			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355048	NON-EXPEDITED			US-PFIZER INC-2018348815		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355114	NON-EXPEDITED			US-PFIZER INC-2018354089		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Methotrexate Sodium	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Simponi	C	Unk	Not Reported
	Ibuprofen	C	Unk	Not Reported
	Oxycodone	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Tramadol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355861	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-17-038			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Nausea; Therapy Non-Responder	Methotrexate			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355872	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-17-046			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Hydroxychloroquine			S	Unknown			Hikma
	Methotrexate			S	Unknown			Westward

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355928	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-014			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea;	Hydroxychloroquine			S	Unknown			Hikma

Therapeutic Response Changed	Methotrexate	S	Oral	15 Mg A Week		Westward
	Leflunomide	C	Unknown			Not Reported
	Enbrel	C	Unknown			Not Reported
	Humira	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15355975	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-011			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Therapeutic Response Changed; Urticaria	Hydroxychloroquine			S	Oral			Hikma
	Methotrexate			S	Oral			Westward

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15356068	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-031			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nodule	Methotrexate			S	Unknown			Westward
	Methotrexate			S	Unknown			Westward
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15356078	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-032			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Response Changed	Hydroxychloroquine			S	Unknown			Hikma
	Methotrexate			S	Oral			Westward

	Leflunomide			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15357628	NON-EXPEDITED			US-SA-2018SA251157			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Sanofi
	Actemra			C				Not Reported
	Methotrexate			S				Not Reported
	Arava			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15357885	EXPEDITED (15-DAY)		OT	PHHY2018FR086246			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2018	15357886	EXPEDITED (15-DAY)		OT	PHHY2018FR086243			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	8256394	EXPEDITED (15-DAY)		HO, OT	NL-SANOFI-AVENTIS-2011SA075352		80 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Confusional State; Fear; Hypoglycaemia; Loss Of Consciousness; Syncope	Plaquenil			S	Unknown	Unk Unk,Qd		Sanofi
	Carbasalate Calcium			C	Unknown	Unk Unk,Unk		Not Reported
	Nifedipine			C	Unknown	Unk Unk,Unk		Not Reported
	Metoprolol			C	Unknown	Unk Unk,Unk		Not Reported
	Paracetamol			C	Unknown	Unk Unk,Unk		Not Reported
	Zolpidem			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15097194	NON-EXPEDITED			US-AMGEN-USASP2018088024			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alopecia; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15242894	EXPEDITED (15-DAY)		DE	US-ROCHE-2163543		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Respiratory Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Oral			Not Reported
	Treprostinil			S	Nasal			Not Reported
	Furosemide			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported

	Nifedipine	S	Unknown		Not Reported
	Rizatriptan	S	Unknown	As Needed	Not Reported
	Singulair	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Ferrous Sulfate Anhydrous	C	Unknown		Not Reported
	Omeprazole	C	Unknown		Not Reported
	Ondansetron	C	Unknown		Not Reported
	Valacyclovir	C	Unknown		Not Reported
	Valacyclovir	C	Unknown		Not Reported
	Valacyclovir	C	Unknown		Not Reported
	Venlafaxine	C			Not Reported
	Zolpidem	C			Not Reported
	Oxygen	C			Not Reported
	Benadryl (United States)	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15305408	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018016362			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Pantoprazole			S	Unknown	Unk, 0-14 Gestaional Week		Macleods
	Aspirin			S	Unknown	Unk, 0-14 Gestational Week		Not Reported
	Prednisolone Tablet			S	Oral	Unk, 0-14 Gestational Week		Not Reported
	Tacrolimus			S	Unknown	Unk, 1 Trimester , 0-14 Gestaional Week		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk, 0-14 Gestational Week		Not Reported

	Rivaroxaban	S	Unknown	Unk, 0-5 Gestational Week	Not Reported
	Rivaroxaban	S	Unknown	Unk, 0-14 Gestational Week	Not Reported
	Ramipril	S	Unknown	20 Milligram, Gestational Week0-13+6 Gw	Not Reported
	Ramipril	S			Not Reported
	Torasemide	S	Unknown	Unk, 0-14 Gestational Week	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, 0-14 Gestional Week	Not Reported
	Metamizole	S	Unknown	Unk, 0-14 Gestational Week	Not Reported
	Aliskiren	S	Unknown	Unk, 0-5 Gestational Week	Not Reported
	Simvastatin	S	Unknown	Unk, 0-14 Gestational Week	Not Reported
	Ezetimibe	S	Unknown	Unk, 0-14 Gestational Week	Not Reported
	Nicotine	S	Unknown	Unk, 0-14 Gestational Week	Not Reported
	Enoxaparin	S	Unknown	Unk, 0-14 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15323750	EXPEDITED (15-DAY)		CA, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003110			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Ramipril			S	Transplacental	Maternal Dose: 20 Mg Exposure Duration; 0-13+6 Weeks		Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental			Not Reported

	Metamizole Salt Not Specified	S	Transplacental	Not Reported
	Nicotine	S	Transplacental	Not Reported
	Pantoprazole	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Simvastatin	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Tacrolimus	S	Transplacental	Not Reported
	Rivaroxaban	S	Transplacental	Not Reported
	Enoxaparin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15338148	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019404			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, One Every 2 Weeks		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, One Every 6 Weeks		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359258	NON-EXPEDITED			US-AMGEN-USASP2018122824			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Injection Site Pain	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359315	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082921		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Qwk		Not Reported
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359471	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181050		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive;	Actemra			S	Unknown			Not Reported

Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Apo-Hydroxyquine		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359783	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181023		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15359965	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-001846			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fabry'S Disease; Phospholipidosis	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Azathioprine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360323	NON-EXPEDITED			US-PFIZER INC-2018354449		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil S			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360331	NON-EXPEDITED			US-PFIZER INC-2018354307		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Plaquenil S			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360380	NON-EXPEDITED			US-PFIZER INC-2018358624		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360382	NON-EXPEDITED			US-PFIZER INC-2018358382		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

Sulfasalazine	S	Unk	Pfizer
Arava	S	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Humira	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360526	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180440			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360959	NON-EXPEDITED			US-SA-2018SA248742			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance	Arava	S	Unknown	Unk			Sanofi
	Hydroxychloroquine Sulfate	S	Unknown				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15360976	NON-EXPEDITED			US-SA-2018SA098354		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qd		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15362359	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1048641		19 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactic Acid Increased; Bundle Branch Block; Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Abnormal; Hypokalaemia; Overdose; Pco2 Increased; Ventricular Hypokinesia	Hydroxychloroquine			S	Oral	6 G, Total		Not Reported
	Paracetamol			C	Oral	16 G, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15362367	NON-EXPEDITED			US-AMGEN-USASP2018122813		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Drug Intolerance; Gastrointestinal Disorder	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Unknown	11 Mg, Qd		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15384512	DIRECT	Y	HO, OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Irritation; Rash; Rash Papular	Hydroxychloroquine			S	Oral			Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2018	15384886	DIRECT		OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2018	15363846	NON-EXPEDITED			PHEH2018US036934		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2018	15364032	EXPEDITED (15-DAY)		OT	US-ABBVIE-18S-163-2477273-00		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C				Not Reported
	Cymbalta			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	11776291	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1665844		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass; Therapy Non-	Actemra			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Arava			S	Oral	Therapy Duration: 9.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 2.0		Not Reported

Responder				Year(S)		
	Methotrexate	S	Oral	Therapy Duration: 3.0 Year(S)		Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Cimzia	S	Unknown	For 10.0 Month		Not Reported
	Orencia	S	Subcutaneous	3.0 Year		Not Reported
	Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	14152209	EXPEDITED (15-DAY)		HO	CA-ROCHE-2013407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	14403085	EXPEDITED (15-DAY)		CA, DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Aphonia; Arthropathy; Bone Erosion; C-Reactive Protein Abnormal; Carpal Tunnel Syndrome; Contraindication To Medical Treatment; Diarrhoea; Diarrhoea; Drug Intolerance; Gastrointestinal Disorder; Hepatotoxicity; Laryngitis; Rheumatoid Arthritis; Synovitis; Toxicity To Various Agents; Trigger Finger; Weight Increased	Hydroxychloroquine			S	Unknown	1 Year 7 Months 21 Days 12 Hrs		Concordia
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown	2 Months 26 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	14560408	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000627		81 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Eyelid Ptosis; Muscular Weakness	Plaquenil			S	Oral	1 Month 18 Days 12 Hrs		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	14910304	EXPEDITED (15-DAY)		OT	US-ROCHE-2123733		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Coronary Artery Bypass; Depressive	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Symptom; Drug Ineffective; Dyspnoea; Osteomyelitis; Paraesthesia	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15099985	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-061268			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Mtx /00113801/			S	Intramuscular	1 Df, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Simponi Aria			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Kevzara			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15230322	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00014579		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diaphragmalgia; Dyspnoea; Fatigue; Headache; Lower Respiratory Tract Infection; Malaise; Nausea; Swollen Tongue	Hydroxychloroquine	S	Unknown			Concordia
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Erelzi [Etanercept]	S	Subcutaneous	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15279593	NON-EXPEDITED			US-PFIZER INC-2018326472		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Depo-Medrol			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Bromocriptine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Gluten			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15328221	EXPEDITED (15-DAY)		HO, LT, OT	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003113		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Cardiac Failure Acute; Drug Interaction; Electrocardiogram Qt Prolonged; Long Qt Syndrome; Presyncope; Sinus Bradycardia	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Reinitiated		Not Reported
	Amiodarone			S	Oral	Was Administered In Bolus		Not Reported
	Amiodarone			S	Unknown	Bolus, Subsequent Dose		Not Reported
	Amiodarone			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Digoxin			C				Not Reported

	Digoxin	C		Not Reported
	Digoxin	C		Not Reported
	Metoprolol	C		Not Reported
	Metoprolol	C		Not Reported
	Metoprolol	C		Not Reported
	Spironolactone	C		Not Reported
	Spironolactone	C		Not Reported
	Spironolactone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15329123	NON-EXPEDITED			US-AMGEN-USASP2018117716			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Drug Ineffective; Drug Intolerance; Neurological Symptom	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15332862	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk, One Every Two Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk, Cyclical		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk, One Every Six Weeks		Not Reported
	Remicade			S	Intravenous (not	300 Mg, Unk, Cyclical		Not Reported

			otherwise specified)			
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel	S	Unknown	25 Mg, Unk, One Every Two Week		Not Reported
	Enbrel	S	Unknown	25 Mg, Unk, Cyclical		Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate	S	Unknown	15 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Wellbutrin	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15355153	NON-EXPEDITED			US-PFIZER INC-2018354343		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15360022	EXPEDITED (15-DAY)		CA, OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002680			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryopyrin Associated Periodic Syndrome; Fragile X Syndrome; Medium-Chain Acyl-Coenzyme A Dehydrogenase Deficiency; Microcephaly; Trisomy 8	Hydroxychloroquine			S	Transplacental			Not Reported
	Diclofenac Sodium			S	Transplacental	Prn Gestational Week Of Exposure 0-19 + 4		Not Reported
	Paracetamol			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15364800	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182396			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15364838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182409		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15364885	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180453		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra	S	Subcutaneous	Not Reported
	Cellcept	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15364892	EXPEDITED (15-DAY)			US-ALEMBIC PHARMACUETICALS LIMITED-2018SCAL000151			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Intolerance; Fear Of Injection; Headache; Rash	Leflunomide			S		Unk		Alembic
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15364893	EXPEDITED (15-DAY)			US-ALEMBIC PHARMACUETICALS LIMITED-2018SCAL000088			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gastrointestinal Disorder;	Leflunomide			S	Unknown	Unk		Alembic
	Humira			S	Subcutaneous	Solution For Injection		Not Reported

Nausea	Methotrexate	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365093	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003519		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Visual Field Defect; Visual Field Defect	Plaquenil 200 Mg Tablet			S	Oral	18 Years 9 Months 17 Days 12 Hrs		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365176	EXPEDITED (15-DAY)		HO	CA-ROCHE-2180431		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown	Not Specified		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Not Specified		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	D-Alpha Tocopherol			C	Unknown			Not Reported

	Diphenoxylate Hcl	C	Unknown			Not Reported
	Diphenoxylate Hcl	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Ferrous Gluconate	C	Unknown			Not Reported
	Gabapentin	C	Unknown	Not Specified		Not Reported
	Nasonex	C	Unknown			Not Reported
	Nortriptyline Hcl	C	Oral			Not Reported
	Prednisone	C	Unknown			Not Reported
	Trazodone Hydrochloride	C	Oral			Not Reported
	Tylenol	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365212	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003195		34 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus; Rash	Plaquenil 200 Mg Tablet			S	Oral	Alternating Doses Of 200 Mg And 400 Mg Every Other Day		Concordia
	Baktar			S	Oral			Not Reported
	Baktar			S				Not Reported
	Prednisolone			C				Not Reported
	Alfarol			C				Not Reported
	Fosamac			C				Not Reported
	Crestor Od			C				Not Reported
	Promac D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365216	EXPEDITED (15-DAY)			CA-APOTEX-2018AP019425		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug	Leflunomide			S	Oral	20 Mg, Qd		Apotex

Hypersensitivity; Drug Ineffective; Headache; Mood Swings; Nausea; Weight Decreased	Hydroxychloroquine	S	Oral	Unk, Qd		Apotex
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Topiramate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365273	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180441		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15365360	NON-EXPEDITED			US-PFIZER INC-2018360574		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15366056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15367409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180424		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Advil		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Ketorolac		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15367988	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2477386-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15368231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182425		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15368234	EXPEDITED (15-DAY)		HO	CA-ROCHE-2182448		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fatigue; Femur Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

						Orencia		S	Intravenous (not otherwise specified)	Not Reported
						Prednisone		S	Unknown	Not Reported
						Folic Acid		C	Unknown	Not Reported
						Hydroxychloroquine Sulfate		C	Unknown	Not Reported
						Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	14336266	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006313		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15065130	EXPEDITED (15-DAY)			PT-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002155			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15080141	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2382823-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gingival Bleeding; Intervertebral Disc Degeneration; Joint Stiffness; Ligament Laxity; Myalgia; Osteoarthritis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15153054	NON-EXPEDITED			US-PFIZER INC-2018286315		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15278617	EXPEDITED (15-DAY)		DE, OT	PHHY2018GB068704		15 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Cyclophosphamide			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Unk Unk, Qw		Novartis
	Prednisolone			S	Unknown	Unk, Bi Weekly		Novartis

Therapeutic Product Effect Incomplete	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Mg, Twice In Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, Once Every 2 Weeks	Not Reported
	Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mol, Bid	Not Reported
	Remicade	S	Unknown	300 Mg,Once Every 6 Weeks	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown	1 G, Bid	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15366290	NON-EXPEDITED			US-SA-2018SA253542		42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368608	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003198		15 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic	Hydroxychloroquine Tablet			S	Unknown			Not Reported
	Hydrocortisone Acetate			C				Not Reported
	Clarithromycin			C				Not Reported
	Flucloxacillin			C				Not Reported

	Clobetasol Propionate	C		Not Reported
	Daktacort	C		Not Reported
	Benzoyl Peroxide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368609	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003214			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Abnormal; Inflammation; Pain; Renal Impairment	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368707	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001079		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368764	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1605457-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Rheumatoid Arthritis; Stress	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Advil	C		Not Reported
	Tylenol	C		Not Reported
	Herpes	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15368823	NON-EXPEDITED			US-AMGEN-USASP2018124597			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369054	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-024666			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Weight Increased	Prednisolone		S	Unknown	Bausch And Lomb
	Loratadine		S	Unknown	Not Reported
	Ranitidine		S	Unknown	Not Reported
	Phenergan		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369190	NON-EXPEDITED			US-AMGEN-USASP2018124615			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Cytoxan			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15369653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180454		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Actemra			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

	Methotrexate				S	Unknown				Not Reported
	Orencia				S	Unknown				Not Reported
	Simponi				S	Subcutaneous				Not Reported
	Plaquenil				S	Unknown				Not Reported
	Remicade				S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15370930	NON-EXPEDITED			US-SA-2018SA246799			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15371755	NON-EXPEDITED			US-SA-2018SA253898			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372391	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183106		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

	Apo-Leflunomide		S	Oral	Not Reported
	Lyrica		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183047		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372416	EXPEDITED (15-DAY)		HO	CA-ROCHE-2183108		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial	Actemra			S	Unknown			Not Reported

Lung Disease; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Anakinra			S	Unknown				Not Reported
	Cimzia			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Cellcept			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Celebrex			C	Unknown				Not Reported
	Humira			C	Unknown				Not Reported
	Methotrexate			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372417	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182933		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372423	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183083		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Tocilizumab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2018	15372461	EXPEDITED (15-DAY)		OT	PHHY2018US089855			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	12304795	EXPEDITED (15-DAY)		OT	CA-ROCHE-1747513		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	12912967	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1772011-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Pain; Headache;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Aspirin			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Tramadol Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	14144331	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017462653		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Glaucoma	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Zoloft			S				Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Aspirin			C	Oral	81 Mg, 1x/Day		Not Reported
	Vitamin D3			C	Oral	1000 Iu, 1x/Day		Not Reported
	Clonidine			C	Oral	0.1 Mg, 1x/Day		Not Reported
	Fish Oil			C	Oral	1000 Mg, 1x/Day		Not Reported
	Hydrocodone			C	Oral	7.5 Mg, 4x/Day		Not Reported
	Potassium Chloride			C	Oral	10 Meq, 1x/Day		Not Reported
	Torsemide			C	Oral	20 Mg, 1x/Day		Not Reported
	Prilosec			C	Oral	10 Mg, 1x/Day, After Evening Meal		Not Reported
	Sennadocusate			C	Oral	8.6/50mg Taking 2 Per Day By Mouth		Not Reported

	Tylenol			C	Oral	325 Mg, As Needed				Not Reported
	Savella			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15077254	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-056657			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Gingival Bleeding; Intervertebral Disc Degeneration; Joint Stiffness; Ligament Laxity; Myalgia; Osteoarthritis; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral	Unk, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15372727	EXPEDITED (15-DAY)		OT	MX-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184081		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Cardiac Failure Acute; Drug Interaction; Electrocardiogram Qt Prolonged; Presyncope	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Every 24 Hours		Sun
	Hydroxychloroquine			S	Unknown	200 Mg, Qid		Sun
	Amiodarone			S	Intravenous bolus	300 Mg, A Subseqent Dose Of 900 Mg For 24 Hours		Taro
	Amiodarone			S	Unknown	200 Unk, Unk		Taro
	Warfarin			C	Unknown	2.5 Mg, Qid		Not Reported
	Furosemide			C	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15372809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182424		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoarthritis; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15373673	NON-EXPEDITED			US-PFIZER INC-2018364455		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15373674	NON-EXPEDITED			US-PFIZER INC-2018364154		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported

		Plaquenil [Hydroxychloroquine Phosphate]			S		Unk			Not Reported
		Leflunomide			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15373784	NON-EXPEDITED			US-PFIZER INC-2018366699		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Verapamil Hcl			S		Unk		Pfizer
	Plavix			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15373993	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183037		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Methotrexate	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15374052	EXPEDITED (15-DAY)		OT	PHHY2018CA065603		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15374734	NON-EXPEDITED			US-AMGEN-USASL2018124490			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Arthritis; Gastric Disorder; Injection Site Erythema; Injection Site Pain; Injection Site Warmth; Malaise; Muscle Strain; Off Label Use; Skin Induration; Weight Decreased; Yellow Skin	Enbrel			S	Subcutaneous	10 Mg, 2 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	10 Mg, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15376153	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2018	15376619	NON-EXPEDITED			US-AMGEN-USASP2018125543			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported
	Otezla			C	Unknown	Unk		Not Reported
	Stelara			C	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	13988243	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166744		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal	Sodium Aurothiomalate			S	Parenteral	1 G,Qd		Not Reported
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S		200 Mg, Bid		Sanofi
	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Sulfasalazine			S	Unknown	1 G,Qd		Not Reported

Disorder; Treatment Failure	Leflunomide		S	Unknown	20 Mg,Qd	Sanofi
	Actemra		S	Unknown	Unk Unk,Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Enbrel		S	Unknown	Unk Unk,Unk	Not Reported
	Gold		S	Unknown	Unk Unk,Unk	Not Reported
	Humira		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Methotrexate Sodium		S	Unknown	20 Mg,Qw	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Prednisone		C	Unknown	15 Mg,Qd	Not Reported
	Xeljanz		C	Oral	5 Mg,Bid	Not Reported
	Lyrica		C	Oral	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	14308200	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S		Unk		Not Reported

	Reactine (Cetirizine Hydrochloride)	S		Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15127801	EXPEDITED (15-DAY)		DE	GB-SHIRE-GB201824280			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	20 G, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	10 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	10 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	20 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	20 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	20 G, Unk		Shire
	Human Normal Immunoglobulin			S		20 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	20 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	5 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	5 G, Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	10 G, Unk		Shire

Human Normal Immunoglobulin	S	Intravenous (not otherwise specified)	10 G, Unk	Shire
Cyclophosphamide	S			Not Reported
Prednisolone	S	Unknown	Unk, Bi Weekly	Not Reported
Prednisolone	S	Unknown		Not Reported
Mycophenolate Accord	S	Unknown		Not Reported
Methotrexate	S	Unknown	1 Unk, Qw	Not Reported
Methotrexate	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Rituximab	S			Not Reported
Privigen	S	Intravenous (not otherwise specified)	10 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	20 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Not Reported
Privigen	S	Intravenous (not otherwise specified)	5 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	5 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	20 G, Unk	Not Reported
Privigen	S	Intravenous (not otherwise specified)	20 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	20 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	10 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	10 G, Unknown	Not Reported
Privigen	S	Intravenous (not otherwise specified)	10 G, Unknown	Not Reported
Privigen	S	Intravenous (not	20 G, Unknown	Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15300151	NON-EXPEDITED			US-PFIZER INC-2018334137		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15376901	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15376962	NON-EXPEDITED			PHEH2018US037336			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Abdominal Pain Upper	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15377067	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183096			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378544	NON-EXPEDITED			US-SEBELA IRELAND LIMITED-2017SEB00376			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma	Imuran			S				Casper Pharma
	Enbrel			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378630	NON-EXPEDITED			US-PFIZER INC-2018366923		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378930	EXPEDITED (15-DAY)		OT	CA-SA-2016SA039707		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Plaquenil			S		200 Mg,Bid		Sanofi
	Arava			S		20 Mg,Qd		Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Paracetamol			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Enbrel			C	Unknown	Unk Unk,Unk		Not Reported
	Acetaminophen			S				Not Reported
	Methotrexate			C		25 Df,Qw		Not Reported

		Synthroid			C		Unk			Not Reported
		Meloxicam			C		Unk			Not Reported
		Sulfasalazine			C	Oral	2000 Mg,Unk			Not Reported
		Acetaminophen And Codeine Phosphate			C					Not Reported
		Tylenol With Codeine No.3			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	13186770	EXPEDITED (15-DAY)		OT	CA-ROCHE-1888678		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 7 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C				Not Reported
	Mefenamic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	13643094	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2017248697		54 YR	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Methotrexate Sodium			S		12.5 Mg, Weekly		Pfizer
	Hydrocortisone Sodium Succinate			S		10 Mg, Daily		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	14745715	EXPEDITED (15-DAY)		CA, OT	PHHY2018DE059069			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryopyrin Associated Periodic Syndrome; Foetal Exposure During Pregnancy; Fragile X Syndrome; Medium-Chain Acyl-Coenzyme A Dehydrogenase Deficiency; Microcephaly; Trisomy 8	Diclofenac			S	Transplacental	Unk (Maternal Dose: 100 Mg, Prn)		Novartis
	Paracetamol			S	Transplacental	Gestational Week Of Exposure- 17-21		Not Reported
	Hydroxychloroquine			S	Transplacental	Gestational Week Of Exposure- 0-13		Not Reported
	Sulfasalazine			S	Transplacental	Unk (Gestational Week Of Exposure- 0-17)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15138098	EXPEDITED (15-DAY)		LT	NL-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002363			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Diarrhoea	Hydroxychloroquine			S	Unknown			Not Reported
	Tetracycline Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15193941	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-037200		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced; Contraindicated Product Administered; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Pantoprazole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Aurobindo
	Pantoprazole	S	Unknown	Gestational Week 0-14	Aurobindo
	Ramipril	S	Unknown	20 Mg, Gestational Week 0-13+6	Aurobindo
	Acetylsalicylic Acid	S	Unknown	Gestational Week 0-14	Not Reported
	Simvastatin	S	Unknown	Gestational Week 0-14	Aurobindo
	Ezetimibe	S	Unknown	Gestational Week 0-14	Aurobindo
	Metamizole	S	Unknown	Gestational Week 0-14	Not Reported
	Prednisolone	S	Unknown	Gestational Week 0-14	Not Reported
	Nicotine	S	Unknown	Gestational Week 0-14	Not Reported
	Hydroxychloroquine	S	Unknown	Gestational Week 0-14	Not Reported
	Tacrolimus	S	Unknown	Gestational Week 0-14	Not Reported
	Aliskiren	S	Unknown	Gestational Week 0-5	Not Reported
	Salbutamol	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Torasemide	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Enoxaparin	S	Unknown	Unk Unk, Unknown Freq. (0-14 Gw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15201713	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002524			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gingival Bleeding; Intervertebral Disc Degeneration; Joint Stiffness; Ligament Laxity;	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Myalgia; Osteoarthritis; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Intramuscular	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Xeljanz		S	Oral	Not Reported
	Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15314339	EXPEDITED (15-DAY)		HO	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003061		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acanthosis; Alopecia; Dermatitis Exfoliative Generalised; Erythema; Erythrodermic Psoriasis; Hyperkeratosis; Leukocytosis; Parakeratosis; Skin Exfoliation	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C		30 Mg Once A Day Increased To 60 Mg Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15355935	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-015			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown			Hikma
	Methotrexate			S	Oral			Westward

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384144	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003285			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Nerve Disorder; Dizziness; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Almarytm			C				Not Reported
	Congescor			C				Not Reported
	Cardioaspirina			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384147	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002965			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Abnormal; Body Height Decreased; Cardiac Failure Congestive; Cataract; Chest Pain; Constipation; Depression; Drug Ineffective; Fibromyalgia; Glaucoma; Hair Texture Abnormal; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mood Altered; Muscle Tightness; Myalgia; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Weight Increased	Plaquenil			S	Unknown			Not Reported
	Savella			S	Unknown	5mg Titration Pack,		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zoloft			S	Unknown			Not Reported
	Zoloft			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Vitamin D3			C		1000 Iu		Not Reported
	Clonidine			C				Not Reported
	Fish Oil			C				Not Reported
	Hydrocodone			C				Not Reported
	Latanoprost			C		Aug Or Sep2012		Not Reported
	Potassium Chloride			C		May Or Jun2012 At 10 Meq Once A Day Because She Was Taking Diuretic,		Not Reported
	Torsemide			C				Not Reported

	Prilosec	C		From May Or Jun2012 At 10mg Once A Day After Evening Meal	Not Reported
	Sennadocusate	C	Oral	8.6/50mg Taking 2 Per Day And Sometimes Took 3-4 A Day	Not Reported
	Tylenol	C	Oral	325mg As Needed And Taken 1-2 For Pain	Not Reported
	Vitamin D2	C			Not Reported
	Hydrocodone	C			Not Reported
	Hydrocodone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384148	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003243		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Cardiotoxicity; Coronary Artery Disease	Plaquenil 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

			Plaquenil		S	Unknown				Not Reported
			Sulfasalazine		S	Unknown				Not Reported
			Xeljanz		S	Unknown				Not Reported
			Hydroxychloroquine Sulfate		C	Unknown				Not Reported
			Leflunomide		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384441	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384496	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2181774		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15384988	NON-EXPEDITED			US-PFIZER INC-2018368965		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385004	NON-EXPEDITED			US-PFIZER INC-2018368640		91 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown

	Methotrexate	S	Oral	Unk		Not Reported
	Arava	S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385118	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA094804		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Ilaris			S	Subcutaneous			Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Kineret			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385232	NON-EXPEDITED			US-SA-2018SA016173		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Response Decreased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			C				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385316	NON-EXPEDITED			US-SA-2018SA257643			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2018	15385342	EXPEDITED (15-DAY)		OT	CA-ROCHE-2183090		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15041715	EXPEDITED (15-DAY)		OT	US-ROCHE-2137783			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Chest Pain; Drug Ineffective; Drug Intolerance; Gingival Bleeding; Intervertebral Disc Degeneration; Joint Stiffness; Ligament Laxity; Myalgia; Osteoarthritis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Treatment Length: 12 Years Ago 2 Or 3 Years. Discontinued Due To Ineffective		Not Reported
	Humira			S	Subcutaneous	Treatment Length: 15 Years Ago 2 Or 3 Years. Discontinued Due To Ineffective		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular	15 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	Treatment Length: 1 Month And Discontinued Due To Insurance		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15388742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184809		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Crying; Drug Ineffective	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Leucovorin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15388746	EXPEDITED (15-DAY)		DS	CA-ROCHE-2184741		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15388749	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182489		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)	Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral	Qd		Not Reported
	Humira			S	Subcutaneous	Once Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	Qd		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral	Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15388754	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2184769			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2018	15388827	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018041567			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Pain; Rheumatoid Arthritis; Sleep Disorder	Cimzia			S	Subcutaneous	Unknown		Ucb
	Enbrel			S		Unknown Dose		Not Reported
	Plaquenil			S		Unknown		Not Reported
	Meloxicam			C		Unknown		Not Reported
	Methotrexate			C		Unknown		Not Reported
	Sulfasalazine			C		Unknown		Not Reported
	Tofacitinib Citrate			C		Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	12811054	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015022197			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Drug Ineffective; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Thrombocytosis	Cimzia			S	Subcutaneous	Solution Subcutaneous		Ucb
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Naprosyn			S		500 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Weekly (Qw) Powder For Solution Intravenous		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Folic Acid			C		5.0 Mg, Unk		Not Reported
	Gabapentin			C				Not Reported
	Lovastatin			C				Not Reported
	Metoprolol			C		50 Mg, Unk		Not Reported
	Naproxen Sodium			C		1000 Mg, Once Daily (Qd)		Not Reported
	Pantoprazole			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tramadol			C				Not Reported
	Vitamin D2			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	13213907	EXPEDITED (15-DAY)		HO	CA-SA-2017SA019925		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Oral	Unk Unk,Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported

Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Ibuprofen	S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine	S				Sanofi
	Naproxen	S	Unknown	Unk Unk,Unk		Not Reported
	Diclofenac Salt Not Specified	S	Unknown	Unk Unk,Unk		Not Reported
	Diclofenac Potassium	S				Not Reported
	Sulfamethoxazole/Trimethoprim	S				Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold	S				Not Reported
	Tramadol Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	13519809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Tablet		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical	Ointment		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown	Tablet		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Phthalylsulphathiazole			S	Unknown				Not Reported
		Reactine /00884302/			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	13996192	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017033385		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unknown Dose		Ucb
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unknown Dose		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			C	Subcutaneous	7.5 Mg, Weekly (Qw)		Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	14298926	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050836			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		20 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S		1 G, Once Daily (Qd)	Not Reported
	Apo-Leflunomide	S		20 Mg, Once Daily (Qd)	Not Reported
	Apo-Hydroxyquine	S		200 Mg, 2x/Day (Bid)	Not Reported
	Prednisone	C		15 Mg, Once Daily (Qd)	Not Reported
	Lyrica	C	Oral		Not Reported
	Tofacitinib	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	14307978	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050701		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Cimzia			S	Subcutaneous	Unk		Ucb
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15201719	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS		66 YR	Female	JPN

INC.-GSH201807-002605

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Capsule Opacification; Rhinitis Allergic	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Edirol			C				Not Reported
	Prednisolone			C				Not Reported
	Pariet			C				Not Reported
	Prograf			C				Not Reported
	Benet			C				Not Reported
	Loxonin			C				Not Reported
	Magmitt			C				Not Reported
	Azilva			C				Not Reported
	Rinderon-Vg			C				Not Reported
	Hirudoid			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15262106	EXPEDITED (15-DAY)		DE	US-BAUSCH-BL-2018-020732		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Respiratory Failure	Lorazepam			S	Unknown	Total		Not Reported
	Nifedipine			S	Unknown			Not Reported
	Furosemide			S	Unknown	20 Mg Qod		Not Reported
	Furosemide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Rizatriptan			S	Unknown	As Needed		Not Reported
	Singulair			S	Unknown			Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Unknown	800-160		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Prednisone	S	Unknown		Not Reported
	Ferrous Sulfate	C			Not Reported
	Omeprazole	C			Not Reported
	Ondansetron	C			Not Reported
	Valacyclovir	C			Not Reported
	Valacyclovir	C			Not Reported
	Valacyclovir	C			Not Reported
	Venlafaxine	C			Not Reported
	Zolpidem	C			Not Reported
	Brexpiprazole	C			Not Reported
	Oxygen	C			Not Reported
	Benadryl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15271412	EXPEDITED (15-DAY)		DE, OT	US-JUBILANT CADISTA PHARMACEUTICALS-2018JUB00319		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyanosis; Fluid Retention; Interstitial Lung Disease; Oedema; Respiratory Failure	Prednisone			S		20 Mg, 1x/Day		Jubilant
	Prednisone			S		50 Mg, 1x/Day		Jubilant
	Prednisone			S		45 Mg, 1x/Day		Jubilant
	Inhaled Treprostanil Vs. Placebo			S		6 Breaths 4x/Day		Not Reported
	Inhaled Treprostanil Vs. Placebo			S	Oral	42 Mg, 4x/Day		Not Reported
	Furosemide			S		20 Mg, Every 48 Hours		Not Reported
	Furosemide			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported
	Lorazepam			S		2 Mg, 1x/Day		Not Reported
	Mycophenolate			S		2000 Mg, 1x/Day		Not Reported
	Nifedipine			S		60 Mg, 1x/Day		Not Reported
	Rizatriptan			S		5 Mg, As Needed		Not Reported
	Singulair			S		Unk Unk, 1x/Day		Not Reported
	Sulfamethoxazole; Trimethoprim			S		1 Tablets, 3x/Week		Not Reported
	Ferrous Sulfate			C		Unk		Not Reported

	Omeprazole	C	Unk	Not Reported
	Ondansetron	C	Unk	Not Reported
	Valacyclovir	C	Unk	Not Reported
	Valacyclovir	C	Unk	Not Reported
	Valacyclovir	C	Unk	Not Reported
	Venlafaxine	C		Not Reported
	Zolpidem	C		Not Reported
	Brexpiprazole	C	Unk	Not Reported
	Benadryl	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15388960	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018041527			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389021	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082896		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Desoximetasone			C	Unknown	10 Mg, Qd		Not Reported
	Diclofenac			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389657	NON-EXPEDITED			US-AMGEN-USASP2018127442			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389800	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184812		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Cellcept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Rituxan			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknonw		Not Reported
	Methotrexate Sodium			S				Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

	Simponi			S	Unknown	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknonw		Not Reported
	Methotrexate			S				Not Reported
	Lyrica			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Piroxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389916	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15389989	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Minocycline	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium	C	Unknown		Not Reported
	Amoxil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390109	EXPEDITED (15-DAY)		HO	CA-ABBVIE-15K-028-1477471-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Atrovent			C				Not Reported
	Benztropine			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Folic Acid			C				Not Reported
	Methoprazine			C				Not Reported
	Pantoprazole			C				Not Reported
	Risedronate			C		Qs		Not Reported
	Salbutamol			C				Not Reported
	Trifluoperazine			C				Not Reported
	Zopiclone			C		Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390449	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS		84 YR	Female	FRA

						INC.-GSH201809-003316			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Cortancyl			S	Oral	10-20µg		Not Reported
	Cortancyl			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Perindopril			S	Oral	2 Months 5 Days		Not Reported
	Perindopril			S	Unknown			Not Reported
	Repaglinide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390453	EXPEDITED (15-DAY)		HO	MX-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003323		61 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke	Plaquenil 200 Mg Tablet			S	Oral	1 Tablet Of 200 Mg Every 24 Hours		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate			S	Oral					Not Reported
	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15390627	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185413		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15391001	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185521		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

		Apo-Hydroxyquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15391082	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15392179	EXPEDITED (15-DAY)		OT	CA-SA-2018SA251993			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hip Surgery; Knee Arthroplasty; Osteoarthritis; Rheumatoid Arthritis; Sciatica; Unevaluable Event	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Enbrel			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15392342	NON-EXPEDITED			US-SA-2018SA252488			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15393738	NON-EXPEDITED			US-SA-2018SA259520			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lasix			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Ibuprofen			S	Unknown	Unk Unk, Unk		Not Reported
	Gabapentin			S	Unknown	Unk Unk, Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Famotidine			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Unk		Not Reported
	Fluticasone			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15393800	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184264		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported

	Methotrexate			C	Unknown					Not Reported
	Naproxen			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15393828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185408		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15393831	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2184821			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Solution For Injection		Not Reported

Humira	S	Subcutaneous	Solution For Injection		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Ilaris	S	Subcutaneous	Single Use Vial; Powder For Injection		Not Reported
Ilaris	S	Unknown	Single Use Vial; Powder For Injection		Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S				Not Reported
Remicade	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2018	15417317	DIRECT	Y				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibiotic Therapy	Xeljanz Xr 11mg Tablet			S	Oral			Pfizer
	Hydroxychloroquine 200 Gm Tab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	12855891	EXPEDITED (15-DAY)		HO	CA-ROCHE-1842514		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 6 Days		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Therapy Duration: 731.0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	13086864	EXPEDITED (15-DAY)		OT	CA-ROCHE-1874590		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

	Methotrexate Sodium		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Apo-Sulfasalazine		S	Unknown	Not Reported
	Orencia		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	13575281	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003121		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	13990008	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005378		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug	Plaquenil 200 Mg Tablet			S	Oral			Concordia

Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Lyrica	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14167012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2016950		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14495876	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007158		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Diarrhoea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	250 Mg, Unk		Bristol Myers Squibb
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Unk		Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14713133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2095769		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringes Single-Use, Preservative-Free Prefilled Synringe; Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14875047	NON-EXPEDITED			US-PFIZER INC-2018189481		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Nexium			S		Unk		Unknown
	Septra			S		Unk		Pfizer
	Estrace			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lotrel			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported
	Nickel			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	14973323	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0633			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Kineret			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

		Desoximetason			C						Not Reported
		Methotrexate			C						Not Reported
		Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15108571	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002178		34 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Endoxan			S	Intravenous (not otherwise specified)			Not Reported
	Medrol			C				Not Reported
	Neoral			C				Not Reported
	Mevalotin			C				Not Reported
	Magmitt			C				Not Reported
	Maxalt			C				Not Reported
	Maxalt			C				Not Reported
	Argamate			C				Not Reported
	Argamate			C				Not Reported
	Lasix Tablet			C				Not Reported
	Lasix Tablet			C				Not Reported
	Tanatril			C				Not Reported
	Nu-Lotan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15368211	EXPEDITED (15-DAY)		DE, OT	US-009507513-1807USA012767		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Interstitial Lung Disease; Oedema; Pulmonary Hypertension; Respiratory Failure; Scleroderma; Weight Increased	Singulair			S		Unk		Merck
	Prednisone			S	Unknown	20 Mg, Qd		Merck
	Prednisone			S	Unknown	50 Mg, Qd		Merck
	Prednisone			S	Unknown	45 Mg, Qd		Merck
	Maxalt			S	Unknown	5 Mg, Prn		Merck

	Furosemide			S	Unknown		20 Mg, Qod		Not Reported
	Furosemide			S	Unknown		20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		200 Mg, Qd		Not Reported
	Lorazepam			S	Unknown		2 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown		2000 Mg, Qd		Not Reported
	Nifedipine			S	Unknown		60 Mg, Qd		Not Reported
	Sulfamethoxazole (+) Trimethoprim			S	Unknown		1 Tablet, Qd		Not Reported
	Ferrous Sulfate			C			Unk		Not Reported
	Omeprazole			C			Unk		Not Reported
	Ondansetron			C			Unk		Not Reported
	Valacyclovir Hydrochloride			C			Unk		Not Reported
	Valacyclovir Hydrochloride			C			Unk		Not Reported
	Valacyclovir Hydrochloride			C			Unk		Not Reported
	Venlafaxine Hydrochloride			C			Unk		Not Reported
	Zolpidem			C			Unk		Not Reported
	Brexpiprazole			C			Unk		Not Reported
	Oxygen			C			Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15369868	NON-EXPEDITED			US-PFIZER INC-2018363652		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394153	NON-EXPEDITED			US-AMGEN-USASP2018127420			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184313		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394512	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184820		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394580	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184309		50 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394848	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002427		32 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Hyperaemia; Erythema; Pruritus; Pyrexia; Stevens-Johnson Syndrome	Plaquenil 200 Mg Tablet			S	Oral	1 Tablet/Day And 2 Tablets/Day, Alternately		Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394919	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003330			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15394920	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003336		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Eosinophilia; Pruritus; Rash Maculo-Papular	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15395267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186083		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15395451	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2183003		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Daily		Not Reported
	Indomethacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Daily		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Oral	Daily		Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Apo-Hydroxyquine	S	Unknown	Daily		Not Reported
	Apo-Leflunomide	S	Unknown	Daily		Not Reported
	Apo-Prednisone	S	Oral	Daily		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Xeljanz	C				Not Reported
	Cymbalta	C				Not Reported
	Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15395738	EXPEDITED (15-DAY)		HO	CA-ROCHE-2184773			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15395848	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184794		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Sodium Aurothiomalate			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Arava			C	Unknown				Not Reported
		Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396724	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477188-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396735	EXPEDITED (15-DAY)		OT	PHHY2018US092946		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fabry'S Disease; Glomerulonephritis Membranous; Phospholipidosis; Pyuria	Hydroxychloroquine			S	Unknown			Novartis
	Azathioprine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396740	EXPEDITED (15-DAY)		OT	PHHY2018US093219			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Foetal Exposure During Pregnancy; Hydrocele; Jaundice; Low Birth Weight Baby	Methylprednisolone			S	Transplacental	Unk(Maternal Dose: 120 Mg Qd)		Novartis
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Sulfasalazine			S	Transplacental	Unk		Not Reported
	Celecoxib			S	Transplacental	Unk		Not Reported
	Anakinra			S	Transplacental	Unk (Maternal Dose: 100 Mg Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15396748	EXPEDITED (15-DAY)		OT	PHHY2018US093217		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Gestational Hypertension; Maternal Exposure During Pregnancy; Oligohydramnios	Methylprednisolone			S	Unknown	120 Mg, Qd		Novartis
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			S	Unknown	100 Mg, Qd		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15398350	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2186096		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Orencia		S	Unknown		Not Reported
					Remicade		S	Unknown		Not Reported
					Rituxan		S	Unknown		Not Reported
					Aspirin		C	Unknown		Not Reported
					Folic Acid		C	Unknown		Not Reported
					Methotrexate		C	Unknown		Not Reported
					Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15398376	EXPEDITED (15-DAY)		HO	CA-ROCHE-2186094		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15398584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399143	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018238773		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Incorrect Route Of Product Administration; Tuberculin Test Positive; Tuberculosis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Arava			S		10 Mg, 1x/Day		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399208	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185520			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Apo-Folic Acid			S	Unknown				Not Reported
	Apo-Hydroxyquine			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185490			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399237	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186052		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete					otherwise specified)			
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399268	NON-EXPEDITED		OT	US-SA-2018SA254070		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Biw		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, Biw		Not Reported
	Anakinra			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2018	15399819	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083433		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling	Orencia			S	Unknown	125 Unk, Unk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	5.0 Mg, Unk		Not Reported
	Arava			S	Unknown	20.0 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	400.0 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50.0 Mg, Unk		Not Reported
	Folate			C	Unknown	1.0 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15.0 Mg, Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	200.0 Mg, Unk		Not Reported
	Actonel			C	Unknown	35 Mg, Unk		Not Reported
	Prevacid			C	Unknown	30.0 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	13704344	EXPEDITED (15-DAY)		OT	CA-ROCHE-1956511			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

	Cimzia		S	Subcutaneous		Not Reported
	Cortisone Acetate		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	13868322	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975764		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	40mg/0.8 Ml, 40 Mg Solution For Injection		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	13947661	EXPEDITED (15-DAY)		OT	CA-ROCHE-1986487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	14223815	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006464		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	14292481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2035115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	14340447	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006723		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported

Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown	7.5 Mg To 22.5 Mg;	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Metronidazole	C			Not Reported
	Pregabalin	C			Not Reported
	Deflazacort	C			Not Reported
	Paracetamol	C			Not Reported
	Dilaudid	C			Not Reported
	Risedronate	C			Not Reported
	Salbutamol	C			Not Reported
	Nitroglycerin	C			Not Reported
	Crestor	C			Not Reported
	Hydromorph	C			Not Reported
	Januvia	C			Not Reported
	Pantoprazole	C			Not Reported
	Calcium	C			Not Reported
	Ergocalciferol	C			Not Reported
	Lactobacillus Acidophilus	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Triamcinolone	C			Not Reported
	Lidocaine	C			Not Reported
	Triamcinolone Acetonide	C			Not Reported
	Ergocalciferol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	14580458	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-E2B_00010184		71 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Central Nervous System Infection;	Hydroxychloroquine			S	Unknown			Concordia

Dizziness; Headache; Infected Varicose Vein; Nocardiosis; Varicose Ulceration; Vomiting	Hydroxychloroquine	S	Unknown	Concordia
	Methylprednisolone	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Salazopirina	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15248969	NON-EXPEDITED			US-PFIZER INC-2018314390		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15301381	EXPEDITED (15-DAY)		DS, HO	GR-PFIZER INC-2018328861		67 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Laboratory Test Abnormal; Muscular Weakness	Atorvastatin Calcium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Metformine [Metformin]			C		Unk		Not Reported
	Saxagliptin			C		Unk		Not Reported

	Pilocarpine			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15392138	NON-EXPEDITED			US-PFIZER INC-2018373024		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15399867	EXPEDITED (15-DAY)		HO	CA-ROCHE-2184711			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400011	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia	S	Intravenous (not otherwise specified)	Bristol Myers Squibb
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Cimzia			S	Unknown			Not Reported

	Cortisone Acetate			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Folic Acid			S	Unknown	Not Reported
	Fosamax			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Phthalylsulfathiazole			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400061	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185411		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400178	NON-EXPEDITED			US-AMGEN-USASP2018128144			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400244	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait	Rituxan			S	Unknown			Not Reported

Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400282	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400394	EXPEDITED (15-DAY)		DS	CA-ROCHE-2185395			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400402	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2185519			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Powder For Solution Subcutaneous Single Use Vial	Not Reported
	Ilaris	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400442	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2185489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported

Actemra	S		Not Reported
Anakinra	S	Unknown	Not Reported
Anakinra	S		Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S		Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Humira	S	Unknown	Not Reported
Humira	S		Not Reported
Ilaris	S	Unknown	Not Reported
Ilaris	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Ilaris	S	Unknown	Not Reported
Ilaris	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400463	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400484	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400576	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		51 YR	Female	CAN

						INC.-GSH201809-003338			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400577	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hip Surgery; Knee Arthroplasty; Osteoarthritis; Rheumatoid Arthritis; Sciatica; Unevaluable Event	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400578	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003358			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion; Exposure During Pregnancy	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400587	EXPEDITED (15-DAY)		HO	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003348		36 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dyspnoea; Pneumonitis; Pruritus; Rash Papular; Wheezing	Hydroxychloroquine	S	Oral		Not Reported
	Fexofenadine Hydrochloride	C			Not Reported
	Naproxen Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400614	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2185441		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15400828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen/Codeine Phosphate	C		Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401008	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180913733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Infection; Localised Infection; Pneumonia; Rheumatoid Arthritis; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	7.5 Mg To 22.5 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported

	Deflazacort	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Crestor	C	Unknown	Not Reported
	Hydromorph	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Vitamin D2	C	Unknown	Not Reported
	Lactobacillus Acidophilus	C	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Triamcinolone	C	Unknown	Not Reported
	Lidocaine	C	Unknown	Not Reported
	Kenalog	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185994		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401203	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2184816		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401261	NON-EXPEDITED			US-SA-2018SA254061			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Rash	Arava			S	Unknown	Unk, Unk		Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401367	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Pantoprazole Sodium			C				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl (Canada)			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dilaudid			C				Not Reported
	Dyclonine Hcl			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog (Canada)			C	Intra-articular			Not Reported
	Lasix			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C	Unknown			Not Reported
	Oxyneo			C	Unknown			Not Reported
	Restasis			C				Not Reported
	Rituxan			C	Intravenous (not			Not Reported

							otherwise specified)			
			Synthroid			C				Not Reported
			Trimethoprim			C				Not Reported
			Urispas			C	Unknown			Not Reported
			Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15401373	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15402442	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186795		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15403510	NON-EXPEDITED			US-PFIZER INC-2018375464		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15403561	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180916749		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Haemorrhage;	Simponi			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Suicidal Ideation	Hydroxychloroquine		S	Unknown		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Azathioprine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404582	EXPEDITED (15-DAY)		HO	CA-ROCHE-2186067		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 1.0 Day(S)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404585	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186072		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Rituximab			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported
	Prednisone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404609	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186800		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mobicox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404611	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2018	15404612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186629			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	13250269	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001094		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder;	Plaquenil			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Oral			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Salt Not Specified		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Diclofenac Potassium		S	Unknown	Not Reported
	Sulfamethoxazole Trimethoprim		S	Unknown	Not Reported
	Tramadol Hydrochloride		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	13566647	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002991		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Response Decreased; Ulcer	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	6 Months 30 Days	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	14223816	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006465		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema	Plaquenil 200 Mg Tablet			S	Oral	Duration: 1 Month 29 Days 12 Hrs		Concordia
	Plaquenil 200 Mg Tablet			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	14265803	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006468			Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema Multiforme	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15113844	EXPEDITED (15-DAY)		CA, DE, OT	DE-NODEN PHARMA DAC-NOD-2018-000056			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Noden Pharma
	Rasilez			S	Transplacental	Unk		Noden Pharma
	Torem /01036501/			S	Transplacental	100 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Torem /01036501/			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported

Ezetimibe Ms-Sp	S	Transplacental	Unk	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Clexane	S	Transplacental	Unk	Not Reported
Xarelto	S	Transplacental	Unk, Not Known If Administered Before Or After Missed Abortion; Trimester Of Exposure: Unknown	Not Reported
Xarelto	S	Transplacental	Unk	Not Reported
Prednisolon /00016201/	S	Transplacental	10 [Mg/D]/Every Second Day; 0-13.6 Gestational Week	Not Reported
Prednisolon /00016201/	S	Transplacental	Unk	Not Reported
Delix (Ramipril) /00885601/	S	Transplacental	20 Mg, Qd; 0-13.6 Gestational Week	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Advagraf	S	Transplacental	6 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Quensyl	S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week	Not Reported
Quensyl	S	Transplacental	Unk	Not Reported
Pantozol /01263204/	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Pantozol /01263204/	S	Transplacental	Unk	Not Reported
Simvastatin	S	Transplacental	Unk	Not Reported
Simvastatin	S	Transplacental	Unknown	Not Reported
Salbutamol /00139502/	S	Transplacental	Unk, If Required; Trimester: First+Second	Not Reported
Salbutamol /00139502/	S	Transplacental	Unk	Not Reported

	Metamizole	S	Transplacental	Unk		Not Reported
	Metamizole	S	Transplacental	Unknown		Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15166169	EXPEDITED (15-DAY)		CA, OT	DE-GLAXOSMITHKLINE-DE2018123280			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Mg, Unk Maternal Dose 20 Mg		Glaxosmithkline
	Nicotine			S	Transplacental	Unk		Glaxosmithkline
	Simvastatin			S	Transplacental	Unknown		Glaxosmithkline
	Tacrolimus			S	Transplacental	Unk		Glaxosmithkline
	Metamizole Sodium			S	Transplacental	Unk		Glaxosmithkline
	Pantoprazole			S	Transplacental	Unk		Glaxosmithkline
	Acetylsalicylic Acid			S	Transplacental	Unk		Glaxosmithkline
	Prednisolone			S	Transplacental	Unk		Glaxosmithkline
	Salbutamol			S	Transplacental	Unknown		Glaxosmithkline
	Ezetimibe			S	Transplacental	Unknown		Not Reported
	Torasemide			S	Transplacental	Unk		Not Reported
	Enoxaparin Sodium			S	Transplacental	Unknown		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Rivaroxaban			S	Transplacental	Unk		Not Reported
	Aliskiren			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15175662	EXPEDITED (15-DAY)		OT	SE-BAUSCH-BL-2018-019432		41 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis	Dexamethasone			S	Unknown	During March-April 2015		Bausch And Lomb
	Dexamethasone			S	Unknown	Two Cycles; During March-April 2015		Bausch And Lomb
	Dexamethasone			S	Unknown	Tapered Dose		Bausch And Lomb
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Tapered Dose		Not Reported
	Bortezomib			S	Unknown	During March-April 2015; Two Cycles		Not Reported
	Bortezomib			S	Unknown	During March-April 2015; Two Cycles		Not Reported
	Bortezomib			S	Unknown	Tapered Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Tapered Dose		Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	Tapered Dose		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Two Weeks Apart, Was Given In October 2014		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Tapered Dose		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	As Maintenance Dose		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	Tapered Dose		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Mycophenolate Mofetil			S	Unknown	Restarted Three Months Later				Not Reported
	Mycophenolate Mofetil			S	Unknown	Tapered Dose				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15183901	EXPEDITED (15-DAY)		OT	CA-SA-2018SA194087			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rash	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15324151	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-18_00004283		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragmalgia; Dyspnoea; Fatigue; Headache; Lower Respiratory Tract Infection; Malaise; Nausea; Swollen Tongue	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Erelzi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15328968	EXPEDITED (15-DAY)		OT	GB-ACCORD-071159		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Foot Fracture; Stress Fracture	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15330223	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2175245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15335264	NON-EXPEDITED			US-AMGEN-USASP2018118354			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Ridaura			S	Unknown	Unk		Not Reported
	Tetracycline			S	Unknown	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15343315	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003165		39 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Lansoprazole			C				Not Reported
	Recalbon [Minodronic Acid]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15404893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186700		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405024	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187342		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Pulmonary Fibrosis	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405078	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003257		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide Tablet			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide Tablet			S	Unknown			Not Reported
	Azathioprine Tablet			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405081	NON-EXPEDITED			US-TEVA-818251ACC		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dizziness Postural; Nausea	Hydroxychloroquine Sulfate			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405082	NON-EXPEDITED			US-TEVA-2018-US-934757		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine			S	Unknown			Teva
	Ustekinumab			S	Unknown	Dose Increased To 90mg Monthly In July 2017		Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Thalidomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405083	NON-EXPEDITED			US-TEVA-814014USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Erythema; Peripheral Swelling; Skin Tightness	Hydroxychloroquine			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185477		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Cimzia			S	Subcutaneous					Not Reported
	Enbrel			S	Subcutaneous					Not Reported
	Methotrexate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405427	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185410		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Swelling	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185449		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186575		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405705	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186015		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	1 Every 1 Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405729	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185982		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

					Enbrel		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Desoximetasone		C	Unknown		Not Reported
					Diclofenac		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15405865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15406086	NON-EXPEDITED			US-PFIZER INC-2018379143		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Ibuprofen			S		Unk		Pfizer
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported
	Aza (Azathioprine)			S		Unk		Not Reported
	Benlysta			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15406180	NON-EXPEDITED			PHEH2018US039231			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Hyperhidrosis; Product Odour Abnormal	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15406800	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018GSK169643		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability; Pain	Wellbutrin			S		Unk		Glaxosmithkline
	Breo Ellipta Inhalation Powder			S		Unk		Glaxosmithkline
	Singulair			S		Unk		Glaxosmithkline
	Diovan			S		160 Mg, Unk		Glaxosmithkline
	Effexor			S		Unk		Glaxosmithkline
	Minocycline			S		Unk		Glaxosmithkline
	Vitamin D Nos			S		Unk		Glaxosmithkline
	Colchicine			S		Unk		Glaxosmithkline
	Proair (Salbutamol Sulfate)			S				Not Reported
	Janumet			S		Unk		Not Reported
	Diovan Hct			S		Unk		Not Reported
	Clonidine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Lyrica			S		Unk		Not Reported
	Lasix			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

	Cpap (Continuous Positive Airway Pressure)			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15408170	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180911342		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15408482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187397		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Oral			Not Reported

Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ativan	C		Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Codeine	C		Not Reported
	Desoximetasone	C		Not Reported
	Dexamethasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine	C		Not Reported
	Enablex	C	Unknown	Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog (Canada)	C	Intra-articular	Not Reported
	Lasix	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium	C		Not Reported
	Restasis	C		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15408890	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187425		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15408982	EXPEDITED (15-DAY)		HO	US-SA-2018SA164249		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Cardiac Chest Pain	Sarilumab			S	Subcutaneous	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Atorvastatin			C	Oral	Unk Unk		Not Reported
	Norco			C	Oral	Unk Unk		Not Reported
	Metoprolol			C	Oral	Unk Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Oral	Unk Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Oral	Unk		Not Reported
	Calcium & Vitamin D [Calcium;Colecalciferol]			C	Oral	Unk Unk		Not Reported
	Zyrtec [Cetirizine Hydrochloride]			C	Oral	Unk Unk		Not Reported
	Flonase [Fluticasone Propionate]			C	Nasal	Unk Unk		Not Reported
	Prolia			C	Subcutaneous	Unk Unk		Not Reported
	Levothyroxine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15408992	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186672		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2018	15408996	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187401		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	11618851	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477190-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Drug Ineffective; Dysgeusia; Dyspepsia; Epistaxis; Nasal Dryness; Sinusitis; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	12884262	EXPEDITED (15-DAY)		OT	CA-ROCHE-1734356		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown	Discontinued		Not Reported
	Enbrel			S	Unknown	Discontinued		Not Reported
	Orencia			S	Unknown	Discontinued		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 4 Months		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported

		Advil			C					Not Reported
		Ketorolac			C					Not Reported
		Plaquenil			C	Unknown				Not Reported
		Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	13614636	EXPEDITED (15-DAY)		OT	CA-ROCHE-1942553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14223817	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-		33 YR	Female	JPN

006466

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema Multiforme; Rash Erythematous; Rash Maculo-Papular	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14223822	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006477		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Macule	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14285075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2035100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

							otherwise specified)			
			Phthalylsulfathiazole			S	Unknown			Not Reported
			Prednisone			S	Unknown			Not Reported
			Reactine (Canada)			S	Unknown			Not Reported
			Remicade			S	Intravenous (not otherwise specified)			Not Reported
			Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14457636	NON-EXPEDITED			US-PFIZER INC-2018038928		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	14988545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018230885		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Pain; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Oral	Unk Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410149	EXPEDITED (15-DAY)		HO	CA-ROCHE-2186098		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme	Rituxan			S	Intravenous (not			Not Reported

Disease			otherwise specified)	
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410338	NON-EXPEDITED			US-AMGEN-USASP2018129593			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410458	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186068		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Infection; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Xeljanz			C	Oral				Not Reported
	Prevacid			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410617	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-18_00004529		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate (Trade Name Unknown)			S	Oral	Unk		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humera			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410731	EXPEDITED (15-DAY)		HO	CA-ROCHE-2187412		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410740	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003343		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Heart Rate Decreased; Hypotension; Nausea; Product Substitution Issue; Weight Decreased	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15410750	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186783		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187973		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411138	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S	Unknown	Not Reported
	Reactine (Canada)		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411343	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187392		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187306		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Minocycline		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186005		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186794		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Sleep Disorder; Treatment Noncompliance	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411488	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186720		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186082		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15411631	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186055		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

					Sulfasalazine	S	Unknown		Not Reported
					Xeljanz	S	Unknown		Not Reported
					Xeljanz	S	Unknown		Not Reported
					Amoxicillin Sodium/Clavulanate Potassium	C	Unknown		Not Reported
					Amoxil	C	Unknown	/00249603/	Not Reported
					Bacillus Calmette-Guerin (Bcg) Vaccine	C	Intravesical		Not Reported
					Clavulin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15412226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186665		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15412303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186769			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

					Cimzia	S	Subcutaneous		Not Reported
					Enbrel	S	Unknown		Not Reported
					Hydroxychloroquine	S	Unknown		Not Reported
					Leflunomide	S	Unknown		Not Reported
					Plaquenil	S	Unknown		Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Varenicline Tartrate	S	Oral		Not Reported
					Methotrexate	S	Subcutaneous		Not Reported
					Methotrexate	S	Subcutaneous		Not Reported
					Acetaminophen/Oxycodone Hydrochloride	C	Unknown		Not Reported
					Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
					Rosuvastatin Calcium	C	Unknown		Not Reported
					Tofacitinib Citrate	C	Unknown		Not Reported
					Valtrex	C	Unknown		Not Reported
					Prednisone	C	Unknown		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
21-Sep-2018	15412352	EXPEDITED (15-DAY)		DS	CA-ROCHE-2185979			Male	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**	
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	

					Orencia		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15412394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187314		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15412479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184771			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous			Not Reported
	Diclofenac Sodium	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15413460	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018GSK169013			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Borderline Glaucoma; Rheumatoid Arthritis	Valtrex			S		Unk		Glaxosmithkline
	Plaquenil			S		200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2018	15414539	NON-EXPEDITED			US-MYLANLABS-2018M1065482			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydrocortisone			C		Unk		Mylan
	Synthroid			C		Unk		Mylan
	Fludrocortisone			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	13658293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1950017			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415866	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186759		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415870	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187406		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Oral			Not Reported
	Naproxen			C	Oral			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Valtrex			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415874	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain;	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Plaquenil		S	Oral	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported
	Orencia		C	Unknown	Not Reported
	Tofacitinib Citrate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186765		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415882	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187269		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Gait Disturbance; Joint Range Of Motion Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186770		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C		Not Reported
	Estradiol	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415887	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186777		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188014		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

	Arava			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Minocycline Hydrochloride			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188003		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415897	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187991		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapy Non-Responder; Treatment Failure	Ibuprofen			C	Oral				Not Reported
	Lipitor			C	Oral				Not Reported
	Xeljanz			C	Oral				Not Reported
	Celebrex			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415898	EXPEDITED (15-DAY)		OT	CA-ROCHE-1841430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 10 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4.0 Years		Not Reported
	Benzalkonium Chloride/Boric Acid/Edetate Disodium/Phenylephrine Hydrochloride/Sodium Borate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rho(D) Immune Globulin Human			S	Unknown			Not Reported
	Tofacitinib			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Lipitor			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415900	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186797		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415901	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186751		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187353			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Rituxan		S	Unknown		Not Reported
	Actemra		S	Unknown	Therapy Duration: 4 Months	Not Reported
	Arava		S	Unknown	Therapy Duration: 2 Months	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Duration: 12 Months	Not Reported
	Plaquenil		S	Unknown		Not Reported
	Methotrexate		S	Unknown	Duration: -60	Not Reported
	Celebrex		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415905	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187969		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415906	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187966		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415907	EXPEDITED (15-DAY)		HO	CA-ROCHE-2187957		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415911	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186753		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Grip Strength Decreased; Headache; Injection Site Reaction; Loss Of Personal Independence In Daily Activities; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2018	15415913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186712		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pemphigus; Swelling; Systemic Lupus Erythematosus	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15271218	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2446769-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab			S	Unknown					Not Reported
	Simponi			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415963	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186758		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bcg			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415965	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186754		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Orencia			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Xeljanz			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187408			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415967	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186729			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Rash; Squamous Cell Carcinoma; Treatment Failure	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Citalopram Hydrobromide			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188017			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415979	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186092		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Rituxan			S	Unknown			Not Reported

Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Imuran		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Parenteral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415980	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187292		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415986	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186681		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15415989	EXPEDITED (15-DAY)		DS	CA-ROCHE-2186803			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15416069	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188011		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15416070	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2018	15416071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187996			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	11385922	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1619365		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Enbrel		S	Subcutaneous		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Ilaris		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	13692084	EXPEDITED (15-DAY)		OT	CA-ROCHE-1954596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

	Kevzara	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	14223818	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006467		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema; Rash Maculo-Papular	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	14223820	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006470		66 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Photosensitivity Reaction	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	14754965	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001226		62 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Pigment Epitheliopathy	Plaquenil 200 Mg Tablet			S	Oral	200mg/Day, 400 Mg/Day		Not Reported
	Medrolacne			C				Not Reported
	Trichlormethiazide			C				Not Reported
	Valsartan			C				Not Reported

	Onealfa				C						Not Reported
	Pariet				C						Not Reported
	Bonoteo				C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	14906942	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001652		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Erythema Multiforme; Mucosal Disorder; Pyrexia; Rash	Plaquenil 200 Mg Tablet			S	Oral	One Tablet Qd And 2 Tablets Qd		Not Reported
	Edirol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	14934816	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018208272		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Drug Ineffective; Upper Respiratory Tract Infection	Sulfasalazine			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	14999366	NON-EXPEDITED			US-PFIZER INC-2018233260		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15285815	NON-EXPEDITED			US-SA-2018SA224116			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fatigue	Arava			S		20 Mg, Qd		Sanofi
	Plaquenil			S		Unk, Unk		Sanofi
	Methotrexate			S		Unk, Unk		Not Reported
	Azulfidine			C		Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15307073	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP018946		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown			Apotex
	Naproxen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15368637	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2477409-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported

	Orencia		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15368724	NON-EXPEDITED			US-AMGEN-USASP2018122823			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Osteoarthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15370511	NON-EXPEDITED			US-JAZZ-2018-US-013479			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; No Adverse Event	Xyrem			S	Oral	1.5 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Hydroxychloroquine Phosphate			S		Unk		Not Reported
	Benzoyl Peroxide			C		Unk		Not Reported
	Clindamycin			C		Unk		Not Reported
	Doxycycline Monohydrate			C		Unk		Not Reported
	Triamcinolone			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported

Propranolol	C	Unk	Not Reported
Aczone	C	Unk	Not Reported
Solodyn	C	Unk	Not Reported
Ranitidine	C	Unk	Not Reported
Vyvanse	C	Unk	Not Reported
Relpax	C	Unk	Not Reported
Advil Cold & Sinus	C		Not Reported
Cevimeline Hcl	C		Not Reported
Elmiron	C		Not Reported
Evekeo	C	Unk	Not Reported
Ibuprofen	C		Not Reported
Imodium A-D	C		Not Reported
Magnesium Oxide	C	Unk	Not Reported
Meclozine	C		Not Reported
Minocycline	C		Not Reported
Mirena	C		Not Reported
Omeprazole	C	Unk	Not Reported
Pilocarpine Hcl	C		Not Reported
Prednisone	C	Unk	Not Reported
Ritalin	C		Not Reported
Spironolactone	C		Not Reported
Tylenol Extra Strength	C		Not Reported
Uribel	C	Unk	Not Reported
Vitamin B-12	C	Unk	Not Reported
Vit C	C		Not Reported
Vitamin D3	C		Not Reported
Ondansetron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15385094	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003222			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported

	Leflunomide			S	Unknown					Not Reported
	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15416376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185463		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15416438	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003346		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic	Plaquenil			S	Oral			Concordia
	Esomeprazole			C				Not Reported
	Cardura			C				Not Reported
	Citalopram			C				Not Reported

	Metformin			C						Not Reported
	Crestor			C						Not Reported
	Triatec 10 Mg			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15416671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15416708	NON-EXPEDITED			US-AMGEN-USASP2018130542			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Hypersensitivity	Enbrel	S	Unknown	Unk		Amgen
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	C	Oral	Unk Unk, Qwk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15416948	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417002	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Reactine (Canada)			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188024		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417144	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187390		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Victim Of Crime	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417166	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185522		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration Is 5 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Myochrysine	S	Intramuscular			Not Reported
	Otezla	S	Unknown			Not Reported
	Plaquenil	S	Unknown	Therapy Duration: 4 Months		Not Reported
	Salazopyrin	S	Unknown	Therapy Duration:4 Months		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration:334		Not Reported
	Sirukumab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration:4 Month		Not Reported
	Ustekinumab	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Orencia	C	Unknown	Therapy Duration: 4 Years		Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417197	NON-EXPEDITED			US-AMGEN-USASP2018129870			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417322	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2055240		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rhabdomyolysis	Hydroxychloroquine Sulfate	S	Unknown	Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15417435	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Canada)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15418583	EXPEDITED (15-DAY)		OT	PHHY2018IN099746		60 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Product Use In Unapproved Indication; Rash Erythematous; Rash Pruritic; Skin Erosion; Skin Plaque; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Folic Acid			S	Unknown	5 Mg, Qd		Not Reported
	Methylprednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15418642	NON-EXPEDITED			US-BIOVITRUM-2018US0433			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Foetal Exposure During Pregnancy; Hydrocele; Jaundice Neonatal; Low Birth Weight Baby	Anakinra			S	Transplacental			Not Reported
	Methylprednisolone			S	Transplacental			Not Reported
	Celecoxib			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15419399	NON-EXPEDITED			US-PFIZER INC-2018381363			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Celebrex			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15419410	NON-EXPEDITED			US-PFIZER INC-2018383312		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect	Methotrexate Sodium			S		Unk		Pfizer

Incomplete	Methotrexate Sodium	S	Unk			Pfizer
	Plaquenil	S				Not Reported
	Plaquenil	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15419768	EXPEDITED (15-DAY)		OT	BR-IPCA LABORATORIES LIMITED-IPC-2018-BR-002012			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ototoxicity	Hydroxychloroquine			S	Oral	400 Mg, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15419994	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported

		Pantoprazole Sodium			C					Not Reported
		Plantago Ovata			C					Not Reported
		Synthroid			C	Unknown				Not Reported
		Vagifem			C	Vaginal				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15420192	NON-EXPEDITED			US-SA-2018SA265772			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Dupixent			S		Unk		Sanofi
	Triamcinolone			S		Unk		Not Reported
	Clobetasol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15420447	EXPEDITED (15-DAY)		OT	PHHY2018GB099760		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Foot Fracture; Hypokinesia; Osteolysis; Pain In Extremity; Stress Fracture	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15421903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187950		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Methotrexate		S	Oral		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Meloxicam		C	Oral		Not Reported
					Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15422020	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187400		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine "Roche"			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2018	15422027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown	4 Months		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	2 Years		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Oral	505 Days		Not Reported
	Advil	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Ketorolac	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	11883803	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1687418		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Every 2 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Orencia			S	Unknown				Not Reported
		Plaquenil			C					Not Reported
		Folic Acid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	13304194	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902139		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Vimovo			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	14391137	NON-EXPEDITED			US-PFIZER INC-2018018356		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Kevzara			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	14957396	EXPEDITED (15-DAY)		CA	DE-PFIZER INC-2018218299			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Microcephaly	Paracetamol			S	Transplacental	Gestational Week Of Exposure- 17-21		Unknown
	Sulfasalazine			S	Transplacental	Gestational Week Of Exposure- 0-17		Pfizer
	Diclofenac			S	Transplacental	100 Mg, As Needed, Geststional Week Of Exposure 0-19 + 4		Not Reported
	Hydroxychloroquine			S	Transplacental	Gestational Week Of Exposure- 0-13		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	14999674	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1742		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Systemic Lupus Erythematosus	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15320170	NON-EXPEDITED			US-PFIZER INC-2018343893			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer

	Tetracycline Hcl		S		Unk		Pfizer
	Arava		S		Unk		Not Reported
	Plaquenil		S		Unk		Not Reported
	Ridaura		S		Unk		Not Reported
	Methotrexate Sodium		S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15395391	NON-EXPEDITED			US-PFIZER INC-2018374962		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15408169	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180908328		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Apo-Leflunomide		S	Oral	Not Reported
	Apo-Prednisone		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Cymbalta		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422543	EXPEDITED (15-DAY)		DS	CA-ROCHE-2187429		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422546	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187437		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Venlafaxine Hydrochloride	S	Oral		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrodiuril	C	Unknown		Not Reported
	M-Eslon	C	Unknown	Extended Release	Not Reported
	Morphine	C	Unknown		Not Reported
	Statex (Canada)	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422631	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185224		27 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy	Prednisolone			S	Oral	20 Mg, Unk		Taro
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Sun
	Methylprednisolone			S	Intravenous (not otherwise specified)	40 Mg, Unk		Not Reported
	Lidocaine			C	Intravenous (not otherwise specified)	1 Mg/Kg/H, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422650	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187431		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422690	NON-EXPEDITED			US-AMGEN-USASP2018131354			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Depression; Photosensitivity Reaction; Therapy Non-Responder; Weight Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422694	NON-EXPEDITED			US-AMGEN-USASP2018131893			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15422796	EXPEDITED (15-DAY)		OT	MX-APPCO PHARMA LLC-2055302		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Amiodarone Hydrochloride			S	Intravenous bolus			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Warfarin Sodium			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15423275	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188671		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15423323	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003371		47 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucomatous Optic Disc Atrophy	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

	Prednisolone	C	Not Reported
	Bredinin	C	Not Reported
	Prograf	C	Not Reported
	Alfacalcidol	C	Not Reported
	Levothyroxine Sodium	C	Not Reported
	Loxonin	C	Not Reported
	Sertraline Hydrochloride	C	Not Reported
	Mirtazapine	C	Not Reported
	Sepazon	C	Not Reported
	Silece	C	Not Reported
	Loxoprofen Na	C	Not Reported
	Irsogladine Maleate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15423642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187976		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15423660	EXPEDITED (15-DAY)		OT	BR-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003381		51 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Ototoxicity; Tinnitus	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15423921	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187358		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Oral				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15425698	NON-EXPEDITED			US-PFIZER INC-2018385567		81 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189301		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189273		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189256		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426700	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189242		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Cyclobenzaprine		C	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Prednisone Acetate		C	Unknown	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426882	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188709		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported

	Furosemide			C	Unknown				Not Reported
	Estradiol			C	Unknown				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown				Not Reported
	Baclofen			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188695		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426944	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188674			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15426959	EXPEDITED (15-DAY)		HO	CA-ROCHE-2188651		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15427030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15427031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15427061	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188625		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Glaucoma; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15427116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188009		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Oral			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15427402	NON-EXPEDITED			US-SA-2018SA264194			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2018	15427699	NON-EXPEDITED			US-			Female	USA

						GLAXOSMITHKLINE-US2018GSK173121			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Loss Of Personal Independence In Daily Activities; Malaise; Nausea	Advair Diskus Inhalation Powder			S	Respiratory (inhalation)	Unk		Glaxosmithkline
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	14020021	NON-EXPEDITED			US-ALLERGAN-1733565US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Decreased	Zenpep			S	Unknown	Unk		Allergan
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	14425035	EXPEDITED (15-DAY)			PT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000290			Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisolone			S	Unknown			Concordia
	Prednisolone			S				Concordia
	Salbutamol Sulfate			S	Unknown			Not Reported
	Salbutamol Sulfate			S				Not Reported
	Dexamethasone Acetate			S	Unknown			Not Reported
	Dexamethasone Acetate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	14999162	NON-EXPEDITED			US-AMGEN-USASP2018077604		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Hypersensitivity; Drug Intolerance	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Levaquin			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15284232	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2018322751		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragmalgia; Dyspnoea; Fatigue; Headache; Lower Respiratory Tract Infection; Malaise; Nausea; Swollen Tongue	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Erelzi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15286418	EXPEDITED (15-DAY)			GR-BAUSCH-BL-2018-021477		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	Dose Reduced		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Adalimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15324350	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-948407		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragmalgia; Dyspnoea; Fatigue; Headache; Lower Respiratory Tract Infection; Malaise; Nausea; Swollen Tongue	Methotrexate			S	Unknown			Barr
	Erelzi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15406023	NON-EXPEDITED			US-PFIZER INC-2018375387		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil Sulfate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15422814	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-958063		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Diltiazem			S	Oral			Teva
	Lisinopril			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428140	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS		65 YR	Female	GBR

INC.-GSH201809-003384

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humera			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428142	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003364			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Persistent Corneal Epithelial Defect	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428144	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003388		71 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Spinal Compression Fracture	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Antebate			C				Not Reported
	Lidomex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428410	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189321			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Lyrica		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428554	EXPEDITED (15-DAY)		OT	CA-ROCHE-1704022		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug	Rituxan			S	Intravenous (not			Not Reported

Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity			otherwise specified)			
	Humira	S	Subcutaneous	Therapy Duration: 5 Years	Not Reported	
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 4 Years	Not Reported	
	Plaquenil	S	Oral		Not Reported	
	Plaquenil	S	Oral		Not Reported	
	Methotrexate	S	Unknown	Therapy Duration: 3 Years	Not Reported	
	Methotrexate	S	Unknown	Therapy Duration: 2 Years	Not Reported	
	Methotrexate	S	Unknown	Therapy Duration: 2 Months	Not Reported	
	Methotrexate	S	Unknown	Therapy Duration: 5 Years	Not Reported	
	Methotrexate	S	Unknown	Therapy Duration: 2 Years	Not Reported	
	Naproxen	C	Unknown		Not Reported	
	Sulfasalazine	C	Unknown		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428740	EXPEDITED (15-DAY)		LT, OT	DK-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003399		66 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Chest Discomfort; Dyspnoea; Leukopenia; Swollen Tongue	Plaquenil			S	Oral			Not Reported
	Alnok			C				Not Reported
	Panodil			C				Not Reported
	Ancozan			C				Not Reported
	Amlodipine			C				Not Reported
	Tradolan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15428746	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Plaquenil		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15429173	NON-EXPEDITED			US-PFIZER INC-2018383492		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15429190	NON-EXPEDITED			US-PFIZER INC-2018384890		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Diclofenac Sodium			S		Unk		Pfizer
	Misoprostol			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Nortriptyline			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15429497	EXPEDITED (15-DAY)		OT	BR-MYLANLABS-2018M1068926		51 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ototoxicity	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	13251480	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006674			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	13704441	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955227			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	14145039	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020351		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Marijuana			C	Unknown	Unk		Not Reported
	Oxycodone			C	Unknown	10 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Week		Not Reported
	Prednisone			C	Unknown	7 Mg, Qd		Not Reported

	Orencia			C	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15041261	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-176220		50 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pityriasis Lichenoides Et Varioliformis Acuta	Hydroxychloroquine			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15266547	EXPEDITED (15-DAY)		OT	PHHY2018ES068488		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Dolquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Lyophilized Powder)		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Dosage Form: Unspecified		Not Reported
	Enbrel			C	Unknown	50 Mg, Unk		Not Reported
	Lornoxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15320376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174131		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15338149	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019409			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15389656	NON-EXPEDITED			US-AMGEN-USASP2018126420			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15393736	NON-EXPEDITED		OT	US-SA-2018SA257865		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Enbrel			S	Subcutaneous	25 Mg, Biw		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, Biw		Not Reported
	Anakinra			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S				Sanofi
	Azathioprine			S				Not Reported
	Gold			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105473		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432629	EXPEDITED (15-DAY)		HO	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003400		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pustular Psoriasis	Plaquenil	S	Oral		Concordia
	Cardioaspirin	C			Not Reported
	Pantoprazole	C			Not Reported
	Totalip	C			Not Reported
	Losartan	C			Not Reported
	Tovanor Breezhaler	C			Not Reported
	Deltacortene	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432632	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189281		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432741	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189379		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C				Not Reported
	Fosamax			C	Unknown			Not Reported

	Ibuprofen		C	Unknown	Not Reported
	Lisinopril		C	Unknown	Not Reported
	Vitamin D3		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15432772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189338		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433343	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188705		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Potassium Chloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433428	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-958864		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate			S	Subcutaneous	Unk		Barr
	Methotrexate			S	Oral	Unk		Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humera			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189316		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Nausea; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433430	EXPEDITED (15-DAY)		DS	CA-ROCHE-2189318		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188016		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433551	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188673		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433665	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188663		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Therapy Non-Responder	Simponi			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Rituxan			C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433675	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189368		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433706	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189375		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433718	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS		51 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Bilateral; Deafness Neurosensory; Dysacusis; Ototoxicity; Tinnitus	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 5mg/Kg/Day		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15433730	EXPEDITED (15-DAY)		HO	CA-ROCHE-2188666		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15434135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189323		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15434158	EXPEDITED (15-DAY)		DE, HO	PHHY2018TR103290		49 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Exfoliative Rash; Generalised Tonic-Clonic Seizure; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Rash Maculo-Papular; Respiratory Failure; Skin Necrosis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Certolizumab Pegol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15434280	EXPEDITED (15-DAY)		OT	PHHY2018US104178		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypocomplementaemia; Maternal Exposure During	Metoprolol			S	Unknown			Novartis

Pregnancy; Pericardial Effusion; Premature Delivery; Product Use In Unapproved Indication; Proteinuria; Systemic Lupus Erythematosus	Metoprolol	S	Unknown	Increasing Doses	Novartis
	Tacrolimus	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	Increased Dose	Not Reported
	Furosemide	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Betamethasone	S	Unknown		Not Reported
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Prednisone	S	Unknown	60 Mg, Qd	Not Reported
	Enoxaparin	S	Unknown		Not Reported
	Aspirin	S	Unknown		Not Reported
	Epoprostenol	S	Unknown	2 Ng/Kg/Min	Not Reported
	Epoprostenol	S	Unknown	Titrated To 12 Ng/Kg/Min	Not Reported
	Methyldopa	S	Unknown		Not Reported
	Magnesium	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15434356	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2018-0009034		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15435631	EXPEDITED (15-DAY)		OT	PHHY2018US104185			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Metoprolol			S	Transplacental			Novartis
	Tacrolimus			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Enoxaparin			S	Transplacental			Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 15 Mg, Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 60 Mg, Qd		Not Reported
	Furosemide			S	Transplacental			Not Reported
	Betamethasone			S	Transplacental			Not Reported
	Epoprostenol			S	Transplacental			Not Reported
	Magnesium			S	Transplacental			Not Reported
	Aspirin			S	Transplacental			Not Reported
	Methyldopa			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15435970	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1070768		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15436086	EXPEDITED (15-DAY)		OT	PHHY2018GB103583			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine	S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15436429	NON-EXPEDITED			US-AMGEN-USASP2018133055			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15436727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189369		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15436824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190444			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190078		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Desoximetasone			C	Unknown				Not Reported
	Prednisone Acetate			C	Unknown				Not Reported
	Tylenol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437208	EXPEDITED (15-DAY)		DS	CA-ROCHE-2189380		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Peripheral Swelling; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190079		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz			S	Oral				Not Reported
	Advil			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Ketorolac			C	Unknown				Not Reported
	Naproxen			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437689	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190095			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189974			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437700	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190006		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437702	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189966		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190041		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190083		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2018	15437710	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188021		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	13250481	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006555		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Latent Tuberculosis; Rash; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Endocervical	40 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.I.W		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15065467	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009454		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Rheumatoid Arthritis; Therapeutic	Hydroxychloroquine			S	Oral			Apotex
	Leflunomide			S	Oral			Apotex
	Gold			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Product Effect Incomplete					otherwise specified)				
	Sulfasalazine			S	Rectal				Not Reported
	Methotrexate Sodium			S	Oral	12.5 Mg, Q.Wk.			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15332601	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP019358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15333540	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019383		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia ; Therapeutic Product	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported

Effect Incomplete	Sulfasalazine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15333549	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019363			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Estradot			S	Transdermal	Unk, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15333563	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk, Unknown		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15333565	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased;	Leflunomide			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	160 Mg, Q.Wk.		Not Reported

Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Arava	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Depo-Medrol	C	Unknown	80 Mg, Unk	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15333576	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019453		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Unknown	5 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Apotex
	Cimzia			S	Subcutaneous	200 Mg, One Every Two Weeks		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, One Every Two Weeks		Not Reported

	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15333883	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019373		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous	200 Mg, One Every Two Weeks		Not Reported
	Enbrel			S	Unknown	50 Unk, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg,One Every Two Weeks		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15334489	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019348			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide	S	Oral			Apotex
	Hydroxychloroquine	S	Oral			Apotex
	Azathioprine	C	Unknown			Not Reported
	Enbrel	C	Unknown			Not Reported
	Humira	C	Unknown			Not Reported
	Imuran /00001501/	C	Unknown			Not Reported
	Methotrexate	C	Unknown	Unk, Qd		Not Reported
	Orencia	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15334491	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019349			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15336898	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019522		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight;	Leflunomide			S	Oral	Unk, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk, Bid		Apotex

Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Humira	S	Subcutaneous	40 Mg, One Every Two Weeks		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Aspirin /00002701/	C	Unknown	Unk		Not Reported
	Clopidrogel Sandoz	C	Unknown	Unk		Not Reported
	Metoprolol	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported
	Ramipril	C	Unknown	Unk		Not Reported
	Rosuvastatin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15337626	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019553		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Fatigue; Hypersensitivity; Malaise; Nasal Congestion; Neuralgia; Pain In Extremity; Productive Cough; Rheumatoid Arthritis; Vision Blurred; Visual Impairment	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Folic Acid			C	Unknown	Unk, Qd		Not Reported
	Plaquenil /00072602/			C	Oral	200 Mg, Bid		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15338799	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019448		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug	Leflunomide			S	Oral	5 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex

Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Apotex
	Cimzia			S	Subcutaneous	200 Mg,One Every Two Weeks		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, One Every Two Weeks		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15345268	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018347291		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humera			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15411271	NON-EXPEDITED			US-PFIZER INC-2017504211		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer

	Sulfasalazine	S	Unk		Pfizer
	Hydroxychloroquine	S	Unk		Not Reported
	Plaquenil	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15423635	NON-EXPEDITED			US-PFIZER INC-2018384996			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Misuse	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		7.5 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15437911	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-047364		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Lisinopril			S	Oral	1 Df, Unk (Total)		Aurobindo
	Lisinopril			S	Oral	1 Df, Unk (Total)		Aurobindo
	Plaquenil /00072603/			S	Oral	1 Df, Unk (Total)		Not Reported
	Hydrochlorothiazide			S	Oral	1 Df, Unk (Total)		Not Reported
	Diltiazem			S	Oral	1 Df, Unk (Total)		Not Reported
	Diltiazem			S	Oral	1 Df, Unk (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438194	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189350		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Enbrel		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate Sodium		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		C		Not Reported
	Infliximab		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188634		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438613	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-06667			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic; Off Label	Hydroxychloroquine			S	Unknown	Unk		Lupin

Use; Rash

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438795	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190077		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15438834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15439610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190002		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15441426	EXPEDITED (15-DAY)		HO	CA-ROCHE-2190020		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15441436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191579		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			C	Unknown			Not Reported

	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15446355	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2017543722		75 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Ophthalmic Herpes Zoster	Enbrel			S		50 Mg, Every 7 Days		Pfizer
	Methotrexat Lederle			S		20 Mg, Weekly		Pfizer
	Azulfidine Ra			S		2000 Mg, Daily		Pfizer
	Hydroxychloroquine/Chloroquine			S		400 Mg, Daily		Not Reported
	Prednisolone			C	Oral	5 Mg, Daily		Not Reported
	Pregabalin			C				Not Reported
	Amitriptylin			C				Not Reported
	Rubiefol			C		Unk		Not Reported
	Quensyl			C		Unk		Not Reported
	Coaprovel			C		Unk		Not Reported
	L-Thyroxine [Levothyroxine Sodium]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Dorzocomp Vision			C		Unk		Not Reported
	Atorvastatin Calcium			C		Unk		Not Reported
	Celecoxib			C		Unk		Not Reported
	Dekristol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15447827	EXPEDITED (15-DAY)		OT	PHHY2018US104229		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dyspnoea; Fatigue; Fluid Overload; Maternal Exposure During	Ciclosporin			S	Oral	100 Mg, Bid		Novartis
	Ciclosporin			S	Oral	125 Mg, Qd		Novartis
	Prednisone			S	Oral	20 Mg, Qd		Not Reported

Pregnancy; Premature Delivery; Productive Cough; Rhinorrhoea	Methylprednisolone			S	Intravenous (not otherwise specified)	16 Mg, Qd		Not Reported
	Ursodeoxycholic Acid			S	Oral	300 Mg, Tid		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Labetalol			S	Oral	400 Mg, Bid		Not Reported
	Furosemide			S	Unknown	80 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Not Reported
	Vancomycin			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported
	Levothyroxine			S	Oral	150 Mg, Qd		Not Reported
	Aspirin			S	Oral	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15447852	EXPEDITED (15-DAY)		OT	PHHY2018US104239			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Transplacental	Maternal Dose: 3 G, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg, Qd		Not Reported
	Ursodeoxycholic Acid			S	Transplacental	Maternal Dose: 300 Mg, Tid		Not Reported
	Labetalol			S	Transplacental	Maternal Dose: 400 Mg, Bid		Not Reported
	Furosemide			S	Transplacental	Maternal Dose: 80 Mg, Qd		Not Reported
	Vancomycin			S	Transplacental			Not Reported
	Ceftriaxone			S	Transplacental			Not Reported
	Methylprednisolone			S	Transplacental	Maternal Dose: 16 Mg, Qd		Not Reported
	Ciclosporin			S	Transplacental	Maternal Dose: 100 Mg,		Not Reported

				Bid	
Aspirin	S	Transplacental	Maternal Dose: 81 Mg, Qd		Not Reported
Calcium	S	Transplacental			Not Reported
Vitamin D	S	Transplacental			Not Reported
Levothyroxine	S	Transplacental	Maternal Dose: 150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15447871	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2018-0009019		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Dilaudid			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15448177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189359		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Increased;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Orencia	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2018	15459611	DIRECT	Y				55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2018	15366301	NON-EXPEDITED		OT	US-SA-2018SA248947			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S	Unknown	Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			C	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2018	15448235	EXPEDITED (15-DAY)		CA, OT	US-AUROBINDO-AUR-APL-2018-047993			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Murmur; Foetal Exposure During Pregnancy; Hydrocele; Jaundice Neonatal	Celecoxib			S				Aurobindo
	Methylprednisolone			S	Transplacental	Unk		Aurobindo
	Anakinra			S	Transplacental	100 Milligram, Daily		Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

	Hydroxychloroquine		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	13319241	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902165		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	14527089	EXPEDITED (15-DAY)		OT	IE-MYLANLABS-2018M1009569		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective For Unapproved Indication; Leukopenia; Off Label Use; Skin Atrophy	Clobetasol			S	Topical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid, 400 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Prednisolone			S				Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Tacrolimus			S	Topical	Unk		Not Reported
	Protopic			S	Topical	Unk		Mylan

	Fluconazole			C	Unknown	Unk			Mylan
	Co-Trimoxazole			C	Unknown	Unk			Mylan
	Efavirenz			C	Unknown	Unk			Mylan
	Lamivudine + Zidovudine			C		Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15333564	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019392			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15337632	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019421		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect	Leflunomide			S	Unknown	5 Mg, Therapy Duration 365		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Apotex
	Cimzia			S	Subcutaneous	200 Mg, Cyclical		Not Reported

Decreased; Tuberculin Test Positive	Enbrel	S	Unknown	50 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Methotrexate	S	Unknown	5 Mg, Unk		Not Reported
	Orencia	S	Unknown	750 Mg, Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Prednisone	C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15385224	NON-EXPEDITED			US-SA-2018SA022554			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil Sulfate			S				Sanofi
	Actemra			C	Unknown	Unk Unk,Unk		Not Reported
	Orencia			C	Unknown	Unk Unk,Unk		Not Reported
	Remicade			C	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15395182	NON-EXPEDITED			US-PFIZER INC-2018376760			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported

	Orencia			S	Unknown	Unk				Not Reported
	Plaquenil			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15426519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium			C				Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15426893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib	S	Subcutaneous	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15429508	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188704		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Advil			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15433581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190058			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Codeine			C				Not Reported
	Darifenacin Hydrobromide			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Hydromorphone			C				Not Reported
	Kenalog (Canada)			C	Intra-articular			Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C				Not Reported
	Oxyneo			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported

					Remicade	C	Unknown		Not Reported
					Restasis	C	Unknown		Not Reported
					Synthroid	C			Not Reported
					Trimethoprim	C	Unknown		Not Reported
					Urispas	C	Unknown		Not Reported
					Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15448829	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA109603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Vitamin C			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191560		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Impairment	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191552		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449271	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449287	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190756		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

		Prednisone			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449428	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192176		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449435	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190738		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Folic Acid			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449486	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191566		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449555	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191578		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

		Enbrel			S	Subcutaneous				Not Reported
		Hydroxychloroquine			S	Oral				Not Reported
		Methotrexate			S	Intramuscular				Not Reported
		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Naprosyn			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449578	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449615	NON-EXPEDITED		OT	US-AMGEN-USASP2018134447			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Interstitial Lung Disease	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449783	EXPEDITED (15-DAY)		HO	CA-ROCHE-2191534		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15449845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190751		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450114	NON-EXPEDITED			US-PFIZER INC-2018392643		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Asa			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Plavix			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Carvedilol			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Norco			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450229	NON-EXPEDITED			US-PFIZER INC-2018389076			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15450369	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Hydroxychloroquine	S	Oral			Not Reported
	Methotrexate	S	Oral			Not Reported
	Folic Acid	C	Unknown	Dosage Forms : 1.0		Not Reported
	Prednisone	C	Unknown			Not Reported
	Simponi	C	Subcutaneous			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451397	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1070118		45 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2018	15451403	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1070112		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	14924491	EXPEDITED (15-DAY)		HO, OT	US-QILU PHARMACEUTICAL CO.LTD.-QLU-000375-2018		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypotension; Torsade De Pointes; Ventricular Arrhythmia; Ventricular	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Unk		Qilu Pharmaceutical
	Hydroxychloroquine			S	Unknown	4 Df, Unk		Not Reported

Extrasystoles; Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	14957430	EXPEDITED (15-DAY)		OT	GB-ABBVIE-18K-167-2368857-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Ceclor			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pethidine Hydrochloride			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cefaclor			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	14962580	NON-EXPEDITED			US-PFIZER INC-2018223269		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15232233	NON-EXPEDITED			US-PFIZER INC-2018309570			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		12.5 Mg, Weekly		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15276542	EXPEDITED (15-DAY)		OT	GB-HORIZON-PRE-0367-2018		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown			Not Reported
	Leflunomide Sandoz			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported

	Arava	S				Not Reported
	Plaquenil	S	Oral	400 Mg, Unk		Not Reported
	Bisoprolol Fumarate	S	Unknown			Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
	Celebrex	S	Oral	200 Mg, Qd		Not Reported
	Ceclor	S				Not Reported
	Norfloxacin	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Demerol	S	Unknown			Not Reported
	Erythromycin	S				Not Reported
	Methotrexate	S				Not Reported
	Meperidine Hydrochloride	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15425271	NON-EXPEDITED			US-SA-2018SA265642			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15453997	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191531		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Cellcept		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Lyrica		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454102	EXPEDITED (15-DAY)		HO	CA-ROCHE-2189300		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454179	NON-EXPEDITED			US-AMGEN-USASP2018135977			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454353	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191564		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192233		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454407	NON-EXPEDITED			US-AMGEN-USASP2018123972			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear Of Injection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	7.5 Mg, Qwk (3 Tab Week)		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454414	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Neomycin Sulfate	S	Unknown		Not Reported
	Polymyxin B Sulfate	S	Unknown		Not Reported
	Prednisone	C	Intramuscular		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454776	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190744		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C				Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15454846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191580		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Eye Disorder; Fatigue	Actemra		S	Unknown		Not Reported
	Apo-Acetaminophen		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Dilaudid		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15455313	EXPEDITED (15-DAY)		OT	PHHY2018FR106109		3 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Product Use In Unapproved Indication; Therapeutic Response Decreased	Ciclosporin			S	Unknown			Novartis
	Rituximab			S	Intravenous drip			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	1.5 Mg/Kg, Qd		Not Reported
	Prednisone			S	Unknown	2 Mg/Kg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15455642	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1071114			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	Maternal Dose: 200 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15455805	NON-EXPEDITED			PHEH2018US040197			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperreflexia; Muscular Weakness; Nerve Conduction Studies Abnormal	Hydroxychloroquine Sandoz	S	Unknown	200 Mg, Bid	Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15456597	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018394285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Acetaminophen			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Indomethacin [Indometacin]			S		Unk		Not Reported
	Plaquenil Sulfate			S		Unk		Not Reported
	Prednisone			S		12.5 Mg, 1x/Day		Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Statex [Morphine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15457452	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2503812-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Pain In	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	For Several Years		Not Reported

Extremity; Peripheral Swelling; Surgery; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide		S	Unknown	For 2 Years	Not Reported
	Enbrel		S	Unknown	For 6 Years	Not Reported
	Arava		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15457481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown	Spray, Metered Dose		Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Plantago Ovata			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Vaginal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2018	15457495	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190757		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	13233258	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001051		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral	Twice A Day		Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Atenolol			S	Unknown			Not Reported
	Folic Acid			S	Unknown	Twice A Week		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Palafer Cf			S	Unknown			Not Reported

	Pantoprazole		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Celebrex		C		Not Reported
	Prednisone		C		Not Reported
	Celecoxib		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	13775859	NON-EXPEDITED			US-AMGEN-USASP2017107518		36 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Drug Hypersensitivity; Finger Deformity; Furuncle; Infection; Lasegue'S Test Positive; Oral Infection; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Gabapentin			S	Oral	600 Mg, Tid (300 Mg 2)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15147694	NON-EXPEDITED			US-PFIZER INC-2018284079		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown

	Hydroxychloroquine			S		Unk				Not Reported
	Methotrexate			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15283001	EXPEDITED (15-DAY)		OT	GB-FLAMINGO-002010		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S				Not Reported
	Bisoprolol			S				Not Reported
	Lyrica			S				Not Reported
	Norfloxacin/Norfloxacin Hydrochloride			S				Not Reported
	Demerol			S				Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Ceclor			S				Not Reported
	Arava			S				Not Reported
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported
	Erythromycin			S				Not Reported
	Leflunomide Sandoz			S				Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Erythro			S				Not Reported
	Meperidine			S				Not Reported
	Arthrotec			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S				Not Reported
	Levofloxacin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15330303	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported

Incomplete	Methotrexate	S	Oral	10 Mg, Qd		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15333539	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019380		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Surgery	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Indometacin			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15334490	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019353			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15354006	NON-EXPEDITED			US-AMGEN-USASP2018121159			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Infection; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15368621	EXPEDITED (15-DAY)			US-ABBVIE-18K-163-2477917-00		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Ocular Toxicity; Rheumatoid Arthritis; Toxicity To Various Agents	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Cymbalta			C				Not Reported
	Cymbalta			C				Not Reported
	Lisinopril			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457508	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190728		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Joint	Actemra			S	Subcutaneous			Not Reported

Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Not Reported
	Folic Acid	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457625	NON-EXPEDITED			US-AMGEN-USASP2018135810			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Injection Site Reaction; Nasal Ulcer; Rash; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457658	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192228		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate		S	Intramuscular	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Naprosyn		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457719	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191504		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191535		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Glaucoma; Synovitis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Potassium Chloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191494		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457791	NON-EXPEDITED			US-AMGEN-USASP2018135609			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported

			Plaquenil	S	Unknown	Unk			Not Reported
			Methotrexate	C	Unknown	Unk			Not Reported
			Arava	C	Unknown	Unk			Not Reported
			Sulfasalazine	C	Unknown	Unk			Not Reported
			Simponi	C	Unknown	Unk			Not Reported
			Humira	C	Unknown	Unk			Not Reported
			Xeljanz	C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457792	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192189			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457827	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003402		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia; Visual Impairment	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			C				Not Reported

Acidex	C	Not Reported
Ondansetron	C	Not Reported
Methadone	C	Not Reported
Calcichew D3	C	Not Reported
Pregabalin	C	Not Reported
Paracetamol	C	Not Reported
Ranitidine	C	Not Reported
Cassia Senna	C	Not Reported
Co-Amoxiclave	C	Not Reported
Salbutamol	C	Not Reported
Lansoprazole	C	Not Reported
Cyclizine	C	Not Reported
Metoclopramide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457854	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003422		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Retinal Depigmentation; Retinal Disorder; Retinal Disorder; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Daily Dosing Based On Actual Body Weight Was 7.1 Mg/Kg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15457855	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003420		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Telangiectasia; Retinopathy; Toxicity To Various Agents	Plaquenil			S	Unknown	Based On Actual Body Weight Was 6.8 Mg/Kg/Day For 38 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189257			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192139		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)			
	Sulfasalazine		C	Unknown			Not Reported
	Wellbutrin		C	Unknown	Extended Release Tablet		Not Reported
	Xeljanz		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458244	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190730		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458520	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003435			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Joint Swelling; Localised Infection; Osteomyelitis	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz Xr			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458550	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192203		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15458830	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2018177181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Glaxosmithkline
	Acetylsalicylic Acid			S	Unknown	Unk		Glaxosmithkline
	Vitamin C			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Naprosyn			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Tramadol			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15459083	EXPEDITED (15-DAY)		OT	PHHY2018CA113219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15459416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189322		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15459456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15459554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189366		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Xeljanz		S	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15460283	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201809012403		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Feeling Hot; Gait Inability; Immunisation Reaction; Loss Of Personal Independence In Daily Activities; Ocular Vascular Disorder; Off Label Use; Ophthalmic Vein Thrombosis; Pain; Pain In Extremity; Pyrexia; Therapeutic Response Decreased; Thrombosis; Vaccination Complication	Cymbalta			S	Unknown	Unk, Unknown		Not Reported
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly (1/W)		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Zostavax			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			C	Oral	20 Mg, Weekly (1/W)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15461175	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2018-0009020		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

			Hydroxychloroquine		S	Unknown	Unk		Not Reported
			Methotrexate Sodium		S	Subcutaneous	25 Mg, 1 Every 1 Week		Not Reported
			Prednisone		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15461201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192198		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15461380	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15461406	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192236		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15461408	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192188		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Prefilled Syringe - Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2018	15462018	NON-EXPEDITED			US-AMGEN-USASP2018136405			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	14719527	NON-EXPEDITED			US-PFIZER INC-2018137570		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15082735	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018092825		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Nodule	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil /00072603/			S		400 Mg, Daily		Not Reported
	Folic Acid			C		5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15328852	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003126		29 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15328853	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003127		28 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Memory Impairment	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15333734	NON-EXPEDITED			US-SA-2018SA242233			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15337647	EXPEDITED (15-DAY)		OT	CA-BAXTER-2018BAX022567		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified.		Baxter
	Cellcept			S	Oral	Dosage Form: Not Specified.		Not Reported
	Cellcept			S				Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Dosage Form: Tablet		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous.		Not Reported
	Rituxan			S				Not Reported
	Cymbalta			C	Unknown	Dosage Form: Not Specified.		Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15462462	EXPEDITED (15-DAY)		DS, OT	IE-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003425		66 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Plaquenil			S	Unknown			Not Reported
	Surmontil			C				Not Reported
	Paroxetine			C				Not Reported
	Folic Acid			C				Not Reported
	Tramadol			C				Not Reported
	Pantoprazole			C				Not Reported
	Arthrotec			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15462478	NON-EXPEDITED			US-AMGEN-USASP2018136407			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15462575	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192211		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15462777	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Acetaminophen		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Indomethacin		S	Unknown	Not Reported
	Plaquenil Sulfate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Statex (Morphine Sulfate)		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15463132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192238		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate			S	Unknown			Not Reported

	Hydroxychloroquine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15463331	NON-EXPEDITED			US-PFIZER INC-2018395498		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15463846	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Leflunomide			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15464074	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2018-015284		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Bausch And Lomb
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported

	Celebrex	S	Oral		Not Reported
	Demerol	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Erythro Base	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Meperidine Hydrochloride	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Norfloxacin	S	Unknown		Not Reported
	Levofloxacin Hemihydrate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15465355	NON-EXPEDITED			US-SA-2018SA012890		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz			C	Oral	Twice Daily 11 Mg Po, Quantity 30 For 30 Days, Onetime Trial 11 Mg, Po, Bid (14 Days, 14 Tablets), I		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2018	15465534	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-959299		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity;	Methotrexate			S	Unknown			Barr

Treatment Failure	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	13734669	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-17K-163-1835818-00		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Discomfort; Fatigue; Frustration Tolerance Decreased; General Physical Health Deterioration; Hip Fracture; Lower Limb Fracture; Malaise; Myalgia; Osteoarthritis; Osteoporosis; Pain; Pathological Fracture; Pneumonia; Sensitivity To Weather Change; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Calcium			C				Not Reported
	Provera			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	14875227	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126522		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Unk		Sanofi
	Plaquenil			S	Oral	400 Mg,Unk		Sanofi
	Arava			S	Oral	10 Mg,Qd		Sanofi
	Methotrexate			S	Oral	Unk Unk,Unk		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Metformin Hydrochloride			S				Not Reported

Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)	1 Df,Qm	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Enbrel	S	Subcutaneous	20 Mg,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg,Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
	Lantus	C	Subcutaneous	Unk Unk,Unk	Not Reported
	Indapamide	C	Unknown	Unk Unk,Unk	Not Reported
	Naproxen	C	Unknown	Unk Unk,Unk	Not Reported
	Prednisone	C	Unknown	Unk Unk,Unk	Not Reported
	Acetylsalicylic Acid	C		81 Mg	Not Reported
	Calcium Carbonate/Vitamin D3	C			Not Reported
	Ergocalciferol	C			Not Reported
	Ramipril	C			Not Reported
	Vitamin D3	C			Not Reported
	Xeljanz	C			Not Reported
	Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	14875538	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126619			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Arava			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Qw		Not Reported

	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	14875637	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126781		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Oral	200 Mg,Qd		Sanofi
	Leflunomide			S	Oral	20 Mg,Qow		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg,Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg,Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Methotrexate			S	Oral	12.5 Mg,Unk		Not Reported
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported
	Methotrexate			S	Oral	12.5 Mg,Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg,Qm		Not Reported
	Xeljanz			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15330299	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019510		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash;	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex

Synovitis	Enbrel			S	Unknown	Unk				Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk				Not Reported
	Methotrexate			S	Subcutaneous	Unk				Not Reported
	Methotrexate			S	Oral	Unk				Not Reported
	Methotrexate			S	Parenteral	Unk				Not Reported
	Orencia			S	Unknown	Unk				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Tofacitinib			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15399924	EXPEDITED (15-DAY)		OT	IT-ALVOGEN-2018-ALVOGEN-097405		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Lisinopril			S	Oral	1.0 Df Once/Single Administration		Not Reported
	Diltiazem			S	Oral	1.0df Once/Single Administration		Not Reported
	Hydrochlorothiazide			S	Oral	1.0df Once/Single Administration		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	1.0df Once/Single Administration		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15450274	NON-EXPEDITED			US-PFIZER INC-2018392870		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15466599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192235		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15467409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192177		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15467728	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-06790		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Pigment Epitheliopathy	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 6.8 Mg/Kg/Day)		Lupin
	Hydroxychloroquine			S				Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15467729	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-06807		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Depigmentation	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 7.1 Mg/Kg/Day)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15467730	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-06805		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Pigment Epitheliopathy	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 5.4 Mg/Kg/Day)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15467738	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-06806		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Pigment Epitheliopathy	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 4.5 Mg//Kg/Day)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15468289	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126582		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence; Pulmonary Hypertension; Tricuspid Valve Incompetence	Hydroxychloroquine Sulfate			S	Oral	200 Mg,Bid		Sanofi
	Amlodipine Besilate			S	Oral	5 Mg,Bid		Not Reported
	Bisoprolol Salt Not Specified			S	Oral	5 Mg,Bid		Not Reported
	Hydrochlorothiazide			S	Oral	12.5 Mg,Qd		Not Reported
	Irbesartan			S	Oral	300 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	400 Mg,Bid		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15468295	EXPEDITED (15-DAY)		OT	CA-SA-2018SA263212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil Sulfate	S	Unk		Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15468656	EXPEDITED (15-DAY)		HO, OT	AU-APOTEX-2018AP021671		53 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Subacute Cutaneous Lupus Erythematosus; Toxic Epidermal Necrolysis	Ramipril			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S				Apotex
	Prednisolone			C	Unknown	12.5 Mg, Daily		Not Reported
	Prednisolone			C	Unknown	50 Mg, Unk,Daily		Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15468696	EXPEDITED (15-DAY)		OT	CA-SA-2018SA097760		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Adalimumab			S	Unknown	Unk Unk,Unk		Not Reported
	Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Etanercept			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S		Unk Unk, Qw		Not Reported
	Prednisone			C	Intramuscular	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15469651	NON-EXPEDITED			US-SA-2018SA275200			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Urticaria	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15470534	EXPEDITED (15-DAY)		OT	PHHY2018CA114485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk (Die)		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk (Die)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2018	15498144	DIRECT	Y				75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinusitis	Hydroxychloroquine 200 Mg Tab			S	Oral			Unknown
	Methotrexate 2.5 Mg Tablet,			S	Oral			Unknown
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2018	15099931	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002229		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Delusional Disorder, Unspecified Type	Hydroxychloroquine			S	Oral			Not Reported
	Prednisolon			C				Not Reported
	Sulfasalazin			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	14311775	EXPEDITED (15-DAY)		DE, LT	BR-ROCHE-2044921		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Histoplasmosis Disseminated; Multiple Organ Dysfunction Syndrome	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	14608007	EXPEDITED (15-DAY)		HO, OT	RO-GLAXOSMITHKLINE-RO2018036686		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Acetylsalicylic Acid			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	150 Mg, Daily		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Clopidogrel			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	5 Mg, Unk		Glaxosmithkline
	Methotrexate			S	Unknown	30 Mg, Qwk		Glaxosmithkline
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	1 G, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15206979	NON-EXPEDITED			US-AMGEN-USASP2018100247			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Treatment Failure	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15211974	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2431206-00		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15326508	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1841381US		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Arthritis; Atelectasis; Bipolar Disorder; Bursitis; Cholecystectomy; Conjunctivitis; Crepitations; Cushingoid; Depression; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Endometrial Ablation; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Fracture; Hypothyroidism; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenderness; Tenosynovitis Stenosans; Thrombosis; Ulcer; Visual Impairment; Wheezing; Wisdom Teeth Removal	Actonel	S	Unknown		Allergan
	Alendronic Acid	S	Unknown	Tablet	Not Reported
	Amitriptyline	S	Oral	75 Mg, Qd	Not Reported
	Meloxicam	S			Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Q Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Naproxen	S	Oral	500 Mg, Bid	Not Reported
	Naproxen	S	Oral	1000 Mg, Qd	Not Reported
	Naproxen	S		1000 Mg, Qd	Not Reported
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Ranitidine	S	Oral	150 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q Week	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q Week	Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Oral		Not Reported
	Depo Medrol	S	Intra-articular		Not Reported
	Methylprednisolone Acetate	S	Intra-articular		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Imuran	S	Unknown	150 Mg, Unk	Not Reported
	Lyrica	S	Oral	300 Mg, Qd	Not Reported
	Septra	S			Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Vimovo	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Pantoprazole	S	Oral		Not Reported
	Methylprednisolone	S	Intra-articular		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
	Azathioprine	S	Unknown	150 Mg, Unk	Not Reported

	Pregabalin			S	Oral	300 Mg, Qd	Not Reported
	Tofacitinib Citrate			S	Oral	10 Mg, Qd	Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Unknown		Not Reported
	Esomeprazole W/Naproxen			S	Unknown		Not Reported
	Apo-Alendronate			S	Unknown		Not Reported
	Apo-Amitriptyline			S	Oral	75 Mg, Qd	Not Reported
	Apo-Meloxicam			S	Unknown		Not Reported
	Apo-Naproxen			S	Oral	500 Mg, Bid	Not Reported
	Apo-Naproxen			S	Oral	250 Mg, Bid	Not Reported
	Apo-Prednisone			S	Unknown	15 Mg, Qd	Not Reported
	Apo-Ranitidine			S	Oral	150 Mg, Qd	Not Reported
	Risedronic Acid			S	Unknown		Not Reported
	Hydroxychloroquine Phosphate			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15333912	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019346			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S	Unknown			Apotex
	Azathioprine			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15367985	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082216		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Liver Injury	Blinded Apixaban			S	Unknown	2.5 Mg, Unk		Bristol Myers Squibb
	Blinded Aspirin			S	Unknown	2.5 Mg, Unk		Bristol Myers Squibb
	Blinded Placebo			S	Unknown	2.5 Mg, Unk		Bristol Myers Squibb
	Sertraline			S	Unknown			Unknown
	Hydroxychloroquine Sulfate			S	Unknown			Unknown
	Varenicline			S	Unknown			Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15427798	NON-EXPEDITED			US-AMGEN-USASP2018132072			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection	Enbrel			S	Subcutaneous	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15442902	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018385750		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Celebrex	S	Oral	200 Mg, Qd		Pfizer
	Arthrotec	S				Pfizer
	Erythromycin	S				Pfizer
	Levofloxacin	S				Pfizer
	Metronidazole	S				Pfizer
	Methotrexate Sodium	S				Pfizer
	Lyrica	S				Pfizer
	Sulfasalazine	S				Pfizer
	Meperidine Hcl	S				Unknown
	Demerol	S				Pfizer
	Prednisone	S				Not Reported
	Humira	S	Subcutaneous	400 Mg		Not Reported
	Bisoprolol Fumarate	S				Not Reported
	Ceclor	S				Not Reported
	Leflunomide	S				Not Reported
	Norfloxacin	S				Not Reported
	Arava	S				Not Reported
	Erythro Base	S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15454774	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1088		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Gait Inability; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15471867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Phthalylsulfathiazole			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Pseudoephedrine Hcl			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15472570	EXPEDITED (15-DAY)		OT	IT-LUPIN PHARMACEUTICALS INC.-2018-06972		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Retinogram Abnormal	Hydroxychloroquine			S	Unknown	1.2 Mg/ Kg/ Day		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15472784	NON-EXPEDITED			US-PFIZER INC-2018400073		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15472834	NON-EXPEDITED			US-PFIZER INC-2018402617			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Codeine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15472875	NON-EXPEDITED			US-PFIZER INC-2018402410			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Simponi			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Xeljanz			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15473367	NON-EXPEDITED			US-PFIZER INC-2018400662		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15473786	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1072090		22 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Candidiasis	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2018	15474931	EXPEDITED (15-DAY)		HO	CA-ROCHE-2190763		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Loperamide Hydrochloride			C	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Trazodone Hydrochloride			C	Oral					Not Reported
	Tylenol			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15245422	EXPEDITED (15-DAY)		OT	CA-SA-2018SA210980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			C		2 G		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Effexor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15246480	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2018M1057910			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Separation Of Placenta	Hydroxychloroquine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15373746	NON-EXPEDITED		OT	US-PFIZER INC-2018364255		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Renal Failure; Urinary Tract Infection	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15472755	NON-EXPEDITED			US-PFIZER INC-2018395500		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15476518	EXPEDITED (15-DAY)		HO	US-ROCHE-2191946		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Infective Therapy; Infection	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Augmentin			C	Unknown			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Indomethacin			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15480375	NON-EXPEDITED			US-AMGEN-USASP2018138731			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2018	15504923	DIRECT		OT			58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blister; Dry Eye; Nail Disorder; Paraesthesia Oral; Rash; Skin Exfoliation; Stevens-Johnson Syndrome	Plaquenil	Y		S	Oral	Quantity:1 Tablet(S);		Actavis
	Benicar			C				Not Reported
	Buspar			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Multivitamin			C				Not Reported
	Fish Oil			C				Not Reported
	Vitamin E			C				Not Reported
	Tumeric			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	13213848	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA019842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Gold			S	Unknown	Unk Unk,Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk Unk,Unk		Not Reported
	Eve Outer Tape [Diclofenac Sodium]			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Ibuprofen			S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	13266498	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX007297		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole 5mg/Ml Injection	S	Unknown		Baxter
	Arava	S	Unknown	Tablet	Not Reported
	Arthrotec	S	Unknown		Not Reported
	Bisoprolol	S	Unknown		Not Reported
	Bisoprolol Fumarate	S	Unknown	Tablet	Not Reported
	Ceclor	S	Unknown	Dosage Form Not Specified	Not Reported
	Celebrex	S	Oral		Not Reported
	Demerol	S	Unknown	Dosage Form Not Specified	Not Reported
	Erythromycin Estolate	S	Unknown	Dosage Form Not Specified	Not Reported
	Erythromycin	S	Unknown	Dosage Form Not Specified	Not Reported
	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Levofloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
	Levofloxacin	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Meperidine Hydrochloride	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Norfloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
	Plaquenil	S	Unknown	Tablet	Not Reported
	Plaquenil	S	Oral	Tablet	Not Reported
	Prednisone	S	Unknown	Dosage Form Not Specified	Not Reported
	Sulfasalazine	S	Unknown	Dosage Form Not Specified	Not Reported
	Erythro Base	S	Unknown		Not Reported

	Methotrexate	S	Unknown			Not Reported
	Levofloxacin Hemihydrate	S	Unknown			Not Reported
	Cefaclor	S	Unknown			Not Reported
	Pregabalin	S	Unknown			Not Reported
	Celecoxib	S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	14675127	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020200		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	500 Mg,Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg,Bid		Not Reported
	Atenolol			S		25 Mg,Qd		Not Reported
	Folic Acid			S	Unknown	5 Mg,Biw		Not Reported
	Methotrexate			S	Oral	25 Mg,Qow		Not Reported
	Methotrexate			S	Oral	20 Mg,Qow		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Naproxen			S	Oral	500 Mg,Bid		Not Reported
	Naproxen			S	Oral	1000 Mg, Qd		Not Reported
	Palafer Cf			S		1 Df,Qd		Not Reported
	Pantoprazole			S		40 Mg,Qd		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S		Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Mg,Qd		Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Celecoxib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	14904936	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001619		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitral Valve Incompetence; Pulmonary Hypertension; Tricuspid Valve Incompetence	Hydroxychloroquine			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Bisoprolol			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15292025	EXPEDITED (15-DAY)			GB-AUROBINDO-AUR-APL-2018-041913		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Bisoprolol Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S		()		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S		()		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Arthrotec			S		()		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Ceclor			S		()		Not Reported
	Celebrex			S	Oral	200 Milligram, Daily		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported

Demerol	S	Unknown	Unk	Not Reported
Demerol	S		()	Not Reported
Erythro Base	S	Unknown	Unk	Not Reported
Erythro Base	S		()	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
Humira	S	Subcutaneous	400 Mg	Not Reported
Leflunomide Sandoz	S	Unknown	Unk	Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
Levofloxacin Hemihydrate	S		()	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Lyrica	S		()	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S		()	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Norfloxacin	S		()	Not Reported
Pethidine Hydrochloride	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S		()	Not Reported
Plaquenil /00072603/	S	Oral	400 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S		()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15343621	NON-EXPEDITED			US-PFIZER INC-2018350892			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Morphine Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

		Dilaudid			S		Unk			Not Reported
		Gold			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15416905	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-18_00004524		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15481041	NON-EXPEDITED			US-AMGEN-USASP2018140967			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15482733	EXPEDITED (15-DAY)		OT	RO-IMPAX LABORATORIES, INC-2018-IPXL-03311		55 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryoglobulinaemia; Drug Ineffective For Unapproved Indication	Acitretin			S	Unknown	Unk		Impax
	Acitretin			S				Impax
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15482849	NON-EXPEDITED			US-SA-2018SA277926			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance; Unevaluable Event	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Qd		Sanofi
	Cellcept [Mycophenolate Mofetil Hydrochloride]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15482913	NON-EXPEDITED			US-PFIZER INC-2018406254		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

	Prednisone	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
	Meloxicam	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2018	15485559	EXPEDITED (15-DAY)		OT	PHHY2018PT118019			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	13669472	EXPEDITED (15-DAY)		OT	CA-SA-2017SA106116		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Synovitis	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Avapro			C	Unknown	Unk Unk,Unk		Not Reported
	Humalog			C	Unknown	Unk Unk,Unk		Not Reported
	Insulin			C	Unknown	Unk Unk,Unk		Not Reported
	Lantus			C	Unknown	Unk Unk,Unk		Not Reported
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14466516	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2237732-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Osteoarthritis; Pain; Physical Disability; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; White Blood Cell Count Increased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14762087	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001262		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Azathioprine			S	Intramuscular			Not Reported
	Etanercept			S	Unknown			Not Reported

			Methotrexate			S	Subcutaneous			Not Reported
			Sulfasalazine			S	Oral			Not Reported
			Orencia			S	Unknown			Not Reported
			Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14831557	NON-EXPEDITED		OT	US-AMGEN-USASP2018056617			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastrointestinal Disorder; Liver Function Test Abnormal; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14906926	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001643		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Toxicity	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14906941	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001650		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Plaquenil Tablet			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14908645	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Plaquenil Tablet			S	Oral			Not Reported
	Silver			S	Unknown			Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Benzylpenicillin Sodium			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Tylenol			C				Not Reported
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	14941543	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001698		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Coronary Artery Bypass; Depression; Drug Ineffective; Dyspnoea; Osteomyelitis;	Plaquenil			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported
	Mtx			S				Not Reported
	Enbrel			S	Unknown	Unknown Formulation		Not Reported

Paraesthesia; Toe Operation	Xeljanz			S	Unknown				Not Reported
	Xeljanz			S					Not Reported
	Humira			S	Subcutaneous				Not Reported
	Orencia			S	Unknown				Not Reported
	Actemra			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported
	Xeljanz Xr			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15396397	EXPEDITED (15-DAY)			CA-PFIZER INC-2018259952		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Oral	15 Mg (Varied Doses), Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil /00072603/			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15482360	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-PFIZER INC-2018363848		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Liver Injury	Apixaban			S	Unknown	2.5 Mg, Unk		Not Reported
	Sertraline Hcl			S		Unk		Pfizer
	Varenicline Tartrate			S		Unk		Pfizer
	Placebo			S	Unknown	2.5 Mg, Unk		Not Reported
	Aspirin			S	Unknown	2.5 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Duloxetine			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15489430	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018405998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	2000 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20.0 Mg, 1x/Day		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200.0 Mg, 2x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Celebrex			C	Oral	200 Mg, 2x/Day		Not Reported
	Hydromorphone Hydrochloride			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Weekly		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2018	15490428	EXPEDITED (15-DAY)		OT	CA-MAYNE PHARMA-2018MYN001451			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Erythromycin	S				Mayne
	Celebrex	S	Oral	200 Mg, Qd		Not Reported
	Lyrica	S				Not Reported
	Metronidazole	S				Not Reported
	Levofloxacin	S				Not Reported
	Arthrotec	S				Not Reported
	Methotrexate Sodium	S				Not Reported
	Sulfasalazine	S				Not Reported
	Meperidine Hydrochloride	S				Not Reported
	Demerol	S				Not Reported
	Prednisone	S				Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
	Bisoprolol Fumarate	S				Not Reported
	Ceclor	S				Not Reported
	Leflunomide	S				Not Reported
	Norfloxacin	S				Not Reported
	Arava	S				Not Reported
	Erythro Base	S				Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	12892068	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007888		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Duration: 2 Years 8 Months 13 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous		Not Reported
	Xeljanz		C			Not Reported
	Lyrica		C			Not Reported
	Codeine		C			Not Reported
	Tylenol 3		C			Not Reported
	Prednisone		C			Not Reported
	Arava		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	13640911	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003411		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Drug Ineffective; Fatigue; Hip Arthroplasty; Hypertension; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	13819301	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2017-022838		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia	Prednisolone			S	Unknown	Over 2 Years		Bausch And Lomb
	Dapsone			S	Unknown	Over 2 Years		Not Reported
	Azathioprine			S	Unknown	Over 2 Years		Not Reported
	Mycophenolate Mofetil			S	Unknown	Over 2 Years		Not Reported
	Methotrexate			S	Unknown	Over 2 Years		Not Reported
	Hydroxychloroquine			S	Unknown	Over 2 Years		Not Reported

	Colchicine			S	Unknown	Over 2 Years				Not Reported
	Rituximab			S	Unknown	Over 2 Years				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14904938	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001621		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Ineffective; Fatigue; Foot Deformity; Musculoskeletal Pain; Pain In Extremity; Pneumonia; Sinusitis	Plaquenil Tablet			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14906504	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001625			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	3 Months 24 Days 12 Hrs		Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14906922	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

INC.-GSH201805-001630

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Plaquenil Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Domperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14906924	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001640		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Methotrexate			S	Oral				Not Reported
		Methotrexate			S	Oral				Not Reported
		Methotrexate			S	Oral				Not Reported
		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14906937	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Hydroxychloroquine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14906938	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001645		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Hydroxychloroquine Tablet			S	Oral			Not Reported

Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Tablet	S	Oral	Not Reported
	Plaquenil Tablet	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Metformin Hydrochloride	S	Unknown	Not Reported
	Lantus	C		Not Reported
	Naprosyn	C		Not Reported
	Prednisone	C		Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Calcium Carbonate Vitamin D3	C		Not Reported
	Ergocalciferol	C		Not Reported
	Ramipril	C		Not Reported
	Vitamin D3	C		Not Reported
	Xeljanz	C		Not Reported
	Calcium	C		Not Reported
	Lozide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908152	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall;	Hydroxychloroquine Tablet			S	Oral			Not Reported

Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine Tablet			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908153	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001670			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Q14day;		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Tofacitinib			S	Unknown					Not Reported
	Xeljanz			S	Unknown					Not Reported
	Rabeprazole Sodium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908249	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Cough; Drug Ineffective; Eye Disorder; Gait Disturbance; Gastrointestinal Disorder; Lung Disorder; Malaise; Nasopharyngitis; Pain; Peripheral Swelling; Pneumonia; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actonel			C				Not Reported
	Ergocalciferol			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908867	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001668		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Hypersensitivity; Hypersensitivity; Hypersensitivity; Hypersensitivity; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Hydroxychloroquine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous				Not Reported
	Morphine			C					Not Reported
	Celebrex			C					Not Reported
	Gold			C					Not Reported
	Hydroxychloroquine Sulfate			C					Not Reported
	Prednisone			C					Not Reported
	Tofacitinib			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908868	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001672		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908870	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001667		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin Sodium Clavulanate Potassium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Erythematosus; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Rituximab			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Tocilizumab			S	Unknown	Not Reported
	Hydroxychloroquine Phosphate			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14908900	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14911069	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001663		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea;	Plaquenil			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cellcept			S	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Colchicine			C				Not Reported

Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea; Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Prednisone	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14911073	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001629		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Tylenol 8 Hr Arthritis Pain			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14911075	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001660		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Plaquenil Tablet		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Allopurinol		C		Not Reported
	Hydromorph Contin		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	14911079	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Gold			C				Not Reported
	Celebrex			C				Not Reported
	Morphine			C				Not Reported

	Tofacitinib			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15119962	EXPEDITED (15-DAY)		OT	PHHY2018AU033402		21 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Disease Progression; Dizziness; Drug-Induced Liver Injury; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Nausea; Tinnitus; Vomiting	Ciclosporin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10-20mg, Qw		Not Reported
	Methotrexate			S	Oral	10-20mg, Qw		Not Reported
	Methotrexate			S	Oral	10-20mg, Qw		Not Reported
	Mycophenolate Mofetil			S	Oral	1000 Mg, Bid		Novartis
	Azathioprine			S	Oral	150 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Up To 75 Mg, Qd		Not Reported
	Topiramate			C	Unknown	50 Mg, Bid		Not Reported
	Caltrate			C	Unknown	2 Ot, Bid		Not Reported
	Sumatriptan			C	Unknown	Unk Unk, Prn		Not Reported
	Prolia			C	Unknown	6 Monthly		Not Reported
	Vitamin B Complex/B12			C	Unknown	Unk, 3 Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15491024	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003500			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Hypoaesthesia Oral; Wrong Technique In Product Usage Process	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15491025	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001673			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Cimzia			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15491475	NON-EXPEDITED			US-AMGEN-USASP2018141076			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

	Xeljanz			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15491675	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-049042		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Hallucination, Auditory	Fluconazole Arrow			S	Oral	Unk		Aurobindo
	Primperan			S	Oral	Si Besoin		Not Reported
	Orozamudol			S	Oral	Si Besoin		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Piperacillin/Tazobactam Mylan			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15492413	NON-EXPEDITED			US-PFIZER INC-2018410655		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15492472	NON-EXPEDITED			US-PFIZER INC-2018413335		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil S			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15493419	NON-EXPEDITED			US-AMGEN-USASP2018141640			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15494991	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016200565		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Pain; Pain In Jaw; Swelling; Therapeutic Response Decreased	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Amitriptyline Hydrochloride + Perphenazine			S	Unknown	Unk		Not Reported
	Diclofenac Sodium + Misoprostol			S	Unknown	Unk		Not Reported
	Celebrate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15494997	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016200563		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Arthrotec			S	Unknown	Unk		Glaxosmithkline
	Celebrex			S	Unknown	Unk		Not Reported
	Elavil (Amitriptylin)			S	Unknown	Unk		Not Reported

	Enbrel			S	Unknown	Unk			Not Reported
	Lyrica			S	Unknown	Unk			Not Reported
	Methotrexate Sodium			S	Unknown	Unk			Not Reported
	Naprosyn			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15495012	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2016200568		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Decreased Appetite; Dizziness; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Aspirin			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15495042	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016200562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory;	Diclofenac			S	Unknown	Unk		Glaxosmithkline

Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Acetylsalicylic Acid	S	Unknown	Unk		Glaxosmithkline
	Motrin	S	Unknown	Unk		Glaxosmithkline
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2018	15200219	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-E2B_00014567		47 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Condition Aggravated; Drug Ineffective	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Prednisolone			S	Unknown			Concordia
	Prednisolone			S				Concordia
	Mycophenolate Mofetil			S	Unknown	2 G Per Day		Not Reported
	Mycophenolate Mofetil			S	Unknown	2.5 G Per Day		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Azathioprine			C				Not Reported
	Rituximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2018	15495704	EXPEDITED (15-DAY)		OT	PHHY2018FR114710		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Low Birth Weight Baby; Maternal Exposure During Pregnancy; Term Baby	Prednisone	S	Unknown	Unk		Novartis
	Acetylsalicylic Acid	S	Unknown	100 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2018	12908695	EXPEDITED (15-DAY)		HO, OT	CA-CANTON LABORATORIES, LLC-1059205		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naprosyn			S				Canton Laboratories
	Prednisone			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2018	15496672	NON-EXPEDITED			US-AMGEN-USASP2018142479			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2018	15496706	EXPEDITED (15-DAY)		HO, OT	PHHY2018TH118677		38 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Syndrome; Eyelid Ptosis; Legionella Infection; Leukopenia; Lupus Myocarditis; Lymphopenia; Myositis; Neutrophilic Panniculitis; Pain In Extremity; Skin Infection; Skin Plaque; Soft Tissue Infection; Varicella Zoster Virus Infection	Prednisolone			S	Unknown	5 Mg, Qd		Novartis
	Prednisolone			S	Unknown	45 Mg, Qd		Novartis
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Mestinon			C	Unknown	240 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2018	15496736	NON-EXPEDITED		OT	US-AMGEN-USASP2018141745			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Sepsis; Headache; Infusion Related Reaction; Pneumonia; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	13680489	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003686		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Synovitis	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Insulin			C				Not Reported
	Lantus			C				Not Reported
	Metformin Hydrochloride			C				Not Reported
	Aspirin			C				Not Reported
	Avapro			C				Not Reported
	Humalog			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	13920301	NON-EXPEDITED			US-PFIZER INC-2017371987		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported
	Duloxetine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Doxepin			C		Unk		Not Reported

	Estradiol	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Gabapentin	C	Unk	Not Reported
	Tramadol	C	Unk	Not Reported
	Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15125813	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-LEO PHARMA-309753			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Protopic			S	Transplacental			Leo Pharm
	Innohep			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Salbutamol			S	Transplacental			Not Reported
	Metamizole			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Acetylsalicylic Acid Sandoz			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Torasemide			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15377337	NON-EXPEDITED			US-PFIZER INC-2018366964			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Methotrexate Sodium		S	Unk		Pfizer
	Plaquenil		S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15432628	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003403			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15477251	NON-EXPEDITED			US-PFIZER INC-2018400398		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15494425	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003439		60 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malabsorption	Plaquenil 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15497241	NON-EXPEDITED			US-PFIZER INC-2018412713		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15497263	NON-EXPEDITED			US-PFIZER INC-2018414394		85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15497948	NON-EXPEDITED			US-PFIZER INC-2018406161			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15497956	NON-EXPEDITED		OT	US-PFIZER INC-2018409220		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15498194	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-		54 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400, Alternately Day		Not Reported
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400, Alternately Day		Not Reported
	Prednisolone			C				Not Reported
	Lansoprazole			C				Not Reported
	Lansoprazole			C				Not Reported
	Alfacalcidol			C				Not Reported
	Alfacalcidol			C				Not Reported
	Azelnidipine			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15499309	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2016200569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S				Glaxosmithkline
	Diclofenac			S				Glaxosmithkline
	Diclofenac			S				Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported

Arava	S				Not Reported
Acetylsalicylic Acid + Clopidogrelum	S	Unknown	Unk		Not Reported
Acetylsalicylic Acid + Clopidogrelum	S				Not Reported
Acetylsalicylic Acid + Clopidogrelum	S				Not Reported
Acetylsalicylic Acid + Clopidogrelum	S				Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S				Not Reported
Enbrel	S				Not Reported
Enbrel	S				Not Reported
Gold	S	Unknown	Unk		Not Reported
Gold	S				Not Reported
Gold	S				Not Reported
Gold	S				Not Reported
Humira	S	Unknown	Unk		Not Reported
Humira	S				Not Reported
Humira	S				Not Reported
Humira	S				Not Reported
Naprosyn	S	Unknown	Unk		Not Reported
Naprosyn	S				Not Reported
Naprosyn	S				Not Reported
Naprosyn	S				Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Plaquenil	S				Not Reported
Plaquenil	S				Not Reported
Tramadol	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15499324	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016200566		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle	Diclofenac			S	Unknown	Unk		Glaxosmithkline

Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Amitriptyline	S	Unknown			Not Reported
	Diclofenac Sodium + Misoprostol	S	Unknown	Unk		Not Reported
	Celebrex	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15499353	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2016200560			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid + Ascorbic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2018	15500036	EXPEDITED (15-DAY)		OT	PHHY2018NL122319		61 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Hepatotoxicity; Steroid Diabetes; Treatment Failure	Ciclosporin			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	14970977	NON-EXPEDITED			US-PFIZER INC-2018227083		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Diclofenac			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported
	Etodolac			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15278926	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Sulfasalazine	C		Not Reported
	Xeljanz	C		Not Reported
	Effexor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15423325	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003377		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Uterine Leiomyoma	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Benet			C				Not Reported
	Prograf			C				Not Reported
	Bredinin			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Loxonin			C				Not Reported
	Alfacalcidol			C				Not Reported
	Esomeprazole Magnesium			C				Not Reported
	Crestor			C				Not Reported
	Lasix Tablet 20mg			C				Not Reported
	Rebamipide			C				Not Reported
	Rebamipide			C				Not Reported
	Aspara-Ca			C				Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15477282	NON-EXPEDITED			US-PFIZER INC-2018404363		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer

	Methotrexate Sodium	S	Unk	Unknown
	Sulfasalazine	S	Unk	Pfizer
	Humira	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15504486	EXPEDITED (15-DAY)		OT	US-SA-2018SA278797			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Drug Intolerance; Infection; Oedema; Rash; Rheumatoid Arthritis; Weight Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Enbrel			S				Not Reported
	Humira			C				Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Tramadol Hydrochloride			C		Unk		Not Reported
	Aleve			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Restasis			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Refresh [Carmellose]			C		Unk		Not Reported
	Feosol			C		Unk		Not Reported
	Candesartan Cilexetil			C		Unk		Not Reported
	Hydrocodone/Acetaminophen			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15505395	EXPEDITED (15-DAY)		HO, OT	TH-ZYDUS-029143		38 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Tenderness; Cachexia; Chest Pain; Conjunctival Discolouration; Cytomegalovirus Infection; Cytomegalovirus Syndrome; Cytomegalovirus Viraemia; Decreased Appetite; Diarrhoea; Dyspnoea; Enteritis; Erythema; Eyelid Ptosis; Hypokinesia; Left Ventricular Dysfunction; Legionella Infection; Lupus Myocarditis; Lymphopenia; Macule; Muscle Atrophy; Muscular Weakness; Myositis; Panniculitis; Papule; Pericardial Effusion; Pleural Effusion; Pyrexia; Rash Vesicular; Scab; Skin Plaque; Skin Swelling; Varicella Zoster Virus Infection; Weight Decreased	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown			Zydus Pharm
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Pyridostigmine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15505650	EXPEDITED (15-DAY)		OT	IR-BAUSCH-BL-2018-027728		22 YR	Female	IRN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Treatment Failure	Prednisolone		S	Unknown			Not Reported
	Hydroxychloroquine		S	Unknown			Not Reported
	Hydroxychloroquine		S				Not Reported
	Azathioprine		S	Unknown			Not Reported
	Intravenous Immunoglobulins		S	Unknown			Not Reported
	Romiplostim		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15505825	NON-EXPEDITED			US-PFIZER INC-2018406268		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15505873	NON-EXPEDITED			US-PFIZER INC-2018411285			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15506066	EXPEDITED (15-DAY)		HO	TH-MYLANLABS-2018M1075131		38 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Gastroenteritis; Cytomegalovirus	Prednisolone			S	Unknown	Initial Dose Not Stated		Not Reported
	Prednisolone			S	Unknown			Not Reported

Syndrome; Infective Myositis; Legionella Infection; Lymphopenia; Myocarditis Infectious; Panniculitis; Pericardial Effusion; Pleural Effusion; Varicella Zoster Virus Infection	Azathioprine	S	Unknown	Initial Dose Not Stated		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Mestinon	C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2018	15507370	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1075763		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanoderma	Tenofovir			S	Oral	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Emtricitabine			S	Oral	Unk		Mylan
	Rilpivirine			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	12932258	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016152956		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Muscular Weakness; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Imuran			S	Unknown	100 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Tylenol #3			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

	Toradol			C	Unknown	Unk			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	13246584	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Arava Tablet			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Eve Outer Tape (Diclofenac Sodium)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	14077124	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017152794		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Intentional Product Misuse; Musculoskeletal Disorder; Product Use Issue; Rheumatoid Arthritis;	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Enbrel			S	Unknown	Unk Unk, Q2wk		Amgen
	Enbrel			S	Unknown	Unk, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	7.5 Mg, Qd		Not Reported
	Naprosyn	C		Unk Unk, Bid		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	14508855	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2063833			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	14986409	NON-EXPEDITED			US-ASTRAZENECA-2018SE62879		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Nexium			S	Oral	Unk		Astrazeneca
	Lexapro			S	Unknown	Unk		Not Reported
	Estrace			S		Unk		Not Reported
	Gabapentin			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported
	Lotrel			S		Unk		Not Reported
	Septra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15299674	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003011		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Plaquenil			S	Oral			Not Reported
	Sulfamethoxazole Trimethoprim			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Enoxaparin Sodium			S	Unknown			Not Reported
	Esomeprazole Magnesium			S	Oral			Not Reported
	Lederfoline			S	Oral			Not Reported
	Cerazette (Desogestrel)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15396457	EXPEDITED (15-DAY)		OT	DE-TORRENT-00010098		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Premature Delivery	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Unknown
	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Metamizole			S	Unknown	Unk, Unknown Freq. (0-14 Gw), Formulation Unknown		Unknown
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw), Formulation Unknown		Unknown
	Prednisolone			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Ramipril			S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)		Unknown
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Unknown
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Torasemide			S	Unknown	Unk, Unknown Freq. (0-14		Unknown

							Gw)			
	Enoxaparin			C	Unknown		Unk Unk, Unknown Freq. (0-14 Gw)			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15498172	NON-EXPEDITED			US-PFIZER INC-2018409653		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		200 Mg, Unk		Not Reported
	Prednisone			S		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516093	NON-EXPEDITED			US-PFIZER INC-2018419245		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516297	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-187927		64 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Ranitidine			S	Unknown	300 Mg, Daily		Ranbaxy
	Aceclofenac			S	Unknown	100 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Sun
	Rebamipide			S	Unknown	100 Mg, Daily		Not Reported

	Azathioprine	S	Unknown	100 Mg, Daily		Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown	22.6 Mg, Daily		Not Reported
	Streptokinase/Streptodornase	S	Unknown	10000/2500 Iu, Daily		Not Reported
	Dihydrocodeine	S	Unknown	150 Mg, Daily		Not Reported
	Di-Methylephedrine Hydrochloride	S	Unknown	393.75 Mg, Daily		Not Reported
	Chlorpheniramine	S	Unknown	45 Mg, Daily		Sun
	Guaifenesin	S	Unknown	1125 Mg, Daily		Not Reported
	Ursodeoxycholic Acid	S	Unknown	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516331	NON-EXPEDITED			US-PFIZER INC-2018411636		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Tylox [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			S		Unk		Not Reported
	Avalox			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Omnisporin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2018	15516917	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2016200567		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness;	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Aspirin			S	Unknown	Unk		Glaxosmithkline

Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15089541	EXPEDITED (15-DAY)		OT	DE-VELOXIS PHARMACEUTICALS, INC.-2018VELDE1012		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Maternal Exposure During Pregnancy	Envarsus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Unknown
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Ramipril			S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Torasemide			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported

	Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Ezetimibe	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Metamizole	S	Unknown	Unk, Unknown Freq. (0-14gw)	Not Reported
	Simvastatin	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Prednisolone	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Enoxaparin	C		Unk, Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Xarelto	S	Unknown	Unk	Not Reported
	Dipyrone	C	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15089544	EXPEDITED (15-DAY)		CA, OT	DE-VELOXIS PHARMACEUTICALS, INC.-2018VELDE1011			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Envarsus			S	Transplacental	Unk, 1 Trimester (0-14 Gw)		Unknown
	Rivaroxaban			S	Transplacental	Unk, (0-5 Gw)		Not Reported
	Ramipril			S	Transplacental	20 Mg, Qd, 0-13+6 Weeks		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk, (0-14 Gw)		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk, (0-14 Gw)		Not Reported
	Pantoprazole			S	Transplacental	Unk, (0-14gw)		Not Reported
	Torasemide			S	Transplacental	Unk, (0-14 Gw)		Not Reported
	Salbutamol			S	Transplacental	Unk, (0-14 Gw)		Not Reported
	Nicotine			S	Transplacental	Unk, (0-14 Gw)		Not Reported
	Aliskiren			S	Transplacental	1 Trimester (0-5 Gw)		Not Reported

	Ezetimibe	S	Transplacental	Unk, (0-14 Gw)	Not Reported
	Metamizole	S	Transplacental	Unk, (0-14 Gw)	Not Reported
	Simvastatin	S	Transplacental	Unk, (0-14 Gw)	Not Reported
	Prednisolone	S	Transplacental	Unk, (0-14 Gw)	Not Reported
	Enoxaparin	S	Transplacental	Unk, 0-14 Weeks	Not Reported
	Xarelto	S	Transplacental	Unk	Not Reported
	Enoxaparin	C	Transplacental	0-14 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15260579	EXPEDITED (15-DAY)		HO, OT	US-MALLINCKRODT-T201803266			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Arthropod Sting; Apparent Death; Atrial Fibrillation; Cardiac Failure Congestive; Cardiac Valve Disease; Electrocardiogram Qt Prolonged; Fluid Retention; Gastrointestinal Haemorrhage; Goitre; Product Dose Omission; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Torsade De Pointes; Tracheostomy	Repository Corticotropin Injection			S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Tuesday/Friday		Mallinckrodt
	Methadone			S	Unknown	Unknown		Mallinckrodt
	Eliquis			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Amiodarone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15466221	EXPEDITED (15-DAY)		OT	PHHY2018CA116440			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Voltaren			S	Unknown	Unk		Novartis

Hypersensitivity; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Joint Swelling; Pain In Extremity; Weight Decreased	Methotrexate			S	Unknown	Unk	Not Reported
	Enbrel			S	Unknown	50 Mg, Unk	Not Reported
	Enbrel			S	Unknown	50 Mg, Unk	Not Reported
	Enbrel			S	Unknown	50 Mg, Unk	Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Plaquenil			S	Unknown	Unk	Not Reported
	Arava			C	Unknown	Unk	Not Reported
	Dexilant			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15483450	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2018CA022967			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Product Use Issue	Infliximab Pfizer (Unknown)			S	Unknown	200 Mg, Monthly (1 Every 1 Month)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly (1 Every 1 Weeks)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15497435	NON-EXPEDITED			US-PFIZER INC-2018412147		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Resistance	Enbrel	S		Unk	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Plaquenil	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Simponi	S		Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15523754	EXPEDITED (15-DAY)		DE	RO-ABBVIE-18K-135-2522781-00		42 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15524544	NON-EXPEDITED			US-PFIZER INC-2018423479		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Prednisone			S		5 Mg, Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15524576	NON-EXPEDITED			US-PFIZER INC-2018419276		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer

	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15524597	NON-EXPEDITED			US-PFIZER INC-2018414906		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15524611	NON-EXPEDITED			US-PFIZER INC-2018419566		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15524625	NON-EXPEDITED			US-PFIZER INC-2018419708		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15524691	NON-EXPEDITED			US-PFIZER INC-2018420848		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Methotrexate Sodium	S	Unk		Pfizer
	Remicade	S	Unk		Not Reported
	Codeine Sulfate	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Alendronate	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15526223	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181016904			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15526290	EXPEDITED (15-DAY)		OT	AU-SA-2018SA281623			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure Timing Unspecified; Intestinal Perforation; Intussusception	Hydroxychloroquine			S	Transplacental	Unk		Sanofi
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Hyoscine Butylbromide			S	Transplacental	Unk		Not Reported
	Enoxaparin Sodium			S	Transplacental	Unk		Sanofi
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Mycophenolate Mofetil			S	Transplacental			Not Reported
	Ondansetron			S	Transplacental	Unk		Not Reported
	Oxycodone			S	Transplacental	Unk		Not Reported
	Codeine			S	Transplacental	Unk		Not Reported

	Phosphate/Paracetamol							
	Paracetamol		S	Transplacental	Unk			Not Reported
	Prednisolone		S	Transplacental	Unk			Not Reported
	Potassium Chloride		S	Transplacental	Unk			Not Reported
	Lidocaine Hydrochloride		S	Transplacental	Unk			Sanofi
	Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride		S	Transplacental				Not Reported
	Aluminium Hydroxide/Magnesium Hydroxide/Simeticone		S	Transplacental	Unk			Not Reported
	Microlax [Sodium Citrate;Sodium Lauryl Sulfoacetate;Sorbitol]		S	Transplacental	Unk			Not Reported
	Azathioprine		S	Transplacental	Unk			Not Reported
	Intragam		S	Transplacental	Unk			Not Reported
	Novorapid		S	Transplacental	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15526814	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201810799		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Dermatitis; Varicella Zoster Virus Infection	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Methotrexate (Manufacturer Unknown)			S				Fresenius Medical Care
	Methotrexate (Manufacturer Unknown)			S				Fresenius Medical Care
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15527043	EXPEDITED (15-DAY)		HO	PHHY2018US124100		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Hypotension; Hypoxia; Overdose; Pulmonary Alveolar Haemorrhage; Suicide Attempt; Systemic Lupus Erythematosus; Torsade De Pointes	Hydroxychloroquine			S	Oral	200 Mg, Unk (Twenty Tablets)		Novartis
	Ethanol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2018	15530657	EXPEDITED (15-DAY)		HO, OT	TH-BAUSCH-BL-2018-027995		38 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Enteritis; Eyelid Ptosis; Immunodeficiency; Legionella Infection; Leukopenia; Lupus Myocarditis; Lymphopenia; Myositis; Neutrophilic Panniculitis; Skin Infection; Soft Tissue Infection; Varicella Zoster Virus Infection	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			C				Not Reported
	Mestino			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	14140631	NON-EXPEDITED			US-PFIZER INC-2017463415		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Daypro			S		Unk		Pfizer
	Diclofenac Sodium			S		Unk		Pfizer

Leflunomide	S	Unk	Not Reported
Naproxen	S	Unk	Not Reported
Salsalate	S	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unk	Not Reported
Nabumetone	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Orencia	S	Unk	Not Reported
Sulfamethoxazole	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	14144725	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201710-006043		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral	At The Dose Of 200 Mg Daily And 400 Mg Daily, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	At The Dose Of 200 Mg Daily And 400 Mg Daily, Alternately		Concordia
	Prednisolone			C				Not Reported
	Alfacalcidol			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Alendronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	14364410	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA268709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain;	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Diclofenac Potassium			S				Not Reported

Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Acetylsalicylic Acid	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk		Not Reported
	Ibuprofen	S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Tramadol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	14931283	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044545			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15524775	EXPEDITED (15-DAY)		OT	SA-MYLANLABS-2018M1075643		26 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Avulsion Fracture; Bursitis; Condition Aggravated; Disseminated Tuberculosis; Drug	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	10-15 Mg Daily		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

Ineffective; Osteomyelitis Chronic; Synovitis	Hydroxychloroquine	S	Unknown			Not Reported
	Enalapril	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Rituximab	S	Unknown	She Received Two 1000-Mg Doses Of Rituximab One Month Apart.		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15524785	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2018M1077566		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alcohol Abuse; Drug Abuse; Toxicity To Various Agents	Zopiclone			S	Oral	Non Renseignée		Not Reported
	Gabapentin			S	Oral	Non Renseignée		Not Reported
	Mirtazapine			S	Oral	Non Renseignée		Not Reported
	Morphine			S	Oral	Non Renseignée		Mylan
	Hydroxychloroquine Sulfate			S	Oral	Nonr Renseignée		Mylan
	Alcool			S	Oral	Non Renseignée		Mylan
	Amitriptyline			S	Oral	Non Renseignée		Mylan
	Oxazepam			S	Oral	Non Renseignée		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15524841	EXPEDITED (15-DAY)		OT	CA-SA-2015SA138634		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S		25 Mg		Sanofi
	Plaquenil			S	Oral	200 Mg,Qd		Sanofi
	Plaquenil			S	Oral	200 Mg,Qd		Sanofi
	Ibuprofen			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi

	Folic Acid	S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone	C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15531308	NON-EXPEDITED			US-AMGEN-USASP2018145315			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Simponi Aria			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15531525	EXPEDITED (15-DAY)		OT	US-HORIZON-PRE-0470-2018		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Dermatitis	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported

	Plaquenil			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15532492	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2017204297		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic; Urticaria	Diclofenac Sodium			S	Oral	75 Mg (1 Df), Qd		Glaxosmithkline
	Plaquenil			S	Oral	400 Mg (2 Df), Qd		Not Reported
	Esomeprazole Magnesium			S	Oral	20 Mg (1 Df), Qd		Not Reported
	Econazole Nitrate			S	Vaginal	150 Mg, Unk		Not Reported
	Econazole Nitrate			S				Not Reported
	Pevaryl			S	Vaginal	Unk		Not Reported
	Levothyrox			C	Unknown	75 Ug, Unk		Glaxosmithkline
	Levocetirizine Dihydrochloride			C	Unknown	Unk		Glaxosmithkline
	Ventoline			C	Unknown	Unk		Glaxosmithkline
	Prozac			C	Unknown	20 Mg, Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Symbicort			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15533500	EXPEDITED (15-DAY)		DE, HO, OT	NL-MYLANLABS-2018M1078494		59 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Multiple Organ Dysfunction Syndrome; Necrotising Fasciitis; Pain; Septic Shock; Streptococcal Infection	Adalimumab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	800 Mg, Q4w		Mylan
	Etanercept			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15534141	NON-EXPEDITED			US-AMGEN-USASP2018145323			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2018	15534320	EXPEDITED (15-DAY)		OT	PHHY2018CL126928		44 YR	Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Zonal Occult Outer Retinopathy; Autoimmune Retinopathy; Disease Progression; Entropion; Night Blindness; Optic Atrophy; Retinal Cyst; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	8321288	EXPEDITED (15-DAY)		CA, OT	CA-SANOFI-AVENTIS-2011SA085293		28 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Cleavage Syndrome; Aphakia; Corneal Opacity; Eye Disorder; Foetal Exposure During Pregnancy	Methotrexate			S	Transplacental	Unk Unk,Qw		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk Unk,Qd		Sanofi
	Folic Acid			S		5 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	13233419	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006371		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Apo-Diclofenac			S	Unknown			Apotex
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15468852	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018180679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gastric Ulcer; Gastric Ulcer	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

Perforation; Joint Swelling; Pain In Extremity; Weight Decreased	Methotrexate		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Arava		C	Unknown	Unk		Not Reported
	Dexilant		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15535227	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003754		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral	Hydroxychloroquine 200 Mg Tablet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15537694	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2701903			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15537886	NON-EXPEDITED			US-SA-2018SA289748			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Rash	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2018	15538162	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1076488		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Hypoxia; Intentional Overdose; Mental Status Changes; Pulmonary Alveolar Haemorrhage; Somnolence; Suicide Attempt; Systemic Lupus Erythematosus; Torsade De Pointes; Toxicity To Various Agents; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral	Total Of 20 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	8181575	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2011243797		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Deep Vein Thrombosis; Drug	Delix (Ramipril)			S	Oral	Unk		Pfizer

Exposure Before Pregnancy; Maternal Drugs Affecting Foetus; Pulmonary Embolism	Falithrom	S	Oral	3 Mg, 2x/Day	Not Reported
	Cyclosporine A	S	Oral	150 Mg, 2x/Day	Not Reported
	Torem (Torasemide)	S	Unknown	100 Mg, Unk	Not Reported
	Quensyl	S	Oral	200 Mg, Daily (Every Days)	Not Reported
	Quensyl	S			Not Reported
	Inegy	S	Oral	Unk40 [Mg/D] / 10 [Mg/D]	Not Reported
	Rituximab	S	Subcutaneous	Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Tacrolimus	S	Oral	6 Mg, Unk	Not Reported
	Advagraf	S	Oral	6 Mg, Unk 6 [Mg/D]	Not Reported
	Clexane	C	Oral	60 Mg And 80 Mg Daily (140 Mg/Day)	Not Reported
	Clexane	C	Oral	Unk	Not Reported
	Prednisolone	C	Oral	7.5 Mg/Day	Not Reported
	Prednisolone	C	Oral	Unk	Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]	C		Unk	Not Reported
	Albuterol [Salbutamol]	C		Unk	Not Reported
	Cytotec	C		Unk	Not Reported
	Cyclophosphamid	C		Unk	Not Reported
	Xarelto	C		10 Mg, Unk	Not Reported
	Novaminsulfon	C		Unk	Not Reported
	Aliskiren	C		Unk	Not Reported
	Mifegyne	C		Unk	Not Reported
	Mifegyne	C			Not Reported
	Rasilez	C		Unk	Not Reported
	Salbutamol	C		Unk	Not Reported
	Ass	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15058374	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-176567		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Tuberculosis; Osteomyelitis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	20 Mg, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15266036	NON-EXPEDITED			US-PFIZER INC-2018320162		64 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Tramadol			S		Unk		Not Reported
	Cefdinir			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15293427	EXPEDITED (15-DAY)		HO	FR-ROCHE-2171527		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Bactrim			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Lovenox			S	Unknown			Not Reported
	Lederfoline			S	Oral			Not Reported
	Cerazette (France)			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported

	Plaquenil			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15540001	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15540342	NON-EXPEDITED			US-PFIZER INC-2018424046		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Cipro [Ciprofloxacin]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15540884	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA134160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Voltaren	S	Unknown	Novartis
	Diclofenac Potassium	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Novartis
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arava	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Motrin	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Diclofenac	S	Unknown	Not Reported
	Sulfametoxazol/Trimetoprim	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15540949	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-079		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Dermatitis	Methotrexate			S	Unknown			Westward
	Methotrexate			S				Westward
	Methotrexate			S				Westward
	Prednisone			S	Unknown			Westward
	Prednisone			S				Westward
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

	Plaquenil			S						Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Sulfasalazine			S						Not Reported
	Sulfasalazine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2018	15542440	NON-EXPEDITED			US-PFIZER INC-2018431077		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	11275088	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-15K-028-1425071-00		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Adverse Drug Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Aspirin			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported

Shoulder Arthroplasty; Vomiting	Sodium Aurothiomalate		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Apo-Diclofenac		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Sulfamethoxazole W/Trimethoprim		S	Unknown	Not Reported
	Tramadol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	12773670	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016128007		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	14148017	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017163491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Enbrel			S	Unknown	Unk, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	14155333	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165150		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk (8 Dosage Form)		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Atenolol			C		Unk		Not Reported
	Clopidogrel Bisulfate			C		Unk		Not Reported
	Clopidogrel Bisulfate			C		Unk		Not Reported
	Cyanocobalamin			C		Unk		Not Reported
	Docusate Sodium			C		Unk		Not Reported
	Escitalopram Oxalate			C		Unk		Not Reported
	Escitalopram Oxalate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Imovane			C		Unk		Not Reported
	Irbesartan			C		Unk		Not Reported
	Irbesartan Hct			C		Unk		Not Reported
	Lipitor			C		Unk		Not Reported
	Loratadine			C		Unk		Not Reported
	Myrbetriq			C		Unk		Not Reported
	Nitroglycerin			C		Unk		Not Reported
	Omnaris			C		Unk		Not Reported
	Venlafaxine Hydrochloride			C		Unk		Not Reported
	Vesicare			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	14343324	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268420		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Rheumatoid Arthritis; Stomatitis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported
	Methotrexate			S	Oral	15 Mg,Qw		Not Reported
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Oral	50 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg,Qd		Not Reported
	Folic Acid			C	Unknown	5 Mg,Qd		Not Reported
	Folinic Acid			C	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			C	Unknown	Unk Unk, Prn		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	300 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	14794365	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268468		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Methotrexate			S	Unknown	15 Mg,Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Enbrel			S	Unknown	25 Mg, Qow		Not Reported

	Humira	S	Subcutaneous	40 Mg,Qow		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Unknown	300 Mg,Q6w		Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine	C	Unknown	1 G,Bid		Not Reported
	Wellbutrin	C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15540382	NON-EXPEDITED			US-PFIZER INC-2018421759		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15545336	NON-EXPEDITED			US-PFIZER INC-2018433094		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15545595	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2018192813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory;	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline

Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac	S	Unknown	Unk		Glaxosmithkline
	Aspirin	S	Unknown	Unk		Glaxosmithkline
	Motrin	S	Unknown	Unk		Glaxosmithkline
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Arava	S	Subcutaneous	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
	Apo-Diclofenac	S	Unknown	Unk		Not Reported
	Sulfametoxazol + Trimetoprima	S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15546197	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2018-US-966606		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Hypoxia; Intentional Overdose; Mental Status Changes; Pulmonary Alveolar Haemorrhage; Somnolence; Suicide Attempt; Systemic Lupus	Hydroxychloroquine			S	Oral	Total Of 20 Tablets		Teva

Erythematosus; Torsade De Pointes; Toxicity To Various Agents; Ventricular Extrasystoles

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15547349	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2018-0009119		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Dilaudid			S	Unknown	Unk		Purdue
	Hydromorphone Hydrochloride			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2018	15547435	EXPEDITED (15-DAY)		DS, OT	CL-MYLANLABS-2018M1077242		60 YR	Female	CHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Blindness; Visual Acuity Reduced; Vitreous Floaters	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Then Continued In An Unspecified Dosage After 2011		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	12713963	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016008817		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Surgery	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	250 Mg, For 5 Days		Not Reported
	Azithromycin			C		250 Mg, For 4 Days		Not Reported
	Cefuroxime Axetil			C		500 Mg, For 6 Days		Not Reported
	Oseltamivir			C	Unknown	75 Mg, For 3 Days		Not Reported
	Budesonide			C		200 Mug 2 Inhalations A Day For 30 Days		Not Reported
	Fluorouracil			C		5 %, Bedtime		Not Reported
	Amoxi-Clav			C		500 Mg, 1 Tab Three Times A Day Until Finished		Not Reported
	Hydrochlorothiazide			C	Unknown	25 Mg, Once Daily		Not Reported
	Bystolic			C		10 Mg, Once Daily		Not Reported
	Apo-Prednisone			C		5 Mg, Unk		Not Reported
	Winpred			C	Unknown	1 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Nebivolol Hydrochloride			C	Unknown	10 Mg, Qd		Not Reported
	Pms Azithromycin			C	Unknown	250 Mg, Unk		Not Reported
	Amoxicillin Trihydrate And			C		500 Mg, 3 Every 1day		Not Reported

Clavulanate Potass

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	14075096	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017432918		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinopathy	Ibuprofen			S		Unk Unk, As Needed		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily (Cumulative Hcq Dose Of 19.8 G)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	14616842	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0037		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Chest Pain; Epistaxis; Gait Disturbance; Malaise; Neuropathy Peripheral; Osteoarthritis; Sinusitis; Skin Laceration	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15212092	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00014759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent;	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Concordia
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Concordia
	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Not Reported

Ventricular Septal Defect	Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Salbutamol	S	Transplacental	From Gestational Week 0-14	Not Reported
	Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
	Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
	Xarelto	S	Transplacental		Not Reported
	Aliskiren	S	Transplacental		Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
	Ramipril	S	Transplacental	Maternal Dose 20 Mg	Not Reported
	Nicotine	S	Transplacental		Not Reported
	Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Enoxaparin Sodium	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15548612	NON-EXPEDITED			US-AMGEN-USASP2018144492			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Drug Ineffective; Joint Swelling; Weight Increased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15549209	NON-EXPEDITED			PHEH2018US045138		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15549381	NON-EXPEDITED			US-PFIZER INC-2018435909		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15549468	NON-EXPEDITED			US-PFIZER INC-2018425934		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15549493	NON-EXPEDITED			US-PFIZER INC-		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15551601	EXPEDITED (15-DAY)		OT	US-SA-2018SA293962			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dizziness; Duodenal Ulcer; Palpitations; Pruritus; Visual Impairment	Arava			S	Unknown			Sanofi
	Thiopental Sodium			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Paracetamol			S				Not Reported
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15551930	EXPEDITED (15-DAY)		DE	PHHY2018RO137320		42 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Methotrexate			S	Unknown	10 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15552322	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268771			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			C		20 Mg, Qw		Not Reported
	Methotrexate			C	Oral	20 Mg,Qw		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2018	15552791	EXPEDITED (15-DAY)		OT	CA-ROCHE-2202229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Discontinues		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	8800930	EXPEDITED (15-DAY)		CA	DE-ROCHE-1133534			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Foetal Exposure During Pregnancy; Maternal Drugs Affecting Foetus; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rituximab			S	Transplacental			Not Reported
	Advagraf			S	Transplacental			Not Reported
	Torem			S	Transplacental			Not Reported
	Quensyl			S	Transplacental			Not Reported
	Inegy			S	Transplacental			Not Reported
	Delix (Ramipril)			S	Transplacental			Not Reported
	Cyclophosphamide			C	Transplacental			Not Reported

	Clexane	C	Transplacental	Not Reported
	Prednisolon	C	Transplacental	Not Reported
	Ass	C	Transplacental	Not Reported
	Pantozol (Germany)	C	Transplacental	Not Reported
	Rasilez	C	Transplacental	Not Reported
	Albuterol	C	Transplacental	Not Reported
	Novaminsulfon	C	Transplacental	Not Reported
	Novaminsulfon	C	Transplacental	Not Reported
	Mifegyne	C	Transplacental	Not Reported
	Cytotec	C	Transplacental	Not Reported
	Xarelto	C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	11588137	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015101752		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Bladder Cancer; C-Reactive Protein Abnormal; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Amgen
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Aurothiomalate De Sodium			S	Parenteral	Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	12267451	EXPEDITED (15-DAY)		HO	CA-AMGEN-CANSP2014059089		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Dyspnoea; Lung Disorder; Pneumonitis	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	12486116	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016078855		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Naproxen			C		500 Mg, Bid		Not Reported
	Atasol (Acetaminophen)			C		500 Mg, If Needed		Not Reported
	Acetaminophen			C		500 Mg, As Required		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	12723661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0729			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Constipation; Decreased Activity; Depressed Mood; Drug Ineffective; Fall; Fatigue; Gait Disturbance; Irritability;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Nasopharyngitis; Poor Quality Sleep; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Stress; Synovitis; Viral Upper Respiratory Tract Infection; Weight Bearing Difficulty; Wound Infection; Wrist Fracture	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Advil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	12974070	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016165995		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Drug Ineffective; Gait Disturbance; Limb Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tooth Infection	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qwk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

	Meloxicam			C	Unknown	50 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14149666	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14156201	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lichen Planus; Rheumatoid Arthritis; Rosacea; Spinal Stenosis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Salazopyrin			S	Oral	500 Mg, Qid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14158025	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165353		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-	Enbrel			S	Subcutaneous	Unk		Amgen

Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Desoximetasone	S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Remicade	C	Unknown	Unk		Not Reported
	Simponi	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14185856	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017169920		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	17.5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin B12			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14186921	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017169977		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Enbrel	S	Unknown	50 Mg, Qwk		Amgen
	Apo-Leflunomide	S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid		Not Reported
	Naprosyn	C		500 Mg, Unk		Not Reported
	Citalopram	C		20 Mg, Qd		Not Reported
	Folic Acid	C		5.0 Mg, Qd		Not Reported
	Losec	C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14212488	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017173378		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14222152	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175591			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

	Sulfasalazine			S	Unknown	1 G, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14222340	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175758			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14223322	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175424		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastric Disorder; Interstitial Lung Disease; Lung Disorder; Pneumonitis; Polyarthritis; Rheumatoid Arthritis; Treatment Failure; Unevaluable Event	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Tid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14227423	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506229		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Enbrel			S	Unknown	Unk		Pfizer

Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate Sodium	S	Oral	22.5 Mg, Qwk	Pfizer
	Methotrexate Sodium	S	Parenteral	25 Mg, Weekly	Pfizer
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk, Qd	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Apo-Sulfasalazine	S		500 Mg, Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	6.0 Mg, Bid	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	14906508	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001636		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphoma	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15210931	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rash	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15417157	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003359		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Morbilliform; Rash Pruritic	Hydroxychloroquine			S	Unknown			Concordia
	Metformin			C				Not Reported
	Ramipril			C				Not Reported
	Tylenol Pm			C				Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15553338	EXPEDITED (15-DAY)		OT	CA-ROCHE-2198166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown	Discontinued		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15553750	NON-EXPEDITED		OT	US-SA-2018SA295221			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache	Arava			S		Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15554256	NON-EXPEDITED			US-PFIZER INC-2018438981		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15554276	NON-EXPEDITED			US-PFIZER INC-2018438074		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15555442	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gait Disturbance; Impaired Work Ability; Insomnia; Joint Swelling; Meniere'S Disease; Pain; Peripheral Swelling; Therapeutic Response Decreased; Vertigo	Plaquenil			S	Unknown	400 Mg,Qd		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Humira			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C				Not Reported
	Omeprazole			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15557127	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018149609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Amgen
	Orencia			S	Unknown	125 Mg, Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2018	15557351	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018149618			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Q2wk		Amgen
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	12886116	EXPEDITED (15-DAY)		OT	GB-UCBSA-2016040174			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Diverticulitis; Joint Swelling; Liver Injury; Pain; Peripheral Swelling	Certolizumab Pegol			S		Unk		Ucb
	Actemra			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		Reduced Dose		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisolone			C				Not Reported
	Endep			C		Unk		Not Reported
	Endep			C				Not Reported
	Tramadol			C		Unk		Not Reported
	Cortisone			C		Unk		Not Reported
	Amitriptyline			C				Not Reported
	Tapentadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14068283	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005649		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14164585	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017478184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lichen Planus; Rheumatoid Arthritis; Rosacea; Spinal Stenosis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Salazopyrin			S	Oral	500 Mg, Qid		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14200371	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491687		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Naprosyn			C		500 Mg, Unk		Not Reported
	Citalopram			C		20 Mg, Qd		Not Reported
	Folic Acid			C		5.0 Mg, Qd		Not Reported
	Losec			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14226285	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017503742		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective;	Enbrel			S	Unknown	Unk		Pfizer

Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Methotrexate Sodium		S	Unknown	Unk	Pfizer
	Sulfasalazine		S	Oral	1 G, Bid	Pfizer
	Actemra		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	400 Mg, Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14228238	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2017175378		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Peripheral Swelling	Enbrel			S	Subcutaneous	Unk, Qwk		Amgen
	Apo-Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14232265	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017508078		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastric Disorder; Interstitial Lung Disease; Lung Disorder; Pneumonitis; Polyarthritis; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Tid		Pfizer
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	14403610	NON-EXPEDITED			US-AMGEN-USASP2018005617			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gastrointestinal Disorder	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15305836	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003057			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Blister; Cerebral Disorder; Decreased Immune Responsiveness; Drug Hypersensitivity; Dysstasia; Fall; Foot Deformity; Foot Operation; Grip Strength Decreased; Hypoaesthesia; Impaired Healing; Impaired Quality Of Life; Joint Swelling; Mobility Decreased; Muscle Rupture; Musculoskeletal Disorder; Musculoskeletal Pain; Pain; Pain In Extremity;	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Peripheral Swelling; Pruritus; Spinal Operation; Surgery; Weight Increased	Benzylpenicillin	S	Unknown		Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Lasix	S	Unknown		Not Reported
	Gabapentin	S	Unknown		Not Reported
	Fluticasone	S	Unknown		Not Reported
	Pepcid Ac	C			Not Reported
	Prednisone	C			Not Reported
	Orencia	C			Not Reported
	Famotidine	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin C	C			Not Reported
	Vitamin D3	C			Not Reported
	Turmeric	C			Not Reported
	Gundry Md Vital Reds	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15483808	EXPEDITED (15-DAY)		HO, OT	FR-SA-2018SA221441		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Ramipril			S	Oral	Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Oral	2 G, Qd		Not Reported
	Mycophenolate Mofetil			S	Oral	1.5 G,Qd		Not Reported
	Enoxaparin Sodium			S		4000 Iu, Qd		Sanofi
	Esomeprazole Magnesium			S	Oral	Unk (Gastro-Resistant Tablet)		Not Reported
	Lederfoline			S	Oral	Unk		Not Reported
	Cerazette [Desogestrel]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15535264	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Atenolol			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15558801	NON-EXPEDITED			US-AMGEN-USASP2018148363			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Flexeril			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15559230	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-051702		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Dermatitis; Keratitis Fungal; Post Herpetic Neuralgia; Skin Plaque; Staphylococcal Infection; Trigeminal Nerve Disorder; Ulcer; Varicella Zoster Virus Infection	Prednisone			S	Oral	Unk		Aurobindo
	Prednisone			S				Aurobindo
	Prednisone			S				Aurobindo
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15560716	NON-EXPEDITED			US-PFIZER INC-2018427272		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15560781	NON-EXPEDITED			US-PFIZER INC-2018438670		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S				Pfizer
	Arava			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15561816	NON-EXPEDITED			US-SA-2018SA295109			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S				Not Reported
	Plaquenil			S				Sanofi
	Meloxicam			S				Not Reported
	Xeljanz			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15561912	NON-EXPEDITED			US-SA-2018SA296376			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15562090	NON-EXPEDITED			US-SA-2018SA297959			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2018	15563491	NON-EXPEDITED			PHEH2018US044955			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate			S	Oral	1 Df, Every Other Day		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	11590304	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015323993			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Bladder Cancer; C-Reactive Protein Abnormal; Drug Ineffective; Inflammation; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Q2wk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Q2wk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Unknown
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Aurothiomalate De Sodium			S	Parenteral	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Daily		Not Reported
	Hydroxychloroquine			C	Oral	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	12956713	EXPEDITED (15-DAY)		OT	CA-SA-2016SA210316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Liver Function Test Increased; Physical Disability; Rheumatoid Arthritis	Plaquenil			S	Unknown	200 Mg,Bid		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported
	Celebrex			C	Oral	200 Mg,Bid		Not Reported
	Xeljanz			C	Oral	5mg/Bid (2x/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	14118109	EXPEDITED (15-DAY)		OT	US-JNJFOC-20171012019		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acquired Pigmented Retinopathy; Drug Interaction; Toxicity To Various Agents	Ibuprofen	Y	S	Unknown			Not Reported
	Ibuprofen		S	Unknown	As Needed		Not Reported
	Hydroxychloroquine		S	Unknown			Not Reported
	Hydroxychloroquine		S	Unknown			Not Reported
	Hydroxychloroquine		S	Unknown	The Patients Cumulative Hcq Dose Was Calculated To Be 19.8 G		Not Reported
	Hydroxychloroquine		S	Unknown	The Patients Cumulative Hcq Dose Was Calculated To Be 19.8 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	14798527	EXPEDITED (15-DAY)		LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001365		77 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Carcinoma	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Alfacalcidol			C				Not Reported
	Pravastatin			C				Not Reported
	Takelda			C				Not Reported
	Xyzal			C				Not Reported
	Hirudoid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15464082	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2018M1036534		73 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Dysaesthesia; Herpes Zoster; Nausea	Methotrexate			S	Unknown	25 Mg, Unk,20-25 (Unit Not Reported)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk,Last Dose Of Rituximab: Sep/2016		Mylan

	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Mylan
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Mylan
	Sulfasalazine	S	Oral	Unk		Mylan
	Orencia	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15481665	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003476		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15493294	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-027651		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Dexamethasone			S	Unknown			Bausch And Lomb
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Intramuscular	0.8 Cc		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Cyclophosphamide			S	Oral			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15563284	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016248641		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Interstitial Lung Disease	Enbrel		S	Subcutaneous	50 Mg, Qwk	Pfizer
	Methotrexate Sodium		S	Intramuscular	25 Mg, Qwk	Pfizer
	Methotrexate Sodium		S	Oral	Unk,Tablet	Pfizer
	Methotrexate Sodium		S	Intramuscular	25 Mg, Qwk	Unknown
	Actemra		S	Intravenous (not otherwise specified)	8 Mg, Qmo	Not Reported
	Arava		S	Oral	10 Mg, Qd	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	1000 Mg, Qmo	Not Reported
	Plaquenil		S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine		S	Oral	400 Mg, Qd	Not Reported
	Prednisone		C		Unk	Not Reported
	Naprosyn		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564166	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003817			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Toxicity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564731	NON-EXPEDITED			US-PFIZER INC-2018431018		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydrocortisone Acetate			S		Unk		Pfizer
	Taclonex			S		Unk		Not Reported
	Plaquenil			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564739	NON-EXPEDITED			US-PFIZER INC-2018438565		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564756	NON-EXPEDITED			US-PFIZER INC-2018431298		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564802	NON-EXPEDITED			US-PFIZER INC-2018431777		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564817	NON-EXPEDITED			US-PFIZER INC-2018432729		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Meloxicam			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Aleve			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565144	NON-EXPEDITED			US-AMGEN-USASP2018150461			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			C	Subcutaneous	Unk		Not Reported
	Humira			C		Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565461	EXPEDITED (15-DAY)		HO	TH-APPCO PHARMA		38 YR	Female	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Legionella Infection; Myasthenia Gravis; Varicella Zoster Virus Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	13238099	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001127		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	13250619	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001135		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Pharyngitis; Vomiting; Weight Decreased	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Tramadol			C				Not Reported
	Arava			C				Not Reported
	Voltaren			C				Not Reported
	Humira			C				Not Reported
	Motrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	13759327	EXPEDITED (15-DAY)		HO, LT, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004155		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blister; Burning Sensation; Diabetic Neuropathy; Drug Reaction With Eosinophilia And Systemic Symptoms; Pain; Skin Exfoliation; Spinal Pain; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Toxic Skin Eruption	Plaquenil 200 Mg Tablet	S	Oral	One In The Morning And One In Evening		Concordia
	Paracetamol	C				Not Reported
	Evista	C				Not Reported
	Prozac	C				Not Reported
	Plavix	C				Not Reported
	Spironolactone	C				Not Reported
	Aerius (Desloratadine)	C				Not Reported
	Uvedose	C				Not Reported
	Levothyrox	C				Not Reported
	Esidrex	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14026517	NON-EXPEDITED		OT	US-APOTEX-2017AP019093		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Etanercept			C	Unknown	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14157095	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017473269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Joint Swelling; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14198806	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3652		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Product Use Issue; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14227045	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017507814			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Qd		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14228796	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3816		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14232254	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017507977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14232469	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017510518		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Peripheral Swelling	Enbrel			S	Subcutaneous	Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk, Qwk		Pfizer
	Apo-Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14242102	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3921		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastric Disorder; Interstitial Lung Disease; Lung Disorder; Pneumonitis; Polyarthritis; Rheumatoid Arthritis; Treatment Failure; Unevaluable Event	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14288668	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20150709954			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder;	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Plaquenil		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Diclofenac Potassium		S	Unknown		Not Reported
	Diclofenac		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Sulfamethoxazole W/Trimethoprim		S	Unknown		Not Reported
	Apo-Diclofenac		S	Unknown		Not Reported
	Tramadol Hydrochloride		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14379107	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000053			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14380880	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000087			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis;	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported

Vomiting; Weight Decreased	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Ibuprofen		S	Unknown		Not Reported
	Naproxen		S	Unknown		Not Reported
	Tramadol		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	14456047	NON-EXPEDITED		OT	QA-LUPIN PHARMACEUTICALS INC.-2017-07079		25 YR	Female	QAT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15124707	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002378			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Steatosis; Hepatotoxicity; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity	Plaquenil			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Pregabalin			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15229517	EXPEDITED (15-DAY)		HO, OT	CZ-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002712		38 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Condition Aggravated; Off Label Use; Papule; Rebound Effect; Skin Lesion; Vasculitis Necrotising	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	Dose Below 10 Mg		Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15386860	NON-EXPEDITED			US-PFIZER INC-2018369318			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15568398	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-090462		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterograde Amnesia; Confusional State; Off Label Use	Methotrexate			S		Patient Also Received Oral Dosage Form.		Accord
	Fluoxetine			S	Oral	Qd		Accord
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Tranxene			S	Oral	1 Df, Unk		Not Reported
	Loxapac			S	Oral	1 Df, Unk 50 Drop (1/12 Millilitre)		Not Reported
	Theralene			S	Oral	1 Df, Qd 50 Drop (1/12		Not Reported

							Millilitre)		
			Codeine Phosphate/Paracetamol	S	Oral	2 Tab, Tid Si Douleur			Not Reported
			Noctamide	S	Oral	1 Tab, Qd			Not Reported
			Abilify	S	Oral	10 Mg, Qd			Not Reported
			Dafalgan Codeine	S	Unknown	Unk, Tid			Not Reported
			Lepticure	S	Oral	2 Tab, Qd			Not Reported
			Imeth	S	Oral	20 Mg, Qwk			Not Reported
			Folic Acid	C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15568418	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003811			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dizziness; Duodenal Ulcer; Palpitations; Pruritus; Visual Impairment	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Thiopental Sodium			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569160	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06226			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eosinophilia; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569163	NON-EXPEDITED		OT	GB-LUPIN PHARMACEUTICALS		68 YR	Female	GBR

INC.-2018-06495

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	200-400 Mg		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569164	NON-EXPEDITED		OT	JP-LUPIN PHARMACEUTICALS INC.-2018-06617		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin
	Prednisolone			C	Oral	10 Mg, Qd		Not Reported
	Prednisolone			C	Oral	50 Mg, Qd		Not Reported
	Prednisolone			C	Oral	60 Mg, Qd		Not Reported
	Prednisolone			C	Oral	Unk, Tapered To Her Baseline Dose Over The Following 6 Weeks		Not Reported
	Azathioprine			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569172	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2018-05141			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Gh 200 Mg Tablet			S	Unknown	Unk		Lupin
	Insulin			C	Unknown	Unk		Not Reported
	Coveram			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569173	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS			Unknown	JPN

INC.-2018-06233

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569174	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06231			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Headache; Nausea	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Restarted With Standard Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569175	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06227			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569176	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06230			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Restarted From 1/10 Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569177	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06229			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photophobia	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Restarted With Standard Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569178	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06222			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Erythema	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569179	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06232			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Restarted From 1/10 Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569180	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06235			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Restarted With Standard Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569181	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06234			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photophobia	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569185	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2018-05172			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Paraesthesia Oral; Product Odour Abnormal	Hydroxychloroquine Gh 200 Mg Tablet			S	Unknown	Unk		Lupin
	Estradiol			C	Unknown	Unk		Not Reported
	Motilium /00498201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569186	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06225			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dyschromatopsia; Urticaria	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569187	NON-EXPEDITED		OT	JP-LUPIN PHARMACEUTICALS INC.-2018-06117		43 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine			S	Oral	400 Mg, Qd		Lupin
	Hydroxychloroquine			S	Oral	2 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569188	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2018-05602		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569189	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2018-06228			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Restarted From 1/10 Dose And Increased To The Standard Dose		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15569854	NON-EXPEDITED			US-PFIZER INC-2018446817		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2018	15571185	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2018-11630		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Etanercept			S	Unknown	Unknown		Not Reported
	Infliximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	13065401	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2014215134		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Dyspnoea; Lung Disorder; Pneumonitis	Enbrel			S	Subcutaneous	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	13103323	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017001849		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Champix			S	Oral	1 Tablet, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Cyclical		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Valacyclovir			C	Oral	1000 Mg, Bid, As Needed		Not Reported
	Vimovo			C	Oral	500 Mg, Bid		Not Reported
	Crestor			C	Oral	1 Tablet, Qd		Not Reported
	Oxycocet			C	Oral	1 Tablet, Q4h, As Needed		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	13338498	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015242901		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Intolerance; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Product Effect	Methotrexate Sodium			S		0.6 Ml, Weekly		Pfizer
	Methotrexate Sodium			S		0.3 Ml, Weekly		Pfizer
	Arava			S				Not Reported
	Plaquenil /00072603/			S				Not Reported
	Orencia			S				Not Reported
	Leflunomide			S				Not Reported

Incomplete	Xeljanz		C	Oral	5 Mg, 2x/Day		Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day		Not Reported
	Xeljanz		C	Oral	10 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	13380939	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017044321		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14078477	NON-EXPEDITED			US-PFIZER INC-2017439272		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported
	Norco			C		Unk		Not Reported
	Oxycodone			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Triamcinolone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14151597	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2017164956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14156786	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14621224	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-012898		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Dermatitis Allergic; Exposure During	Prednisone			S		15 Milligram		Aurobindo
	Prednisone			S	Unknown	10 Mg,Qd		Aurobindo

Pregnancy; Normal Newborn; Off Label Use	Prednisone		S	Unknown	20 Mg,Qd		Aurobindo
	Hydroxychloroquine		S	Unknown	400 Milligram, Daily		Not Reported
	Hydroxychloroquine		S				Not Reported
	Acetylsalicylic Acid		S	Unknown	75 Mg,Qd		Not Reported
	Acetylsalicylic Acid		S	Unknown	160 Milligram, Daily		Not Reported
	Acetylsalicylic Acid		S	Unknown	100 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14867552	EXPEDITED (15-DAY)		DE, HO	PHHY2018AU074433			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Pancytopenia	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	14993711	NON-EXPEDITED			US-AMGEN-USASP2018076989			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Burning Sensation; Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Prolia			S	Unknown	Unk		Amgen
	Codeine			S	Unknown	Unk		Not Reported
	Pencillin			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Clinoril			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported

	Gabapentin	C		Unk	Not Reported
	Ultram	C		Unk	Not Reported
	Baclofen	C		Unk	Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd	Not Reported
	Meloxicam	C		Unk	Not Reported
	Provera	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15337733	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-NODEN PHARMA DAC-NOD-2015-000306			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez			S	Transplacental	300 Mg, Qd		Noden Pharma
	Advagraf			S	Transplacental	6 Mg, Qd		Not Reported
	Advagraf			S	Transplacental	Unk		Not Reported
	Advagraf			S				Not Reported
	Simvastatin			S	Transplacental	Unknown		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unknown, Prn		Not Reported
	Salbutamol Sulfate			S	Transplacental			Not Reported
	Metamizole Sodium			S	Transplacental	Unknown		Not Reported
	Heparin Lmw			S	Transplacental	Unknown		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Xarelto			S	Transplacental	Unknown		Not Reported
	Rituximab			S	Transplacental	Unk		Not Reported
	Torem /01036501/			S	Transplacental	100 Mg, Qd		Not Reported
	Torem /01036501/			S	Transplacental	Unk		Not Reported
	Pantozol /01263204/			S	Transplacental	40 Mg, Qd		Not Reported
	Nicotine			S	Transplacental	Unknown		Not Reported

	Nicotine	S	Transplacental	Unk		Not Reported
	Novaminsulfon	S	Transplacental	Unknown		Not Reported
	Delix /00885601/	S	Transplacental	20 Mg, Qd		Not Reported
	Quensyl	S	Transplacental	400 Mg, Qd		Not Reported
	Quensyl	S	Transplacental	Unk		Not Reported
	Prednisolon /00016201/	S	Transplacental	10 Mg, Qd		Not Reported
	Clexane	S	Transplacental	200 Mg, Qd		Not Reported
	Ezetimibe Msd	S	Transplacental	Unknown		Not Reported
	Rivaroxaban	S	Transplacental			Not Reported
	Mifegyne	C	Transplacental	Unk		Not Reported
	Cytotec	C	Transplacental	Unk		Not Reported
	Cyclophosphamide	C	Transplacental	3000 Mg, Cumulative		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15373734	NON-EXPEDITED			US-PFIZER INC-2018367174			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15524715	NON-EXPEDITED			US-PFIZER INC-2018420884		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Effexor Xr			S		Unk		Pfizer
	Doxepin Hcl			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Femhrt			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported

	Actemra	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Darvocet	S	Unk	Not Reported
	Imuran	S	Unk	Not Reported
	Percocet	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Remicade	S	Unk	Not Reported
	Tylenol W/Codeine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15573207	EXPEDITED (15-DAY)		OT	BR-ABBVIE-18K-020-2538623-00		27 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Decreased Appetite; Dizziness; Dry Skin; Immunodeficiency; Loss Of Personal Independence In Daily Activities; Malaise; Nail Disorder; Psychiatric Symptom; Vomiting	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Omeprazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reuquinol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15573517	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3132		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Pain; Drug Intolerance; Eye Disorder; Impaired Healing; Localised	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Infection; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Disorder; Peripheral Swelling; Peripheral Swelling; Therapeutic Product Effect Incomplete	Enbrel		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Hepatitis A Vaccine Intact W/Hepatitis B Vaccine Rhbsag Yeast		C	Unknown	Not Reported
	Hepatitis B Surface Antigen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15573951	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018153426		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd (200 Mg 2 Dosage)		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil			C	Oral	400 Mg, Qd (200 Mg 2 Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15574659	EXPEDITED (15-DAY)		HO	CH-ROCHE-2205363		20 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Cellcept			S	Unknown			Not Reported
	Dafalgan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tavanic			S	Unknown			Not Reported
	Paspertin (Switzerland)			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported

	Novalgin (Switzerland)			C	Unknown					Not Reported
	Marcoumar			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15574950	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2018-07557		50 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Pigment Epitheliopathy; Retinal Vein Occlusion; Vision Blurred	Hydroxychloroquine			S	Unknown	Cumulative Dose 11.2 G, Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15574951	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-06023		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Interaction; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin
	Ibuprofen			S	Unknown	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15575331	EXPEDITED (15-DAY)		OT	PHHY2018CN139663		50 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinal Pigment Epitheliopathy; Retinal Vein Occlusion	Hydroxychloroquine			S	Unknown	11.2 G, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576158	NON-EXPEDITED			US-PFIZER INC-2018433586		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Otezla			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Robinul			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576518	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018080434		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Hot Flush; Nausea; Rhinorrhoea; Sinus Congestion	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Leflunomide			S		10 Mg, Daily		Not Reported
	Plaquenil /00072602/			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576636	NON-EXPEDITED			US-PFIZER INC-2018448115		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576648	NON-EXPEDITED			US-PFIZER INC-2018447956		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576657	NON-EXPEDITED			US-PFIZER INC-2018447625		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576759	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017204366			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Amitriptyline			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576760	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017204391			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576762	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017204360			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576764	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2017204363			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory;	Methotrexate			S	Unknown	Unk		Not Reported

Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium			S	Unknown	Unk			Glaxosmithkline
	Arava			S	Unknown	Unk			Not Reported
	Aspirin			S	Unknown	Unk			Glaxosmithkline
	Enbrel			S	Subcutaneous	Unk			Not Reported
	Humira			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Motrin			S	Unknown	Unk			Glaxosmithkline
	Naprosyn			S	Unknown	Unk			Not Reported
	Tramadol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2018	15576768	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017204362			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Amitriptyline			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	11475113	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015084414		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Operation; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Enbrel	S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	12449447	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016071351		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazin			S	Oral	Unk		Not Reported
	Sulfasalazin			S	Oral	1 G, Bid		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	12687119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1420		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Pain; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	13158909	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017004280		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	13188194	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2012063337		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthritis Bacterial; Drug Ineffective; Drug Intolerance; Gastric Disorder; Mobility Decreased; Nerve Injury; Pain; Post Procedural Complication; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	400mg /200 Mg, Qd (During Five Year)		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk Unk, Qd		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	13989288	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005362		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14151324	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164830			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14158870	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14164820	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017477275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Oral	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Qwk		Pfizer
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14189737	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017170217		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pneumonitis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Cyclical		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14190996	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491071		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk	Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk	Pfizer
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Ergocalciferol			C	Unknown	Unk	Not Reported
	Prednisone			C	Unknown	Unk	Not Reported
	Vitamin B12			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14216044	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017174741			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Gold			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14260910	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017181191		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma Stage Iii	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14361155	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gait Disturbance; Impaired Work Ability; Insomnia; Joint Swelling; Meniere'S Disease; Pain; Peripheral Swelling; Therapeutic Response Decreased; Vertigo	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported
	Omeprazole			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14379113	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000068		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Rheumatoid Arthritis; Stomatitis; Treatment Failure	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Folinic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14400788	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

						INC.-GSH201801-000120			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14502123	EXPEDITED (15-DAY)		CA, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010651			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Cleavage Syndrome; Foetal Exposure During Pregnancy	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	14524451	NON-EXPEDITED			US-PFIZER INC-2018062472		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

	Arava	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15155416	EXPEDITED (15-DAY)		HO, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-028517		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Squamous Cell Carcinoma Of Lung	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15490201	EXPEDITED (15-DAY)		OT	CA-SA-2018SA277838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Hydroxychloroquine			S		200 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Kevzara			S		Unk		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15557107	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017019002		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

		Leflunomide			S	Unknown	Unk			Not Reported
		Hydroxychloroquine			S	Unknown	Unk			Not Reported
		Methotrexate			S	Oral	25 Mg, Qwk			Not Reported
		Methotrexate			S	Unknown	Unk			Not Reported
		Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
		Apo-Hydroxyquine			S	Unknown	Unk			Not Reported
		Apo-Leflunomide			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15577922	NON-EXPEDITED			US-PFIZER INC-2018447968			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15578553	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-029450		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Hypoxia; Intentional Overdose; Mental Status Changes; Pulmonary Haemorrhage; Somnolence; Suicide Attempt; Systemic Lupus Erythematosus; Torsade	Hydroxychloroquine			S	Oral	Twenty 200mg (Total 4g) Tablets Of Hydroxychloroquine Along With Alcohol		Zydus Pharm

De Pointes; Toxicity To Various Agents; Ventricular Extrasystoles

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15579953	EXPEDITED (15-DAY)		DS	CA-SAKK-2018SA299505AA		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Remicade			S		3 Mg/G;0,2,6 Weeks Then For Q8h		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Q4w		Not Reported
	Orencia			S				Not Reported
	Methotrexate			C		Oral, Then Sc		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15579958	NON-EXPEDITED			US-SA-2018SA302453			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Unevaluable Event	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15580287	DIRECT		DS				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Balance	Hydroxychloroquine Sulfate			S	Oral	Quantity:1 Tablet(S);	2 MTH	Amneal

Disorder; Ear Pain;	Aderral 20mg Bid	C		Not Reported
Fatigue; Libido	Tramadol Hcl	C		Not Reported
Decreased; Memory	Chonazepam	C		Not Reported
Impairment; Speech	Gabepentin	C		Not Reported
Disorder; Tinnitus; Vision	Omeprazole	C		Not Reported
Blurred	Meloxicam	C		Not Reported
	Vitamin D-3	C		Not Reported
	Hydroxychlor	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15581088	NON-EXPEDITED			US-PFIZER INC-2018440343		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15581693	EXPEDITED (15-DAY)			US-RADIUS HEALTH INC.-2018US001657			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chapped Lips; Rash	Tymlos			S	Subcutaneous	80 Mcg, Once A Day		Radius Pharm
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15584799	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018152801		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Juvenile Idiopathic Arthritis	Etanercept			S	Unknown	Unk		Amgen
	Adalimumab			S	Unknown	Unk		Not Reported

		Hydroxychloroquine		S	Unknown	Unk			Not Reported
		Tocilizumab		S	Subcutaneous	Unk Unk, Qwk			Not Reported
		Prednisone		C	Oral	Unk			Not Reported
		Methotrexate		C	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15585115	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018152794		7 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Juvenile Idiopathic Arthritis; Microcytic Anaemia; Therapeutic Product Effect Incomplete	Etanercept			S	Unknown	Unk		Amgen
	Rituximab			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Nov-2018	15597191	DIRECT	Y				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Product Dose Omission	Hydroxychloroquine 200 Mg Tab			S	Oral	Take 2 Tablets By Mouth Every Day With Yearly Eye Exams		Not Reported
	Xeljanz Xr 11 Mg Tablet			S	Oral			Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2018	14170435	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015219			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2018	14636675	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA018531			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Infliximab Pfizer (Unknown)			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2018	15582904	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA010955			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2018	14161493	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017477163			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Sulfasalazine			S	Oral	1 G, Bid		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2018	15457828	EXPEDITED (15-DAY)		HO, OT	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003412		60 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macule; Ochronosis; Pigmentation Disorder	Plaquenil			S	Unknown			Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	11331574	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2015DE091766			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Rituximab			S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional		Not Reported
	Rasilez			S	Transplacental	Maternal Dose, 300 Mg Qd		Not Reported
	Prednisolone			S	Transplacental	Maternal Dose, 10 Mg (Every Other Day)		Novartis
	Pantoprazole			S	Transplacental	Maternal Dose, 40 Mg, Qd		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental	Maternal Dose, 100 Mg Qd		Not Reported
	Salbutamol			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Salbutamol			S	Transplacental	Unk, If Required; Trimester: First+Second		Not Reported
	Clexane			S	Transplacental	Maternal Dose, 200 Mg, Qd		Not Reported

Novaminsulfon	S	Transplacental	Maternal Dose: Unknown	Not Reported
Advagraf	S	Transplacental	Maternal Dose, 6 Mg Qd	Not Reported
Quensyl	S	Transplacental	Maternal Dose, 400 Qd	Not Reported
Quensyl	S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week	Not Reported
Torasemide	S	Transplacental		Not Reported
Torem	S	Transplacental	Maternal Dose, 100 Mg Qd	Not Reported
Torem	S	Transplacental	100 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Torem	S			Not Reported
Xarelto	S	Transplacental	Unk	Not Reported
Nicotine	S	Transplacental		Not Reported
Delix (Ramipril)	S	Transplacental	20 Mg, Qd 0-13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cytotec	C	Transplacental	Unk	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Heparin	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	13053397	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2016180126		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Drug Intolerance; Infection; Pericardial Effusion;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Methotrexate	S	Unknown	25 Mg, Qwk		Not Reported
	Arava	S	Oral	20 Mg, Qd		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	14195525	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017494030		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pneumonitis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Qwk		Pfizer
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	14258387	NON-EXPEDITED			US-PFIZER INC-2017514953		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

	Enbrel	S	Unk	Pfizer
	Advil	S	Unk	Pfizer
	Effexor Xr	S	Unk	Pfizer
	Methotrexate Sodium	S	Unk	Pfizer
	Morphine Sulfate	S	Unk	Unknown
	Sulfasalazine	S	Unk	Pfizer
	Orencia	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
	Leflunomide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	14268781	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017526663		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma Stage Iii	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	14547028	NON-EXPEDITED			US-PFIZER INC-2018068037			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Minocycline			S		Unk		Pfizer
	Hydrocodone			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	14985006	NON-EXPEDITED			US-PFIZER INC-2018232121		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Clinoril			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Cyclobenzaprine			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prolia			C		Unk		Not Reported
	Centrum			C		Unk		Not Reported
	Baclofen			C		Unk		Not Reported
	Vit D3			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15414993	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018382166		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.0 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer

Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15.0 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	10.0 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Unknown
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	360 Mg, Monthly	Not Reported
	Actemra	S	Unknown	680 Mg, Monthly	Not Reported
	Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
	Humira	S	Unknown	40 Mg, Unk (1 Every 2 Week)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
	Orencia	S	Unknown	780 Mg, Weekly	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	1000 Mg, 2x/Day	Not Reported
	Ciclosporin	C	Unknown	150 Mg, 1x/Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15572487	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016303384		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis	Enbrel			S	Unknown	Stopped On 26-May -Year Unknown		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Acetaminophen			C		500 Mg, As Required		Not Reported

	Atasol (Acetaminophen)			C		500 Mg, As Needed				Not Reported
	Naproxen			C		500 Mg, 2x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15577944	NON-EXPEDITED			US-PFIZER INC-2018440252		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15586371	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2018M1081363			Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoid Tissue Hyperplasia	Penicillamine			S	Unknown			Not Reported
	Ledertrexate /00113801/			S	Unknown			Mylan
	Plaquenil /00072602/			S	Unknown			Mylan
	Allochrysine /00499201/			S	Unknown			Mylan
	Ridaura			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15588061	NON-EXPEDITED			US-PFIZER INC-2018452545			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine			S		Unk		Not Reported

Sulfate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2018	15598430	DIRECT	Y				40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tendon Injury	Humira 40 Mg/0.8 Ml Pen			S	Subcutaneous	Inject 40mg Subcutaneously Every 2 Weeks As Directed		Abbvie
	Humira 40 Mg/0.8 Ml Pen			S				Abbvie
	Hydroxychloroquine 200 Mg Tab			S	Oral	Take 2 Tablets By Mouth Once Every Day Milk As Directed		Not Reported
	Hydroxychloroquine 200 Mg Tab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	11489777	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015275679		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eating Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	12312530	EXPEDITED (15-DAY)		HO	CA-ROCHE-1748893		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydromorphone Hydrochloride	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 1 Week		Not Reported
	Methotrexate Sodium	S	Subcutaneous			Not Reported
	Prednisone	S	Unknown			Not Reported
	Dilaudid	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Apo-Acetaminophen	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Humira	C				Not Reported
	Orencia	C				Not Reported
	Remicade	C				Not Reported
	Diphenhydramine Hydrochloride	C				Not Reported
	Fosavance	C				Not Reported
	Hydrocortisone	C				Not Reported
	Hyzaar	C				Not Reported
	Methylprednisolone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	12974844	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Hepatotoxicity; Liver Function Test Increased; Physical Disability; Rheumatoid Arthritis	Plaquenil		S	Unknown	Concordia
	Arava		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Celebrex		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	13057963	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006525		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Rupture Of Membranes	Plaquenil 200 Mg Tablet			S	Unknown			Concordia
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	13498577	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00008097		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Haemorrhagic Leukoencephalitis; Aphasia; Aphasia; Aspergillus Infection; Brain Midline Shift; Brain Oedema; Cerebral	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Voriconazole			S	Unknown			Not Reported

Aspergillosis; Confusional State; Culture Tissue Specimen Positive; Hemiparesis; Intracranial Mass; Leukopenia	Voriconazole	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	13527924	NON-EXPEDITED			US-PFIZER INC-2017197327			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Advil			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Dimetapp		Y	S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Terramycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Aleve			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cipro /00697201/			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Rocephin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Valium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14154826	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164961		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rash; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Cimzia			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	300 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	300 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14157864	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164990		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Cimzia			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qwk		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, 4 Times/Wk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14580850	EXPEDITED (15-DAY)		OT	CA-ROCHE-2076577		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diabetic Eye Disease; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra	S	Unknown		Not Reported
	Bactrim	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	14648196	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA018597			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15188664	NON-EXPEDITED			US-PFIZER INC-2018296583		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15404852	NON-EXPEDITED			US-AMGEN-USASP2018129185			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15560841	NON-EXPEDITED			US-PFIZER INC-2018440357		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15568510	NON-EXPEDITED			US-AMGEN-USASP2018151510			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Stomatitis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

	Orencia			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15589046	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003842			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crepitations; Haemorrhage; Pain; Rash; Swelling	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15589218	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0769		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Hot Flush; Nausea; Rhinorrhoea; Sinus Congestion	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15589335	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003849		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Blister; Disability; Fatigue; Joint Swelling; Nausea; Product Dose Omission; Quality Of Life Decreased; Rheumatoid Arthritis; Rheumatoid Factor	Plaquenil			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Positive; Skin Discolouration; Visual Impairment; Vomiting	Methotrexate	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15589373	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Cough; Gait Disturbance; Pain; Rheumatoid Arthritis; White Blood Cell Count Decreased	Plaquenil			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15590611	EXPEDITED (15-DAY)		HO	SA-PFIZER INC-2018451304		46 YR	Male	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Plaquenil S			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15591130	EXPEDITED (15-DAY)		DS	CA-ROCHE-2209747			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Etanercept	S				Not Reported
	Methotrexate	S	Unknown			Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Infliximab	S	Unknown			Not Reported
	Infliximab	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Adalimumab	S				Not Reported
	Abatacept	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15592130	EXPEDITED (15-DAY)		OT	CA-SA-2018SA302437		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Remicade			S				Not Reported
	Stelara			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15592559	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016290883			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Plaquenil			S	Unknown	200 Mg, 2x/Day		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15592906	EXPEDITED (15-DAY)		OT	PHHY2018NL102347		42 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Immunoglobulin G4 Related Disease; Off Label Use; Product Use In Unapproved Indication; Rebound Effect; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk (Tapering)		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15593887	NON-EXPEDITED			US-PFIZER INC-2018450255		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15593964	NON-EXPEDITED			US-PFIZER INC-2018450323		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Daypro			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Cipro [Ciprofloxacin]			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2018	15594188	NON-EXPEDITED			US-PFIZER INC-2018453336		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	13076863	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016586763		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Drug Intolerance; Infection; Pericardial Effusion; Pneumonia; Rheumatoid Arthritis; Urticaria	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

	Folic Acid			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	13834401	EXPEDITED (15-DAY)		OT	PHHY2017GB111542		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Lethargy; Leukopenia; Off Label Use; Product Use In Unapproved Indication; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk (Over 2 Years)		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Methotrexate			S	Unknown	Unk (Over 2 Years)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk (Over 2 Years)		Not Reported
	Rituximab			S				Not Reported
	Prednisolone			S	Unknown	Unk (Over 2 Years)		Novartis
	Prednisolone			S				Novartis
	Colchicine			S	Unknown	Unk (Over 2 Years)		Not Reported
	Colchicine			S				Not Reported
	Dapsone			S	Unknown	Unk (Over 2 Years)		Not Reported
	Dapsone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk (Over 2 Years)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk (Over 2 Years)		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	13876635	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2016CA011331			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug	Inflectra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported

Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate Sodium		S	Unknown	20 Mg, Unk		Not Reported
	Xeljanz		S	Oral	5 Mg, Unk		Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, Unk		Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone		S	Unknown	9 Mg, Unk		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	13921649	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA011443			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	9 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14160183	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016542768		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Burning Sensation; Drug Ineffective; Gait Disturbance; Limb Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tooth Infection	Enbrel	S	Unknown	50 Mg, Unk		Pfizer
	Celebrex	S	Unknown	Unk		Pfizer
	Celebrex	S	Unknown	Unk		Pfizer
	Methotrexate Sodium	S	Oral	17.5 Mg, Weekly		Pfizer
	Methotrexate Sodium	S	Oral	17.5 Mg, Qwk		Pfizer
	Apo-Hydroxyquine	S	Unknown	200 Mg, Unk		Not Reported
	Plaquenil	S	Unknown	200 Mg, Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Meloxicam	C	Unknown	50 Mg, Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14163769	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017477170		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Intramuscular	25 Mg, 4 Times/Wk		Unknown
	Cimzia			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14168311	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Disturbance; Limb Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Response Decreased; Tooth Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown	Ongoing		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14169506	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3417		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Gastrointestinal Disorder; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	Stopped On 26-May		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Atasol (Acetaminophen)			C	Unknown	If Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14187657	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017170172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14227519	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017505214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	22.5 Mg, Unk		Pfizer
	Gold			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14242109	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3924		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	14648274	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA018575			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg		Not Reported
	Apo-Prednisone			S	Unknown	9 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15592910	EXPEDITED (15-DAY)		HO	IT-ACCORD-091292		79 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Cancer Stage Ii	Methotrexate			S	Oral			Accord
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alendronic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2018	15595480	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2517789-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antineutrophil Cytoplasmic Antibody Positive; Arthralgia; Gait Disturbance; Henoch-Schonlein Purpura; Kidney Fibrosis; Protein Urine Present; Rash Macular; Red Blood Cells Urine Positive; Renal Tubular Atrophy; Vasculitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	14203621	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3694		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Hypersensitivity; Lung	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Disorder; Pneumonitis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15234536	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Localised Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15472780	NON-EXPEDITED			US-PFIZER INC-2018396700		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unk		Pfizer
	Methotrexate Sodium	S	Unk		Pfizer
	Sulfasalazine	S	Unk		Pfizer
	Hydroxychloroquine	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Azathioprine	S	Unk		Not Reported
	Cyclosporine	S	Unk		Not Reported
	Humira	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15570384	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2018440080		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Doxycycline Hyclate			S		Unk		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Amoxicillin			S		6 G, Daily		Not Reported
	Amoxicillin			S		12 G, Daily		Not Reported
	Gentamycin			S		1.5 Mg/Kg, Daily		Not Reported
	Gentamycin			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15596818	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3211		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	200 Mg 2 Dosage				Not Reported
	Plaquenil			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15596988	EXPEDITED (15-DAY)		HO, LT	US-APPCO PHARMA LLC-2058575		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Intentional Overdose; Pulmonary Alveolar Haemorrhage; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Ethanol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15597059	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-054196		42 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immunoglobulin G4 Related Disease; Off Label Use; Rebound Effect	Prednisone Tablet			S	Unknown	Unk		Aurobindo
	Prednisone Tablet			S	Unknown	Unk, Tapering		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15598228	EXPEDITED (15-DAY)		HO, OT	CH-SAKK-2018SA299930AA		39 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Myoclonus	Plaquenil			S				Sanofi
	Chloroquine (Salt Not Specified)			S				Sanofi
	Depakine [Valproate Sodium]			C				Not Reported
	Depakine [Valproate Sodium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15598301	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA021997		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown	Unk Unk, Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S		15 Mg Qwk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Infliximab			S	Unknown	200 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15599054	NON-EXPEDITED			PHEH2018US046701			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Therapy Non-Responder	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported
	Stelara			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2018	15599484	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2018M1084043		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Citalopram			S	Transplacental	10 [Mg/D]		Not Reported
	Quensyl			S	Transplacental	200 [Mg/D]		Mylan
	Femibion 1			C	Transplacental	0.8 [Mg/D]		Mylan
	Cytotec			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	12691301	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016403486			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported

				Folic Acid	S	Unknown	Unk		Not Reported
				Fosamax	S	Unknown	Unk		Not Reported
				Humira	S	Subcutaneous	Unk		Not Reported
				Orencia	S	Subcutaneous	Unk		Not Reported
				Prednisone	S	Unknown	Unk		Not Reported
				Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk		Not Reported
				Remicade	S	Unknown	Unk		Not Reported
				Rituxan	S	Unknown	Unk		Not Reported
				Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	13826402	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1732428US		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective For Unapproved Indication; Lethargy; Leukopenia; Off Label Use	Dapsone Unk			S	Unknown	Unk		Allergan
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	14164614	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017477921		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	14248473	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2017-0008114		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Oxycodone Hydrochloride			S	Unknown	10 Mg, Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Marihuana			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown	7 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15498011	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Sarilumab Pre-Filled Syringe			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15600483	EXPEDITED (15-DAY)		OT	IE-ACCORD-091080		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Leukopenia; Off Label Use; Skin Atrophy	Methotrexate			S	Unknown	10 Mg Weekly		Accord
	Tacrolimus			S	Topical			Not Reported
	Hydroxychloroquine			S		200 Mg, Bid		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Oral			Not Reported
	Clobetasol			S	Topical	Unk		Not Reported
	Protopic			S	Topical			Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported
	Efavirenz			C	Unknown	Unk		Not Reported
	Co-Trimoxazole			C	Unknown			Not Reported
	Lamivudine/Zidovudine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15600487	EXPEDITED (15-DAY)		OT	PT-ACCORD-091032		71 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Infected Varicose Vein; Pulmonary Nocardiosis; Varicose Ulceration	Methotrexate			S	Subcutaneous			Accord
	Salazopirina			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquinol			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15600805	EXPEDITED (15-DAY)		DE, OT	BE-ROCHE-2208432			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiocentric Lymphoma; B-Cell Lymphoma; B-Cell Lymphoma; Burkitt'S Lymphoma; Chronic Lymphocytic Leukaemia; Diffuse Large B-Cell Lymphoma; Extranodal Marginal Zone B-Cell Lymphoma (Malt Type); Hepatosplenic T-Cell Lymphoma; Hodgkin'S Disease; Hodgkin'S Disease Nodular Sclerosis; Lymphocytic Leukaemia; Lymphoid	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Intravenous (not otherwise specified)			Not Reported
	Pirfenidone			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Intravenous (not otherwise specified)			Not Reported

Tissue Hyperplasia; Lymphoma; Lymphoproliferative Disorder; Plasmablastic Lymphoma; Plasmacytoma	Anakinra	S	Intravenous (not otherwise specified)	Not Reported
	Auranofin	S	Intravenous (not otherwise specified)	Not Reported
	Aurotioprol	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine	S	Intravenous (not otherwise specified)	Not Reported
	Canakinumab	S	Intravenous (not otherwise specified)	Not Reported
	Cipemastat	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Intravenous (not otherwise specified)	Not Reported
	Mercaptopurine	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Nimesulide	S	Intravenous (not otherwise specified)	Not Reported
	Penicillamine	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
	Tacrolimus	S	Intravenous (not otherwise specified)	Not Reported

	Thalidomide			S	Intravenous (not otherwise specified)				Not Reported
	Ustekinumab			S	Intravenous (not otherwise specified)				Not Reported
	Vedolizumab			S	Intravenous (not otherwise specified)				Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2018	15603439	EXPEDITED (15-DAY)		OT	IT-SHIRE-IT201842674			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Kiovig			S	Intravenous (not otherwise specified)			Shire
	Kiovig			S				Shire
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2018	15355355	EXPEDITED (15-DAY)		HO, OT	RO-ACCORD-071313		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Clopidogrel			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	150 Mg, Daily		Not Reported
	Sulfasalazine			S		1 G In 2000		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	12404907	NON-EXPEDITED			US-PFIZER INC-2016272656		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Interaction	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	13079689	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0007		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Infection; Pericardial Effusion; Pneumonia; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	13821063	EXPEDITED (15-DAY)		OT	GB-ROCHE-1970781		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Lethargy; Leukopenia; Off Label Use; Product Use In Unapproved Indication; Treatment Failure	Rituximab			S	Unknown	Over 2 Years		Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Over 2 Years		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine			S	Unknown	Over 2 Years		Not Reported
	Hydroxychloroquine			S				Not Reported
	Colchicine			S	Unknown	Over 2 Years		Not Reported

	Colchicine	S				Not Reported
	Methotrexate	S	Unknown	Over 2 Years		Not Reported
	Methotrexate	S				Not Reported
	Prednisolone	S	Unknown	Over 2 Years		Not Reported
	Prednisolone	S				Not Reported
	Dapsone	S	Unknown	Over 2 Years		Not Reported
	Dapsone	S				Not Reported
	Azathioprine	S	Unknown	Over 2 Years		Not Reported
	Azathioprine	S				Not Reported
	Ciclosporin	C	Unknown			Not Reported
	Ciclosporin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	14196387	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	14236380	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Therapy Non-Responder; Treatment Failure	Enbrel		S	Unknown		Not Reported
	Gold		S	Intramuscular		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Oral		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Oral		Not Reported
	Rituxan		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	14280404	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-4071		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Cell Lymphoma Stage Iii	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15392137	NON-EXPEDITED			US-PFIZER INC-2018372251		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15410038	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018129516			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fear Of Injection; Mycobacterium Tuberculosis Complex Test Positive; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	17.5 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15476259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022037			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Asacol			S	Oral	800 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Amlodipine Besilate			C	Unknown	Unk		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Omega Allergenic Extracts			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15589111	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3187		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Inability; Hypokinesia; Rheumatoid Arthritis; Sleep Disorder	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15591730	NON-EXPEDITED			US-PFIZER INC-2018442453		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Diclofenac Sodium			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Gadolinium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15591817	NON-EXPEDITED			US-PFIZER INC-2018442615			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Methocarbamol			S		Unk		Pfizer
	Flexeril [Cyclobenzaprine Hydrochloride]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15599155	NON-EXPEDITED			US-PFIZER INC-2018447240		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605036	EXPEDITED (15-DAY)		OT	CA-ROCHE-2209036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Spleen Disorder;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Urticaria	Xeljanz	S	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Cimzia	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605068	EXPEDITED (15-DAY)		OT	PT-ACCORD-091178		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Off Label Use; Progressive Multifocal Leukoencephalopathy	Methotrexate			S	Unknown	Not Provided		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown	Not Provided		Not Reported
	Azathioprine			S	Unknown	Not Provided		Not Reported
	Thalidomide			S	Oral	Not Provided		Not Reported
	Hydroxychloroquine			S	Unknown	Not Provided		Not Reported
	Rituximab			S	Unknown	Not Provided		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605071	EXPEDITED (15-DAY)		DE, OT	GB-ACCORD-091543		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Immunosuppression	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605386	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003863		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

	Remicade	S	Unknown	0,2,6 Weeks Then For Q8h		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Methotrexate	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605690	EXPEDITED (15-DAY)		OT	NL-ACCORD-091298		38 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Pregnancy On Oral Contraceptive	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605865	EXPEDITED (15-DAY)		HO	DE-ACCORD-091482		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown	Dose _ 10-15mg		Not Reported
	Rituximab			S	Unknown	Also Received Jul-2013 Feb-201, .Jun-2015		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15606654	EXPEDITED (15-DAY)		DE, OT	PHHY2018IT145465		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Asthenia; Blindness; Coma; Disorientation; Dysarthria; Hemiparesis; Impaired Driving Ability; Jc Virus Infection; Neurologic Neglect Syndrome; Ophthalmoplegia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy; Quadriplegia; Visual Impairment	Hydroxychloroquine	S	Unknown	200 Mg, Unk		Novartis
	Oxycodone	C	Unknown			Not Reported
	Levothyroxine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15606999	EXPEDITED (15-DAY)		DE, HO	IT-MYLANLABS-2018M1083698		50 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coma; Jc Virus Infection; Off Label Use; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Maraviroc			S	Unknown			Mylan
	Oxycodone			C	Unknown			Mylan
	Levothyroxine			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15608583	EXPEDITED (15-DAY)		OT	US-SA-2018SA307884			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15609333	EXPEDITED (15-DAY)		OT	GB-AQUA PHARMACEUTICALS-2018AQU000344			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia	Aczone			S		Unk		Aqua
	Hydroxychloroquine			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Prednisolone			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15609479	EXPEDITED (15-DAY)		OT	NO-MYLANLABS-2018M1085267		30 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Breast Feeding; Maternal Exposure During Pregnancy	Azathioprine			S	Unknown	75 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Initial Dose Unknown; Dose Gradually Escalated Up To 25 Mg/Week But Without Effect		Not Reported
	Methotrexate			S	Unknown	Initial Dose Unknown; Dose Gradually Escalated Up To 25 Mg/Week But Without Effect		Not Reported
	Prednisone			S	Unknown			Not Reported
	Belimumab			S	Unknown	10 Mg/Kg, Monthly, Formulation: Infusion		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	11618849	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477029-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	13059588	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015780		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Twice A Week		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Q.Wk.		Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	13072062	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2016-2844		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Mouth; Dyspnoea; Lung Disorder; Pneumonitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	13496435	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2017183529		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection	Methotrexate Sodium			S		Once Weekly		Pfizer
	Sulfasalazine			S		Once Weekly		Pfizer
	Hydroxychloroquine			S		Once Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	13823387	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00008285		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia; Off Label Use	Prednisolone			S	Unknown	Over 2 Years		Concordia
	Prednisolone			S				Concordia
	Hydroxychloroquine			S	Unknown	Over 2 Years		Concordia
	Hydroxychloroquine			S				Concordia

	Methotrexate	S	Unknown	Over 2 Years	Not Reported
	Methotrexate	S			Not Reported
	Azathioprine	S	Unknown	Over 2 Years	Not Reported
	Azathioprine	S			Not Reported
	Mycophenolate Mofetil	S	Unknown	Over 2 Years	Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Dapsone	S	Unknown	Over 2 Years	Not Reported
	Dapsone	S			Not Reported
	Colchicine	S	Unknown	Over 2 Years	Not Reported
	Colchicine	S			Not Reported
	Rituximab	S	Unknown	Over 2 Years	Not Reported
	Rituximab	S			Not Reported
	Ciclosporin	C			Not Reported
	Nonsteroidal Anti Inflammatory Drugs	C			Not Reported
	High Dose Glucocorticoids	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	13929298	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006311		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Blood Creatine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea;	Apo-Acetaminophen			S	Unknown			Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Hydromorphone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Apotex
	Acetaminophen			S	Oral	65 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Folic Acid			S	Unknown	15.5 Mg, Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Mg, Once Every 4 Weeks		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported

Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Enbrel	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
	Fosavance	C	Unknown	Unk	Not Reported
	Hydrocortisone	C	Unknown	Unk	Not Reported
	Hyzaar	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Orencia	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	13995585	NON-EXPEDITED			US-PFIZER INC-2017403383			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		20 Mg, Daily		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	14100676	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1064243		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia	Azathioprine			S	Unknown	Over 2 Years		Not Reported
	Mycophenolate Mofetil			S	Unknown	Over 2 Years		Not Reported
	Hydroxychloroquine			S	Unknown	Over 2 Years		Not Reported
	Prednisolone			S	Unknown	Over 2 Years		Not Reported
	Methotrexate			S	Unknown	Over 2 Years		Not Reported
	Colchicine			S	Unknown	Over 2 Years		Mylan
	Dapsone			S	Unknown	Over 2 Years		Mylan
	Rituximab			S	Unknown	Over 2 Years		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	14357043	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268247		91 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Drug Intolerance; Gait Inability; Rheumatoid Arthritis	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S	Oral	20 Mg,Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	14841592	EXPEDITED (15-DAY)		DE, OT	CA-SA-2017SA268733		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug	Leflunomide			S	Oral	20 Mg,Qd		Sanofi

Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S		200mg/400mg Daily		Sanofi
	Sulfasalazine	S	Unknown	500 Mg,Qid		Not Reported
	Methotrexate	S	Oral	22.5 Mg,Qw		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg,Qw		Not Reported
	Humira	S	Subcutaneous	40 Mg,Qw		Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Qw		Not Reported
	Xeljanz	C	Oral	50 Mg, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	Unk Unk,Unk		Not Reported
	Arava	C	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15609763	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003869		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Pain In Extremity; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Cortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15609821	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003894		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported

Arthritis; Spleen Disorder; Urticaria	Actemra			S	Unknown	Not Reported
	Xeljanz			S	Oral	Not Reported
	Sulfasalazine			C		Not Reported
	Methotrexate			C		Not Reported
	Cimzia			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15609856	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003897		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access	Plaquenil Tablet			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported

Complication; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15609971	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-3246		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Knee Arthroplasty; Malaise; Pain; Post Procedural Complication; Product Complaint; Sensory Loss; Swelling; Therapeutic Product Effect Incomplete; Thrombosis; Unevaluable Event	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612200	EXPEDITED (15-DAY)		DE, HO	AU-MYLANLABS-2018M1080219			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612454	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2018M1083816		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Cardiac Arrest;	Diltiazem			S	Oral			Not Reported

Hyperkalaemia; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Oral			Not Reported
	Venlafaxine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Clonazepam			S	Oral			Not Reported
	Fluoxetine			S	Oral			Not Reported
	Baclofen			S	Oral			Not Reported
	Insulin Glargine			S	Other	70 U/Hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612498	EXPEDITED (15-DAY)		OT	PHHY2018ES109862		22 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oesophageal Candidiasis; Opportunistic Infection; Product Use In Unapproved Indication	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Prednisone			S	Unknown	2.70 G, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Imurel			S	Unknown	Unknown Dose		Not Reported
	Imurel			S				Not Reported
	Imurel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15612504	EXPEDITED (15-DAY)		HO, OT	PHHY2018FR119240		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Ramipril			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Oral	2 G, Qd		Novartis
	Mycophenolate Mofetil			S	Oral	1.5 G, Qd		Novartis
	Bactrim			S	Oral	Unk		Not Reported
	Cellcept			S	Oral	2 G, Qd (Puis 1.5g 2/J À Partir Du 09/07/18)		Not Reported
	Cellcept			S	Oral	1.5 G, Qd		Not Reported

	Lovenox			S	Unknown	4000 Iu, Qd			Not Reported
	Lederfoline			S	Oral				Not Reported
	Cerazette [Desogestrel]			S	Oral				Not Reported
	Inexium			S	Oral				Not Reported
	Plaquenil			S	Oral	400 Mg, Qd			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Oral	Unk			Not Reported
	Enoxaparin Sodium			S	Unknown	4000 Iu, Qd			Not Reported
	Esomeprazole Magnesium			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15613630	NON-EXPEDITED			PHEH2018US047856			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Penicillin G Sodium			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15613644	NON-EXPEDITED			PHEH2018US047848			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection	Cosentyx			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15613657	NON-EXPEDITED			PHEH2018US047852			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2018	15614168	NON-EXPEDITED			US-PFIZER INC-2018461585		80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	11557898	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015094576		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder;	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Remicade			C		Unk		Not Reported

Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Simponi	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	11618911	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477033-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hypertension; Injection Site Inflammation; Pruritus; Rheumatoid Arthritis; Urosepsis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Salicylates			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	12890992	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013491		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk, Unknown		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk, Unknown		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported

	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Voltaren /00372301/	C	Unknown	100 Mg, Qd		Not Reported
	Cortisone	C	Unknown	10 Mg, Qd		Not Reported
	Desoximetasone	C	Oral	10 Mg, Qd		Not Reported
	Xeljanz	C	Unknown			Not Reported
	Zostavax	C	Unknown			Not Reported
	Diclofenac	C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	13124732	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000470		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	13973982	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005111		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Subretinal Fluid; Visual Acuity Reduced	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	14141829	NON-EXPEDITED			US-AMGEN-USASP2017161886			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Tylenol			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Iodine			S	Unknown	Unk		Not Reported
	Betadine			S	Unknown	Unk		Not Reported
	Ultram			S	Unknown	Unk		Not Reported
	Neurontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	14328951	NON-EXPEDITED			US-PFIZER INC-2017550287		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer

		Hydroxychloroquine			S		Unk			Not Reported
		Humira			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	14836028	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15108407	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0762		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Anakinra	S			Not Reported
	Apo-Leflunomide	S			Not Reported
	Azathioprine	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Intramuscular		Not Reported
	Methotrexate	S			Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15614832	EXPEDITED (15-DAY)			CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010722		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Plaquenil Tablet			S	Unknown			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15614833	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-			Female	CAN

003914

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyarthritis	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15615572	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003916			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15617533	EXPEDITED (15-DAY)		OT	PHHY2018GB154853			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Psoriatic Arthropathy	Methotrexate			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15617696	NON-EXPEDITED			US-PFIZER INC-2018463960		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine			S				Not Reported

Sulfate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15618061	NON-EXPEDITED			US-PFIZER INC-2018461247		71 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15619102	EXPEDITED (15-DAY)		OT	US-SA-2018SA311753			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown			Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2018	15619127	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA309581AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Arava			S		10 Mg		Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	11223892	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2013005487		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Tolerance; Hyperhidrosis; Influenza; Product Use	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Subcutaneous	22.5 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported

Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil	S	Unknown	200 Mg, Unk		Not Reported
	Prednisone	S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Vitamin D2	C		Unk		Not Reported
	Vitamins Nos	C		Unk		Not Reported
	Celebrex	C		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Ergocalciferol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	14169504	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15497310	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2018-027148		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective For Unapproved Indication; Lethargy; Leukopenia; Off Label Use	Dapsone			S	Unknown			Not Reported
	Dapsone			S				Not Reported
	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15606434	EXPEDITED (15-DAY)		OT	ES-ACCORD-091520		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia	Methotrexate Sodium			S		Unk		Accord
	Etanercept			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Abatacept			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Dolquine			S		Unk		Not Reported
	Adalimumab			S		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Paracetamol			C				Not Reported
	Enbrel			C	Unknown			Not Reported
	Lornoxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619411	EXPEDITED (15-DAY)		OT	GB-ACCORD-091725		56 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diaphragmalgia; Dyspnoea; Fatigue; Headache; Lower Respiratory Tract Infection; Malaise; Nausea; Swollen Tongue	Methotrexate			S	Unknown			Accord
	Erelzi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619582	EXPEDITED (15-DAY)		OT	RO-ACCORD-092523		66 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Urinary Tract Infection	Methotrexate			S	Intramuscular			Accord
	Plaquenil			S				Not Reported
	Rituximab			C		500 Mg X 2 Every 2 Weeks		Not Reported
	Alfacalcidol			C	Oral			Not Reported
	Metformin			C	Oral			Not Reported
	Insulin Human			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15619946	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2018-US-975297		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Cardiac Arrest; Hyperkalaemia; Overdose; Toxicity To Various Agents	Diltiazem			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Venlafaxine			S	Oral			Teva
	Methotrexate			S	Oral			Barr

	Clonazepam	S	Oral		Teva
	Fluoxetine	S	Oral		Barr
	Baclofen	S	Oral		Ivax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620056	EXPEDITED (15-DAY)		OT	GB-ACCORD-092336		65 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Epistaxis; Neck Mass	Methotrexate			S	Subcutaneous	Unk		Accord
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humera			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620057	EXPEDITED (15-DAY)		OT	GB-ACCORD-092342		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Bisoprolol			S				Not Reported
	Methotrexate			S				Accord
	Levofloxacin/Levofloxacin Mesylate			S				Not Reported
	Metronidazole			S				Not Reported
	Prednisone			S				Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Lyrica			S				Not Reported
	Meperidine Hydrochloride			S				Not Reported
	Erythromycin			S				Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Ceclor			S				Not Reported
	Leflunomide			S				Not Reported
	Norfloxacin			S				Not Reported
	Arava			S				Not Reported
	Demerol			S				Not Reported
	Erythro Base			S				Not Reported

	Arthrotec			S					Not Reported
	Plaquenil			S	Oral	400 Mg			Not Reported
	Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620072	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2555437-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620126	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556601-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arthrotec Forte			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Tylenol			C						Not Reported
	Advil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620757	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1072		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15620807	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555911-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Sulfasalazine			S	Oral				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15621033	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-975828			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			S	Oral	6 Milligram Daily;		Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulins			S				Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15621729	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555939-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Nausea; Retinal Disorder; Rheumatoid Arthritis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Isoniazid W/Pyridoxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15621866	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557497-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15621899	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2557338-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Malaise; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Prednisone			C					Not Reported
	Rituxan			C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15622202	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557333-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Leucovorin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15622523	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557222-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia;	Humira			S	Subcutaneous			Not Reported

Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15622674	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557515-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15623737	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557348-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2018	15623758	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2526093-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liquid Product Physical Issue; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Nifedipine			C	Oral			Not Reported
	Lisinopril			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Vesicare			C	Oral			Not Reported
	Simvastatin			C	Oral			Not Reported
	Fexofenadine			C	Oral			Not Reported
	Potassium			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported

	Methotrexate	C	Not Reported
	Alendronate	C	Not Reported
	Restasis	C	Not Reported
	Xarelto	C	Not Reported
	Vitamin A	C	Not Reported
	Vitamin B12	C	Not Reported
	Vitamin C	C	Not Reported
	Vitamin E	C	Not Reported
	Omega 3	C	Not Reported
	Calcium	C	Not Reported
	Glucosamine	C	Not Reported
	Famotidine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	11444250	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2015088725		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Surgery; Venous Operation; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	8 Mg, Qd (Once Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	12304140	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Systemic Lupus Erythematosus	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine (Canada)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	12745120	EXPEDITED (15-DAY)		HO, LT, OT	US-ZYDUS-012051		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Atrioventricular Block Complete; Cardiac Arrest; Electrocardiogram U Wave Present; Hyperkalaemia; Hypokalaemia; Hypomagnesaemia;	Hydroxychloroquine			S	Oral	60 Tabs Of Hydroxychloroquine 200 Mg		Zydus Pharm
	Venlafaxine/Venlafaxine Hydrochloride			S	Oral			Zydus Pharm
	Oxycodone			S	Unknown	35 Tabs Of Oxycodone/		Not Reported

Hypotension; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydrochloride/Paracetamol			Acetaminophen, 5/325 Mg	
	Diltiazem	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Clonazepam	S	Oral		Not Reported
	Baclofen	S	Oral		Not Reported
	Fluoxetine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	13159492	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-006548		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Abatacept			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	13196229	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890688		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Risedronate		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Hydroxychloroquine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	13519599	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038053		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown	0.8 Ml, Qwk		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	13520579	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038278		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Orencia			S	Unknown	750 Mg, Qwk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	13784886	EXPEDITED (15-DAY)		OT	CA-ROCHE-1967450			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	13923432	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2658		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	14364460	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268796			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Arava			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	200 Mg,Qd		Sanofi
	Folic Acid			S	Unknown	1 Mg,Qd		Not Reported
	Actemra			S	Unknown	200 Mg,Qm		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15486366	NON-EXPEDITED			US-AMGEN-USASP2018141133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15563953	NON-EXPEDITED			US-AMGEN-USASP2018150793			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Somnolence	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15582480	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003822		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Mass; Abdominal Pain; Acute Kidney Injury; Cushing'S Syndrome; Deafness; Electrocardiogram Qt Prolonged; Glucose	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Cellcept			S	Unknown			Not Reported
	Cellcept			S				Not Reported
	Prednisone			S	Unknown			Not Reported

Tolerance Impaired; Mycobacterium Abscessus Infection; Obesity; Osteoporosis; Sleep Apnoea Syndrome	Prednisone	S				Not Reported
	Amikacin	S	Intravenous (not otherwise specified)	Every Monday, Wednesday And Friday		Not Reported
	Amikacin	S	Unknown	Instillation 250 Mg In 100 Ml Normal Saline Every Monday Wednesday, Friday Via Wound Vacuum For Appr		Not Reported
	Methylprednisolone	S	Unknown			Not Reported
	Methylprednisolone	S				Not Reported
	Imuran	S	Unknown			Not Reported
	Imuran	S				Not Reported
	Voriconazole	S	Unknown	Every Morning		Not Reported
	Voriconazole	S	Unknown	Every Evening		Not Reported
	Azithromycin	S	Oral			Not Reported
	Azithromycin	S	Oral			Not Reported
	Azithromycin	S	Unknown			Not Reported
	Azithromycin	S	Oral			Not Reported
	Clofazimine	S	Oral			Not Reported
	Clofazimine	S	Unknown			Not Reported
	Clofazimine	S	Unknown			Not Reported
	Isavuconazole	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15623984	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557392-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Orencia		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624440	NON-EXPEDITED			US-ZYDUS-020497			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Expired Product Administered	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624441	NON-EXPEDITED			US-ZYDUS-019158		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Pain; Rash	Hydroxychloroquine			S	Oral			Zydus Pharm
	Metformin			C				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624442	NON-EXPEDITED			US-ZYDUS-026909		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Urticaria	Hydroxychloroquine			S	Oral			Zydus Pharm
	Celecoxib			C	Unknown			Not Reported
	Vitamins Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624443	NON-EXPEDITED			US-ZYDUS-017982			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective	Hydroxychloroquine	S	Oral		Zydus Pharm
	Esomeprazole	C			Not Reported
	Ranitidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624450	NON-EXPEDITED			US-ZYDUS-020729		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Pain; Product Administration Error	Hydroxychloroquine			S	Oral			Zydus Pharm
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624451	NON-EXPEDITED			US-ZYDUS-019363			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624452	NON-EXPEDITED			US-ZYDUS-017565			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624453	NON-EXPEDITED			US-ZYDUS-017994			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624454	NON-EXPEDITED			US-ZYDUS-018280		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus	Hydroxychloroquine			S	Oral			Zydus Pharm
	Potassium			C				Not Reported
	Pantoprazole			C				Not Reported
	Fluticasone Propionate/Salmeterol Xinafoate			C				Not Reported
	Atorvastatin			C				Not Reported
	Clobetasol			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Levothyroxine			C				Not Reported
	Metoprolol			C				Not Reported
	Estradiol			C				Not Reported
	Tiotropium			C		One Inhalation		Not Reported
	Salbutamol			C				Not Reported
	Aspirin			C				Not Reported
	Clobetasol			C				Not Reported
	Glyceryl Trinitrate			C				Not Reported
	Salbutamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624794	EXPEDITED (15-DAY)		HO, OT	PHHY2018GB155571		70 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Squamous Cell Carcinoma Of Lung	Methotrexate			S	Oral	25 Mg, Qw		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Bid (400 Mg Qd)		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624865	EXPEDITED (15-DAY)		OT	PHHY2018BR152019		48 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dermatosis; Macule; Oral Disorder; Papule; Stevens-Johnson Syndrome; Toxic	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Unk		Novartis

Epidermal Necrolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15624867	EXPEDITED (15-DAY)		OT	PHHY2018EC151823		57 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Product Use In Unapproved Indication; Quality Of Life Decreased; Therapy Non-Responder; Urticarial Vasculitis	Omalizumab			S	Unknown	150 Mg, Q4w		Not Reported
	Omalizumab			S	Unknown	150 Mg, Unk		Not Reported
	Prednisone			S	Oral	40 Mg, Unk		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxyzine			S	Unknown	50 Mg, Qd		Not Reported
	Fexofenadine			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15625013	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557557-00		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Latent Tuberculosis; Rash; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15625189	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556812-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Folic Acid			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15625409	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557577-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15625719	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557504-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Altace	C		Not Reported
Altace	C	Unknown	Not Reported
Atorvastatin	C	Oral	Not Reported
Atorvastatin	C	Oral	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Citalopram Hydrobromide	C	Oral	Not Reported
Cymbalta	C	Unknown	Not Reported
Escitalopram Oxalate	C	Unknown	Not Reported
Estrace	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Gabapentin	C	Oral	Not Reported
Gabapentin	C	Unknown	Not Reported
Hydrochlorothiazide	C	Oral	Not Reported
Hydromorphone Hydrochloride	C		Not Reported
Mupirocin Calcium	C	Topical	Not Reported
Shark Liver Oil	C		Not Reported
Tapentadol	C	Unknown	Not Reported
Tramacet	C	Unknown	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported

	Prednisone			C	Oral					Not Reported
	Prednisone			C	Oral					Not Reported
	Prednisone			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15626423	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268242		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg,Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg,Qw		Not Reported
	Sulfasalazine			S	Unknown	500 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15627254	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015305028		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Lung Disorder; Synovitis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil Sulfate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15627443	EXPEDITED (15-DAY)		CA, OT	PHHY2009US16745			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blindness Congenital; Congenital Eye Disorder; Foetal Exposure During Pregnancy; Optic Neuropathy	Hydrochlorothiazide,Triamterene		S	Transplacental	Novartis
	Infliximab		S	Transplacental	Not Reported
	Methotrexate		S	Transplacental	Not Reported
	Hydroxychloroquine		S	Transplacental	Not Reported
	Prednisone		S	Transplacental	Not Reported
	Famotidine		C	Transplacental	Not Reported
	Ibuprofen		C	Transplacental	Not Reported
	Levothyroxine		C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15627719	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558802-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Nausea; Retinitis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15628201	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1084055			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Off Label Use	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15629186	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557555-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2018	15629200	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003922		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Drug Ineffective; Hypotension; Intentional Overdose; Overdose; Pulse Absent; Shock; Tachyarrhythmia	Hydroxychloroquine			S	Oral			Concordia
	Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Norepinephrine Salt Not Specified			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15240630	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-AUROBINDO-AUR-APL-2018-038865			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly;	Ezetimibe			S	Transplacental	Unk		Aurobindo
	Pantoprazole			S	Transplacental	Unk		Aurobindo

Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril		S	Transplacental	20 Mg, Qd	Aurobindo
	Simvastatin		S	Transplacental	Unk	Aurobindo
	Acetylsalicylic Acid		S	Transplacental	Unk	Not Reported
	Torasemide		S	Transplacental	Unk	Not Reported
	Rivaroxaban		S	Transplacental	Unk	Not Reported
	Prednisolone		S	Transplacental	Unk	Not Reported
	Nicotine		S	Transplacental	Unk	Not Reported
	Aliskiren		S	Transplacental	Unk	Not Reported
	Tacrolimus		S	Transplacental	Unk	Not Reported
	Hydroxychloroquine		S	Transplacental	Unk	Not Reported
	Heparin		S	Transplacental	Unk	Not Reported
	Salbutamol Sulfate		S	Transplacental	Unk	Not Reported
	Salbutamol Sulfate		S	Transplacental	()	Not Reported
	Metamizole		S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15372562	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1775178-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Vaginal			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Arava	C		Not Reported
	Ativan	C		Not Reported
	Benadryl	C		Not Reported
	Cortisone	C		Not Reported
	Dilaudid	C		Not Reported
	Enablex	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C	Spray, Metered Dose	Not Reported
	Pantoloc	C		Not Reported
	Laxisoft	C		Not Reported
	Synthroid	C		Not Reported
	Vagifem	C		Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C		Not Reported
	Diphenhydramine	C		Not Reported
	Plantago Ovata	C		Not Reported
	Pantoprazole Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15426434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Fatigue; Glaucoma; Headache; Lacrimation Increased; Photophobia; Rheumatoid Arthritis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Apo-Acetaminophen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Remicade	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Fosavance	C		Not Reported
	Hydrocortisone	C		Not Reported
	Hyzaar	C		Not Reported
	Methylprednisolone	C		Not Reported
	Humira	C		Not Reported
	Orencia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15629277	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554319-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15629363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558911-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen/Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15629527	EXPEDITED (15-DAY)			US-CELLTRION INC.-2018US022383			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Infliximab (Unknown)			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Simponi	C	Not Reported
	Ibuprofen	C	Not Reported
	Oxycodone	C	Not Reported
	Prednisone	C	Not Reported
	Tramadol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15629599	EXPEDITED (15-DAY)		HO	CA-TEVA-2018-CA-976241			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Oral	6 Milligram Daily;		Actavis
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Mg/Kg Daily;		Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15629824	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2018M1051641			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Product Substitution Issue	Mylan-Hydroxychloroquine			S	Oral	200 Mg, Unk		Mylan
	Leflunomide			C		Unk		Mylan
	Methotrexate			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2018	15629931	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1086415		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Fluid Overload; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Tachyarrhythmia; Toxicity To Various Agents	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2018	13516413	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038202		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

			Leflunomide		S	Unknown	20 Mg, Qd		Not Reported
			Hydroxychloroquine Sulfate		S	Unknown	200 Mg, Unk		Not Reported
			Methotrexate		S	Oral			Not Reported
			Methotrexate		S	Subcutaneous	12.5 Mg, Unk		Not Reported
			Xeljanz		C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2018	15630178	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT157455			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Chills; Cushingoid; Drug Ineffective; Haematuria; Headache; Hypertransaminasaemia; Lupus Nephritis; Meningitis Cryptococcal; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria; Pyrexia	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg 3 Pulse Therapies		Novartis
	Methylprednisolone			S				Novartis
	Prednisone			S	Oral	1 Mg/Kg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1 G, Qd		Not Reported
	Rituximab			S	Intravenous drip	375 Mg/M2		Not Reported
	Cyclophosphamide			S	Oral	1 Mg/Kg, Qd		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg, 1x Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Mg, 1x Pulse		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2018	15630181	EXPEDITED (15-DAY)		OT	PHHY2018US153818			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic; Rash	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	13153207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	13168836	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

					Prednisone		S	Unknown	Unk	Not Reported
					Reactine /00884302/		S	Unknown	Unk	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Simponi		S	Subcutaneous	Unk	Not Reported
					Sulfasalazine		S	Unknown	Unk	Not Reported
					Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	13519416	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038266			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Mg, Unk		Not Reported
	Methotrexate			C	Oral	15 Mg, Qwk		Not Reported
	Methotrexate			C	Oral	10 Mg, Unk		Not Reported

	Pantoprazole	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Oral	40 Mg, Unk		Not Reported
	Tenofovir Disoproxil	C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	300 Mg, Unk		Not Reported
	Xeljanz	C	Unknown			Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	13519757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038156		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Xeljanz			S	Oral	2.5 Mg, Qd		Not Reported
	Methotrexate /00113802/			S	Subcutaneous	12.5 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	14165914	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210506		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Arava	S	Oral	20 Mg,Qd	Sanofi
	Paracetamol	S	Unknown	Unk Unk,Unk	Not Reported
	Sulfasalazine	S	Oral	Unk Unk,Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg,Bid	Sanofi
	Paracetamol	S		325 Mg	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	50 Mg,Qw	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia	S	Unknown	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C	Unknown	25 Mg/Ml, Qw	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk, Unk	Not Reported
	Synthroid	C		Unk Unk,Unk	Not Reported
	Tylenol [Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	14364462	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268828		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Celecoxib			S	Oral	200 Mg,Tid		Not Reported
	Celecoxib			S		200 Mg, Bid		Not Reported

Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra		S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel		S	Unknown	Unk Unk,Unk	Not Reported
	Humira		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia		S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Prednisone		C		7-10 Mg Sliding Scale As Per Rheumatologist	Not Reported
	Tramadol		C	Unknown	100 Mg, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	14372924	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268486		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg,Bid		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Lyrica			C	Oral	Unk Unk,Unk		Not Reported
	Prednisone			C	Unknown	15 Mg,Qd		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	14378374	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268317		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Plaquenil			S	Oral			Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Actemra			S	Subcutaneous	162 Mg,Qw		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Qw		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Four Times A Week		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	14378378	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268259		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fluid Retention; Memory Impairment; Mouth Ulceration; Rheumatoid Arthritis	Arava			S	Oral	20 Mg,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15202253	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-SA-2018SA201378			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	Maternal Dose 20 Mg, Unk		Sanofi
	Pantoprazole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Metamizole Sodium			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Sanofi
	Nicotine			S	Transplacental			Sanofi
	Salbutamol Sulfate			S	Transplacental	From Gestational Week 0-14		Not Reported
	Enoxaparin Sodium			S	Transplacental			Sanofi
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Xarelto			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15370786	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1676490-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo Risedronate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15495192	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018411881		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Ramipril			S	Oral	Unk		Pfizer
	Lederfoline			S	Oral	Unk		Pfizer
	Inexium			S	Oral	Unk (Gastro-Resistant Tablet)		Unknown
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Bactrim			S	Oral	Unk (Non Renseigne)		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral	2 G, 1x/Day		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral	1.5 G, 1x/Day		Not Reported
	Lovenox			S	Unknown	4000 Iu, 1x/Day		Not Reported
	Cerazette [Desogestrel]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15516058	NON-EXPEDITED			US-PFIZER INC-2018412012		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Neurontin			S		Unk		Pfizer
	Tylenol			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Betadin			S		Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Ultram [Tramadol Hydrochloride]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15626412	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268443		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Infusion Related Reaction; Insomnia; Pneumonitis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Arava			S	Oral	20 Mg,Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Celecoxib			S	Unknown	Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Erythromycin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630510	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra	S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630549	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Mg, Tid		Not Reported

	Premarin			C	Unknown				Not Reported
	Tylenol /00020001/			C	Unknown	650 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630652	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630674	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556274-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported

Folic Acid	S	Unknown		Not Reported
Fosamax	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Subcutaneous		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15630818	EXPEDITED (15-DAY)		OT	NO-TEVA-2018-NO-977309		30 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	Initial Dose Unknown; Dose Gradually Escalated Up To 25 Mg/Week But Without Effect		Barr
	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Belimumab			S	Unknown	Formulation: Infusion		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15631123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2215684		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported
	Supeudol		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15631357	EXPEDITED (15-DAY)		HO	CA-ROCHE-2215627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15631438	EXPEDITED (15-DAY)		OT	EC-ROCHE-2215837		57 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Product Use In Unapproved Indication; Quality Of Life Decreased; Therapy Non-Responder; Urticarial Vasculitis	Omalizumab			S	Unknown			Not Reported
	Omalizumab			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxyzine			S	Unknown			Not Reported
	Fexofenadine			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15631947	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-07936		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypotension; Intentional Overdose; Pulse Absent; Toxicity To Various Agents	Hydroxychloroquine Sulfate Tablets Usp, 200 Mg			S	Oral	45 Df, Single		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15632344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2215638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine (Canada)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15632570	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105432			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Treatment Failure; Urticaria	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Arthrotec			S	Oral	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q3wk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported

Mefenamic Acid	C	Oral	200 Mg, Unk	Not Reported
Tylenol /00020001/	C	Unknown	650 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15633973	EXPEDITED (15-DAY)		HO, LT	PHHY2018US154511		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	45 Df, Unk (9 Grams)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15635042	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15635110	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105549			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Orencia			S	Intravenous (not	250 Mg, Qmo		Bristol Myers Squibb

Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting			otherwise specified)		
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 4 Every 1 Week	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, Qd	Not Reported
	Immune Globulin Nos	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Infliximab	S	Unknown	5 Mg, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Qwk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	13813075	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-17_00002520		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia	Methotrexate			S	Unknown	Over 2 Years		Not Reported
	Methotrexate			S				Not Reported
	Prednisolone			S	Unknown	Over 2 Years		Not Reported
	Prednisolone			S				Not Reported
	Colchicine			S	Unknown	Over 2 Years		Not Reported
	Colchicine			S				Not Reported
	Rituximab			S	Unknown	Over 2 Years		Not Reported

	Rituximab			S					Not Reported
	Dapsone			S	Unknown	Over 2 Years			Not Reported
	Dapsone			S					Not Reported
	Mycophenolate Mofetil			S	Unknown	Over 2 Years			Not Reported
	Mycophenolate Mofetil			S					Not Reported
	Hydroxychloroquine			S	Unknown	Over 2 Years			Not Reported
	Hydroxychloroquine			S					Not Reported
	Azathioprine			S	Unknown	Over 2 Years			Not Reported
	Azathioprine			S					Not Reported
	Ciclosporin			C	Unknown				Not Reported
	Ciclosporin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	13849465	EXPEDITED (15-DAY)		DS, OT	GB-ALVOGEN-2017-ALVOGEN-092947		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia	Dapsone			S		Over 2 Years		Not Reported
	Mycophenolate Mofetil			S		Over 2 Years		Not Reported
	Prednisolone			S		Over 2 Years		Not Reported
	Colchicine			S		Over 2 Years		Not Reported
	Methotrexate			S		Over 2 Years		Not Reported
	Rituximab			S		Over 2 Years		Not Reported
	Hydroxychloroquine			S		Over 2 Years		Not Reported
	Azathioprine			S		Over 2 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	13903037	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP016892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection;	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Asa 81			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Vitamin C /00008001/			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	14235776	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3877		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15188193	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS		44 YR	Female	JPN

INC.-GSH201807-002559

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Toxic Skin Eruption	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Plaquenil 200 Mg Tablet			S	Oral			Not Reported
	Predonine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15635678	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3344		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Lung Disorder; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636134	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3343		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Clavulin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636138	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978075			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2215715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Reactine (Canada)			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636499	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine /00884302/	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636551	NON-EXPEDITED			PHEH2018US048289			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sandoz			S	Oral	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15636718	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105861		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15640136	EXPEDITED (15-DAY)		OT	CA-SA-2018SA314262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown			Sanofi
	Folic Acid			S	Unknown			Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Enbrel			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15640141	EXPEDITED (15-DAY)		OT	CA-SA-2018SA314266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Subcutaneous	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Alendronate Sodium			S				Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Reactine [Cetirizine Hydrochloride]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15640647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Cortisone	S	Oral			Not Reported
	Desoximetasone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd		Not Reported
	Prednisone	S	Unknown			Not Reported
	Reactine /00884302/	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Tofacitinib Citrate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	11454267	EXPEDITED (15-DAY)			CA-PFIZER INC-2015272329		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haematocrit Decreased; Haemoglobin Decreased;	Methotrexate Sodium			S	Oral	25 Mg (10 X 2.5 Mg), Weekly		Pfizer

Red Blood Cell Count Decreased	Methotrexate Sodium		S	Oral	25 Mg [10 Weekly]	Pfizer
	Pantoloc		S		40 Mg, 1x/Day	Pfizer
	Naprosyn		S	Oral	500 Mg, 2x/Day	Not Reported
	Pms-Sulfasalazine		S	Oral	1000 Mg (2 X 500 Mg), 2x/Day	Not Reported
	Palafer Cf		S		1 Df, 1x/Day	Not Reported
	Co Atenolol		S		25 Mg (Half Of 50 Mg), 1x/Day	Not Reported
	Folic Acid		S		5 Mg, 2x/Week	Not Reported
	Plaquenil		S		200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	11458862	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015293752		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angiopathy; Condition Aggravated; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Visual Impairment	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	8 Mg, Qd (Once Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	13005113	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear	Apo-Sulfatrim			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex

Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium		S	Unknown	Unk		Apotex
	Apo Asa Tab 325mg		S	Unknown	Unk		Not Reported
	Arava		S	Unknown	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium Lederle		S	Unknown	Unk		Not Reported
	Naprosyn /00256201/		S	Unknown	Unk		Not Reported
	Mortin		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	13180610	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2013036446		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Tolerance; Fatigue; Hyperhidrosis; Influenza; Product Use Issue; Rheumatoid Arthritis	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	22.5 Mg, Weekly		Unknown
	Plaquenil			S		200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Bi-Weekly		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D2			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	14235408	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3871		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Parenteral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	14333343	EXPEDITED (15-DAY)		OT	CA-SA-2017SA097548		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade			C	Unknown	Unk Unk,Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg,Bid		Not Reported
	Leflunomide			C	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	14579930	EXPEDITED (15-DAY)		OT	PT-CONCORDIA PHARMACEUTICALS INC.-E2B_00010132		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Haemophagocytic Lymphohistiocytosis; Herpes Zoster; Listeria Sepsis; Lymphopenia; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	Not Provided		Concordia
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Cyclophosphamide			S	Unknown	Not Provided		Not Reported
	Cyclophosphamide			S				Not Reported
	Cellcept			S	Oral			Not Reported
	Cellcept			S	Oral			Not Reported
	Cellcept			S				Not Reported
	Thalidomide			S	Oral			Not Reported
	Thalidomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15026892	EXPEDITED (15-DAY)		OT	US-LUNDBECK-DKLU2050135			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Optic Nerve Disorder; Seizure; Visual Field Defect	Sabril (Tablet)			S	Oral			Lundbeck
	Sabril (Tablet)			S				Lundbeck
	Sabril (Tablet)			S				Lundbeck
	Plaquenil			S	Unknown			Not Reported
	Onfi			C	Unknown			Lundbeck
	Prednisone			C	Unknown			Not Reported
	Keppra			C	Unknown			Not Reported
	Lorazepam			C	Unknown	0.5-1 Milligram		Not Reported

	Fluticasone			C	Unknown					Not Reported
	Sumatriptan			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15524245	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2522454-00		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Eye Haemorrhage; Foreign Body In Eye	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Synthroid			C				Not Reported
	Lialda			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15615756	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2018-055047		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Amoxicillin			S	Unknown	12 G, Daily		Aurobindo
	Amoxicillin			S	Unknown	6 G, Daily		Aurobindo
	Doxycycline			S	Unknown	Unk		Not Reported
	Doxycycline			S				Not Reported
	Gentamycin /00047101/			S	Unknown	Unk		Not Reported
	Gentamycin /00047101/			S	Unknown	1.5 Milligram/Kilogram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15641623	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2232429-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Ineffective; Joint Swelling; Rheumatoid Arthritis	Meloxicam	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Lansoprazole	C	Unknown		Not Reported
	Symbicort Inhaler	C	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15642256	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Reactine /00884302/			S	Unknown	Unk			Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15643372	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978043		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2018	15643611	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018477813		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk (1 Every 2		Not Reported

						Week(S))			
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk			Not Reported	
	Prednisone		C	Unknown	Unk			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	13469238	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017056756		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15291604	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2017CA015260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg, Qwk		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qwk (1 Every 1 Week)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day (1 Every 24 Hour(S))		Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	5.0 Mg/Kg, 1x/Day (1 Every 24 Hour(S))		Not Reported
	Immunoglobulin /07494701/	S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Immunoglobulin /07494701/	S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qmo (1 Every 1 Month (S))		Not Reported
	Apo-Prednisone	S	Oral	3.00 Mg, Bid		Not Reported
	Apo-Prednisone	S	Oral	5 Mg, Bid		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15617651	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015098070		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15646724	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP024684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Potassium		S	Unknown	Unk		Apotex
	Arava		S	Oral	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported
	Humira		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Motrin		S	Unknown	Unk		Not Reported
	Naprosyn /00256201/		S	Unknown	Unk		Not Reported
	Plaquenil /00072602/		S	Oral	Unk		Not Reported
	Sodium Aurothiomalate		S	Parenteral	Unk		Not Reported
	Tramadol Hydrochloride		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647293	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2563704-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Operation; Coronary Artery Occlusion; Drug Ineffective; Fluid Retention; Pain; Post Procedural Complication; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	30 Count Size		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647417	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3366		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Infection; Pneumonia; Post Procedural	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Contusion; Rheumatoid Arthritis; Vein Disorder	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Kineret		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15647531	NON-EXPEDITED			US-SA-2018SA312855			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Somnolence	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Humira			C				Not Reported
	Enbrel			C				Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15648749	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181126693		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Hepatotoxicity; Loss Of Consciousness; Mobility Decreased; Pain	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2018	15649650	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20181120178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	12626976	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016100545		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Epigastric Discomfort; Foot Deformity; Headache; Herpes Zoster; Hip Arthroplasty; Hypothyroidism; Joint Swelling; Knee Arthroplasty; Migraine; Rheumatoid Arthritis;	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Simponi			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	50 Mg, Die		Not Reported
	Azathioprine			S	Unknown	50 Mg, Bid		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			C	Oral	20 Mg, Weekly		Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	12628714	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015315226		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	12937838	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2016527944		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Body Height Below Normal; Bone Density Decreased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction; Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate Sodium			S	Unknown	15 Mg/M2, Weekly		Pfizer
	Sulfasalazine			S	Oral	250 Mg, 1x/Day		Pfizer
	Triamcinolone Acetonide			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Cyclic (1 Every 2 Weeks)		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	250 Mg, Monthly		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

Anakinra	S	Subcutaneous	Unk		Not Reported
Etanercept	S	Subcutaneous	25 Mg, Cyclic (2x/Week)		Not Reported
Etanercept	S	Subcutaneous	12.5 Mg, Weekly		Not Reported
Hydroxychloroquine /00072603/	S	Oral	Unk		Not Reported
Immune Globulin Nos	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	13913470	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017128865		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arrhythmia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Sarilumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14061604	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005641			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

		Sulfasalazine			S	Oral					Not Reported
		Methotrexate Sodium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14374406	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000111		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14378548	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000075		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14378551	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Unevaluable Event	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14378553	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000094			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14378557	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000132		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14379114	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000069		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14379124	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000110		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14379128	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000121		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Responder; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Tramadol			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14380884	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000112		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fluid Retention; Memory Impairment; Mouth Ulceration; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14445501	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2018008647		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Hypoaesthesia; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Muscular Weakness; Osteoarthritis; Renal Impairment	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported
	Adalat Xl			C	Unknown	20 Mg, Qd		Not Reported
	Coversyl			C	Unknown	4 Mg, Qd		Not Reported
	Hctz			C	Unknown	25 Mg, Qd		Not Reported

	Lyrica			C	Unknown	50 Mg, Qd		Not Reported
	Prednisone			C	Unknown	4 Mg, Qd		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Nifedipine			C	Unknown	20 Mg, Qd		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14534888	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018020711		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Hypersensitivity; Mycobacterium Tuberculosis Complex Test Positive; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	14911076	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15523854	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-965577		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Ramipril			S	Oral			Actavis
	Bactrim			S	Oral	No Information		Not Reported
	Cellcept			S	Oral	2 Gram Daily; Then 1.5 G 2/D From 09/07/18		Not Reported
	Cellcept			S	Oral	1.5 Gram Daily; 1.5 G,Qd		Not Reported
	Lovenox			S	Unknown	4000 Iu (International Unit) Daily;		Not Reported
	Lederfoline 25 Mg, Comprimé			S	Oral			Not Reported
	Cerazette 0,075 Mg, Comprimé Pelliculé			S	Oral			Not Reported
	Esomeprazole Magnesium			S	Oral			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15609866	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003899		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling;	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported

Malaise; Mobility Decreased; Musculoskeletal Stiffness; Nodule; Osteomyelitis; Pain; Pain; Pulmonary Mass	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Methotrexate	C				Not Reported
	Xeljanz	C		Xeljanz To Be Taken In Monotherapy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650040	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR-APL-2018-056658		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Intentional Self-Injury; Suicidal Ideation	Sertraline Film-Coated Tablet			S	Unknown	150 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650191	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003982			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650830	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181119715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis;	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Vomiting; Weight Decreased	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Acetylsalicylic Acid		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Diclofenac		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650831	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181121683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650832	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181119815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite;	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported

Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Acetylsalicylic Acid		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Diclofenac		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Vitamine C		S	Unknown	Not Reported
	Tramadol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650842	EXPEDITED (15-DAY)		OT	KW-STRIDES ARCOLAB LIMITED-2018SP009914			Unknown	KWT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Osteonecrosis	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Strides
	Prednisolone			S	Unknown	1 Mg/Kg/Day, Unknown		Not Reported
	Prednisolone			S	Unknown	Unk, 5 Mg Daily By The Third Month		Not Reported
	Prednisolone			S	Unknown	Unk, 5 Mg Daily		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk, 1g/M2		Not Reported
	Solumedrol			S	Unknown	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15650927	EXPEDITED (15-DAY)		OT	KW-STRIDES ARCOLAB LIMITED-2018SP009915			Unknown	KWT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Osteonecrosis	Mycophenolate Mofetil			S	Oral	1 G, Bid		Strides

Prednisolone	S	Unknown	1 Mg/Kg/Day, Unk		Not Reported
Prednisolone	S	Unknown	5 Mg Daily By Third Month		Not Reported
Prednisolone	S	Unknown	5 Mg Daily, Maintenance Dose		Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1 G/M2		Not Reported
Solumedrol	S	Unknown	1 G, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15651512	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP024683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Liver Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Diclofenac Sodium			S	Unknown			Apotex
	Pantoprazole			S	Unknown			Apotex
	Arava			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2018	15651590	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20181121721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Aspirin C	S	Unknown		Not Reported
	Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15293722	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20180813839		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Voltaren			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15654284	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181121234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite;	Motrin		Y	S	Unknown			Not Reported

Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Motrin		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Naprosyn		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Aspirin		S	Unknown		Not Reported
	Diclofenac		S	Unknown		Not Reported
	Tramadol		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2018	15654285	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181131289			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin		Y	S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	12581039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016246968		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	13995654	NON-EXPEDITED			US-PFIZER INC-2017405744		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	14087351	EXPEDITED (15-DAY)		HO	CA-SA-2017SA191788		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Chest Discomfort; Condition Aggravated; Diarrhoea; Drug Ineffective; Exostosis;	Leflunomide			S	Oral	10 Mg,Qd		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi

Hypertension; Joint Swelling; Pain; Pain In Extremity; Tinnitus	Plaquenil	S	Unknown	Unk		Sanofi
	Cortisone Acetate	S	Unknown	5 Mg,Unk		Not Reported
	Cortisone Acetate	S	Unknown	2.5 Mg,Unk		Not Reported
	Xeljanz	S	Oral	5 Mg,Bid		Not Reported
	Amlodipine	C	Unknown	5 Mg,Qd		Not Reported
	Paracetamol	C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	14364457	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268758		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	14365934	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017188223		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hangover; Ill-Defined Disorder; Malaise; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	0.4 Ml, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Up To 20 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	14546353	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022124			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Gastrooesophageal Reflux Disease; Infection; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200.0 Mg, Qd		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	14551457	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022362		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Pain; Facial Pain; Influenza; Lung Neoplasm Malignant; Lymphadenopathy; Nasopharyngitis; Ocular Toxicity; Pneumonia; Pneumonia; Productive Cough; Pulmonary Mass; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Incomplete; Vision Blurred	Enbrel			S	Subcutaneous	50 Mg, Qwk (Solution For Injection)		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Oral	Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Methotrexate			C		0.3 Ml, Qwk		Not Reported
	Methotrexate			C		Unk (Injection)		Not Reported
	Ondansetron			C		Unk		Not Reported
	Prednisone			C		1 Mg, Qd		Not Reported
	Vit B6			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15219594	EXPEDITED (15-DAY)		OT	US-SA-2018SA167248			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Leukopenia; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased	Arava	S	Oral	1 Df, Bid		Sanofi
	Hydroxychloroquine Sulfate	S	Oral	1 Df, Bid		Sanofi
	Humira	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Methotrexate	S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qow		Not Reported
	Remicade	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15454536	NON-EXPEDITED			US-PFIZER INC-2018393393		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate Sodium			S				Unknown
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Remicade			S		Unk		Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15654462	EXPEDITED (15-DAY)		HO, OT	ES-IPCA LABORATORIES LIMITED-IPC-2018-ES-002334			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Coma Scale Abnormal; Electrocardiogram Qt Prolonged; Fall; Hypokalaemia; Hypotension; Lactic Acidosis; Overdose; Pupils Unequal; Suicide Attempt; Torsade De Pointes; Toxicity To Various Agents; Ventricular	Hydroxychloroquine			S	Oral	42 Df, Single		Ipca

Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15654654	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-030575		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Blood Potassium Decreased; Fluid Overload; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	45 Tablets Of 200mg (A Total Of 9g) Of Oral Hydroxychloroquine		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15657840	EXPEDITED (15-DAY)		OT	US-SAKK-2018SA223870AA		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelinating Polyneuropathy; Neutropenia; Treatment Failure	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2018	15658647	EXPEDITED (15-DAY)		OT	CA-PURDUE-CAN-2018-0009269		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sarcoidosis	Morphine Sulfate		S	Unknown		Purdue
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Oral	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Oral	25 Mg, Weekly	Not Reported
	Sulfasalazine		S	Oral	1000 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	12913807	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	13900274	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-075305			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	14378546	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000072		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

			Remicade			S	Intravenous (not otherwise specified)				Not Reported
			Rituxan			S	Intravenous (not otherwise specified)				Not Reported
			Sulfasalazine			C					Not Reported
			Wellbutrin			C					Not Reported
			Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15247978	EXPEDITED (15-DAY)		DS, HO, LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002748		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Chest Discomfort; Chest Pain; Coronary Artery Occlusion; Vomiting	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Benlysta			C				Not Reported
	Prednisolone			C				Not Reported
	Prograf			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Warfarin Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15428143	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003382		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Headache; Pharyngitis; Sjogren'S Syndrome	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Benethamine Penicillin/Benzylpenicillin Sodium			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Neoral			C				Not Reported
	Loxoprofen Na			C				Not Reported
	Mosapride Citrate			C				Not Reported
	Sertraline Hydrochloride			C				Not Reported
	Flunitrazepam			C				Not Reported

	Triazolam	C	Not Reported
	Tandospirone Citrate	C	Not Reported
	Eperisone Hydrochloride	C	Not Reported
	Etizolam	C	Not Reported
	Escitalopram Oxalate	C	Not Reported
	Paracetamol	C	Not Reported
	Lidocaine Hydrochloride	C	Not Reported
	Tokishakuyakusan	C	Not Reported
	Yokukansan	C	Not Reported
	Adetphos	C	Not Reported
	Mecobalamin	C	Not Reported
	Travelmin Churop	C	Not Reported
	Valproate Sodium	C	Not Reported
	Migsis	C	Not Reported
	Sennoside A	C	Not Reported
	Jzoloft	C	Not Reported
	Halcion	C	Not Reported
	Lexapro	C	Not Reported
	Calonal	C	Not Reported
	Xylocaine Polyamp	C	Not Reported
	Saireito Extract	C	Not Reported
	Nyoshinsan Extract	C	Not Reported
	Meylon Injection 8.4	C	Not Reported
	Methycobal	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15585862	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018451537		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Deformity; Bone Erosion; Condition Aggravated; Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported
	Sulfasalazine			C	Oral	1 G, Unk		Not Reported
	Sulfasalazine			C	Oral	500 Mg, Unk		Not Reported
	Lederle Leucovorin			C		5 Mg, After Methotrexate		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15659073	EXPEDITED (15-DAY)		OT	CA-SA-2018SA316939			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15659485	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1284		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15659685	EXPEDITED (15-DAY)		DS, OT	GB-LUPIN PHARMACEUTICALS INC.-2018-08115		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Intentional Self-Injury; Suicidal Ideation	Sertraline Hydrochloride Tablets			S	Unknown	150 Mg, Qd		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660764	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016125650		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis; Rosacea; Sinus Node Dysfunction	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S				Not Reported
	Humira			S				Not Reported
	Remicade			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15662324	EXPEDITED (15-DAY)		OT	SA-MYLANLABS-2018M1087956		13 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Urinary Tract Infection; Treatment Failure	Tacrolimus			S	Unknown			Not Reported
	Prednisone			S	Oral	60 Milligram/Sq. Meter, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	For Six Doses		Mylan
	Rituximab			S	Unknown	Two Doses Of 350 Mg/M2/Dose		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	12492527	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115634		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Asthenia; Decreased Appetite; Drug Ineffective; Influenza Like Illness; Infusion Related Reaction; Nasal Congestion; Pruritus; Upper Respiratory Tract Congestion; Weight Decreased; Weight	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Actemra			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	560 Mg,Qm		Not Reported

Increased	Actemra		S	Subcutaneous	680 Mg,Qm		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported
	Diphenhydramine		C	Oral	50 Mg,Unk		Not Reported
	Methylprednisolone Sodium Succinate		C	Intravenous (not otherwise specified)	100 Mg,Unk		Not Reported
	Paracetamol		C	Oral	650 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	12968779	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA206534		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S				Sanofi
	Myochrysine			S	Unknown	50 Mg,Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg,Unk		Sanofi
	Orencia			C		Unk Mg		Not Reported
	Orencia			C		750 Mg		Not Reported
	Meloxicam			C		Unk		Not Reported
	Methotrexate			C		20 Mg,Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Enbrel			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Gold			C		50 Mg		Not Reported
	Actemra			S		8 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	13238449	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Decreased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Unevaluable Event; Vision Blurred; White Blood Cell Count Decreased	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Paracetamol			S	Oral			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Fosavance			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hyzaar			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14174104	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14336548	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006718		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			C				Not Reported
	Actemra			C				Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14557681	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018071955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer

Disturbance; Gastrooesophageal Reflux Disease; Infection; Rheumatoid Arthritis	Methotrexate Sodium		S	Unknown	20 Mg, Qwk		Pfizer
	Plaquenil		S	Unknown	200.0 Mg, Qd		Not Reported
	Celebrex		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14874921	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA125906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Asthenia; Depression; Fibromyalgia; Gait Disturbance; Joint Lock; Joint Noise; Pain; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown	400 Mg,Unk		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14911068	EXPEDITED (15-DAY)		DS, HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Hydroxychloroquine Tablet			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
			Simponi			S	Subcutaneous			Not Reported
			Xeljanz			S	Unknown			Not Reported
			Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	14995421	EXPEDITED (15-DAY)		OT	CA-SA-2016SA167558			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexat [Methotrexate Sodium]			S		20 Mg,Unk		Not Reported
	Methotrexat [Methotrexate Sodium]			S		20 Mg,Unk		Not Reported
	Methotrexat [Methotrexate Sodium]			S		20 Mg,Unk		Not Reported
	Sulfasalazine			S		2 G,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qcy		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15026716	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115409		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Gastrointestinal Disorder; Hypersensitivity; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported

	Humira			S						Not Reported
	Simponi			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15462235	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018137384			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Body Height Decreased; Deep Vein Thrombosis; Depressed Mood; Drug Ineffective; Emotional Distress; Feeling Abnormal; Foot Fracture; Gait Inability; Hypophagia; Impaired Quality Of Life; Loss Of Personal Independence In Daily Activities; Osteoporosis; Osteoporotic Fracture; Pelvic Fracture; Pruritus Allergic; Psoriasis; Quality Of Life Decreased; Rheumatoid Arthritis; Spinal Fracture; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Dilaudid			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	20 Mg, Qwk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Otezla			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Vioxx			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15599369	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018435066		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Malaise; Pain; Post Procedural	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Arava			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported

Complication; Sensory Loss; Swelling; Therapeutic Product Effect Incomplete; Thrombosis	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15623928	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557147-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Investigation Abnormal; Joint Swelling; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C				Not Reported
	Myochrysine			C	Intramuscular			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15646025	EXPEDITED (15-DAY)		HO, OT	IT-BAXTER-2018BAX027798		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Chills; Cushingoid; Drug Ineffective; Haematuria; Headache; Hypertransaminasaemia; Lupus Nephritis; Meningitis Cryptococcal; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria;	Endoxan Baxter			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Baxter
	Endoxan Baxter			S	Intravenous (not otherwise specified)	300 Mg, 1x Pulse		Baxter
	Endoxan Baxter			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Baxter
	Endoxan Baxter			S	Oral	1 Mg/Kg, Qd		Baxter
	Endoxan Baxter			S				Baxter

Pyrexia	Hydroxychloroquine	S	Oral			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown	1 G, Qd		Not Reported
	Mycophenolate Mofetil	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	375 Mg/M2 Infusion		Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	500 Mg 3 Pulse Therapies		Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	500 Mg 3 Pulse Therapies For Ln		Not Reported
	Prednisone	S	Oral	1 Mg/Kg, Qd		Not Reported
	Prednisone	C	Oral			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15663499	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1538		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Surgery	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Bystolic			C	Unknown			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported
	Winpred			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Oseltamivir	C	Unknown		Not Reported
	Budesonide	C	Respiratory (inhalation)		Not Reported
	Fluorouracil	C	Unknown		Not Reported
	Amoxi-Clav	C	Unknown		Not Reported
	Cefuroxime Axetil	C	Unknown		Not Reported
	Nebivolol Hydrochloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15663603	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980805		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Minocycline Hydrochloride			S	Unknown	200 Milligram Daily;		Actavis
	Hydroxychloroquin Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15663742	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2570284-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Plaquenil	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15663979	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1038		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Feeling Hot; Gait Inability; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Retinal Vascular Thrombosis; Sensitivity To Weather Change	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15664732	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570650-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Pyoderma Gangrenosum	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15665094	EXPEDITED (15-DAY)		OT	CA-SA-2018SA145144		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Enbrel			S		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15665615	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571389-00		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported
	Plaquenil			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15666234	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-2018-IT-980153		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bronchitis; Cushingoid; Gastrointestinal Disorder; Haematuria; Hypertransaminasaemia; Meningitis Cryptococcal; Muscle Atrophy; Off Label Use; Pneumonia;	Mycophenolate Mofetil			S	Unknown			Teva
	Prednisone			S	Oral			Actavis
	Tacrolimus			S	Unknown			Actavis
	Cyclophosphamide			S	Unknown	Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	One Pulse Administered		Not Reported

Proteinuria	Cyclophosphamide		S	Intravenous (not otherwise specified)	One Pulse Administered	Not Reported
	Cyclophosphamide		S	Oral		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Rituximab		S	Other		Not Reported
	Methylprednisolone		S	Intravenous (not otherwise specified)	Three Pulse Administered	Not Reported
	Belimumab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15667527	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016372055		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Epigastric Discomfort; Headache; Herpes Zoster; Hypothyroidism; Migraine	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Apo-Azathioprine			S	Unknown	50 Mg, Daily		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported
	Simponi			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2018	15667942	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1087932		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bronchitis; Cushingoid; Gastrointestinal Disorder; Haematuria; Hypertransaminasaemia; Meningitis Cryptococcal;	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Tacrolimus			S	Unknown			Not Reported

Muscle Atrophy; Pneumonia; Proteinuria	Tacrolimus	S				Not Reported
	Cyclophosphamide	S	Unknown	Pulse		Mylan
	Cyclophosphamide	S	Intravenous (not otherwise specified)	One Pulse Administered		Mylan
	Cyclophosphamide	S	Intravenous (not otherwise specified)	One Pulse Administered		Mylan
	Cyclophosphamide	S	Oral			Mylan
	Rituximab	S	Other			Mylan
	Methylprednisolone	S	Intravenous (not otherwise specified)	Three Pulse Administered		Mylan
	Belimumab	S	Unknown	Infusion		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	13611281	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017081983		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Malaise; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14224270	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175450		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Headache; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

		Sulfasalazine			S	Unknown	Unk			Not Reported
		Hydroxychloroquine			S	Unknown	Unk			Not Reported
		Xeljanz			S	Unknown	Unk			Not Reported
		Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14231787	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2017CA016340			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg, Qwk		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S		12.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Sulfasalazine			S	Oral	250 Mg, Daily		Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral	5 Mg, Daily		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Daily		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg,Bid		Not Reported
	Hydroxychloroquine			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14425038	EXPEDITED (15-DAY)		HO, OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201801-		71 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Dyspnoea; Hyperpyrexia; Respiratory Failure	Plaquenil Tablet			S	Oral			Concordia
	Methylprednisolone			S	Oral			Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14456726	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0228		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Hypoaesthesia; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Muscular Weakness; Osteoarthritis; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Adalat Xl			C	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Hctz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Nifedipine			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14546485	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018021728		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk (Six Months)		Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported
	Ibuprofen			C		Unk, As Necessary		Not Reported
	Zostavax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14555672	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022483			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14611498	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Penicillin G Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Silver			S	Oral	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported

		Desoximetasone			C	Unknown	Unk			Not Reported
		Hydroxychloroquine			C	Unknown	Unk			Not Reported
		Tofacitinib Citrate			C	Unknown	Unk			Not Reported
		Tylenol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14625143	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018032018			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	14985385	NON-EXPEDITED		OT	US-SA-2018SA148462		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Lung Disorder; Pneumonia; Pulmonary Fibrosis	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S		Unk		Not Reported
	Orencia			S				Not Reported
	Codeine Sulfate			C				Not Reported
	Dilantin D.A.			C				Not Reported
	Morphine			C				Not Reported
	Tetanus Toxoid			C				Not Reported
	Tramadol			C				Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15120737	NON-EXPEDITED			US-SA-2018SA143770			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Humira			C		Unk		Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15219916	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1110		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Apo-Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15236851	NON-EXPEDITED		OT	US-SA-2018SA180523			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Urinary Tract Infection	Arava	S	Unknown			Sanofi
	Plaquenil	S				Sanofi
	Prednisone	S				Not Reported
	Humira	S		Unk		Not Reported
	Orencia	S				Not Reported
	Enbrel	S		Unk		Not Reported
	Mtx [Methotrexate]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15535855	NON-EXPEDITED			US-PFIZER INC-2018424691		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Joint Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Synovitis	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15619950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555996-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15629611	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558591-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported
	Bacillus Calmette-Guerin Vaccine			C	Intravenous (not otherwise specified)			Not Reported
	Bacillus Calmette-Guerin Vaccine			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15659435	EXPEDITED (15-DAY)		OT	BR-TEVA-2018-BR-980090		67 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Gastrointestinal Disorder; Leukopenia; Lymphopenia	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Unknown			Not Reported

	Leflunomide			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668190	NON-EXPEDITED			PHEH2018US050313			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668579	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3462		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Lung Infiltration	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown	40 Mg, 5/Qg 2 Weeks		Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668826	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571474-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Abnormal; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Plaquenil			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668854	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-084		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Heart Rate Increased; Hypertension; Hypotension; Intentional Overdose; Pulseless Electrical Activity; Tachycardia	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668973	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980790		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668974	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980798		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate		S	Subcutaneous		Barr
	Minocycline Hydrochloride		S	Unknown		Actavis
	Minocycline Hydrochloride		S	Unknown		Actavis
	Apo-Azathioprine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Xeljanz		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15668983	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980780		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amoxicillin/Clavulanate			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported

	Bacillus Calmette-Guerin (Bcg) Vaccine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15669907	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018GSK210721			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation	Benlysta Solution For Injection			S	Subcutaneous	200 Mg, Unk		Glaxosmithkline
	Cellcept			S				Glaxosmithkline
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15670006	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2018-US-980536		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Fluid Overload; Hypotension; Intentional Overdose; Pulse Absent; Suicide Attempt; Tachyarrhythmia; Toxicity To Various Agents	Hydroxychloroquine			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15671148	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324578AA		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy;	Myochrysine			S	Intramuscular	50 Mg, Qw		Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Isoniazid			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Sanofi

Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Actemra			S				Not Reported
	Remicade			S		200 Mg		Not Reported
	Remicade			S		200 Mg		Not Reported
	Zostavax			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15671753	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-033177		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Prednisolone			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2018	15674101	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004019			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	13119212	EXPEDITED (15-DAY)		OT	US-SA-2017SA004994		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills;	Alprazolam			S	Oral	.5 Mg,Tid		Not Reported
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Lasix			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi

Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Wheezing	Isosorbide Dinitrate	S	Unknown	Unk Unk,Unk	Not Reported
	Cetylpyridinium Chloride;Dichlorobenzyl Alcohol;Lidocaine Hydrochlorid	S	Unknown	Unk Unk,Unk	Not Reported
	Ampicillin Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Pregabalin	S	Oral	100 Mg,Hs	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg,Qd	Not Reported
	Ziprasidone Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
	Meclozine Hydrochloride	S	Oral	12.5 Mg,Tid	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
	Colchicine	S	Unknown	Unk Unk,Unk	Not Reported
	Prochlorperazine	S	Unknown	Unk Unk,Unk	Not Reported
	Acetazolamide	S	Unknown	Unk Unk,Unk	Not Reported
	Hydromorphone Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
	Doxycycline	S	Unknown	Unk Unk,Unk	Not Reported
	Hydrochlorothiazide/Triamterene	S	Unknown	Unk Unk,Unk	Not Reported
	Erythromycin	S	Unknown	Unk Unk,Unk	Sanofi
	Hepatitis B Vaccine	S	Unknown		Not Reported
	Iron (Salt Not Specified)	S	Unknown	Unk Unk,Unk	Not Reported
	Cefalexin	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Potassium Canrenoate	S	Unknown	Unk Unk,Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk Unk,Unk	Sanofi
	Sulfamethoxazole/Trimethoprim	S			Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
	Oxcarbazepine	S	Unknown	Unk Unk,Unk	Not Reported
	Tramadol Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
	Zenpep	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk	Not Reported

Actemra	S	Unknown	Unk Unk,Unk	Not Reported
Simponi	S	Unknown	Unk Unk,Unk	Not Reported
Humira	S	Unknown	Unk Unk,Unk	Not Reported
Abreva	S			Not Reported
Cyclosporine	S	Unknown	Unk Unk,Unk	Not Reported
Vitamin D2	C	Unknown	Unk Unk,Unk	Not Reported
Mupirocin	C	Unknown	Unk Unk,Unk	Not Reported
Citalopram Hydrobromide	C	Unknown	Unk Unk,Unk	Not Reported
Tamiflu	C	Unknown	Unk Unk,Unk	Not Reported
Paracetamol	C	Unknown	Unk Unk,Unk	Not Reported
Singulair	C	Unknown	Unk Unk,Unk	Not Reported
Synthroid	C	Unknown	Unk Unk,Unk	Not Reported
Zoloft	C	Unknown	Unk Unk,Unk	Not Reported
Vitamins Nos	C	Unknown	Unk Unk,Unk	Not Reported
Restasis	C	Unknown	Unk Unk,Unk	Not Reported
Folic Acid	C	Unknown	Unk Unk,Unk	Not Reported
Nasocort	C	Unknown	Unk Unk,Unk	Not Reported
Advair	C	Unknown	Unk Unk,Unk	Not Reported
Prevacid	C	Unknown	Unk Unk,Unk	Not Reported
Cyclobenzaprine Hydrochloride	C	Unknown	Unk Unk,Unk	Not Reported
Vicodin	C	Unknown	Unk Unk,Unk	Not Reported
Carmellose	C	Unknown	Unk Unk,Unk	Not Reported
Fosamax	C	Unknown	Unk Unk,Unk	Not Reported
Promethazine	C	Unknown	Unk Unk,Unk	Not Reported
Piperacillin/Tazobactam	C	Unknown	Unk Unk,Unk	Not Reported
Ergocalciferol	C	Unknown	Unk Unk,Unk	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unknown	Unk Unk,Unk	Not Reported
Zinc	C	Unknown	Unk Unk,Unk	Not Reported
Hypromellose	C	Unknown	Unk Unk,Unk	Not Reported

	Mobic	C	Unknown	Unk Unk,Unk	Not Reported
	Lamictal	C	Unknown	Unk Unk,Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	Unk Unk,Unk	Not Reported
	Esomeprazole	C	Unknown	Unk Unk,Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk Unk,Unk	Not Reported
	Zanaflex	C	Unknown	Unk Unk,Unk	Not Reported
	Retin A	C	Unknown	Unk Unk,Unk	Not Reported
	Vitamin D3	C	Unknown	Unk Unk,Unk	Not Reported
	Hydrocortisone	C	Unknown	Unk Unk,Unk	Not Reported
	Ketotifen	C	Unknown	Unk Unk,Unk	Not Reported
	Rubramin	C	Unknown	Unk Unk,Unk	Not Reported
	Zantac	C	Unknown	Unk Unk,Unk	Not Reported
	Dexamethasone	C	Unknown	Unk Unk,Unk	Not Reported
	Cyanocobalamin	C	Unknown	Unk Unk,Unk	Not Reported
	Protopic	C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	14264013	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2017-0008157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis; Sarcoidosis	Morphine Sulfate			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	200 Mg, Cyclical		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	14364161	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268251		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Actemra			S	Unknown	162 Mg,Qw		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk Unk,Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	14566793	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	14694061	EXPEDITED (15-DAY)		OT	PHHY2018FR047317		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Exposure During Pregnancy; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Missed Labour; Off Label Use	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Novartis
	Hydroxychloroquine	S				Novartis
	Hydroxychloroquine	S				Novartis
	Prednisone	S	Unknown	15 Mg, Qd		Not Reported
	Prednisone	S				Not Reported
	Prednisone	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	14853499	EXPEDITED (15-DAY)		OT	PHHY2018FR047311		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Aspirin			S	Unknown	75 Mg, Qd		Not Reported
	Aspirin			S	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	14922815	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-019920		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use	Prednisone Tablet			S	Unknown	10 Mg, Qd		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Aspirin /00002701/			S	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15113150	EXPEDITED (15-DAY)		OT	ES-ABBVIE-18K-144-2398792-00		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Hypersensitivity; Neutropenia	Remicade	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Dolquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Abatacept	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Pantoprazole	C			Not Reported
	Lornoxicam	C			Not Reported
	Paracetamol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15150854	NON-EXPEDITED		HO, OT	US-SA-2018SA160958			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Rash; Skin Lesion; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Oedema; Toothache; Ulcer Haemorrhage	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q8w		Not Reported
	Cyclosporin			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15365276	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003215		60 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Femoroacetabular Impingement; Pain; Peripheral Coldness; Surgery	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Predonine			C				Not Reported
	Prednisolone			C				Not Reported
	Co Dio Combination			C				Not Reported
	Amlodin			C				Not Reported
	Pariet			C				Not Reported
	Ganaton			C				Not Reported
	Methycobal			C				Not Reported
	Bredinin			C				Not Reported
	Eperisone Hydrochloride			C				Not Reported
	Shakuyakukanzoto			C				Not Reported
	Loxonin			C				Not Reported
	Tamsulosin Hydrochloride			C				Not Reported
	Betanis			C				Not Reported
	Lyrica			C				Not Reported
	Tramcet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15471612	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003259		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Decreased Appetite; Diarrhoea; Raynaud'S Phenomenon; Seasonal Allergy; Vomiting; Weight Decreased	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Glakay			C				Not Reported
	Epadel T			C				Not Reported
	Neoral			C				Not Reported
	Calonal			C				Not Reported
	Prednisolone			C				Not Reported
	Zopiclone			C				Not Reported
	Teleminsoft			C				Not Reported
	Sawacillin			C				Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15574651	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3109		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15582830	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Unknown					Not Reported
	Simponi			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15632716	NON-EXPEDITED			US-JNJFOC-20181109627			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Injection Site Reaction	Stelara			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15639610	NON-EXPEDITED			US-PFIZER INC-2018475018		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674191	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000579			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gastrointestinal Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674323	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2018US050584			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Premature Baby	Tacrolimus			S	Transplacental	Unk, Unknown Freq.		Astellas
	Hydroxychloroquine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674596	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3480		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Limb Injury;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Plaquenil		S	Oral	Not Reported
	Arava		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674604	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3464			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15674648	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3473		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rosacea; Supraventricular Extrasystoles	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Doxycycline				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15675011	EXPEDITED (15-DAY)		HO	US-APPCO PHARMA LLC-2059448		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15675155	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2731		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arrhythmia; C-Reactive Protein Increased; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Swelling; Swollen Joint Count Increased; Therapeutic Response Decreased; Urticaria	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15675157	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1330		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Epigastric Discomfort; Headache; Herpes Zoster;	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Hypothyroidism; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	2 Per Week		Not Reported
	Apo-Azathioprine	S	Unknown			Not Reported
	Apo-Azathioprine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Po-Hydroxyquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15676320	EXPEDITED (15-DAY)		DS	GB-PFIZER INC-2018485890		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Intentional Self-Injury; Suicidal Ideation	Sertraline Hcl			S		150 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15676778	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573178-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15676783	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573327-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Humira		S	Subcutaneous		Not Reported
	Desoximetasone		S	Unknown		Not Reported
	Diclofenac Sodium		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15677471	EXPEDITED (15-DAY)		OT	SA-MYLANLABS-2018M1089129		14 YR	Male	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	750 Mg/M2 For Six Cycles Monthly And Then Another Six Doses For Every 3 Months		Mylan
	Rituximab			S	Unknown	Two Cycles Of 350 Mg/M2/Dose		Mylan
	Immunoglobulin /00025201/			C	Intravenous (not otherwise specified)			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15677472	EXPEDITED (15-DAY)		OT	SA-MYLANLABS-2018M1089128		13 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Prednisone			S	Unknown	Various Doses Of Prednisone Depending On The Disease Activity		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Azathioprine	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Cyclophosphamide	S	Unknown	Six Doses 750 Mg/M2/Dose Monthly		Mylan
	Rituximab	S	Unknown	Two Doses Of 350 Mg/M2/Dose		Mylan
	Lasix /00032601/	C	Unknown			Mylan
	Enalapril	C	Unknown			Mylan
	Immunoglobulin /00025201/	C	Intravenous (not otherwise specified)			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15677683	NON-EXPEDITED		OT	US-PFIZER INC-2018492919		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Neutropenia; Product Use Issue	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	4 Mg, Weekly		Unknown
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15678015	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-057516		35 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Intentional Product Use Issue; Off Label Use	Prednisone Tablet			S	Unknown	15 Milligram, Daily		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2018	15678016	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-057498		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Threatened; Exposure During Pregnancy; Intentional Product Use Issue; Off Label Use	Prednisone Tablet	S	Unknown	10 Milligram, Daily		Aurobindo
	Acetylsalicylic Acid	S	Unknown	160 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2018	15678525	EXPEDITED (15-DAY)		HO	PHHY2018FR170196		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Prednisolone			S	Oral	40 Mg, Qd		Novartis
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2018	15678802	EXPEDITED (15-DAY)		OT	PHHY2018FR047284		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Threatened; Amenorrhoea; Exposure During Pregnancy; Intentional Product Use Issue; Maternal Exposure Timing Unspecified; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Aspirin			S	Unknown	160 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2018	15680409	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Burning Sensation; Hepatic Pain; Manufacturing Materials Issue; Therapy Change	Hydroxychloroquine 200 Mg Tab			S	Oral	Quantity:1 Tablet(S);		Prasco

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	12906727	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016505568		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Pneumonitis; Polyneuropathy; Rash; Sepsis	Methotrexate Sodium			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine /00072603/			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	13340004	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-021181		63 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dyspnoea; Fatigue; Feeling Hot; Haematuria; Malaise; Neoplasm Malignant; Pain; Swelling; Urinary Bladder Polyp	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Enalapril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	14199103	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3630		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	14631649	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018103505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Qwk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Naprosyn			S		Unk		Not Reported
	Penicillin G Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Silver			S	Oral	Unk		Not Reported
	Sulfadiazine			S		Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported

	Hydroxychloroquine			C		Unk			Not Reported
	Tofacitinib Citrate			C		Unk			Not Reported
	Tylenol			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	14635302	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018104199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15080191	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-059736			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15581830	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-190336		50 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acquired Pigmented Retinopathy	Hydroxychloroquine			S	Unknown	Unk			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15679705	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15679736	EXPEDITED (15-DAY)		OT	CA-ROCHE-2223950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15679772	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15680038	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-187225		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Chest Pain; Oesophageal Pain; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15680041	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-186167			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Discomfort; Euphoric Mood; Nausea; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15680285	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018489566			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Psoriatic Arthropathy	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15680334	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018491815		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15681475	EXPEDITED (15-DAY)		OT	CA-SA-2018SA017968		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Ineffective; Hepatic Enzyme Increased	Hydroxychloroquine			S	Oral	200 Mg,Bid		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Enbrel			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported
	Champix			C	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			C	Unknown	Unk Unk,Unk		Not Reported
	Actemra			C	Unknown	Unk Unk,Unk		Not Reported

	Humira			C	Unknown	Unk Unk,Unk				Not Reported
	Remicade			C	Unknown	Unk Unk,Unk				Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15681479	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2018489929		69 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Recurrence; Product Use In Unapproved Indication	Salazopyrin			S	Oral	500 Mg, Daily		Pfizer
	Methotrexate Pfizer			S	Oral	20 Mg, Weekly		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15681657	EXPEDITED (15-DAY)		OT	EC-MYLANLABS-2018M1088095		57 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone			S	Oral	Followed By Gradual Tapering Off For A Total Of 12 Days		Not Reported
	Hydroxyzine			S	Unknown	At Night		Not Reported
	Fexofenadine			S	Unknown	Up To Fourfold Dosage		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2018	15682183	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018129623		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Deformity; Gastrointestinal Disorder; Loss Of Personal Independence In Daily	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	> 2 Gm Daily For 3 Months		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Parenteral	15 Mg, Unk		Pfizer

Activities; Nausea	Methotrexate Sodium		S	Parenteral	25 Mg, Unk	Pfizer
	Hydroxychloroquine		S	Unknown	400 Mg, Qd	Not Reported
	Leflunomide		S	Unknown	20 Mg, Qd, For 10 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	12350349	NON-EXPEDITED			US-PFIZER INC-2016209168		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Prazosin Hcl			S		Unk		Pfizer
	Boniva			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Paxil [Paroxetine Hydrochloride]			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Savella			S		Unk		Not Reported
	Catapres			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	13078273	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2016079069		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Amnesia; Arthralgia; C-Reactive Protein Increased; Cough; Disease Progression; Drug Dependence; Drug Ineffective; Drug Use Disorder; Dyspnoea; Fall; Haemoptysis; Hand Dermatitis; Hypertension;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Joint Contracture; Joint Swelling; Liver Function Test Increased; Loss Of Consciousness; Nausea; Palpitations; Pneumonia; Product Dose Omission; Productive Cough; Rheumatoid Arthritis; Seizure; Stress; Upper Respiratory Tract Infection; Vomiting	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qwk		Not Reported
	Cannabidiol	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Unk		Not Reported
	Folic Acid	C		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14278580	EXPEDITED (15-DAY)		OT	CA-PURDUE-CAN-2017-0008174		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Morphine Sulfate			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Biw		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14379129	EXPEDITED (15-DAY)		DE, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000122		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In	Hydroxychloroquine			S	Unknown	200mg/400mg		Concordia
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral				Not Reported
	Adalimumab			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Xeljanz			C					Not Reported
	Arava			C					Not Reported
	Plaquenil			C					Not Reported
	Hydroxychloroquine Phosphate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14495735	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000485		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Hydroxychloroquine			S	Oral			Concordia
	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14570431	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0513		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Greater Than 4 Months		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral	Greater Than 3 Months		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			S	Oral	10-15 Mg, As Needed		Not Reported

	Plaquenil			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14644137	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017235345		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Malaise; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Plaquenil			S		200 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	14751955	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-019846		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hellp Syndrome; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pre-Eclampsia	Prednisone			S	Unknown	10 Mg, Qd, (10mg/Day)		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Mg, Qd, (400 Mg/Day)		Not Reported
	Hydroxychloroquine			S				Not Reported
	Oxytocin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15213182	NON-EXPEDITED			US-PFIZER INC-2018302929		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15346429	NON-EXPEDITED			US-PFIZER INC-2018353929			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer
	Methotrexate Sodium			S		1 G, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Glimepiride			S		1 Mg, Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Pravastatin			S		Unk		Not Reported
	Tiger Balm			S		Unk		Not Reported
	Gluten			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15664773	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017366426		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arrhythmia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Swelling; Swollen Joint Count Increased; Urticaria	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S				Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Sarilumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15683620	EXPEDITED (15-DAY)		OT	EC-TEVA-2018-EC-982781		57 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone			S	Oral	Followed By Gradual Tapering Off For A Total Of 12 Days		Actavis
	Hydroxyzine			S	Unknown	At Night		Not Reported
	Fexofenadine			S	Unknown	Up To Fourfold Dosage		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15683995	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004016		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Faeces Discoloured	Hydroxychloroquine			S	Oral			Concordia
	Avelumab			S	Intravenous (not otherwise specified)	(Days 1, 15)		Not Reported
	Gemcitabine Hydrochloride			S	Intravenous (not otherwise specified)	(Days 1, 8, 15)		Not Reported
	Abraxane			S	Intravenous (not otherwise specified)	(Days 1, 8, 15)		Not Reported
	Ibuprofen			C				Not Reported
	Eliquis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15684319	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2018-0009388		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sarcoidosis	Morphine Sulfate			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

			Hydroxychloroquine /00072603/		S	Unknown	Unk		Not Reported
			Methotrexate		S	Oral	25 Mg, Weekly		Not Reported
			Methotrexate		S	Unknown	Unk		Not Reported
			Methotrexate		S	Oral	Unk		Not Reported
			Sulfasalazine		S	Oral	1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15684935	EXPEDITED (15-DAY)		HO	US-ANTARES PHARMA, INC.-2018-LIT-ME-0539		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Diarrhoea; Fatigue; Headache; Hepatosplenomegaly; Histoplasmosis; Interstitial Lung Disease; Lymphadenopathy; Nausea; Night Sweats; Pyrexia; Splenomegaly; Vomiting	Methotrexate			S				Not Reported
	Hydroxychloroquine			S		Unk, Qd		Not Reported
	Sulfasalazine			S		Unk, Qd		Not Reported
	Rituximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15684937	EXPEDITED (15-DAY)		HO, LT	US-ANTARES PHARMA, INC.-2018-LIT-ME-0548		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Mass; Off Label Use; Ovarian Cancer	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Dexamethasone			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Quinacrine /00221301/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15685158	EXPEDITED (15-DAY)		HO	US-ANTARES PHARMA, INC.-2018-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bipolar Disorder; Clostridium Difficile Infection; Contraindicated Product Administered; Drug Intolerance; Fear Of Injection; Injection Site Infection; Mastocytosis; Nausea; Orthostatic Hypotension; Pain; Skin Lesion; Treatment Failure; Vomiting	Otrexup			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Clindamycin			S		Unk		Not Reported
	Amoxicillin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15685583	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2018AMN00925			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bladder Cancer	Azathioprine			S	Unknown	3x/Day		Amneal
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Alprazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15685756	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324307AA		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Acetonide			S		Unk		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg		Sanofi
	Immune Globulin Nos			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qow		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Anakinra			S		50 Mg		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	12.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, 1 Every 1 Minute		Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15685761	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324316AA			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Triamcinolone Acetonide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Oral	5.0 Mg/Kg, Qd		Sanofi
	Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Prednisone	S	Oral	5.0 Mg, Bid		Not Reported
	Prednisone	S	Oral	3.0 Mg, Bid		Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Enbrel	S	Subcutaneous	25.0 Unk		Not Reported
	Sulfasalazine	S	Oral	250.0 Unk, Qd		Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Anakinra	S	Subcutaneous	50.0 Mg, Qd		Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg/Kg		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250.0 Mg, Qm		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280.0 Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15685771	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324297AA			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity;	Triamcinolone Acetonide			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Adalimumab			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qw		Not Reported

Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2018	15686373	EXPEDITED (15-DAY)		OT	CA-ICU MEDICAL, INC.-ICU2018CA00122			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Morphine Sulfate Injection			S	Unknown			Icu Medical
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	200 Milligram (1 Every 2 Weeks) 3.0 Years		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sulfasalazine			S		1000 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	25 Milligram (1 Every 1 Week)		Not Reported
	Plaquenil /00072602/			C		200 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	5 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	13203126	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889218		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	13921466	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372780		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	2 G, Unk		Pfizer
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported

	Arava			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	14379119	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000092		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	14775657	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018157963		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Celebrex			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Not Reported

	Arava	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	300 Mg, Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	14819128	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112163		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 6 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 471 Days		Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 10 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 471 Days		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15126388	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20180706384		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neutropenia	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Dolquine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported
	Lornoxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15179510	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-066472			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15298963	EXPEDITED (15-DAY)		CA, DS	FR-CONCORDIA PHARMACEUTICALS INC.-E2B_00016139		< 1 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cystic Lung; Premature Baby	Plaquenil 200 Mg			S	Transplacental			Concordia

	Neomercazole			S	Transplacental					Not Reported
	Levothyrox			S	Transplacental					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15633355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2215678		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15636052	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1226		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Nausea	Methotrexate (Trade Name Unknown)			S	Unknown	20-25 Mg; Dosage 3/2 To 1/7		Not Reported
	Methotrexate (Trade Name			S	Unknown			Not Reported

	Unknown)				
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Zostavax	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15647418	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3370		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg, 100 Ct Bottle		Not Reported
	Enbrel			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15687618	EXPEDITED (15-DAY)		DS	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192609		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Intentional Self-Injury; Suicidal Ideation	Sertraline			S	Unknown	150 Milligram, Daily		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15688687	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1690		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Prozac			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15688776	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-002379			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Drug Ineffective	Cetirizine			S	Unknown	Unk		Ipca
	Levocetirizine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15689780	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA324552AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Arava			S				Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Gold			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15691676	EXPEDITED (15-DAY)		HO	PHHY2018ES171996		29 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Mycophenolate Mofetil			S	Oral	500 Mg, Q12h		Novartis
	Mycophenolate Mofetil			S	Oral	1500 Mg, Qd		Novartis
	Hidroxicloroquina Sulfato			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15692209	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2018M1088015		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Ineffective	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	Single Dose		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2018	15744460	DIRECT	Y	DE, HO			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Pulmonary Hypertension; Respiratory Distress	Opsumit Tablets 30/Bo: 10mg			S	Oral			Actelion
	Spironolactone			C				Not Reported
	Furosemide			C				Not Reported
	Sertraline			C				Not Reported
	Sildenafil			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Albuterol			C				Not Reported
	Dulera Hfa			C				Not Reported
	Percocet			S				Not Reported
	Lidocaine Top Cream			C				Not Reported
	Fluocinonide Top			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	6970235	EXPEDITED (15-DAY)		OT	DE-TEVA-190448ISR		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome	Ceftriaxone			S	Unknown			Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Doxycycline			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Not Reported
	Streptomycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	11130461	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2015049074		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen

Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass	Methotrexate	S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate	S	Oral	25 Mg, Qmo		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Plaquenil	S	Oral	400 Mg, Qd		Not Reported
	Arava	S	Oral	20 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Qmo		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd		Not Reported
	Leflunomide	S	Oral	20 Mg, Qd		Not Reported
	Prednisone	S	Unknown	5-20 Mg, As Necessary		Not Reported
	Cimzia	S	Unknown	Unk		Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	11631404	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1643958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Enbrel			S	Subcutaneous		Not Reported
	Prednisone			S	Oral		Not Reported
	Prednisone			S	Oral		Not Reported
	Prednisone			S	Unknown		Not Reported
	Sulfasalazine			S	Oral		Not Reported
	Plaquenil			S	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Ketoprofen			C	Unknown		Not Reported
	Losec			C			Not Reported
	Celexa (United States)			C			Not Reported
	Crestor			C	Unknown		Not Reported
	Xeljanz			C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	11923355	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1537832-00		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Tolerance; Drug Tolerance; Fatigue; Hyperhidrosis; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Influenza; Influenza; Joint Swelling; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	11927027	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1490044-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	12560884	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2015105337		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dysstasia; Gastrointestinal Disorder; Loss Of Personal Independence In	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q4wk		Not Reported

Daily Activities; Malaise; Migraine; Mobility Decreased; Nausea; Pain; Rheumatoid Arthritis; Treatment Failure	Arava	S	Subcutaneous	20 Mg, Bid		Not Reported
	Methotrexate	S	Unknown	20 Mg, Qwk		Not Reported
	Celebrex	S	Oral	Unk Unk, Qd		Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qwk		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Advil	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	12905960	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005480		40 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral	On Day 1 (Dissolved A Hydroxychloroquine Sulfate 200mg Tablet In Water 100 Ml And Administered 1 Ml)		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Day 2 (Dissolved A Hydroxychloroquine Sulphate 200mg Tablet In Water 100 Ml And Administered 2 Ml)		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Day 3 (Dissolved A Hydroxychloroquine Sulfate 200mg Tablet In Water 100 Ml And Administered 4 Ml)		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Day 4		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Day 5-11(Dissolved A Hydroxychloroquine Sulfate 200mg Tablet In Water 100 Ml And Administered 10 Ml)		Concordia

	Plaquenil 200 Mg Tablet	S	Oral	Day 12(Dissolved A Hydroxychloroquine Sulfate 200mg Tablet In Water 100 Ml And Administered 20 Ml)	Concordia
	Plaquenil 200 Mg Tablet	S	Oral	Day 13(Dissolved A Hydroxychloroquine Sulfate 200mg Tablet In Water 100 Ml And Administered 40 Ml)	Concordia
	Plaquenil 200 Mg Tablet	S	Oral	Day 14(Dissolved A Hydroxychloroquine Sulfate 200mg Tablet In Water 100 Ml And Administered 80 Ml)	Concordia
	Plaquenil 200 Mg Tablet	S	Oral	Day 15-21	Concordia
	Plaquenil 200 Mg Tablet	S	Oral	On Day 22	Concordia
	Plaquenil 200 Mg Tablet	S	Oral		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	13111555	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878349		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Arava			C				Not Reported

	Ativan	C		Not Reported
	Benadryl (Canada)	C		Not Reported
	Cortisone	C	Oral	Not Reported
	Dilaudid	C		Not Reported
	Darifenacin	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Pantoprazole Sodium	C		Not Reported
	Plantago Ovata	C		Not Reported
	Synthroid	C		Not Reported
	Vagifem	C	Vaginal	Not Reported
	Diphenhydramine	C		Not Reported
	Pantoprazole Sodium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	13246219	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1870607-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	14033431	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-017645		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cervicobrachial Syndrome; Diffuse Alopecia; Erythema; Photodermatosis; Radiculopathy	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dekristol			C	Unknown			Not Reported
	Nebivolol			C	Unknown			Not Reported
	Palexia			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Thyronajod			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	14146864	EXPEDITED (15-DAY)		OT	CA-SA-2016SA066034		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Rash; Syncope; Urticaria	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Arava			S	Oral	10 Mg,Qd		Sanofi
	Methotrexate			S	Unknown	25 Mg,Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Actemra			S	Unknown	4 Mg/Kg,Unk		Not Reported
	Humira			S	Unknown	40 Mg,Qow		Not Reported
	Simponi			S	Subcutaneous	50 Mg,Qm		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg,Qm		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G,Unk		Not Reported

	Prednisone	C		Unk		Not Reported
	Xeljanz	C	Unknown	Unk Unk,Unk		Not Reported
	Prevacid	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	14651442	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000964		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Drug Reaction With Eosinophilia And Systemic Symptoms; Pruritus; Purpura	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	14899323	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001571			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Asthenia; Depression; Fibromyalgia; Gait Disturbance; Joint Lock; Joint Noise; Pain; Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown	400 Mg For 5 Days Per Week		Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	14987131	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001968		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased;	Hydroxychloroquine			S	Unknown			Concordia

Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Arava		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Parenteral	Not Reported
	Enbrel		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15034329	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010695		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Hypersensitivity; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15041866	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002104		66 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disease Recurrence; Hyperhidrosis; Hyperinsulinaemic Hypoglycaemia; Tremor	Hydroxychloroquine			S	Unknown			Concordia
	Hydrocortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15170242	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002218		66 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Generalised Exanthematous Pustulosis; Erythema; Hyperthermia; Leukocytosis; Neutrophilia; Pustule; Red Blood Cell Sedimentation Rate Increased	Plaquenil 200 Mg Tablet	S	Oral		Concordia
	Prednisolone	S	Unknown		Concordia
	Neoral	S	Unknown		Not Reported
	Ciclosporin	C			Not Reported
	Prednisolone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15253461	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002854		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Blood Pressure Decreased; Conjunctival Hyperaemia; Drug Eruption; Erythema; Face Oedema; Flushing; Hypokalaemia; Hyponatraemia; Oedema; Oliguria; Protein Total Decreased; Pruritus; Pyrexia; Pyrexia; Shock Symptom; Swelling	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone Tablet			S	Oral			Not Reported
	Prednisolone Tablet			S	Unknown			Not Reported
	Azulfidine En			C				Not Reported
	Solu Medrol			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Lixiana			C				Not Reported
	Edirol			C				Not Reported
	Famotidine			C				Not Reported
	Fosamac			C				Not Reported
	Bayaspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15567239	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016317105		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Increased; Amnesia; Arthralgia; C-Reactive Protein Increased; Cough; Disease Progression; Drug Dependence; Drug	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer

Ineffective; Drug Use Disorder; Dyspnoea; Fall; Haemoptysis; Hand Dermatitis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Loss Of Consciousness; Nausea; Palpitations; Pneumonia; Product Dose Omission; Productive Cough; Rheumatoid Arthritis; Seizure; Stress; Upper Respiratory Tract Infection; Vomiting	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qwk		Unknown
	Plaquenil	S	Oral	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Cannabidiol	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Folic Acid	C		5 Mg, Qd Daily		Not Reported
	Marijuana	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15692766	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002102		62 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Hypoglycaemia; Loss Of Consciousness	Hydroxychloroquine			S				Concordia
	Sulphasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C				Not Reported
	Leflunomide			C				Not Reported
	Nsaids			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15693309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2223954		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Arthritis; Sciatica	Humira	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Codeine Phosphate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tylenol	C		Not Reported
	Caffeine	C		Not Reported
	Codeine Phosphate	C		Not Reported
	Paracetamol	C		Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15693654	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2581146-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Amlodipine	C		Not Reported
	Arava	C		Not Reported
	Benadryl	C	Unknown	Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15694026	EXPEDITED (15-DAY)		OT	US-SA-2018SA323659		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Drug Ineffective; Papule; Pruritus; Rash Erythematous; Skin Lesion; Skin Plaque	Levocetirizine			S		Unk Unk, Unk		Sanofi
	Cetirizine Hydrochloride			S		Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15695086	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-086			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Prednisone			S	Transplacental	()		Westward
	Azathioprine			S	Transplacental	()		Not Reported
	Hydroxychloroquine			S	Transplacental	()		Not Reported
	Tacrolimus			S	Transplacental	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15695430	EXPEDITED (15-DAY)			US-SA-2018SA173144		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event	Hydroxychloroquine Sulfate	S				Sanofi
	Methotrexate	C		Unk		Not Reported
	Leflunomide	C		Unk		Sanofi
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15695985	EXPEDITED (15-DAY)		OT	PHHY2018CA174116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Nausea; Rash; Therapeutic Product Effect Decreased	Hydrochlorothiazide			S	Unknown			Novartis
	Lopressor			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Avelox			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Keflex			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Diazide [Hydralazine Hydrochloride]			S	Unknown			Not Reported
	Tecta			S	Unknown			Not Reported
	Pariet			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Venofer	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Ciprofloxacin	C	Unknown	Not Reported
	Hidroxicloroquina	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15696434	EXPEDITED (15-DAY)		OT	PHHY2018CA174568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Neoral			S	Oral	20 Mg, Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15696437	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA174543		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Cimzia			S	Subcutaneous	Unk			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Imuran			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15696658	NON-EXPEDITED			US-ANTARES PHARMA, INC.-2018-SPO-ME-0551		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Pain	Methotrexate			S		Unk		Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15717181	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blister; Furuncle; Liver Injury	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2018	15717788	DIRECT		OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blister; Furuncle; Liver Injury	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	13199675	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019964		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Plaquenil			S	Unknown	400 Mg,Unk		Sanofi

Intolerance; Rheumatoid Factor Positive; Synovitis	Leflunomide	S	Unknown	20 Mg,Unk		Sanofi
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk		Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	13380301	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1909275-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	13386388	EXPEDITED (15-DAY)		OT	CA-SA-2016SA152974		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported

	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium	S		Unk		Not Reported
	Orencia	S		Unk Unk,Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Celebrex	S	Oral	200 Mg, Bid		Not Reported
	Xeljanz	S	Oral	5 Mg,Bid		Not Reported
	Arava	C	Unknown	20 Mg,Qd		Not Reported
	Arava	C	Unknown	20 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	14132144	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1857367-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	4 Mg/Kg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

	Xeljanz			S	Oral					Not Reported
	Prednisone			C						Not Reported
	Prevacid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	14475215	EXPEDITED (15-DAY)		OT	IE-SA-2017SA124549		37 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Drug Ineffective; Leukopenia; Off Label Use; Skin Atrophy	Hydroxychloroquine Sulfate			S	Unknown	200 Mg,Bid		Sanofi
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Clobetasol Propionate			S	Topical	Unk Unk,Unk		Not Reported
	Prednisolone			S	Oral	Unk Unk,Unk		Not Reported
	Triamcinolone Acetonide			S	Unknown	Unk Unk,Unk		Sanofi
	Protopic			S	Topical	Unk Unk,Unk		Not Reported
	Fluconazole			C				Not Reported
	Cotrimoxazole			C				Not Reported
	Efavirenz			C				Not Reported
	Lamivudine/Zidovudine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15698088	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004082			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Tongue Neoplasm Malignant Stage Unspecified	Plaquenil 200 Mg Tablet			S	Oral	At A Dose Of 1df/Day And 2df/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	At A Dose Of 1df/Day And 2df/Day, Alternately		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15698137	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES			Unknown	USA

LIMITED-IPC-2018-US-002396

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Premature Baby	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Tacrolimus			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15698628	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3584			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Ezetrol			C	Unknown			Not Reported
	Niaspan			C	Unknown			Not Reported
	Nitro			C	Unknown			Not Reported

		Rosuvastatin Calcium			C	Unknown				Not Reported
		Tylenol			C	Unknown				Not Reported
		Nitroglycerin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15699381	NON-EXPEDITED		HO	US-APOTEX-2018AP026416			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Mycophenolate			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Isotretinoin			S	Unknown			Not Reported
	5-Fluorouracil /00098801/			S	Unknown			Not Reported
	Acitretin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15699556	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA330044AA		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Plaquenil			S		200 Mg, Qow		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Cefazolin			S				Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Qow		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Qow		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qw		Not Reported
	Orencia			S				Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S				Not Reported
	Arava			C				Not Reported
	Amlodipine			C				Not Reported
	Benadryl [Diphenhydramine			C				Not Reported

	Hydrochloride]									
	Methotrexate			C						Not Reported
	Naproxen			C						Not Reported
	Prednisone			C						Not Reported
	Tofacitinib Citrate			C						Not Reported
	Viread			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15699580	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015170154		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Pain; Peripheral Swelling	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Intramuscular	Unk		Unknown
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Remicade			S		Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8mg/Kg Monthly		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15699707	EXPEDITED (15-DAY)		HO	PHHY2018DE172604			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Ischaemia	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis

Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Methotrexate	S	Unknown	15 Mg, Unk	Novartis
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1500 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported

			Hydroxychloroquine		S	Unknown	200 Mg, Unk		Not Reported
			Hydroxychloroquine		S	Unknown	200 Mg, Unk		Not Reported
			Hydroxychloroquine		S	Unknown	200 Mg, Unk		Not Reported
			Hydroxychloroquine		S	Unknown	200 Mg, Unk		Not Reported
			No Treatment Received		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15700341	EXPEDITED (15-DAY)		DE	PHHY2018DE176306			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	No Treatment Received			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15700792	EXPEDITED (15-DAY)		OT	FR-SA-2018SA138087		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Maculopathy; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Average Of 5.9 Mg/Kg/Day)		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	300 Mg, Qd(Average Of 4.4 Mg/Kg/Day)		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2018	15701740	NON-EXPEDITED			PHEH2018US050996		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Product Shape Issue	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	12953906	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005859		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Myochrysine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			C				Not Reported
	Orencia			C		Last Dose Was 6 Weeks Ago; Tolerability Issues - Infections And Vomiting		Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Enbrel			C				Not Reported
	Remicade			C				Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	14576300	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000677		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthrodesis; Arthrodesis; Bone Erosion; Condition Aggravated; Drug Ineffective; Fall; Foot Deformity; Hand Deformity; Impaired Work Ability; Joint Prosthesis User; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Pneumonia; Post Procedural Infection; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rheumatoid Nodule; Sensitivity To Weather Change; Surgery; Synovitis; Treatment Failure	Plaquenil	S	Unknown		Concordia
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Xeljanz	C			Not Reported
	Celecoxib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	15035344	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010721		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Asthenia; Decreased Appetite; Drug Ineffective; Influenza Like Illness; Infusion Related Reaction; Nasal Congestion; Pruritus; Upper Respiratory Tract Congestion; Weight Decreased; Weight Increased	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Diphenhydramine			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported

	Tylenol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	15219736	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-070467			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	15702279	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Inflammation; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Sulfasalazine			C		4 Pills		Not Reported
	Humira			C				Not Reported
	Rogaine			C				Not Reported
	Clindamycin			C				Not Reported
	Vitamins			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	15702290	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004028			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Leflunomide	S	Unknown		Not Reported
	Methotrexat	S	Unknown		Not Reported
	Methotrexat	S	Unknown		Not Reported
	Methotrexat	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2018	15702291	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	12336780	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015043695		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Prednisone			S	Oral	Unk, As Required		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Apo-Prednisone			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	12849099	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016139679		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Impaired Work Ability; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Xeljanz			C				Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	12936084	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016157973		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Naprosyn			C		Unk		Not Reported
	Rabeprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13133324	EXPEDITED (15-DAY)		DS, OT	CA-ORION		39 YR	Female	CAN

						CORPORATION ORION PHARMA-TREX2016-1011			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Mobility Decreased; Nausea; Pain; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Apo Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Cyclical		Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13380263	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017045350			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13563721	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017074123		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	25 Mg, 2 Times/Wk	Amgen
	Plaquenil		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	300 Mg, Q6wk	Not Reported
	Rituxan		S	Unknown	1000 Mg, Unk	Not Reported
	Rituxan		S	Unknown	2000 Mg, 1 Every 6 Months	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	2000 Mg, Unk (1000 Mg, 2 Doses Every 6 Months)	Not Reported
	Rituximab		S	Unknown	1000 Mg, Every 12 Weeks	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		C	Oral	10 Mg, Qwk	Not Reported
	Gold		C	Intramuscular	50 Mg, Qwk	Not Reported
	Prednisone		C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13767455	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017107185			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13904219	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017126690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Tofacitinib			C	Oral	5 Mg, Bid		Not Reported
	Oxycodone			C	Unknown	Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Acetaminophen W/Codeine Phosphate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	13919323	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2017128977		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	7.5 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	14497819	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000502			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelinating Polyneuropathy; Neutropenia; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported
	Restasis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	14744370	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1036		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	14819943	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2018152359		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Coma; Drug Ineffective; Head Injury; Seizure	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Pfizer
	Hydroxychloroquine			S	Unknown	40 Mg, Qd		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15608217	NON-EXPEDITED			US-PFIZER INC-2018459485		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702345	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-058382			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Prednisone			S	Transplacental			Aurobindo
	Azathioprine			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702457	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-			Female	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702458	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004030			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Simponi			C				Not Reported
	Methotrexate Disodium			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702459	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004033		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Joint Stiffness; Musculoskeletal Pain; Pain In Extremity; Pain In Extremity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702531	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2582470-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15702740	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2581919-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Hypersensitivity; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Gold			C				Not Reported
	Morphine			C				Not Reported

	Prednisone			C	Oral					Not Reported
	Tofacitinib			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15703336	EXPEDITED (15-DAY)		OT	CA-ROCHE-2226719		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease	Rituxan			S	Intravenous (not otherwise specified)	Ongoing		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Ongoing		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg/Q 0, 2, 6		Not Reported
	Methotrexate			S	Unknown	Discontinued		Not Reported
	Sulfasalazine			S	Unknown	Ongoing; Yes		Not Reported
	Lyrica			S	Unknown	Ongoing		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Tylenol			C	Unknown	Ongoing; Up To 3000 Mg Daily		Not Reported
	Tylenol			C	Unknown			Not Reported
	Valsartan			C	Unknown	Ongoing		Not Reported
	Nexium			C	Unknown	Ongoing		Not Reported
	Wellbutrin Xl			C	Unknown	300 Mg Qd; Ongoing		Not Reported
	Lumigan Rc			C	Ophthalmic	0.01 %Eye Drops Qd; Ongoing		Not Reported
	Trazodone			C	Unknown	Ongoing		Not Reported

	Esomeprazole	C	Unknown	Ongoing: Yes		Not Reported
	Suphedrine Pe Product Nos	C	Unknown	Ongoing: Yes		Not Reported
	Valsartan	C	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15705204	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2583647-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hypersensitivity; Infusion Related Reaction; Pericarditis; Swelling; Wound	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

		Reactine (Cetirizine Hydrochloride)			S	Unknown				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15707116	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Procytox			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Ezetrol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	13129248	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017007184		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Fatigue; Nausea; Nodule; Prostate Cancer; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

	Plaquenil	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Iron	C		Unk		Not Reported
	Meloxicam	C		Unk		Not Reported
	Meloxicam	C				Not Reported
	Aspirin	C		81 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	13289149	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017028404		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	13975747	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166576		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation	Arava			S	Oral	10 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg,Qd		Sanofi
	Sulfasalazine			S	Unknown	1500 Mg,Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported

Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Kineret			C	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	14222251	NON-EXPEDITED			US-AMGEN-USASP2017176010		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteoarthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15207008	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018100986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C		20 Mg, Qwk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15290018	EXPEDITED (15-DAY)		CA, DS	FR-MERCK KGAA-2053879			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Cystic Lung; Premature Baby	Euthyrox			S				Provell Pharmaceuticals
	Neo-Mercazole			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15345854	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-079330			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15626411	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268188		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg,Qd		Sanofi
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported

	Humira	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Abatacept	C		Unk Unk, Unk		Not Reported
	Hydroxychloroquine	C	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide	C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	C	Unknown	Unk Unk,Unk		Not Reported
	Folic Acid	C	Oral	5 Mg, Unk		Not Reported
	Tofacitinib Citrate	C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15707949	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181203990		79 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Pressure Systolic Increased; Condition Aggravated; Hypoaesthesia	Tylenol Arthritis Pain 8h		Y	S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15708021	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1424		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Pain; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Xeljanz	S	Oral			Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Cyclical		Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Cimzia	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15708067	EXPEDITED (15-DAY)		OT	US-ACCORD-095250			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Off Label Use	Tacrolimus			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15708122	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-983944		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Prednisolone			S	Oral	40 Milligram Daily;		Actavis
	Plaquenil			S	Oral	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15709602	EXPEDITED (15-DAY)		OT	US-VELOXIS PHARMACEUTICALS, INC.-2018VELUS1290			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphocytopenia Neonatal; Premature Baby; Thymus Disorder	Envarsus Xr		S	Transplacental	Unk		Unknown
	Hydroxychloroquine		S	Transplacental			Not Reported
	Azathioprine		S	Transplacental			Not Reported
	Prednisone		S	Transplacental			Not Reported
	Steroids		S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710022	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE176582			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenocarcinoma Of Colon; Atrioventricular Block Complete	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported

					Hydroxychloroquine		S	Unknown	400 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	400 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					No Treatment Received		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710041	EXPEDITED (15-DAY)		OT	PHHY2018CN176178			Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy; Heart Block Congenital; Patent Ductus Arteriosus; Premature Baby	Methylprednisolone			S	Transplacental			Novartis
	Hydroxychloroquine			S	Transplacental			Not Reported
	Dexamethasone			S	Transplacental	3.75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710630	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181203762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Actemra			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710631	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181203820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710710	EXPEDITED (15-DAY)		OT	IL-SAKK-2018SA330878AA		60 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Malignant Melanoma; Skin Lesion	Arava	S	Unknown	Unk, Unk		Sanofi
	Plaquenil	S	Unknown	Unk, Unk		Sanofi
	Xeljanz	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15710711	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA330053AA			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Diarrhoea; Drug Ineffective; Fungal Infection; Hepatotoxicity; Herpes Zoster; Rash; Rheumatoid Arthritis	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Apixaban			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported
	Amitriptylene			C		Unk		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Novo Pranol			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	13386953	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017137907			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15433297	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-089930			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Liver Function Test Increased; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15633947	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT156440		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bronchitis; Chills; Cushingoid; Drug Ineffective; Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Lupus Nephritis; Meningitis Cryptococcal; Muscle Atrophy; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	1 G, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	375 Mg/M2, Unk		Not Reported
	Prednisone			S	Oral	1 Mg/Kg, Qd		Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	350 Mg, Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Cyclophosphamide			S	Oral	1 Mg/Kg, Qd		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Mg, 1x Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg, 1x Pulse		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15696139	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015153501		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly, For Years		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day, Greater Than 4 Months		Not Reported
	Apo-Prednisone			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day, Greater Than 3 Months		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Prednisone			S	Oral	10-15 Mg 1x/Day, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15698183	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA011509			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	716.25 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Aspirin /00002701/			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported
	Ezetrol			C				Not Reported
	Niaspan			C				Not Reported
	Nitro /00003201/			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tylenol /00020001/			C				Not Reported

	Nitroglycerin			C					Not Reported
	Methotrexate Sodium			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Leflunomide			S					Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15711696	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587622-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15712585	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588068-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15712700	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588209-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15713403	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018GSK209914		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Nausea;	Benlysta Solution For Injection			S		Unk, We		Glaxosmithkline

Ocular Toxicity; Surgery; Therapeutic Product Effect Decreased; Therapy Interrupted	Plaquenil	S	Unk		Not Reported
	Imuran	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15714206	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-034290			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Intussusception	Prednisolone			S	Unknown			Bausch And Lomb
	Aspirin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enoxaparin			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Buscopan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Intragam 10			S	Unknown			Not Reported
	Microlax (Sodium Citrate\Sodium Lauryl Sulfoacetate\Sorbitol)			S	Unknown			Not Reported
	Movicol			S	Unknown			Not Reported
	Mylanta			S	Unknown			Not Reported
	Novorapid			S	Unknown			Not Reported
	Panadeine [Codeine Phosphate;Paracetamol]			S	Unknown			Not Reported
	Slow-K			S	Unknown			Not Reported
	Xylocaine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15714963	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE077955			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Contusion; Renal Impairment	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	No Treatment Received			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2018	15714965	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE177211			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Lentigo Maligna; Salmonellosis	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	5 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Methotrexate	S	Unknown	10 Mg, Unk	Novartis
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported

					Leflunomide		S	Unknown	20 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					No Treatment Received		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	12842433	EXPEDITED (15-DAY)		OT	CA-ROCHE-1841433		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Every 24 Hrs		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Plaquenil			C	Unknown				Not Reported
		Plaquenil			C	Unknown				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	13121108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0809		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis; Synovitis; Thyroid Cancer	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lantus			C	Unknown			Not Reported
	Insulin			C	Unknown			Not Reported
	Humalog			C	Unknown			Not Reported
	Avapro			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Gluconorm			C	Unknown			Not Reported
	Metformin Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	13136342	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1644573-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Piroxicam	C		Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	13141326	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1848452-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Cimzia		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Procytox		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Methotrexate Sodium		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	13186698	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1856011-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	14400789	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000125		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Myocrisin			S	Unknown			Not Reported
	Arava			C				Not Reported
	Ativan			C				Not Reported
	Dilaudid			C				Not Reported
	Darifenacin			C				Not Reported
	Furosemide			C				Not Reported
	Loperamide			C				Not Reported
	Orphenadrine Citrate			C				Not Reported
	Omnaris			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C				Not Reported
	Abatacept			C				Not Reported
	Rituxan			C				Not Reported

	Kineret	C		Not Reported
	Benadryl Allergy	C		Not Reported
	Cortisone	C		Not Reported
	Desoximetasone	C		Not Reported
	Diphenhydramine	C		Not Reported
	Plantago Ovata	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	14825665	EXPEDITED (15-DAY)		LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1284		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Cerebrovascular Accident; Coma; Drug Ineffective; Head Injury; Seizure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2 Times		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	14836034	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15610247	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP024045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Sodium			S	Unknown	75 Mg, Bid		Apotex
	Naproxen			S	Unknown	500 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, Qd		Not Reported
	Piroxicam			C	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15669254	EXPEDITED (15-DAY)		OT	AU-LUPIN PHARMACEUTICALS INC.-2018-08222		69 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Retinal Pigmentation; Visual Field Defect	Hydroxychloroquine			S	Unknown	500 Mg, Qd, (11.4 Mg/Kg Actual Bodyweight Cumulative Dose >440 G))		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15714289	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588203-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15717030	NON-EXPEDITED			US-PFIZER INC-2018504511		68 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Bumetanide			S		Unk		Unknown
	Furosemide			S		Unk		Unknown
	Carafate			S		Unk		Not Reported
	Nickel			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15719055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017212234		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Enbrel			S		25 Mg, Twice Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S		Unk		Not Reported

	Remicade	S		300 Mg, Every 6 Weeks	Not Reported
	Rituxan	S	Unknown	1000 Mg, 2 Doses Every 6 Months	Not Reported
	Rituxan	S	Unknown	2000 Mg, 1 Every 6 Months	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15719424	EXPEDITED (15-DAY)		OT	PHHY2018US180533			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia; Premature Baby	Tacrolimus			S	Transplacental			Novartis
	Hydroxychloroquine			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15720200	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE181423			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Atrial Fibrillation; Insulin Resistance; Nasopharyngitis; Nausea; Urinary Tract Infection	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Novartis
	No Treatment Received			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2018	15802921	DIRECT					70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Back Pain;	Radiological Iodine (Iv)			S				Not Reported
	Lisinopril			S				Not Reported

Confusional State;	Norvasc	S	Not Reported
Constipation; Coordination	Fosamax	S	Not Reported
Abnormal; Diarrhoea;	Tegratol	S	Not Reported
Diplopia; Disorientation;	Flagyl	S	Not Reported
Disturbance In Attention;	Remeron	S	Not Reported
Dysuria; Generalised	Levsin	S	Not Reported
Oedema; Hallucination;	Tetracycline	S	Not Reported
Headache;	Neurontin	S	Not Reported
Hypoaesthesia;	Cymbalta	S	Not Reported
Hypoaesthesia Oral;	Restoril	S	Not Reported
Insomnia; Nausea;	Soma	S	Not Reported
Nervousness; Nightmare;	Ambien	S	Not Reported
Nightmare; Pain In	Levaquin	S	Not Reported
Extremity; Palpitations;	Gabitril	S	Not Reported
Palpitations; Psychomotor	Provigil	S	Not Reported
Hyperactivity;	Topamax	S	Not Reported
Somnambulism;	Imdur	S	Not Reported
Somnolence; Thinking	Pletal	S	Not Reported
Abnormal; Tremor; Vision	Cipro	S	Not Reported
Blurred; Vomiting	Percocet	S	Not Reported
	Loratab	S	Not Reported
	Codeine	S	Not Reported
	Percodan	S	Not Reported
	Chantix	S	Not Reported
	Nortriptyline	S	Not Reported
	Doxepin	S	Not Reported
	Trazadone	S	Not Reported
	Nexium	S	Not Reported
	Motrin	S	Not Reported
	Toradol	S	Not Reported
	Paxil	S	Not Reported
	Zoloft	S	Not Reported
	Prevacid	S	Not Reported
	Plaquenil	S	Not Reported
	Lorabid	S	Not Reported
	Floxin	S	Not Reported
	Cefzil	S	Not Reported
	Augmentin	S	Not Reported
	Rocephin	S	Not Reported
	Lyrica	S	Not Reported
	Savella	S	Not Reported
	Toprol [Succinate] 25mg	S	Not Reported

	Morphine			S					Not Reported
	Clindamycin (2014)			S					Not Reported
	Coreg			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	11649697	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015335751		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysstasia; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Mobility Decreased; Nausea; Pain; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Weekly (Once Weekly)		Pfizer
	Celebrex			S	Oral	Unk Unk, Qd		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, Twice A Day (Bid)		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Cyclic (Every 4 Weeks)		Not Reported
	Arava			S	Subcutaneous	Unk, Daily		Not Reported
	Arava			S	Subcutaneous	20 Mg, 2x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day (Qd (1 Every 24hours))		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13011431	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865032		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 486.0 Nos	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Tocilizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13397229	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002127		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Hydroxychloroquine Tablet			S	Oral			Concordia
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Neoral			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13419090	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010763		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Plaquenil			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13592611	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13687627	EXPEDITED (15-DAY)		DS, HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003721		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported

Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Liver Function Test Increased; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Rheumatoid Arthritis; Stomatitis; Treatment Failure; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Abatacept	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Advair	C		Not Reported
	Actonel	C		Not Reported
	Amlodipine	C		Not Reported
	Ascorbic Acid	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Citalopram	C		Not Reported
	Copper Sulfate Ferrous Gluconate Folic Acid Manganese Sulfate Vitamin	C		Not Reported
	Docusate Sodium Senna Alexandrina	C		Not Reported
	Ergocalciferol	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Olmesartan Medoxomil	C		Not Reported
	Docosahexaenoic Acid	C		Not Reported
	Oxybutynin	C		Not Reported
	Prednisone	C		Not Reported
	Rabeprazole	C		Not Reported
	Rabeprazole Sodium	C		Not Reported
	Senna Alexandrina	C		Not Reported
	Spiriva	C		Not Reported
	Tiotropium Bromide	C		Not Reported
	Vitamin B12	C		Not Reported
	Zinc Gluconate	C		Not Reported
	Zopiclone	C		Not Reported
	Tylenol	C		Not Reported
	Folinic Acid	C		Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13868918	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cortisone			C				Not Reported
	Plaquenil			C				Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	13976615	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166728			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Skin Cancer; Squamous Cell Carcinoma; Treatment Failure	Arava			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Sulfasalazine			S	Oral	1 G,Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Azathioprine			S	Unknown	150 Mg,Tid		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk,Qw		Not Reported
	Neoral			S	Unknown	125 Mg,Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G,Unk		Not Reported

		Prednisone			C	Unknown	10 Mg,Qd			Not Reported
		Citalopram Hydrobromide			C	Unknown	40 Mg,Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	14150830	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006151		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Rash; Syncope; Urticaria	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	14528249	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000580		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cellulitis; Deep Vein Thrombosis; Iron	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400mg/Day, Alternately		Concordia

Deficiency Anaemia	Plaquenil 200 Mg Tablet	S	Oral	200 Mg/Day And 400 Mg/Day, Alternately	Concordia
	Predonine	C			Not Reported
	Bredinin	C			Not Reported
	Sarpogrelate	C			Not Reported
	Takecab	C			Not Reported
	Urso	C			Not Reported
	Epl Cap.	C			Not Reported
	Mecobalamin	C			Not Reported
	Loxoprofen Sodium	C			Not Reported
	Eperisone	C			Not Reported
	Atorvastatin	C			Not Reported
	Bio-Three	C			Not Reported
	Astomin	C			Not Reported
	Ambroxol	C			Not Reported
	Tramcet	C			Not Reported
	Fosamac	C			Not Reported
	Fosamac	C			Not Reported
	Reflap	C			Not Reported
	Fucidin Leo	C			Not Reported
	Lunesta	C			Not Reported
	Silece	C			Not Reported
	Rhythmy	C			Not Reported
	Rozerem	C			Not Reported
	Zolpidem Tartrate	C			Not Reported
	Lexapro	C			Not Reported
	Levotomin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15214460	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018304872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			C		20 Mg, Qwk		Not Reported

	Sulfasalazine			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15720873	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001001		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Factor Positive; Synovitis	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721076	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004115		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721079	EXPEDITED (15-DAY)		OT	IL-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004122		60 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma; Skin Lesion	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721218	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3732		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721413	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1001		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Plaquenil		S	Unknown				Not Reported
					Arava		S	Unknown				Not Reported
					Humira		S	Subcutaneous				Not Reported
					Simponi		S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721528	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Diarrhoea; Drug Ineffective; Fungal Infection; Hepatotoxicity; Herpes Zoster; Rash; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Apixaban			C				Not Reported
	Atorvastatin			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol			C				Not Reported
	Amitriptylene			C				Not Reported
	Pantoloc			C				Not Reported
	Novo Pranol			C				Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721621	EXPEDITED (15-DAY)		HO, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-115961		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Pancytopenia; Pulmonary Arterial Hypertension	Abatacept			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported
	Mepacrine			S	Unknown			Not Reported
	Ruxolitinib			S	Unknown	10 Mg, Bid		Not Reported
	Ruxolitinib			S	Unknown	7.5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263100-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15721714	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017144297		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cough; Haemoptysis; Hypertension; Joint Contracture; Joint Swelling; Liver Function Test Increased; Pneumonia; Productive Cough; Seizure	Enbrel	S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil	S	Oral	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Oral	Unk		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qwk		Not Reported
	Folic Acid	C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15722753	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2017SA166649		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Rheumatoid Arthritis	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	17.5 Mg,Qw		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qw		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Acetaminophen			C	Unknown	Unk Unk,Prn		Not Reported
	Acetaminophen W/Oxycodone			C	Unknown	Unk Unk,Prn		Not Reported
	Folic Acid			C	Unknown	Unk Unk,Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			C	Unknown	Unk Unk, Unk		Not Reported
	Thiamine Hydrochloride			C				Not Reported
	Oxycodone Terephthalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15723914	EXPEDITED (15-DAY)		HO	PHHY2018DE179838			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Nausea; Spinal Osteoarthritis	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	No Treatment Received			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2018	15725075	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-193575		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness;	Bactrim			S	Unknown	Unk		Mutual
	Ampicillin			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Sun
	Doxycycline			S	Unknown	Unk		Sun
	Erythromycin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Sun
	Sulfasalazine			S	Unknown	Unk		Sun
	Humira (Solution For Injection)			S	Subcutaneous	Unk		Not Reported
	Simponi Aria			S	Unknown	Unk		Not Reported
	Xanax			S	Oral	0.5 Milligram, Tid, (1 Tablet, As Required)		Not Reported
	Isordil			S	Unknown	Unk		Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Wheezing; Wound	Lyrica	S	Oral	1 Dosage Form, Daily, (At Bedtime)	Not Reported
	Zyrtec	S	Unknown	Unk, Prn	Not Reported
	Geodon	S	Unknown	Unk	Not Reported
	Antivert(Ancovert)	S	Oral	Unk, Tid, (As Required)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Colchicine	S	Unknown	Unk	Not Reported
	Compazine	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Diamox	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Dyazide	S	Unknown	Unk	Not Reported
	Hepatitis B Vaccine	S	Unknown	Unk	Not Reported
	Iron	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Lasix	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Potassium	S	Unknown	Unk	Not Reported
	Sudafed	S	Unknown	Unk	Not Reported
	Trileptal	S	Unknown	Unk	Not Reported
	Ultram	S	Unknown	Unk	Not Reported
	Zenpep	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Lialda	S	Unknown	Unk	Not Reported
	Vitamin D2	C	Unknown	Unk	Not Reported
	Bactroban	C	Unknown	Unk	Not Reported
	Celexa	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

Singulair	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Zoloft	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nasocort	C	Unknown	Unk	Not Reported
Advair(Seretide)	C	Unknown	Unk	Not Reported
Prevacid	C	Unknown	Unk	Not Reported
Flexeril	C	Unknown	Unk	Not Reported
Vicodin	C	Unknown	Unk	Not Reported
Refresh	C	Unknown	Unk	Not Reported
Fosamax	C	Unknown	Unk	Not Reported
Phenergan	C	Unknown	Unk	Not Reported
Tazact(Pip/Tazo)	C	Unknown	Unk	Not Reported
Vitamin D2	C	Unknown	Unk	Not Reported
Systane(Systane Lubricant)	C	Unknown	Unk	Not Reported
Isopto Tears	C	Unknown	Unk	Not Reported
Mobic	C	Unknown	Unk	Not Reported
Lamictal	C	Unknown	Unk	Not Reported
Diamode	C	Unknown	Unk	Not Reported
Nexium	C	Unknown	Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk	Not Reported
Zanaflex	C	Unknown	Unk	Not Reported
Retin A	C	Unknown	Unk	Not Reported
Flu Vaccine Vii	C	Unknown	Unk	Not Reported
Pneumococcal Vaccine	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Norco(Vicodin)	C	Unknown	Unk	Not Reported
Hydrocortisone	C	Unknown	Unk	Not Reported

	Zinc			C	Unknown	Unk			Not Reported
	Zaditor			C	Unknown	Unk			Not Reported
	Rubramin			C	Unknown	Unk			Not Reported
	Zantac			C	Unknown	Unk			Not Reported
	Deltasone			C	Unknown	Unk			Not Reported
	Protopic			C	Unknown	Unk			Not Reported
	Vitamin B12			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2018	13599619	EXPEDITED (15-DAY)		OT	CA-ROCHE-1940992		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Supeudol			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2018	15726337	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004102		44 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2018	15726338	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004101			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Retinal Detachment	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	13404968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16P-028-1771943-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown	486.0 (Units Not Specified)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			C	Unknown	2-3 Mg/Kg		Not Reported
	Methotrexate			C	Parenteral			Not Reported
	Ciclosporin			C				Not Reported

	Minocycline	C	Not Reported
	Penicillamine	C	Not Reported
	Prednisolone	C	Not Reported
	Prednisone	C	Not Reported
	Phenylbutazone	C	Not Reported
	Tofacitinib	C	Not Reported
	Actemra	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	13828718	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2017SP011387		55 YR	Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication; Hypogammaglobulinaemia	Mycophenolate Mofetil			S	Unknown	3 G, Unknown		Strides
	Mycophenolate Mofetil			S	Unknown	2 G, Unknown		Strides
	Prednisolone			S	Unknown	(Low Dose), Unk		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Cyclical		Not Reported
	Rituximab			S				Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg, Cyclical		Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	13912544	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017127721			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Impaired Work Ability; Pain; Therapy Non-Responder	Simponi			S	Unknown	Unk	Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	716.25 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	Unk	Not Reported
	Leflunomide			S	Unknown	Unk	Not Reported
	Methotrexate			S	Unknown	Unk	Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Aspirin			C	Unknown	Unk	Not Reported
	Clopidogrel Bisulfate			C	Oral	Unk	Not Reported
	Ezetrol			C	Oral	Unk	Not Reported
	Niaspan			C	Unknown	Unk	Not Reported
	Nitro			C	Transdermal	Unk	Not Reported
	Rosuvastatin Calcium			C	Oral	Unk	Not Reported
	Tylenol			C	Oral	Unk	Not Reported
	Nitroglycerin			C	Transdermal	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	14648764	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018102242		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Drug Intolerance; Herpes Zoster; Liver Disorder; Myocardial Infarction; Polyarthritis; Rash; Seronegative Arthritis	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Salazopyrin			S	Oral	1000 Mg, 2x/Day		Pfizer
	Celebrex			S		Unk Unk, As Needed		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported
	Brenzys			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15017086	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002051		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Pregabalin			C				Not Reported
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15206132	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Condition Aggravated; Peripheral Swelling; Rheumatoid Arthritis; Tenderness	Plaquenil			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Kevzara			C				Not Reported
	Humira			C				Not Reported
	Rituximab			C				Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported
	Calcium			C				Not Reported
	Vitamin B12 (Vitamin B12 Nos)			C				Not Reported
	Flovent			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Metoclopramide Hcl			C				Not Reported
	Zopiclone			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vitamin B6			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15225630	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION			Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15414665	EXPEDITED (15-DAY)		OT	PHHY2018NL102356		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Gastrointestinal Toxicity; Immunoglobulin G4 Related Disease; Off Label Use; Product Use In Unapproved Indication; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown			Novartis
	Prednisone			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15683928	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004014			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyarthritis; Weight Increased	Plaquenil			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Naprosyne			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15683994	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004018		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Haemoglobin Decreased; Surgery	Plaquenil			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15686479	EXPEDITED (15-DAY)		OT	SE-JNJFOC-20181137495		51 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intraductal Proliferative Breast Lesion	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Myocrisin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15700228	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Thiamine Hydrochloride			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported
	Acetaminophen W/Oxycodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15702280	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown	400mg/200mg		Concordia
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15702281	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004029			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Panic Attack; Suicidal Ideation	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726438	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004091			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Retinopathy Hypertensive	Plaquenil			S	Unknown			Concordia
	Plaquenil			S				Concordia
	Codeine			S				Not Reported
	Minocycliine			S				Not Reported
	Oxaprozin			S				Not Reported
	Sulfamethoxazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726439	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004108		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Occlusion; Fear	Plaquenil			S	Unknown			Concordia
	Belimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726823	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004067			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Plaquenil			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726824	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyneuropathy	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15726825	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004088		38 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Subcutaneous			Concordia
	Calcium + Vit D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15727316	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004057		51 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2018	15727317	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004062		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Actemra			C				Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	12988986	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1860198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported

Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Minocycline	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Ilaris	S	Unknown	Not Reported
	Gp2013 (Rituximab Biosimilar)	C		Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	13162671	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1777383-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Rate Abnormal; Rheumatoid Arthritis; Swelling	Enbrel		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Prednisone		C		Not Reported
	Celebrex		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	13224700	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890670			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	13914642	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2017128951		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Calcium			C	Unknown	Unk	Not Reported
	Duloxetine Hydrochloride			C	Unknown	Unk	Not Reported
	Ergocalciferol			C	Unknown	Unk	Not Reported
	Folic Acid			C	Unknown	Unk	Not Reported
	Humira			C	Unknown	Unk	Not Reported
	Methotrexate			C	Unknown	Unk	Not Reported
	Orencia			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	14040581	EXPEDITED (15-DAY)		HO, LT, OT	NL-ELI_LILLY_AND_COMPANY-NL201710000415		51 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Serotonin Syndrome	Fluoxetine Hydrochloride			S	Oral	20 Mg, Daily		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Oral	40 Mg, Daily		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Oral	40 Mg, Daily		Eli Lilly And Co
	Fluoxetine Hydrochloride			S	Oral	40 Mg, Daily		Eli Lilly And Co
	Plaquenil /00072603/			S	Oral	200 Mg, Bid		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Ethinylestradiol/Desogestrel			C	Oral	1 Df, Daily		Not Reported
	Esomeprazol /01479301/			C	Oral	40 Mg, Bid		Not Reported
	Esomeprazol /01479301/			C		20 Mg, Bid		Not Reported
	Celecoxib			C	Oral	200 Mg, Bid		Not Reported
	Celecoxib			C		100 Mg, Bid		Not Reported
	Oxazepam			C	Oral	10 Mg, Prn		Not Reported
	Nasacort			C	Nasal	1 Df, Daily		Not Reported
	Zopiclon			C	Oral	7.5 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	14549474	EXPEDITED (15-DAY)		HO, OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000633		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Fall; Rhabdomyolysis; Sopor; Syncope	Plaquenil Tablet			S	Oral			Concordia
	Medrol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	14945437	EXPEDITED (15-DAY)		CA, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-03345			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anophthalmos; Anotia; Congenital Nail Disorder; Dysmorphism; External Auditory Canal Atresia; Fallot'S Tetralogy; Foetal Exposure During Pregnancy; Hypertelorism Of Orbit; Microglossia; Microstomia; Polydactyly; Renal Hypoplasia; Retrognathia	Mycophenolate Mofetil			S	Transplacental	Unk		Alkem
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Perindopril			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15124708	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002382		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15245728	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA064017		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Novartis
	Methotrexate			S				Novartis
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab	S				Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine	S				Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Apo Leflunomida	S	Unknown			Not Reported
	Marijuana	S	Unknown			Not Reported
	Minocycline	S	Unknown			Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk		Not Reported
	Xeljanz	S	Oral	Unk Unk, Bid		Not Reported
	Minocycline Hydrochloride	S	Unknown			Not Reported
	Kineret	C	Unknown	Unk		Not Reported
	Lyrica	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15673274	EXPEDITED (15-DAY)		OT	PHHY2018SE168322		50 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Immune Thrombocytopenia; Intraductal Proliferative Breast Lesion; Invasive Ductal Breast Carcinoma	Infliximab			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Myocrisin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15691017	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017376221			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Pfizer
	Infliximab			S	Intravenous (not otherwise specified)	716.25 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Clopidogrel Bisulfate			C	Oral	Unk		Not Reported
	Ezetrol			C	Oral	Unk		Not Reported
	Niaspan			C	Unknown	Unk		Not Reported
	Nitro			C	Transdermal	Unk		Not Reported
	Rosuvastatin Calcium			C	Oral	Unk		Not Reported
	Tylenol			C	Oral	Unk		Not Reported
	Nitroglycerin			C	Transdermal	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15732996	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004147		14 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Therapy Non-Responder	Hydroxychloroquine			S				Concordia
	Azathioprine			S				Not Reported

					Methotrexate	S			Not Reported
					6-Mercaptopurine	S			Not Reported
					Mesalamine	S			Not Reported
					Infliximab	S			Not Reported
					Adalimumab	S			Not Reported
					Entocort-Ec	S			Not Reported
					Entocort-Ec	S	Decrease His Dose		Not Reported
					Interferon-Gamma	S			Not Reported
					Prednisone	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15733216	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004061		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Ineffective; Hepatic Enzyme Increased	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C				Not Reported
	Champix			C				Not Reported
	Cimzia			C				Not Reported
	Actemra			C				Not Reported
	Humira			C				Not Reported
	Remicade			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15734887	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1091973			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15734951	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595799-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15735811	EXPEDITED (15-DAY)		OT	PHHY2018FR005323		4 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Dyspnoea; Haemoptysis; Product Use In Unapproved Indication; Product Use Issue; Pulmonary Haemosiderosis	Mycophenolate Mofetil			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15737362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595974-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Pregabalin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2018	15831075	DIRECT	Y				40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia; Gastrooesophageal Reflux Disease	Orencia Pfs 125mg/Ml			S				Bristol Myers Squibb
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	6920667	EXPEDITED (15-DAY)		OT	DE-ROCHE-614854		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Dermatitis; Immune Reconstitution Inflammatory Syndrome; Nodule; Orbital Infection; Skin Papilloma	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Ceftriaxone Sodium			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown	Dose Reduced		Not Reported
	Prednisone	S	Unknown	Dose Increased		Not Reported
	Prednisone	S	Unknown			Not Reported
	Acyclovir	S	Unknown	Every 4 Hours.		Not Reported
	Azathioprine	S	Unknown			Not Reported
	Streptomycine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	11871242	EXPEDITED (15-DAY)		OT	CA-SA-2015SA219686		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Gastrointestinal Disorder; Musculoskeletal Disorder; Rheumatoid Arthritis; Sarcoidosis	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral	1000 Mg,Bid		Not Reported
	Enbrel			S				Not Reported
	Morphine Sulphate			S				Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			C				Not Reported
	Morphine			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	12678680	EXPEDITED (15-DAY)		OT	CA-ROCHE-1817079		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Celebrex			S	Oral				Not Reported
	Arava			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Xeljanz			S	Oral				Not Reported
	Enbrel			S	Unknown				Not Reported
	Methotrexate Sodium			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Orencia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	12898892	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2143		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Malaise; Nasopharyngitis; Oral Herpes; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13121088	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA006035		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Methotrexate			S	Oral	20 Mg, Qw		Not Reported

Protein Abnormal; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Sulfasalazine		S	Oral	1000 Mg,Bid		Not Reported
	Sulfasalazine		S	Oral	1000 Mg,Bid		Not Reported
	Arava		S	Oral	20 Mg,Qd		Sanofi
	Plaquenil		S	Unknown	Unk Unk,Unk		Sanofi
	Enbrel		S	Subcutaneous	Unk Unk,Unk		Not Reported
	Remicade		S	Unknown	Unk Unk,Unk		Not Reported
	Humira		S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia		S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium		S	Oral	20 Mg,Qw		Not Reported
	Prednisone		C	Unknown	5 Mg,Qd		Not Reported
	Celebrex		C	Unknown	200 Mg,Qd		Not Reported
	Xeljanz		C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13360035	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA043034		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13370179	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA043886		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Prednisone			S	Oral	25 Mg,Qd		Not Reported
	Prednisone			S		50 Mg, Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk Unk,Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported
	Indometacin			S		Unk		Not Reported
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Indocid [Indometacin]			S				Not Reported
	Apo-Prednisone			S		50 Mg, Unk		Not Reported
	Apo-Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Apo-Leflunomide			S		20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Gold (198 Au)			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Unk, Qd		Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Cymbalta			C	Oral	30 Mg,Hs		Not Reported
	Folic Acid			C	Oral	Unk Unk,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13618016	EXPEDITED (15-DAY)		OT	CA-SA-2017SA097876		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cortisone			C		10 Mg,Qd		Not Reported
	Voltaren [Diclofenac]			C		100 Mg,Qd		Not Reported
	Desoximetasone			C		10 Mg, Qd		Not Reported
	Diclofenac			C		100 Mg, Qd		Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Zostavax			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13670276	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105929		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug	Leflunomide			S	Oral	10 Mg,Qd		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg,Qd		Sanofi

Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate	S	Oral	25 Mg,Qw		Not Reported
	Prednisone	S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide	S	Unknown	10 Mg, Qd		Sanofi
	Prednisone	S	Unknown			Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Xeljanz	C	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk Unk,Unk		Not Reported
	Arava	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	13670310	EXPEDITED (15-DAY)		OT	CA-SA-2017SA106162		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Qw		Not Reported
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Abatacept			S	Unknown	Unk Unk,Unk		Not Reported
	Adalimumab			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Infliximab			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg,Qw		Not Reported
	Methotrexate			S	Oral	22.5 Mg,Qw		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Subcutaneous	Unk Unk,Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk Unk,Unk		Not Reported
	Apo-Leflunomide	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Methotrexate Sodium	S	Oral	22.5 Mg, Qw		Not Reported
	Azathioprine	C	Unknown	Unk Unk,Qd		Not Reported
	Ciclosporin	C				Not Reported
	Minocycline	C				Not Reported
	Penicillamine	C				Not Reported
	Prednisone	C	Unknown	6 Mg,Bid		Not Reported
	Tocilizumab	C				Not Reported
	Prednisolone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	14986644	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001809			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Lung Disorder; Pneumonia; Pulmonary Fibrosis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Ornecia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codeine Sulfate			C				Not Reported
	Dilantin D.A			C				Not Reported
	Morphine			C				Not Reported
	Tetanus Toxoid			C				Not Reported
	Tramadol			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	14996520	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115154		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Plaquenil			S		300 Mg, Qd		Sanofi
	Actonel			S		35 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Actemra			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		20 Mg, Qh		Sanofi
	Kineret			S	Subcutaneous	100 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Qcy		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine			S		300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Risedronate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15034247	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002077		60 YR	Female	DEU

Preferred Term | Product | Comp. | OTC | Role | Route | Dosage Text | Duration | Mfr

Cervicobrachial Syndrome; Diffuse Alopecia; Erythema; Photodermatosis; Radiculopathy	Hydroxychloroquine	S	Unknown		Concordia
	Abatacept	S	Subcutaneous		Not Reported
	Palexia	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Dekristol	C			Not Reported
	Nebivolol	C			Not Reported
	Thyronajod	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15255110	NON-EXPEDITED			US-PFIZER INC-2018317700		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Darvon			S		Unk		Not Reported
	Humalog			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15416081	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186799			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15552963	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003804		27 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Body Tinea; Condition Aggravated; Condition Aggravated; Decreased Appetite; Decreased Appetite; Haemorrhoids; Headache; Herpes Zoster; Iron Deficiency Anaemia; Oedema Peripheral; Oral Disorder	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Ferromia			S	Unknown			Not Reported
	Prednisolone Acetate			C				Not Reported
	Prednisolone			C				Not Reported
	Ciclosporin			C				Not Reported
	Atorvastatin			C				Not Reported
	Menatetrenone			C				Not Reported
	Alfacalcidol			C				Not Reported
	Rabeprazole Na			C				Not Reported
	Samtirel			C				Not Reported
	Diquas			C				Not Reported
	Latanoprost			C				Not Reported
	Furosemide			C				Not Reported
	Lyrica			C				Not Reported
	Actonel			C				Not Reported
	Bonoteo			C				Not Reported
	Risperidone			C				Not Reported
	Tapros			C		One Drop		Not Reported
	Heparin Na Lock			C				Not Reported

	Tramcet			C						Not Reported
	Magmitt			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15665447	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018485547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15683156	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004047		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Drug Ineffective; Peripheral Sensorimotor Neuropathy; Polymyositis	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15683158	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004050		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Phosphokinase Increased; Muscular Weakness; Myopathy Toxic	Hydroxychloroquine 200 Mg Tablet	S	Unknown			Concordia
	Azathioprine	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15693363	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004026		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Chest Discomfort; Condition Aggravated; Diarrhoea; Drug Ineffective; Exostosis; Hypertension; Joint Swelling; Pain; Pain In Extremity; Tinnitus	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amlodipine			C				Not Reported
	Paracetamol			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15693893	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018GSK219357		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthma; Blood Count Abnormal; Cardiac Dysfunction; Chest Discomfort; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Conjunctival	Salbutamol Sulphate			S	Respiratory (inhalation)	2 Puff(S), Prn		Glaxosmithkline
	Zenhale			S	Respiratory (inhalation)	2 Puff(S), Bid		Not Reported
	Omnaris Nasal Spray			S		1 Puff(S), Qd		Not Reported

Hyperaemia; Eye Pruritus; Flushing; Ill-Defined Disorder; Obstructive Airways Disorder; Rash; Rash Pruritic; Respiratory Tract Congestion; Rhinitis; Rhinorrhoea; Sinus Headache; Sinusitis; Therapeutic Product Effect Incomplete; Upper-Airway Cough Syndrome; Urinary Tract Infection; Vasculitis	Plaquenil	S		Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Unk	Glaxosmithkline
	Azathioprine	C	Oral	125 Mg, Qd	Glaxosmithkline
	Levothyroxin	C	Oral	150 Ug, Unk	Glaxosmithkline
	Synthroid	C	Oral	150 Ug, Unk	Not Reported
	Premarin	C		Unk	Not Reported
	Risedronate	C	Oral	150 Mg, Unk(Monthly)	Not Reported
	Saline Nasal Rinse	C		Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15701095	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166786		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk Unk, Unk		Not Reported
	Naproxen			C	Unknown	500 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15702282	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Ineffective; Infection	Plaquenil			S	Oral			Concordia
	Plaquenil			S	Oral			Concordia
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			C	Oral	15-25mg		Not Reported
	Prednisone			C		10-40 Mg Od Prn		Not Reported
	Arava			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15727318	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004058			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gait Disturbance; Malaise; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15733217	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004125		50 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Renal Impairment; Spinal Compression Fracture	Plaquenil 200 Mg Tablet		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prednisolone		S	Oral	Concordia
	Prograf		S	Oral	Not Reported
	Ulcerlmin		C		Not Reported
	Bonoteo		C		Not Reported
	Diovan		C		Not Reported
	Takepron		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15737664	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594606-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Ineffective; Hypersensitivity; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Celebrex			C					Not Reported
	Gold			C					Not Reported
	Hydroxychloroquine Sulfate			C					Not Reported
	Morphine			C					Not Reported
	Prednisone			C	Oral				Not Reported
	Tofacitinib			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15740973	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA340822AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S		25 Mg, Twice A Week		Not Reported
	Remicade			S		300 Mg		Not Reported
	Rituxan			S		1000 Mg		Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S				Sanofi
	Humira			S		Unk		Not Reported
	Gold			C				Not Reported
	Cortisone			C		Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15740980	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA340887AA		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

	Orencia	S		Not Reported
	Remicade	S		Not Reported
	Rituxan	S		Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Adalimumab	S		Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported
	Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C		Not Reported
	Pantoprazole Magnesium	C		Not Reported
	Tenofovir Disoproxil	C		Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C		Not Reported
	Tenofovir	C		Not Reported
	Tenofovir Disoproxil Fumarate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15740982	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA340861AA		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported

	Imuran [Azathioprine]	C	Not Reported
	Arthrotec	C	Not Reported
	Ergocalciferol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15741022	EXPEDITED (15-DAY)		OT	CA-SA-2015SA139094		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,1x		Not Reported
	Cimzia			C	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15741775	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20181216635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

					Cimzia		S	Unknown		Not Reported
					Humira		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Plaquenil		S	Oral		Not Reported
					Rituxan		S	Unknown		Not Reported
					Imuran		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15742419	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2018-035461		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Prednisolone			S	Unknown	For 2 Months		Not Reported
	Prednisolone			S	Unknown	Decreased Gradually, For 2 Months		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15742498	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2018-034744		32 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Decreased Gradually		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15742883	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004153		76 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Chondrocalcinosis Pyrophosphate; Constipation; External Ear Disorder	Plaquenil 200 Mg Tablet			S	Oral	Administered Every Day		Concordia
	Ferrous Sodium Citrate			C				Not Reported
	Rimatil			C				Not Reported
	Nexium			C				Not Reported
	Feburic			C				Not Reported
	Diclofenac Sodium			C				Not Reported
	Loxonin			C				Not Reported
	Tramcet			C				Not Reported
	Primperan			C				Not Reported
	Calonal			C				Not Reported
	Bonalon			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	13861770	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017349287		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; C-Reactive Protein Abnormal; Chronic Sinusitis; Drug Intolerance; Infection; Monocytosis; Nausea; Neutropenia; Pruritus; Psoriasis; Red Blood Cell Sedimentation Rate Abnormal; Sinusitis; Synovitis; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, 78.0 Days		Pfizer
	Hydroxychloroquine			S	Unknown	Unk, 110.0 Days		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	14236384	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3842		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain;	Methotrexate (Trade Name			S	Unknown			Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Unknown)				
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15214560	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-SA-BI2016BI13338BI			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Mg, Qd From Gestational Week 0-113+6		Sanofi
	Clexane			S	Transplacental	From Gestational Week 0-14		Sanofi
	Busco Pantoprazole			S	Transplacental	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Transplacental	Unk Unk,Unk		Sanofi
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported

Prednisolone	S	Transplacental	Unk Unk,Unk	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	Unk Unk,Unk	Not Reported
Pantoprazole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Pantoprazole Sodium	S	Transplacental	Unk Unk,Unk	Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Torasemide	S	Transplacental	Unk Unk,Unk	Not Reported
Heparin (Salt Not Specified)	S	Transplacental	Unk Unk,Unk	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Sanofi
Salbutamol Sulfate	S	Transplacental	Unk Unk,Unk	Not Reported
Salbutamol Sulfate	S		Unk Unk,Unk	Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	Unk Unk,Unk	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Simvastatin	S	Transplacental	Unk Unk,Unk	Not Reported
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	Unk Unk,Unk	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S			Not Reported
Aliskiren	S	Transplacental		Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15613499	EXPEDITED (15-DAY)		OT	PHHY2018NL102313		60 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Off Label Use; Product Use In Unapproved Indication; Treatment Failure	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15662048	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016072927		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Lung Infiltration	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil /00072603/			S		200 Mg, Unk		Not Reported
	Humira			S		40 Mg, 5/Qg 2 Weeks		Not Reported
	Prednisone			S	Oral	7.5 Mg, Daily		Not Reported
	Remicade			S		4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15733772	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595031-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15746070	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018519875		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Humira			S		40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	15746850	EXPEDITED (15-DAY)		LT, OT	PHHY2018US187084		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Aphthous Ulcer; Diarrhoea; Neutropenia; Oropharyngeal Pain; Pharyngitis; Pyrexia; Syncope; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Methimazole			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	13868894	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2453		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; C-Reactive Protein	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Abnormal; Chronic Sinusitis; Drug Intolerance; Infection; Monocytosis; Nausea; Neutropenia; Pruritus; Psoriasis; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; Urinary Tract Infection	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	13989422	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005280			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Skin Cancer; Squamous Cell Carcinoma; Treatment Failure	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	14053974	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3032		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Count Abnormal; Drug Hypersensitivity;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Gastrointestinal Disorder; Malaise; Sjogren'S Syndrome; Weight Decreased; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	14175497	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210609		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	20 Mg,Unk		Sanofi
	Methotrexate			S	Subcutaneous	7.5 Mg,Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg,Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		20 Mg, Unk		Sanofi
	Hydroxychloroquine			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Enbrel			S		Unk Unk,Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Actemra	S	Unknown	Unk Unk,Unk		Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium	S		7.5 Mg, Unk		Not Reported
	Diclofenac Sodium And Misoprostol	S		50 Mg, Bid		Not Reported
	Arthrotec	C	Unknown	50 Mg,Bid		Not Reported
	Gold	C				Not Reported
	Imuran [Azathioprine]	C				Not Reported
	Vitamin D [Colecalciferol]	C				Not Reported
	Ergocalciferol	C				Not Reported
	Vitamin D3	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	14379122	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000107		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported
	Abatacept			C				Not Reported

Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15035343	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010718		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Invasive Ductal Breast Carcinoma; Pleural Effusion	Plaquenil Tablet			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ativan			C				Not Reported
	Calcium Carbonate/Calcium Lactogluconate			C				Not Reported
	Clopidogrel Bisulfate			C				Not Reported
	Diclofenac Diethylamine			C				Not Reported
	Elavil			C				Not Reported
	Ergocalciferol			C				Not Reported
	Escitalopram Oxalate			C				Not Reported
	Fosamax			C				Not Reported
	Lipitor			C				Not Reported
	Prednisone Acetate			C				Not Reported
	Rivotril			C				Not Reported
	Tenormin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15108399	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0761		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Kineret			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
		Apo-Azathioprine			S					Not Reported
		Gold			S		Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15455234	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018391378			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Methylprednisolone Acetate			S	Transplacental	Unk (Pulse)		Pfizer
	Cyclophosphamide			S	Transplacental	Unk, Cyclic (Given Two Cycles Of Cyclophosphamide)		Not Reported
	Hydroxychloroquine			S	Transplacental	5 Mg/Kg, Unk		Not Reported
	Azathioprine			S	Transplacental	2 Mg/Kg, Unk, (To Goal 2 Mg/Kg)		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15535016	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3114		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Hepatotoxicity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Salazopyrine			C	Unknown					Not Reported
	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15657109	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15748474	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004119			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Chondrectomy; Drug Ineffective; Elbow Operation; Joint Swelling	Plaquenil			S	Oral			Concordia
	Shingrix			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752071	EXPEDITED (15-DAY)		HO, LT, OT	ES-ASTELLAS-2018US053690		24 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Product Use In Unapproved Indication	Tacrolimus			S	Oral			Astellas
	Rituximab			S	Intravenous (not otherwise specified)	2 G, 6 Month		Not Reported

	Dolquine	S	Oral	Not Reported
	Paracetamol	C	Oral	Not Reported
	Prednisolona /00016201/	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752269	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE186987			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Deep Vein Thrombosis; Foot Fracture; Hypogammaglobulinaemia; Intervertebral Disc Protrusion; Radiculopathy; Stomatitis; Thrombosis	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Novartis
	Methotrexate			S	Unknown	25 Mg, Unk		Novartis
	Methotrexate			S	Unknown	25 Mg, Unk		Novartis
	Methotrexate			S	Unknown	25 Mg, Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Unk		Not Reported
	No Treatment Received			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Mabthera			S	Unknown	Unk		Not Reported
	Quensyl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15752867	EXPEDITED (15-DAY)		OT	FR-TAKEDA-2018TUS036066		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sinus Bradycardia; Syncope	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk		Takeda
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Metoject			S	Unknown	15 Mg, 1/Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15837361	DIRECT	Y				77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough	Hydroxychloroquine 200 Mg Tab			S	Oral			Unknown
	Hydroxychloroquine 200 Mg Tab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	13091515	EXPEDITED (15-DAY)		DS, HO	DE-ROCHE-1874873		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthrodesis; Joint Instability; Joint Range Of Motion Decreased; Musculoskeletal Disorder; Nerve Compression; Pseudarthrosis; Silicon Granuloma; Sinusitis; Tendon Rupture	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Further Administarions On 18/Nov/2009, 17/Nov/2010, 22/Jun/2011, 21/Feb/2012, Jun/2013, Jan/2014, Au		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Hydroxychloroquine		S	Unknown		Not Reported
					Lodotra		C			Not Reported
					Decortin		C			Not Reported
					Ursofalk		C			Not Reported
					L-Thyroxin		C			Not Reported
					Simvastatin		C			Not Reported
					Ibuprofen		C			Not Reported
					Pantoprazol		C			Not Reported
					Novalgin (Germany)		C			Not Reported
					Palladon		C			Not Reported
					Fragmin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	13692178	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003771		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo- Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	13926212	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017373626		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Calcium	C	Unknown	Unk		Not Reported
	Duloxetine Hydrochloride	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Humira	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Orencia	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	14549473	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201802-000632			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Off Label Use; Retinal Toxicity; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown	>1500 G On Varying Doses Over Time, 200-400 Mg Daily		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15614899	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477031-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Peripheral Swelling	Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15709453	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018503473		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use	Infliximab Hospira			S	Unknown	Unk, Monthly		Not Reported
	Infliximab Hospira			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Calcium Carbonate			S	Unknown	Unk		Pfizer
	Acetazolamide			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15755046	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2018-CA-990538		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular	Mycophenolate Mofetil			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	50 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported

Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox	S	Intravenous (not otherwise specified)		Not Reported
	Procytox	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Methylprednisolone Sodium Succinate	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Methylprednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15755205	EXPEDITED (15-DAY)		DE, HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004192		72 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Pancytopenia	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Predonine			C				Not Reported
	Prograf			C				Not Reported
	Pletaal			C				Not Reported
	Beraprost Sodium			C				Not Reported
	Revatio			C				Not Reported
	Sarpogrelate Hydrochloride			C				Not Reported
	Lixiana			C				Not Reported
	Edirol			C				Not Reported
	Edirol			C				Not Reported
	Takecab			C				Not Reported
	Takecab			C				Not Reported
	Ferrous Citrate Na			C				Not Reported
	Tramcet			C				Not Reported
	Tenelia			C				Not Reported
	Surepost			C				Not Reported
	Zolpidem Tartrate			C				Not Reported
	Tenormin			C				Not Reported
	Ecard			C				Not Reported
	Fosamac			C				Not Reported

	Fosamac			C						Not Reported
	Magmitt			C						Not Reported
	Atelec			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15755439	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2229884			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15756360	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT193594		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Pancytopenia; Pulmonary Arterial Hypertension	Ruxolitinib			S	Unknown	20 Mg, Qd		Not Reported
	Ruxolitinib			S	Unknown	15 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Mepacrine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15757198	EXPEDITED (15-DAY)		OT	PHHY2018MY191983		17 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Pulmonary Tuberculosis	Hydroxychloroquine			S	Unknown	10 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	13380271	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002013		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Ineffective; Dyspnoea; Mobility Decreased; Movement Disorder; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Sensitivity To Weather Change; Swelling Face	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	13640241	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003360		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Intravenous (not otherwise specified)			Concordia
	Leflunomide			S	Oral			Not Reported

					Enbrel		S	Unknown	Not Reported
					Orencia		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Humira		S	Subcutaneous	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Not Reported
					Sulfasalazine		S	Unknown	Not Reported
					Apo-Leflunomide		S	Unknown	Not Reported
					Desoximetasone		C		Not Reported
					Diclofenac		C		Not Reported
					Cortisone		C		Not Reported
					Methotrexate		C		Not Reported
					Xeljanz		C		Not Reported
					Zostavax		C		Not Reported
					Voltaren		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	14804210	EXPEDITED (15-DAY)		HO, LT, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001386		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Consciousness Fluctuating; Diplopia; Eyelid Ptosis; Granuloma; Hydrocephalus; Memory Impairment; Meningitis; Off Label Use; Ophthalmoplegia; Product Use Issue; Pulmonary Tuberculosis; Tuberculosis; Tuberculosis Of Central Nervous System	Hydroxychloroquine			S	Unknown			Concordia
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Three Courses		Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Fortnightly		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported

	Ivabradine	C				Not Reported
	Bisoprolol	C				Not Reported
	Isosorbide Mononitrate	C				Not Reported
	Glyceryl Trinitrate	C				Not Reported
	Furosemide	C		120/80mg		Not Reported
	Furosemide	C		Dose Reduced		Not Reported
	Spironolactone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15757821	EXPEDITED (15-DAY)		HO, LT	ES-CELLTRION INC.-2018ES024708			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	2 G, 6 Month		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	2 G, 6 Month		Not Reported
	Tacrolimus			S	Oral	5 Mg, Daily		Not Reported
	Dolquine			S	Oral	200 Mg, Daily		Not Reported
	Prednisolona /00016201/			C	Oral	5 Mg		Not Reported
	Paracetamol			C	Oral	1.5 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15758519	EXPEDITED (15-DAY)		DE, OT	PHHY2018DE191405			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Encephalitis; Enterocolitis Bacterial	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis

	Methotrexate			S	Unknown	20 Mg, Unk	Novartis
	Leflunomide			S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Not Reported
	Remicade			S	Unknown	158 Mg, Unk	Not Reported
	Remicade			S	Unknown	158 Mg, Unk	Not Reported
	Remicade			S	Unknown	158 Mg, Unk	Not Reported
	No Treatment Received			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15758832	EXPEDITED (15-DAY)		OT	PHHY2018CA194219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Diclofenac			S	Unknown	50 Mg, Bid		Novartis
	Leflunomide			S	Oral	10 Mg, Qd (Proir To 2016)		Not Reported
	Methotrexate			S	Oral	15 Mg (10-15 Mg), Qw (Prior To 2011)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Prior To 2011)		Not Reported
	Naproxen			S	Unknown	500 Mg, Q6h		Not Reported
	Indocid			S	Unknown	50 Mg, (20 To 50 Mg)Tid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Methotrexate Pfizer	S	Oral	10 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	12457798	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016074137		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13124427	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000476		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Xeljanz (Tofacitinib Citrate)			S	Oral			Not Reported
	Tetanus Vaccine			C				Not Reported
	Prevnar 13			C				Not Reported
	Haemophilus Influenzae			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13372547	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001960		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Plaquenil 200 Mg Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13380675	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001984		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Indometacin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Failure; Treatment Failure	Indocid	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Gold (198 Au)	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Xeljanz	C		Not Reported
	Folic Acid	C		Not Reported
	Cymbalta	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13687625	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003687		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Abatacept			S	Unknown			Not Reported

Adalimumab	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Infliximab	S	Unknown	Not Reported
Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Prednisone	C		Not Reported
Tocilizumab	C		Not Reported
Azathioprine	C		Not Reported
Ciclosporin	C		Not Reported
Minocycline	C		Not Reported
Penicillamine	C		Not Reported
Prednisolone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13692176	EXPEDITED (15-DAY)		HO, LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003681		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia

Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Concordia
	Hydroxychloroquine	S	Unknown	Concordia
	Hydroxychloroquine	S	Unknown	Concordia
	Hydroxychloroquine	S	Unknown	Concordia
	Plaquenil Tablet	S	Unknown	Concordia
	Plaquenil Tablet	S	Unknown	Concordia
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Marijuana	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Gold	S	Unknown	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	C		Not Reported
Methotrexate	C		Not Reported
Hydroxychloroquine Phosphate	C		Not Reported
Rituximab	C		Not Reported
Anakinra	C		Not Reported
Lyrica	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13793961	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00012344		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Gastrointestinal Disorder; Musculoskeletal Disorder	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia

Arava	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Morphine Sulphate	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Xeljanz	C		Not Reported
Leflunomide	C		Not Reported
Morphine	C		Not Reported
Prednisone	C		Not Reported
Methotrexate	C	Oral	Not Reported
Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	13996203	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005393		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	14068284	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005712		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Constipation; Dactylitis; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Finger Deformity; Hyperaesthesia; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Physical Disability; Psoriasis; Reflexes Abnormal; Sacroiliitis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Oral			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Unknown			Not Reported
	Duloxetine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Clonazepam			C				Not Reported
	Vitamin D [Ergocalciferol]			C				Not Reported
	Flax Seed Oil			C				Not Reported
	Omega 3 [Fish Oil;Tocopheryl Acetate]			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	14400798	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000165		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Crohn'S Disease; Drug Ineffective; Elbow Operation; Neck Pain; Pain In Extremity; Product Dose Omission; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15183295	EXPEDITED (15-DAY)		DE, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-065506		38 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Oedema Peripheral; Pulmonary Haemorrhage; Pulmonary Oedema	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15676096	NON-EXPEDITED			US-PFIZER INC-2018482845		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15689844	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2018487497		51 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Invasive Ductal Breast Carcinoma	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Daily		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Myocrisin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15732907	EXPEDITED (15-DAY)		OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004100		38 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophy; Ataxia; Muscular Weakness; Nerve Injury; Oedema Peripheral; Pain In Extremity	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Leflunomide			C				Not Reported
	Prednisone Acetate			C		2 Tabs/Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15733601	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA024654			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hair Follicle Tumour Benign; Off Label Use	Infliximab Pfizer (Unknown)	S		Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Methotrexate Sodium	S			Not Reported
	Calcium Carbonate	S	Unknown	Unk	Not Reported
	Acetazolamide	S		Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S			Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Cyclosporine	S			Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Leflunomide	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15758205	EXPEDITED (15-DAY)		OT	SE-CELLTRION INC.-2018SE024732			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Immune Thrombocytopenia; Intraductal Proliferative Breast Lesion	Infliximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Myocrisin			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, 1 Day		Not Reported
	Salazopyrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15759194	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS			Female	CAN

INC.-GSH201812-004186

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Gold			C				Not Reported
	Cortisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15759229	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004187		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Naproxen	C				Not Reported
	Indocid	C		20-50 Milligrams		Not Reported
	Diclofenac	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15759703	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010558		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone (Prednisone)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1x		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15759711	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004195		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis;	Hydroxychloroquine			S	Unknown			Concordia
	Alendronate Sodium			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			S	Oral			Not Reported

Crepitations; Cushingoid; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Naproxen	S	Oral	Not Reported
	Naproxen	S	Oral	Not Reported
	Naproxen	S	Oral	Not Reported
	Naproxen	S	Oral	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ranitidine Hydrochloride	S	Unknown	Not Reported
	Ranitidine Hydrochloride	S	Oral	Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Pantoprazole	S	Oral	Not Reported
	Pregabalin	S	Oral	Not Reported
	Pregabalin	S	Oral	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
	Naproxen	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	S	Unknown	Not Reported
	Depo-Medrol	S	Intra-articular	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Esomeprazole Sodium	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methylprednisolone Acetate	S	Intra-articular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Esomeprazole Magnesium;Naproxen	S	Unknown	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Oral	Not Reported

	Oxycocet	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760032	EXPEDITED (15-DAY)		OT	PHHY2018MY191990		64 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis; Urticaria	Hydroxychloroquine			S	Unknown	10 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760320	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010609		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting;	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

Wrist Deformity	Actemra			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Xeljanz			S	Oral	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760458	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1093866		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Maternal Exposure During Pregnancy; Premature Baby	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ursodeoxycholic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15760608	NON-EXPEDITED			US-PFIZER INC-2018525306		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15761272	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-06			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Spiriva			S	Unknown			Boehringer Ingelheim
	Zenhale			S	Unknown	Dosage Form: Aerosol, Metered Dose.		Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15761291	EXPEDITED (15-DAY)		OT	PHHY2018DE194946		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown	17.5 Mg, Qw		Novartis
	Chloroquine			S	Unknown	1 Mg/L, Qd		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Phenprocoumon			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15761765	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018231986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Diclofenac			S	Unknown	50 Mg, Bid		Glaxosmithkline
	Indocid			S	Unknown	50 Mg, (20 To 50 Mg)Tid		Glaxosmithkline
	Leflunomide			S	Oral	10 Mg, Qd (Proir To 2016)		Not Reported
	Methotrexate			S	Oral	15 Mg (10-15 Mg), Qw		Not Reported

					(Prior To 2011)	
	Hydroxychloroquine	S	Oral	400 Mg, Qd (Prior To 2011)		Not Reported
	Naproxen	S	Unknown	500 Mg, Q6h		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Methotrexate	S	Oral	10 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2018	15763178	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004181			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Pyrexia; Systemic Lupus Erythematosus	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	12851490	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1992		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			S	Unknown	Tapering Dose		Not Reported
	Teva-Methacin			C	Unknown			Not Reported

	Risedronate			C	Unknown					Not Reported
	Indometacin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	13519808	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038331			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)		
	Remicade		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	13628283	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017235633		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatic Lesion; Hepatitis B Core Antibody Positive; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pneumonia Cryptococcal; Pulmonary Mass; Pyrexia; Renal Cyst	Methotrexate Sodium			S	Subcutaneous	20-25mg , Weekly		Unknown
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Daily		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Weekly		Not Reported
	Remicade			S		200 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported

					Isoniazid		S		Unk	Not Reported
					Actemra		S		Unk	Not Reported
					Zostavax		S		Unk, Single	Not Reported
					Gold		S	Intramuscular	50 Mg, Weekly	Not Reported
					Celebrex		C	Oral	200 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	13989292	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005366		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Kineret			C				Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	14776013	EXPEDITED (15-DAY)		HO, LT, OT	GB-SA-2018SA100386		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cachexia; Confusional State; Consciousness Fluctuating; Diplopia;	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

Dizziness; Drug Ineffective; Dyspnoea; Eyelid Ptosis; Granuloma; Headache; Hydrocephalus; Lymphadenopathy; Memory Impairment; Meningitis; Mycobacterium Tuberculosis Complex Test Positive; Nausea; Night Sweats; Off Label Use; Ophthalmoplegia; Pleural Effusion; Product Use Issue; Productive Cough; Pulmonary Tuberculosis; Pyrexia; Somnolence; Sputum Discoloured; Tuberculosis; Tuberculosis Of Central Nervous System; Vision Blurred; Vomiting; Weight Decreased	Methylprednisolone	S	Intravenous (not otherwise specified)	1 G,Unk,Three Courses	Not Reported
	Cyclophosphamide	S	Unknown	Unk Unk,Unk	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	500 Mg,Fortnightlyunk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk Unk,Unk	Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Rifampicin	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Sanofi
	Isoniazid	S	Unknown	Unk Unk,Unk	Not Reported
	Amikacin Sulfate	S	Unknown	Unk Unk,Unk	Not Reported
	Azathioprine	S	Unknown	Unk Unk,Unk	Not Reported
	Azathioprine	S			Not Reported
	Ivabradine	C	Unknown	5 Mg,Bid	Not Reported
	Furosemide	C	Unknown	120/80mg Unk Unk,Bid	Not Reported
	Furosemide	C	Unknown	40 Mg,Bid	Not Reported
	Spironolactone	C	Unknown	50 Mg,Unk	Not Reported
	Bisoprolol	C	Unknown	10 Mg,Qd	Not Reported
	Rituximab	C	Unknown	1 G,Unk	Not Reported
	Isosorbide Mononitrate	C	Unknown	20 Mg,Tid	Not Reported
	Glyceryl Trinitrate	C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	14794341	EXPEDITED (15-DAY)		OT	CA-SA-2017SA118980		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Joint Swelling; Multiple Allergies; Musculoskeletal	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported

Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Hydroxychloroquine	S	Unknown			Sanofi
	Piroxicam	S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone	S	Unknown	1 Df,Qd		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin	S	Oral	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Sanofi
	Humira	S	Subcutaneous	40 Mg,Unk		Not Reported
	Actemra	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold	S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15269381	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

	Arava	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15394849	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003325		58 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema; Erythema Multiforme; Lip Swelling; Oral Mucosa Erosion; Pruritus; Pustular Psoriasis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Alfacalcidol			C				Not Reported
	Nexium 1-2-3			C				Not Reported
	Azulene-Glutamine			C				Not Reported
	Amlodipine			C				Not Reported
	Tacrolimus			C				Not Reported
	Glufast			C				Not Reported
	Onglyza			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15400584	EXPEDITED (15-DAY)		DS, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003329		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy; Condition Aggravated; Retinal Detachment	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Calblock			C				Not Reported
	Febuxostat			C				Not Reported
	Alfacalcidol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Diart			C				Not Reported

	Carvedilol			C						Not Reported
	Bio-Three			C						Not Reported
	Lansoprazole			C						Not Reported
	Atelec			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15694351	EXPEDITED (15-DAY)		OT	SE-AMGEN-SWESP2018172814		51 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Invasive Ductal Breast Carcinoma	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Myocrisin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15721066	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004113		14 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine			S	Transplacental			Concordia
	Prednisone			S	Transplacental			Not Reported
	Prednisone			S				Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Azathioprine			S				Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15721077	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004116		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Contact; Drug Ineffective; Papule; Pruritus; Rash Erythematous; Skin Lesion; Skin Plaque	Hydroxychloroquine			S	Unknown			Concordia
	Levocetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15764814	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3841		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15764926	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268198		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug	Leflunomide			S	Oral	10 Mg,Qod		Sanofi

Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate	S	Unknown	15 Mg,Unk		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg,Unk		Sanofi
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituximab	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium	S		15 Mg, Unk		Not Reported
	Simponi	C	Subcutaneous	Unk Unk,Unk		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15765263	EXPEDITED (15-DAY)		OT	CH-SA-2018SA389561			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Leukopenia	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15765384	NON-EXPEDITED			US-SA-2018SA391276			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammatory Marker Increased	Plaquenil			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Enbrel			S		Unk Unk, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15765406	NON-EXPEDITED			US-SA-2018SA391300			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder	Plaquenil			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15766676	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-992728			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine			S	Transplacental			Teva
	Prednisone			S	Transplacental			Actavis
	Tacrolimus			S	Transplacental			Actavis
	Azathioprine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2018	15767359	EXPEDITED (15-DAY)		OT	PHHY2018FR192780			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Ursodeoxycholic Acid			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental	Maternal Dose:150, Mg Qd And .2 Mg/Kg Qd		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 5 Mg Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: 150 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	12309820	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-115548			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental			Sun
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Ranbaxy
	Simvastatin			S	Transplacental			Sun
	Ezetimibe			S	Transplacental			Sun
	Tacrolimus			S	Transplacental			Not Reported
	Xarelto			S	Unknown			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental			Not Reported
	Heparin Lmw			S	Transplacental			Not Reported
	Metamizole			C	Transplacental			Not Reported
	Aliskiren			C	Transplacental			Not Reported
	Clexane			S	Transplacental			Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	12849259	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2016DEP012505			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory;	Diclofenac Potassium			S	Unknown	Unk		Assertio Therapeutics
	Arava			S	Oral	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Gold	S				Not Reported
	Gold	S				Not Reported
	Gold	S				Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Plaquenil /00072602/	S				Not Reported
	Plaquenil /00072602/	S				Not Reported
	Plaquenil /00072602/	S				Not Reported
	Vitamin C /00008001/	S	Unknown	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk		Not Reported
	Diclofenac Potassium	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Tramadol	C		Unk		Not Reported
	Tramadol Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	13103553	EXPEDITED (15-DAY)		HO	US-ROCHE-1876555		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	14299661	EXPEDITED (15-DAY)		DS	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006585		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Exposure During Pregnancy; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Prednisone			C		Patient Takes 15-20mg Daily When She Was In A Flare		Not Reported
	Xeljanz			C				Not Reported
	Gabapentin			C				Not Reported
	Nexium			C				Not Reported
	Azithromycin			C				Not Reported
	Tylenol			C				Not Reported

	Amitriptyline			C						Not Reported
	Metonia			C						Not Reported
	Ranitidine			C						Not Reported
	Domperidone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	14379105	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000047		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Drug Intolerance; Pain; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Abatacept			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15138102	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00013599			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease	Hydroxychloroquine			S	Transplacental			Concordia
	Hydroxychloroquine			S	Transplacental			Concordia
	Prednisolone Tablet			S	Transplacental	From Gestational Week 0-14		Not Reported

Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Prednisolone Tablet	S	Transplacental		Not Reported
	Ramipril	S	Transplacental	Mother Dose: 20 Mg Per Day	Not Reported
	Busco Pantoprazole	S	Transplacental		Not Reported
	Clexane	S	Transplacental		Not Reported
	Acetylsalicylic Acid Sandoz	S	Transplacental		Not Reported
	Acetylsalicylic Acid Sandoz	S	Transplacental		Not Reported
	Pantoprazole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
	Pantoprazole Sodium	S	Transplacental		Not Reported
	Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Torasemide	S	Transplacental		Not Reported
	Heparin	S	Transplacental		Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Salbutamol Sulfate	S	Transplacental		Not Reported
	Salbutamol Sulfate	S	Unknown		Not Reported
	Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
	Ezetimibe	S	Transplacental		Not Reported
	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Simvastatin	S	Transplacental		Not Reported
	Metamizole Sodium	S	Transplacental		Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental		Not Reported
	Aliskiren	S	Transplacental		Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-14	Not Reported
	Dalteparin Sodium	S	Transplacental		Not Reported

	Rituximab			S	Transplacental					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15683157	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004048		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Nexium			C				Not Reported
	Nexium			C				Not Reported
	Onealfa			C				Not Reported
	Onealfa			C				Not Reported
	Predonine			C				Not Reported
	Predonine			C				Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Warfarin			C				Not Reported
	Warfarin			C				Not Reported
	Cellcept			C				Not Reported
	Cellcept			C				Not Reported
	Miya Bm			C				Not Reported
	Miya Bm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15759627	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA024900			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	200-500 Mg;		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	200-500 Mg;		Not Reported
	Methotrexate			C				Not Reported
	Leflunomide			C				Not Reported

	Cyclosporine	C				Not Reported
	Azathioprine	C				Not Reported
	Ciclosporin	C				Not Reported
	Acetazolamide	C				Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S				Not Reported
	Hydroxychloroquine Sulfate	S		Unk		Not Reported
	Ferric Hydroxide Polymaltose Complex	S		Unk		Not Reported
	Etanercept	S	Unknown			Not Reported
	Etanercept	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Alendronate Sodium	C				Not Reported
	Calcium	C				Not Reported
	Hydroxychloroquine	C				Not Reported
	Iron	C				Not Reported
	Alendronate	C				Not Reported
	Cyclosporine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15770043	EXPEDITED (15-DAY)		OT	CA-ROCHE-2236947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15771205	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2606196-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773235	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2018-035932		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Simplex; Staphylococcal Infection; Therapeutic Product Effect Incomplete	5-Fluorouracil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Isotretinoin			S	Unknown			Not Reported
	Acitretin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15773613	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2018-062734		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Tamsulosin			S	Oral			Aurobindo
	Ranitidine			S	Oral			Aurobindo
	Salicylate Sodium			S	Unknown			Not Reported
	Atropine Sulfate W/Diphenoxylate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2018	15785726	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Manufacturing Production Issue; Petechiae; Product Quality Issue; Pruritus; Rash; Urticaria	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2018	15014453	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018079303			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Herpes Zoster; Injection Site Reaction; Paralysis; Transaminases Increased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

	Kevzara			S	Unknown				Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd			Not Reported
	Methotrexate			C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2018	11778936	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1503807-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Apo-Diclofenac			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2018	13848640	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2064025-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Cortisone	C		Not Reported
	Gold	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2018	14378556	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000131		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide 10 Mg Tablet			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2018	15777172	DIRECT		DS			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Macular Opacity; Product Complaint; Toxicity To Various Agents; Visual Impairment	Hydroxychlorquine	Y	S	Oral	Quantity:1 Tablet(S);	13 YR	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	13067385	EXPEDITED (15-DAY)		OT	CA-ROCHE-1871931			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	13160468	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17P-028-1847699-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Cimzia			S	Subcutaneous				Not Reported
	Enbrel			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Leflunomide			S	Oral				Not Reported
	Methotrexate Sodium			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Apo-Leflunomide			S	Oral				Not Reported
	Naproxen			C					Not Reported
	Viread			C					Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	14378544	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000065		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15544652	EXPEDITED (15-DAY)		DS, HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003770		61 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis	Plaquenil 200 Mg Tablet			S	Oral	200mg/Day And 400mg/Day, Alternatively,		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200mg/Day And 400mg/Day, Alternatively,		Concordia
	Prednisolone			C				Not Reported
	Prograf			C				Not Reported
	Ezetimibe			C				Not Reported
	Talion			C				Not Reported
	Famotidine			C				Not Reported
	Famotidine			C				Not Reported
	Paracetamol Tramadol Hydrochloride			C				Not Reported
	Forteo			C				Not Reported
	Januvia			C				Not Reported
	Telmisartan			C				Not Reported
	Amlodipine Besilate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15751881	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181218452		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Diarrhoea; Drug Ineffective; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15776304	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-242446		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Arava			S	Oral			Not Reported
	Celebrex			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Ow		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Ow		Not Reported
	Methotrexate			S	Intra-articular	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported
	Prednisone			S		5 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15776943	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-242514		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Aleve			S				Bayer
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			C				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15776986	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-242523		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Xeljanz		S	Oral	5 Mg, Bid			Not Reported
	Methotrexate		C	Unknown	Unk			Not Reported
	Folic Acid		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15777051	EXPEDITED (15-DAY)		HO	CA-BAYER-2018-242561		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15777084	EXPEDITED (15-DAY)		HO	CA-BAYER-2018-242573		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Aleve			S				Bayer
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		400 Mg		Not Reported
	Leflunomide			S				Not Reported

		Methotrexate			C						Not Reported
		Orencia			S						Not Reported
		Prednisone			S						Not Reported
		Xeljanz			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15777468	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-242576		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Swelling	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Apo-Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15777482	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-242581		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15777673	EXPEDITED (15-DAY)		HO	CA-BAYER-2018-242630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium (<= 220 Mg)			S				Bayer
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		40 Mg		Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			C				Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisone			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15778083	EXPEDITED (15-DAY)		HO, OT	IT-INCYTE CORPORATION-2018IN013198			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Pancytopenia; Pulmonary Arterial Hypertension	Jakavi			S	Unknown	20 Mg, Qd		Incyte
	Jakavi			S	Unknown	15 Mg, Qd		Incyte
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mepacrine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15778267	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018532941			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromatopsia	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Pfizer
	No Subject Drug			S		No Dose Given		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2018	15778279	EXPEDITED (15-DAY)		HO	CA-BAYER-2018-242743		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use;	Aleve			S	Unknown			Bayer
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	11408593	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15P-028-1411178-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Skin Mass	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	5-20 Mg, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	13128604	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201701-		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Wheezing	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Alprazolam			S	Oral			Not Reported
	Isosorbide Dinitrate			S	Unknown			Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S	Unknown			Not Reported
	Ampicilin Sodium			S	Unknown			Not Reported
	Pregabalin			S	Oral	At Bedtime, ,Hs		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Ziprasidone Hydrochloride			S	Unknown			Not Reported
	Meclozine Hydrochloride			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Prochlorperazine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Dyazide			S	Unknown			Not Reported

Erythromycin	S	Unknown	Not Reported
Hepatitis B Vaccine	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Iron	S	Unknown	Not Reported
Cefalexin	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Potassium Canrenoate	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Oxcarbazepine	S	Unknown	Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Zenpep	S	Unknown	Not Reported
Cetylpyridinium Chloride;Dichlorobenzyl Alcohol;Lidocaine Hydrochlorid	S	Unknown	Not Reported
Hydrochlorothiazide/Triamterene	S	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
Abreva	S	Unknown	Not Reported
Calcium Carbonate	C		Not Reported
Protopic	C		Not Reported
Esomeprazole	C		Not Reported
Mobic	C		Not Reported
Ergocalciferol	C		Not Reported
Vicodin	C		Not Reported
Cyclobenzaprine Hydrochloride	C		Not Reported
Singulair	C		Not Reported
Tamiflu	C		Not Reported
Paracetamol	C		Not Reported
Synthroid	C		Not Reported
Zoloft	C		Not Reported
Restasis	C		Not Reported
Folic Acid	C		Not Reported
Nasocort	C		Not Reported
Advair	C		Not Reported
Prevacid	C		Not Reported
Refresh	C		Not Reported

	Fosamax	C	Not Reported
	Promethazine	C	Not Reported
	Piperacillin Tazobactam	C	Not Reported
	Isopto Tears	C	Not Reported
	Lamictal	C	Not Reported
	Loperamide Hydrochloride	C	Not Reported
	Zanaflex	C	Not Reported
	Retin A	C	Not Reported
	Vitamin D3	C	Not Reported
	Hydrocortisone	C	Not Reported
	Zinc	C	Not Reported
	Ketotifen	C	Not Reported
	Rubramin	C	Not Reported
	Zantac	C	Not Reported
	Deltasone	C	Not Reported
	Cyanocobalamin	C	Not Reported
	Vitamin D2	C	Not Reported
	Mupirocin	C	Not Reported
	Citalopram Hydrobromide	C	Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Not Reported
	Carmellose	C	Not Reported
	Hypromellose	C	Not Reported
	Dexamethasone	C	Not Reported
	Vitamins Nos	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	13663116	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951182		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Tenofovir	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15327744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176025		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

Mobicox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15535307	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003694		21 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Azilva			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Famotidine			C				Not Reported
	Febuxostat			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Carvedilol			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Alendronate Sodium			C				Not Reported
	Nifedipine			C				Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15711409	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018174373		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Memory Impairment; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	Unk			Not Reported
	Methotrexate Sodium			S	Unknown	Unk			Not Reported
	Methotrexate			C		Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15721078	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779033	EXPEDITED (15-DAY)		OT	PHHY2018IT197858		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown			Novartis
	Minoxidil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779545	EXPEDITED (15-DAY)		OT	CA-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-06196		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Virus Infection; Progressive Multifocal Leukoencephalopathy	Mycophenolate Mofetil			S	Unknown	1500 Mg, Bid		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, Unk		Not Reported

	Belimumab			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779571	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2017-01855		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Chelonae Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779650	EXPEDITED (15-DAY)		OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-03344			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779657	EXPEDITED (15-DAY)		OT	CH-ALKEM LABORATORIES LIMITED-IT-ALKEM-2018-01563		23 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	2.5 Mg, Qd		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2019	15779662	EXPEDITED (15-DAY)		OT	IT-ALKEM LABORATORIES LIMITED-IT-ALKEM-2018-08698			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Intolerance; Gastrointestinal Disorder; Hypertransaminasaemia	Mycophenolate Mofetil			S	Unknown	1 G, Qd		Alkem
	Tacrolimus			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Prednisone			C	Unknown	1 Mg/Kg, Qd		Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	13640238	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	13741238	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004049		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Plaquenil Tablet			S	Oral			Concordia

Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Hydroxychloroquine	S	Unknown	Concordia
	Hydroxychloroquine	S	Unknown	Concordia
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Arava	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Pregabalin	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	13972660	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA166442		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Operation;	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Leflunomide			S	Oral	10 Mg,Unk		Sanofi
	Cefazolin			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported

Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cimzia	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	S	Oral	5 Mg,Bid		Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk		Not Reported
	Viread	C	Unknown	Unk Unk,Unk		Not Reported
	Naproxen	C	Unknown	500 Mg,Bid		Not Reported
	Arava	C	Oral	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	14995535	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268180		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis; Therapeutic Product Effect Decreased; Weight Decreased	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Plaquenil			S	Oral	400 Mg, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Actemra			S	Unknown	Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qcy		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Valtrex			C	Oral	1000 Mg, Bid		Not Reported
	Esomeprazole Magnesium;Naproxen			C	Oral	500 Mg, Bid		Not Reported

	Rosuvastatin Calcium			C	Oral	1 Df, Qd		Not Reported
	Acetaminophen W/Oxycodone			C	Oral	1 Df, Q4h		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15475776	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug Resistance; Ocular Toxicity; Pain; Rheumatoid Arthritis; Swelling	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15716338	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3674		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Blood Creatine Phosphokinase Increased; Drug Intolerance; Dyshidrotic Eczema; Joint Swelling; Mitral Valve Prolapse; Pain In Extremity; Synovial Cyst; Tendonitis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hepatitis B			C	Unknown			Not Reported
	Pneumovax			C	Unknown			Not Reported
	Prevnar			C	Unknown			Not Reported

	Cholestyramine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15752183	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180908356			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actonel			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15759186	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Leukopenia; Retinopathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported
	Shingrix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15779918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2237478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780089	EXPEDITED (15-DAY)		OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-04824			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780124	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2017-01291		59 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Danazol			C	Unknown	Unk		Not Reported
	Dapsone			C	Unknown	Unk		Not Reported
	Cyclophosphamide			C	Unknown	Unk		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Vincristine			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Bendroflumethiazide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780126	NON-EXPEDITED			GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2017-01293		46 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Treatment Failure	Mycophenolate Mofetil			S	Unknown	1.5 G, Bid		Alkem
	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	20 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Clobetasol			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Mepacrine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780128	NON-EXPEDITED			GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2017-01294		42 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Treatment Failure	Mycophenolate Mofetil			S	Unknown	1.5 Mg, Bid		Alkem
	Tacrolimus			S	Unknown	0.1 %, Unk		Not Reported
	Iloprost			S	Intravenous drip	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	20 Mg, Qd		Not Reported
	Isotretinoin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Clobetasol			S	Unknown	Unk		Not Reported

	Fluoxetine			S	Unknown	Unk				Not Reported
	Losartan			S	Unknown	Unk				Not Reported
	Diltiazem			S	Unknown	Unk				Not Reported
	Mepacrine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780132	EXPEDITED (15-DAY)		OT	FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2018-06194		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Polyomavirus Test Positive; Progressive Multifocal Leukoencephalopathy	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Alkem
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780617	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Nausea	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780751	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-09162		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitochondrial Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

	Prednisone			C	Unknown	Unk					Not Reported
	Azathioprine			C	Unknown	Unk					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780752	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-09143		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitochondrial Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780753	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-09161		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mitochondrial Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Azathioprine			C				Not Reported
	Immunoglobulin /00025201/			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Immunoglobulin /00025201/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15780754	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-09163		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Mitochondrial Myopathy	Hydroxychloroquine			S	Unknown	Unk			Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781013	EXPEDITED (15-DAY)		HO, OT	SA-ALKEM LABORATORIES LIMITED-SA-ALKEM-2018-00570			Unknown	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Therapy Partial Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781014	EXPEDITED (15-DAY)		HO, OT	SA-ALKEM LABORATORIES LIMITED-SA-ALKEM-2018-00571			Unknown	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapy Partial Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781022	EXPEDITED (15-DAY)		HO, OT	SA-ALKEM LABORATORIES LIMITED-SA-ALKEM-2018-00569			Unknown	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapy Partial Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781203	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil Sulfate			C				Not Reported
	Desoximetasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781205	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi

Injury; Treatment Failure	Enbrel		S		Unk Unk, Unk	Not Reported
	Actemra		S		Unk Unk, Unk	Not Reported
	Humira		S			Not Reported
	Orencia		S		Unk Unk, Unk	Not Reported
	Remicade		S		Unk Unk, Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Mobicox		C		Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781495	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-09128		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd (5.2 Mg/Kg Actual Body Weight)		Lupin
	Hydroxychloroquine			S				Lupin
	Levothyroxine			C	Unknown	Unk		Not Reported
	Dexlansoprazole			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Coenzyme Q10			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781503	EXPEDITED (15-DAY)		HO	CA-BAYER-2018-242757		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine	S	Unknown	400 Mg		Not Reported
	Methotrexate	S		Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Prednisone Acetate	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Folic Acid	C	Subcutaneous	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781544	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-242793		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Aleve			S		Unk		Bayer
	Celebrex			S		Unk		Not Reported
	Depo-Medrol			C	Intra-articular	40 Mg		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781576	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-242880		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Ow		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported

Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra	S	Unknown	50 Unk		Not Reported
	Enbrel	S	Unknown	1.5 Mg, Ow		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral	5 Mg		Not Reported
	Immunglobulin	S	Intravenous (not otherwise specified)	70 Gram Per Gram		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg, Ow		Not Reported
	Methotrexate	S		15 Mg/M2, Q2wk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q1min		Not Reported
	Prednisone	S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone	S	Other			Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15781731	EXPEDITED (15-DAY)		OT	PHHY2018US198325		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Creatine Phosphokinase Increased; Myopathy; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S	Unknown			Novartis
	Methotrexate			S				Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15782396	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-242885		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Aleve			S		Unk		Bayer
	Aspirin			S	Oral	Unk		Bayer
	Arava			S	Oral			Not Reported
	Diclofenac			S				Not Reported
	Diclofenac Potassium			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin [Ibuprofen]			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Sulfamethoxazole And Trimethoprim			S				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Ascorbic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15783322	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Nausea; Retinal Toxicity; Therapeutic Product Effect Decreased; Vomiting	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Enbrel			S				Not Reported
	Xeljanz			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C		Unk		Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2019	15783586	EXPEDITED (15-DAY)		OT	PHHY2018US198327		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Myopathy; Neuropathic Muscular Atrophy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Novartis
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	14543911	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018065048		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash Vesicular	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Alprazolam			S		0.5 Mg, Unk		Pfizer
	Atorvastatin Calcium			S		20 Mg, Unk		Pfizer
	Levothyroxine Sodium			S		Unk		Pfizer
	Metoprolol Tartrate			S		Unk		Unknown
	Nifedipine			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	B-12			S		Unk		Not Reported
	Hcq			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Norco			S		Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Zolpidem			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15766527	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2009S1006025		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Herpetiformis; Erythema Nodosum; Idiopathic Orbital Inflammation; Immune Reconstitution Inflammatory Syndrome	Ceftriaxone Sodium			S		Unk		Pfizer
	Bactrim			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Streptomycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15781694	NON-EXPEDITED			US-PFIZER INC-2018533541		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Tetanus Toxoid, Adsorbed			S		Unk		Not Reported
	Tetanus Diphtheria			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784261	EXPEDITED (15-DAY)		OT	ES-ROCHE-2152317			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Melanocytic Naevus	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported
	Cyclosporine			S	Unknown				Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)				Not Reported
	Losartan			S	Unknown				Not Reported
	Ivabradine			S	Unknown				Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)				Not Reported
	Acetylsalicylic Acid			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784570	NON-EXPEDITED			DE-ALKEM LABORATORIES LIMITED-DE-ALKEM-2018-11377		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784572	NON-EXPEDITED			GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2017-01210		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unknown		Alkem
	Mycophenolate Mofetil			S				Alkem
	Clobesol			S	Topical	0.05 %, Unk		Not Reported
	Clobesol			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	9 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	15 Mg, Unk		Not Reported

Azathioprine	S	Unknown	Unknown	Not Reported
Azathioprine	S			Not Reported
Thalidomide	S	Unknown	Unknown	Not Reported
Thalidomide	S			Not Reported
Prednisolone	S	Unknown	20 Mg, Unk	Not Reported
Prednisolone	S	Unknown	25 Mg, Unk	Not Reported
Prednisolone	S	Unknown	9 Mg, Unk	Not Reported
Prednisolone	S	Unknown	15 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S			Not Reported
Ciclosporin	S	Unknown	75 Mg, Od	Not Reported
Ciclosporin	S			Not Reported
Alitretinoin	S	Unknown	30 Mg, Unk	Not Reported
Alitretinoin	S			Not Reported
Salicylic Acid	S	Topical	Unknown	Not Reported
Salicylic Acid	S			Not Reported
Propylene Glycol	S	Topical	Unknown	Not Reported
Propylene Glycol	S			Not Reported
Mepacrine	S	Unknown	Unknown	Not Reported
Mepacrine	S			Not Reported
Betaloc Zok	C		200 Mg, Unk	Not Reported
Helicid	C	Unknown	20 Mg, Unk	Not Reported
Furorese	C	Unknown	40 Mg, Unk	Not Reported
Insulin	C	Unknown	Unknown	Not Reported
Anopyrin	C	Unknown	100 Mg, Unk	Not Reported
Verospiron	C		25 Mg, Unk	Not Reported
Warfarin	C	Unknown	5 Mg, Unk	Not Reported
Tulip	C	Unknown	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784650	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-US-ALKEM-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784654	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-05370			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784709	EXPEDITED (15-DAY)		DE, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-06190		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15784728	NON-EXPEDITED			US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-04103		16 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	270 Mg/M2, Bid		Alkem
	Mycophenolate Mofetil			S	Unknown	540 Mg/M2, Qd		Alkem
	Tacrolimus			S	Unknown	Unk, Ointment		Not Reported
	Fluocinonide			S	Unknown	Unk, Ointment		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Prednisone			S	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15785289	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000007		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Blindness; Optic Nerve Compression; Photopsia; Retinal Vascular Disorder; Retinopathy; Toxicity To Various Agents; Visual Field Defect	Hydroxychloroquine			S	Unknown	5.2mg/Kg Actual Body Weight		Concordia
	Hydroxychloroquine			S				Concordia
	Levothyroxine			C				Not Reported
	Dexlansoprazole			C				Not Reported
	Ramipril			C				Not Reported
	Atorvastatin			C				Not Reported
	Coenzyme Q10			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15786540	EXPEDITED (15-DAY)		OT	PHHY2018US198326		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Hyperplasia; Muscle Atrophy; Peripheral Sensorimotor Neuropathy; Polymyositis; Product Use In Unapproved Indication; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Novartis
	Hydroxychloroquine			S		Novartis
	Hydroxychloroquine			S		Novartis
	Hydroxychloroquine			S		Novartis
	Prednisone			S	Unknown	Not Reported
	Prednisone			S		Not Reported
	Prednisone			S		Not Reported
	Prednisone			S		Not Reported
	Azathioprine			S	Unknown	Not Reported
	Azathioprine			S		Not Reported
	Azathioprine			S		Not Reported
	Azathioprine			S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15786834	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001091			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Aspirin			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Tylenol Regular			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15786848	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001105			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Aspirin	S		Unk	Bayer
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S		Unk	Not Reported
	Methotrexate	S			Not Reported
	Penicillin G [Benzylpenicillin]	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Pregabalin	C			Not Reported
	Tylenol With Codeine No.3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15786904	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Aspirin			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15787250	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001158			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Aspirin			S	Unknown				Bayer
	Enbrel			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Oral				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Penicillin G [Procaine Benzylpenicillin]			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
	Pregabalin			C		Unk			Not Reported
	Tylenol [Paracetamol]			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2019	15878432	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Unevaluable Event	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	13833078	NON-EXPEDITED			US-PFIZER INC-2017335299		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	14893653	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180501635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Otezla	S	Oral	Celgene
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15616546	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA153750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	520 Mg (0, 2, 6 Weeks, Then Every 8 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15698905	NON-EXPEDITED			US-PFIZER INC-2018501334		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15789218	NON-EXPEDITED			US-PFIZER INC-2018535491		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Disorder; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15789571	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001133			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Aspirin			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Pregabalin			C		Unk		Not Reported

	Tylenol [Paracetamol]	C	Unk		Not Reported
	Xeljanz	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15790264	EXPEDITED (15-DAY)		OT	PHHY2019IN000591			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis B Reactivation	Hydroxychloroquine			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15791064	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-001333		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Aspirin			S				Bayer
	Acetylsalicylic Acid (> 100 Mg)			S	Unknown			Bayer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin [Naproxen]			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported

		Diclofenac			S	Unknown				Not Reported
		Tramadol Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15791068	DIRECT		OT			34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria; Urticaria	Hydroxychloroquine			S	Oral	Quantity:1 Capsule(S);		Not Reported
	Birth Control Pill			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2019	15886078	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Feeling Abnormal	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	13263200	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001210		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate		S	Oral		Not Reported
	Prednisone		C			Not Reported
	Celebrex		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	13989278	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005271		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Viread			C				Not Reported
	Naproxen			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	14380889	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000147		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis; Therapeutic Product Effect Decreased; Weight Decreased	Hydroxychloroquine	S	Unknown			Concordia
	Plaquenil Tablet	S	Oral			Concordia
	Leflunomide	S	Oral			Not Reported
	Actemra	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Received Only Two Infusion		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Varenicline Tartrate	S	Oral			Not Reported
	Valtrex	C				Not Reported
	Xeljanz	C				Not Reported
	Acetaminophen W/Oxycodone	C				Not Reported
	Esomeprazole Magnesium;Naproxen	C				Not Reported
	Rosuvastatin Calcium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15568294	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003810		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Enbrel			C				Not Reported
	Actemra			C				Not Reported
	Humira			C				Not Reported
	Remicade			C				Not Reported
	Rituximab			C				Not Reported
	Simponi			C				Not Reported
	Orencia			C				Not Reported

	Hydroxychloroquine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15702278	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004022		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Diverticulitis; Drug Ineffective; Malaise; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15737661	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004128		65 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Predonine			C				Not Reported
	Imuran			C				Not Reported
	Micardis			C				Not Reported
	Bayaspirin			C				Not Reported
	Takepron			C				Not Reported
	Takepron			C				Not Reported
	Baktar			C				Not Reported
	Baktar			C				Not Reported

	Bonalon			C					Not Reported
	Bonalon			C					Not Reported
	Edirol			C					Not Reported
	Edirol			C					Not Reported
	Lendormin			C					Not Reported
	Depas [Diclofenac\Dicycloverine]			C					Not Reported
	Magnesium Oxide			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792245	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792321	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792323	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Azathioprine			C				Not Reported
	Humira			C				Not Reported
	Metoprolol			C				Not Reported
	Naproxen			C				Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792599	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792604	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995407			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792637	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004219			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Extraocular Muscle Paresis; Vision Blurred	Plaquenil 200 Mg			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15792899	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2239330			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Cellulitis; Gastroenteritis; Herpes Zoster; Influenza; Influenza; Pericarditis; Pneumonia; Pneumonia; Urinary Tract Infection; Varicella Zoster Virus Infection	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15793682	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous	Therapy Duration- 365		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794315	EXPEDITED (15-DAY)		OT	PHHY2019US000693		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Loss Of Visual Contrast Sensitivity; Night Blindness; Photopsia; Product Use In Unapproved Indication; Retinal Degeneration; Retinal Depigmentation; Toxicity To Various Agents; Visual Field Defect; Visual Impairment	Hydroxychloroquine	S	Unknown	400 Mg, Qd (5.2mg/Kg)		Novartis
	Hydroxychloroquine	S				Novartis
	Levothyroxine	C	Unknown			Not Reported
	Dexlansoprazole	C	Unknown			Not Reported
	Ramipril	C	Unknown			Not Reported
	Atorvastatin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15794808	NON-EXPEDITED			PHEH2019US000887			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Facial Pain; Rash	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15795809	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1098234		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Motor-Sensory Axonal Neuropathy; Muscle Atrophy; Myopathy; Myopathy Toxic	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported

		Simvastatin			C					Not Reported
		Statex			C					Not Reported
		Telmisartan			C					Not Reported
		Xeljanz			C					Not Reported
		Actonel			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15795947	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2019	15797085	DIRECT		HO, LT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Disorientation; Dizziness; Hyperglycaemia; Hypertension; Unresponsive To Stimuli; Visual Impairment	Hydroxychloroquine	Y		S	Oral	Quantity:1 Tablet(S);		Zydus Pharm
	Mycophenolate Mofetil			C				Not Reported
	Multivitamin			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Vitamin A			C				Not Reported
	Probiotic			C				Not Reported
	Zinc			C				Not Reported
	Milk Thistle			C				Not Reported
	Turmeric			C				Not Reported
	Ginger			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15239109	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2018-016248			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Rheumatrex			S	Unknown	Unk Unk, Unknown		Dava
	Prednisone			S	Unknown	Unk Unk, Unknown		Vintage
	Hydroxychloroquine			S	Unknown	Unk Unk, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15761028	NON-EXPEDITED			US-PFIZER INC-2018522382		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Tacrolimus			S	Oral	0.085 Mg/Kg, Daily(0.085 Mg Per Kilogram0		Pfizer
	Methotrexate Sodium			S		Unk Unk, Weekly (15 To 20 Mg)		Pfizer
	Apremilast			S		30 Mg, 2x/Day		Not Reported
	Minocycline			S		100 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Adalimumab			S		40 Mg, Unk (40 Mg Every Other)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15796132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2240255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure; Treatment Failure; Treatment Failure	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown	1 Year		Not Reported
	Etanercept			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Ongoing		Not Reported
	Hydroxychloroquine			S	Oral	Ongoing		Not Reported
	Prednisone			S	Oral	Ongoing		Not Reported

	Methotrexate			S	Unknown	Discontinued			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15796176	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-064012		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache	Tramadol			S	Oral	Unk		Aurobindo
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Daily		Not Reported
	Atacand			C	Unknown	Unk		Not Reported
	Bricanyl			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Flixonase			C	Unknown	Unk		Not Reported
	Kardegic			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported
	Movicol /01749801/			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	Unk		Not Reported
	Temesta /00273201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15797541	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001119			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Aspirin			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported

	Tylenol [Paracetamol]			C	Unknown	Unk				Not Reported
	Pregabalin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15798082	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2019	15800543	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000036		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Headache	Plaquenil			S	Unknown			Concordia
	Ambrlsentan			S	Unknown			Not Reported
	Uptravi			S	Unknown			Not Reported
	Uptravi			S	Unknown			Not Reported
	Adcirca			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	12645973	NON-EXPEDITED			US-PFIZER INC-2016200972			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	13762067	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004136		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	14416182	EXPEDITED (15-DAY)		HO, OT	SE-AUROBINDO-AUR-APL-2018-003169		81 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Metoprolol 50mg			S	Unknown	50 Milligram, Once A Day		Aurobindo
	Plaquenil /00072602/			S	Unknown	200 Milligram, Once A Day		Not Reported
	Kalcipos			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported

	Zopiclone			C	Unknown	Unk				Not Reported
	Xarelto			C	Unknown	Unk				Not Reported
	Citalopram			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15800734	EXPEDITED (15-DAY)		OT	PT-LUPIN PHARMACEUTICALS INC.-2018-09212		90 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Hyperpigmentation	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Lupin
	Prednisolone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15801139	EXPEDITED (15-DAY)		HO	CA-ABBVIE-19K-028-2617050-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

					Xeljanz	S	Oral		Not Reported
					Folic Acid	C	Unknown		Not Reported
					Folic Acid	C	Subcutaneous		Not Reported
					Methotrexate	C			Not Reported
					Plaquenil	C	Unknown		Not Reported
					Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15801143	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Leukopenia	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Etanercept			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15801208	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996359		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Celebrex			C				Not Reported

	Loperamide			C	Unknown					Not Reported
	Methotrexate			C						Not Reported
	Pantoprazole			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15801331	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617243-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802081	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995672		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Musculoskeletal Pain; Pancytopenia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802165	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2019-CA-996461		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Hypersensitivity; Hypersensitivity; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	5.7143 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802193	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996389			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617851-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C		25		Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15802972	EXPEDITED (15-DAY)		OT	US-CASPER PHARMA LLC-2018CAS000411		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness;	Antivert			S	Oral	12.5 Milligram, Tid,As Necessary		Casper Pharma
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi Aria			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xanax			S	Oral	0.5 Milligram, Tid, As Needed		Not Reported

Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Wheezing; Wound	Isordil	S	Unknown	Unk	Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Ampicillin	S	Unknown	Unk	Not Reported
	Lyrica	S	Oral	100 Milligram, Qd, At Bedtime	Not Reported
	Zyrtec	S	Unknown	10 Milligram, Qd, As Needed	Not Reported
	Geodon	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	12.5 Milligram, Tid	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Colchicine	S	Unknown	Unk	Not Reported
	Compazine	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Diamox	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Dyazide	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Hepatitis B Vaccine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Iron	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Lasix	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Potassium	S	Unknown	Unk	Not Reported
	Sudafed	S	Unknown	Unk	Not Reported

Sulfasalazine	S	Unknown	Unk	Not Reported
Trileptal	S	Unknown	Unk	Not Reported
Ultram	S	Unknown	Unk	Not Reported
Lialda	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Abreva	S	Unknown	Unk	Not Reported
Zenpep	S	Unknown	Unk	Not Reported
Vitamin D2	C	Oral	Unk	Not Reported
Bactroban	C	Topical		Not Reported
Tamiflu	C	Unknown		Not Reported
Celexa	C	Unknown		Not Reported
Tylenol	C	Oral		Not Reported
Singular	C	Unknown		Not Reported
Synthroid	C	Oral		Not Reported
Zoloft	C	Unknown		Not Reported
Mvi	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Folic Acid	C	Oral		Not Reported
Nasocort	C	Unknown		Not Reported
Advair	C	Unknown		Not Reported
Prevacid	C	Unknown		Not Reported
Flexeril	C	Unknown		Not Reported
Vicodin	C	Unknown		Not Reported
Refresh	C	Topical		Not Reported
Fosamax	C	Unknown		Not Reported
Phenergan	C	Unknown		Not Reported
Tazact	C	Unknown		Not Reported
Vitamin D2	C	Unknown		Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unknown		Not Reported

	Isopto Tears	C	Unknown		Not Reported
	Mobic	C	Oral		Not Reported
	Lamictal	C	Oral		Not Reported
	Diamode	C	Oral		Not Reported
	Nexium	C	Oral		Not Reported
	Calcium Carbonate	C	Oral		Not Reported
	Zanaflex	C	Oral		Not Reported
	Retin A	C	Topical		Not Reported
	Flu Vaccine Vii	C	Unknown	Unk	Not Reported
	Pneumococcal Vaccine	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Oral		Not Reported
	Norco	C	Oral	Unk	Not Reported
	Hydrocortisone	C	Topical		Not Reported
	Zinc	C	Unknown		Not Reported
	Zaditor	C	Unknown		Not Reported
	Rubramin	C	Unknown		Not Reported
	Zantac	C	Oral		Not Reported
	Deltasone	C	Oral		Not Reported
	Vitamin B12	C	Unknown		Not Reported
	Protopic	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15803193	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019009390			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Oral	7.5 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported

					Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Prednisone	C	Oral	15 Mg, 1x/Day	Not Reported
					Infliximab	C		Unk	Not Reported
					Xeljanz	C		5 Mg, 2x/Day	Not Reported
					Xeljanz Xr	C		Unk Unk, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15804310	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996068		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Dermatitis Allergic; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	750 Milligram Daily;		Not Reported
	Hydrochlorothiazide/ Lisinopril Dihydrate			C				Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Rituxan			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15804462	EXPEDITED (15-DAY)		DE, HO	DE-PFIZER INC-2019009686		61 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Device Related Infection; Postoperative Wound Complication	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2019	15895136	DIRECT		DS, HO, RI, OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Nodule	Hydroxychloroquine	Y		S	Oral	Quantity:200mg Take 1/2 Tab;Other Frequency:Twice Daily W/Meal;		Zydus Pharm
	Vitamin D3			C				Not Reported
	Vitamin C			C				Not Reported
	Aleeve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15035385	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010726		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Actonel	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Xeljanz	C		Not Reported
	Risedronate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15120397	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-GLAXOSMITHKLINE-DE2018117077			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Mg, Qd		Glaxosmithkline
	Salbutamol			S	Transplacental	Unk		Glaxosmithkline
	Metamizole Sodium			S	Transplacental	From Gestational Week 0-14		Glaxosmithkline
	Simvastatin			S	Transplacental	Unk		Glaxosmithkline
	Simvastatin			S	Unknown	Unk		Glaxosmithkline
	Nicotine			S	Transplacental	Unk		Glaxosmithkline
	Tacrolimus			S	Transplacental	6 Mg, Qd		Glaxosmithkline
	Tacrolimus			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Transplacental	40 Mg, Qd		Glaxosmithkline
	Pantoprazole			S	Transplacental	Unk		Glaxosmithkline
	Prednisolone			S	Transplacental	10 Mg, Bid		Glaxosmithkline
	Prednisolone			S	Transplacental	Unk		Glaxosmithkline
	Novaminsulfon			S	Transdermal	Trimester: First; Probably Only In Hospital In Week 5		Glaxosmithkline
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Glaxosmithkline
	Lmw Heparin (Dalteparin			S	Transplacental	Unk		Not Reported

	Sodium)				
	Hydroxychloroquine Sulfate	S	Transplacental	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	Unk	Not Reported
	Torasemide	S	Transplacental	100 Mg, Qd	Not Reported
	Torasemide	S	Unknown	Unk	Not Reported
	Ezetimibe	S	Transplacental	Unk	Not Reported
	Ezetimibe	S	Transplacental	Unk	Not Reported
	Xarelto	S	Transplacental	Unk	Not Reported
	Aliskiren	S	Transplacental	300 Mg, Qd	Not Reported
	Acetylsalicylic Acid Sandoz	S	Transplacental	Unk Unk, Qd	Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Enoxaparin Sodium	S	Transplacental	Unk	Not Reported
	Dalteparin Sodium	S	Transplacental	Unk	Not Reported
	Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Cytotec	S	Transplacental	Unk	Not Reported
	Clexane	S	Transplacental	100 Mg, Bid	Not Reported
	Cyclophosphamide	C	Transplacental	Unk	Not Reported
	Mifegyne	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15796434	EXPEDITED (15-DAY)		HO, LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000039		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy; Lupus Nephritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Paracetamol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15805080	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617272-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Loss Of Consciousness; Mobility Decreased; Unevaluable Event	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15805319	EXPEDITED (15-DAY)		OT	CN-LUPIN PHARMACEUTICALS INC.-2019-00016		55 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nail Bed Bleeding; Nail Pigmentation	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin
	Hydroxychloroquine			S	Unknown	100 Mg, Unk		Lupin
	Prednisone			C	Oral	40 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15805402	EXPEDITED (15-DAY)		OT	KR-LUPIN PHARMACEUTICALS INC.-2018-09144		57 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15808966	EXPEDITED (15-DAY)		HO	PHHY2019DE001532			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Empyema	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	22.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis

Leflunomide	S	Unknown	10 Mg, Unk	Not Reported
Leflunomide	S	Unknown	10 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	2000 Mg, Unk	Not Reported
No Treatment Received	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2019	15899327	DIRECT	Y				65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Weight Decreased	Leflunomide Tab 10 Mg			S				Not Reported
	Plaquenil Tab 200 Mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	14158558	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Paracetamol			S				Not Reported
	Paracetamol			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C		25 Mg/Ml		Not Reported
	Synthroid			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported
	Leflunomide			C				Not Reported
	Celebrex			C				Not Reported
	Hydromorphone Hcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15737662	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004140		43 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Iron Deficiency Anaemia; Retinal Vein Occlusion	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Prednisolone			C				Not Reported
	Cellcept			C				Not Reported
	Neoral			C				Not Reported
	Mevalotin			C				Not Reported
	Edirol			C				Not Reported
	Edirol			C				Not Reported
	Micardis			C				Not Reported
	Brotizolam			C				Not Reported
	Beraprost Sodium			C				Not Reported
	Anplag			C				Not Reported
	Bonalon			C				Not Reported
	Calblock			C				Not Reported
	Dermovate			C				Not Reported
	Prostandin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15810512	NON-EXPEDITED			US-ROCHE-2111277			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea	Rituxan			S	Unknown	Ongoing		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

	Enbrel			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15810867	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000060			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Immobile; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral	(Morning)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15811353	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2618121-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hand Deformity; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Cortisone Acetate			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Phthalylsulfathiazole			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15812111	NON-EXPEDITED			US-PFIZER INC-2019010068			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Singulair			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15814014	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019011083		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Small For Dates Baby	Sulfasalazine			S	Transplacental	2000 [Mg/D]		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Transplacental	300 [Mg/D] 1x/Day		Not Reported
	Dreisafol			C	Transplacental	5 [Mg/D]		Not Reported
	Prednisolon			C	Transplacental	2 [Mg/D]/ Conflicting Data On The Begin And Duration Of Therapy During Pregnancy		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15814834	EXPEDITED (15-DAY)		DE, HO	DE-AMGEN-DEUNI2019004419		61 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Device Related Infection; Postoperative Wound Complication	Etanercept			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2019	15923196	DIRECT	Y				76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sciatic Nerve Injury	Hydroxychloroquine 200 Mg Tab			S	Oral			Unknown
	Methotrexate 2.5 Mg Tablet			S	Oral			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	11923531	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1539429-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Drug Ineffective; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Arava			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	13058399	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015757		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cortisone			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	13059166	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015754		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Transaminases Abnormal	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	13569177	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086292			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Cortisone			C	Unknown	Unk Unk,Unk		Not Reported
	Diclofenac			C	Unknown	100 Mg,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Desoximetasone			C	Oral	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15242440	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018106052		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Gait Disturbance; Hypersensitivity; Influenza; Musculoskeletal Stiffness; Pain In Extremity; Pain In Jaw; Peripheral Swelling; Rheumatoid Nodule; Sjogren'S Syndrome; Splenomegaly; Therapeutic Product Effect Decreased; Tinnitus; Vertigo	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rasuvo			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Aspirin			S	Oral	81 Mg, Qd		Not Reported
	Folic Acid			C	Oral	3 Mg, Qd		Not Reported
	Gabapentin			C	Oral	100 Mg, Qd		Not Reported
	Gabapentin			C	Oral	200 Mg, Qd		Not Reported
	Lipitor			C	Oral	40 Mg, Bedtime		Not Reported
	Meloxicam			C	Oral	7.5 Mg, As Necessary		Not Reported
	Proair Hfa			C		90 Mug, Q6h (As Necessary)		Not Reported
	Tofacitinib			C	Oral	11 Mg, Qd		Not Reported
	Flu Vaccine Vii			C		Unk		Not Reported
	Pneumococcal Vaccine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15267508	NON-EXPEDITED			PHEH2018US033187		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Exfoliative Rash; Ill-Defined Disorder; Nasopharyngitis; Pain; Skin Hypertrophy	Cosentyx			S	Subcutaneous	150 Mg, Qw		Not Reported
	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15338166	EXPEDITED (15-DAY)		DS, HO	PHHY2017DE204616		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Joint Instability; Joint Range Of Motion Decreased; Musculoskeletal Disorder; Nerve Compression; Pseudarthrosis; Silicon Granuloma; Sinusitis; Tendon Rupture	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Novartis
	Hydroxychloroquine	S	Unknown	200 Mg, Unk		Novartis
	L-Thyroxin	C	Unknown	Unk		Not Reported
	Palladon	C	Unknown	Unk		Not Reported
	Lodotra	C	Unknown	Unk		Not Reported
	Ursofalk	C	Unknown	Unk		Not Reported
	Simvastatin	C	Unknown	Unk		Not Reported
	Fragmin	C	Unknown	Unk		Not Reported
	Decortin	C	Unknown	Unk		Not Reported
	Ibuprofen	C	Unknown	Unk		Not Reported
	Pantoprazol	C	Unknown	Unk		Not Reported
	Novalgin (Metamizole Sodium)	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15471808	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2507373-00		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient; Deafness Neurosensory; Headache; Injection Site Bruising; Retinal Disorder; Retinitis; Uveitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Meloxicam			C				Not Reported
	Metformin			C				Not Reported
	Omeprazole			C				Not Reported
	Vitamin D2			C				Not Reported
	Vitamin B			C				Not Reported
	Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15819418	EXPEDITED (15-DAY)		HO	DE-UCBSA-2019001191			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cystitis; Fatigue; Mixed Incontinence; Nausea; Parotitis; Pruritus; Vomiting	Cimzia			S		200 Mg		Ucb
	Methotrexate			S		15 Mg, Unk		Not Reported
	Methotrexate			S		15 Mg, Unk		Not Reported
	Methotrexate			S		15 Mg, Unk		Not Reported
	Methotrexate			S		15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Botox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15819546	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20190109710		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Therapeutic Response Decreased	Minoxidil		Y	S	Unknown			Not Reported
	Minoxidil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15820484	EXPEDITED (15-DAY)		HO, OT	DE-ABBVIE-19K-062-2617422-00			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Deep Vein Thrombosis; Foot Fracture; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Radiculopathy; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Mabthera	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Quensyl	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15820763	NON-EXPEDITED			US-SA-2019SA008664			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Decreased; Diarrhoea; Product Dose Omission; Unevaluable Event; Vision Blurred	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg Caplet By Mouth Twice A Day		Sanofi
	Calcium Folinate			S	Oral	5 Mg, Bid		Not Reported
	Methylprednisolone			S	Oral	4 Mg, Prn		Not Reported
	Atorvastatin			S	Oral	10 Mg, Qd		Not Reported
	Raloxifene Hydrochloride			S	Oral	60 Mg, Qd		Not Reported
	Omeprazole			S	Oral	40 Mg, Bid		Not Reported
	Diphenhydramine			S	Oral	25 Mg In Morning And Before Bed And As Needed		Sanofi
	Simeticone			S		Unk		Sanofi

	Xeljanz Xr	S	Oral	11 Mg, Qd		Not Reported
	Tizanidine Hydrochloride	S	Oral	4 Mg, Bid (1-2 Tablets Up To Twice A Day)		Not Reported
	Vitamin D [Vitamin D Nos]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15821533	NON-EXPEDITED			US-PFIZER INC-2019009865			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Reaction To Excipient	Pantoprazole			S		80 Mg, Each Day		Pfizer
	Diltiazem Hcl			S		120 Mg, Each Day		Unknown
	Folic Acid			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Lactose Monohydrate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15822147	EXPEDITED (15-DAY)		DE, OT	PHHY2019AU004646		77 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Upper Airway Obstruction	Temazepam			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Paracetamol			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Tapentadol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2019	15824058	NON-EXPEDITED		OT	US-AMGEN-USASP2019004286		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Hypoaesthesia; Joint Swelling; Pneumonia	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	15 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15536565	EXPEDITED (15-DAY)		OT	CA-ROCHE-2203318			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Swelling; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15795946	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Nausea; Retinal Toxicity;	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Vomiting	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Sulfasalazine	C			Not Reported
	Prednisone	C			Not Reported
	Humira	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15824940	EXPEDITED (15-DAY)		OT	CN-IPCA LABORATORIES LIMITED-IPC-2019-CN-000034			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Nail Pigmentation	Hydroxychloroquine			S	Oral	200 Mg, Qd		Ipca
	Hydroxychloroquine			S	Oral	100 Mg, Qd		Ipca
	Prednisone			S	Oral	400 Mg, Qd		Not Reported
	Prednisone			S	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15826345	EXPEDITED (15-DAY)		OT	PHHY2019GB005000		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15826900	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019015688		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Positive; Synovitis; X-Ray Abnormal	Humira	S	Unknown	40 Mg, Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	5 Mg/Kg, Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15827059	EXPEDITED (15-DAY)		DS	CA-ROCHE-2245785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2019	15827091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189146		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	12838058	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840826		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Solution For Injection In Pre-Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	13229205	EXPEDITED (15-DAY)		DS	CA-ROCHE-1892598		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Cyclical		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral			Not Reported
	Plaquenil	S	Oral			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Apo-Hydroxyquine	S	Oral			Not Reported
	Cimzia	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	13303889	EXPEDITED (15-DAY)		OT	CA-ROCHE-1900072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tylenol	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Acetaminophen	S	Unknown			Not Reported
	Acetaminophen/Codeine Phosphate	C				Not Reported
	Leflunomide	C	Unknown	Therapy Duration: 4 Months		Not Reported
	Meloxicam	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Celebrex	C				Not Reported
	Hydromorphone Hcl	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	14371183	NON-EXPEDITED			US-PFIZER INC-2018009827		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15334946	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018309896		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fatigue; Gait	Enbrel			S		Unk		Pfizer

Disturbance; Hypersensitivity; Influenza; Musculoskeletal Stiffness; Pain In Extremity; Pain In Jaw; Peripheral Swelling; Rheumatoid Nodule; Sjogren'S Syndrome; Splenomegaly; Tinnitus; Vertigo	Methotrexate Sodium	S	Subcutaneous		Unknown
	Hcq	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Once Evenry Two Weeks (Q2wk)	Not Reported
	Rasuvo	S	Subcutaneous	20 Mg, Weekly	Not Reported
	Aspirin	S	Oral	81 Mg, Daily	Not Reported
	Folic Acid	C	Oral	3 Mg, Daily (Qd)	Not Reported
	Gabapentin	C	Oral	100 Mg, Daily (Qd)	Not Reported
	Gabapentin	C	Oral	200 Mg, Daily (Qd)	Not Reported
	Lipitor	C	Oral	40 Mg, 1x/Day (Bedtime)	Not Reported
	Meloxicam	C	Oral	75 Mg, As Needed	Not Reported
	Proair Hfa	C		90 Mu, Q6h As Necessary	Not Reported
	Tofacitinib	C	Oral	11 Mg, Daily (Qd)	Not Reported
	Flu Vaccine Vii	C		Unk	Not Reported
	Pneumococcal Vaccine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15368520	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1857818-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Visual Impairment	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported
	Celecoxib	C		Not Reported
	Hydromorphone Hcl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15786995	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2609673-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15811530	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Infliximab			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15832061	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1770670-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; C-Reactive Protein Abnormal; Cataract; Cerebrovascular Accident; Crying; Depression; Disability; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Fine Motor Skill Dysfunction; Foot Deformity; Foot Deformity; Gait Disturbance; Hand Deformity; Hepatic	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tylox			C				Not Reported
	Ativan			C	Sublingual			Not Reported
	Coversyl			C				Not Reported
	Cyclobenzaprine Hydrochloride			C	Subcutaneous			Not Reported
	Lovastatin			C				Not Reported

Enzyme Increased; Hepatitis C; Hypokinesia; Impaired Healing; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Muscle Spasms; Musculoskeletal Disorder; Musculoskeletal Pain; Myalgia; Nodule; Papule; Peripheral Swelling; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Shoulder Deformity; Surgical Failure; Swelling; Weight Decreased; Wrist Deformity	Senokot			C					Not Reported
	Percocet			C					Not Reported
	Flexeril			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2019	15834762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2245786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	12299427	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016051438		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Overdose	Enbrel			S	Subcutaneous	50 Mg, Unk		Amgen
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Naprosyn			S	Unknown	500 Mg, Bid		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	12370677	EXPEDITED (15-DAY)		OT	CA-ROCHE-1756598		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown Dose And Frequency		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown	End Date: Unknown		Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Leflunomide	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	12920263	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16P-028-1771856-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported

	Orencia		S	Subcutaneous	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	13058749	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015733		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S	Oral	20.0 Mg, Qd		Apotex
	Mefenamic Acid			S	Unknown	400 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	1 Df, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unknown		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Advil /00044201/			S	Unknown	400 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	14633940	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018033844		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Rheumatoid	Enbrel			S	Unknown	25 Mg, Unk		Amgen
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

Arthritis; Therapeutic Product Effect Decreased	Orencia	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported
	Simponi	S	Unknown	50 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	14959059	EXPEDITED (15-DAY)		DS, OT	FR-MYLANLABS-2018M1035289		32 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Maculopathy; Retinal Degeneration; Retinal Fovea Disorder; Retinopathy; Visual Acuity Reduced; Visual Field Defect; Visual Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Receiving For 8 Years; Average Of 5.9 Mg/Kg/Day)		Not Reported
	Chloroquine			S	Unknown	300 Mg, Qd (Receiving For 9 Years; Average Of 4.4 Mg/Kg/Day)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15073352	EXPEDITED (15-DAY)		OT	US-ROCHE-2144316			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Dyspnoea; Herpes Zoster; Injection Site Reaction; Paralysis; Rash; Transaminases Increased; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15073514	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2398150-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Dyspnoea; Headache; Herpes Zoster; Injection Site Reaction; Paralysis; Rash; Transaminases Increased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15299341	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018113577			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Episcleritis; Herpes Zoster; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Mg, Qwk		Amgen
	Enbrel			S				Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	200 Mg, Unk		Not Reported
	Actemra			S	Unknown	162 Mg, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Methotrexate			C	Oral	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15795778	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1097919		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown	300 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15835312	EXPEDITED (15-DAY)		OT	FR-ZYDUS-032513		4 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown	Unk ()		Not Reported
	Cyclophosphamide			S	Unknown	()		Not Reported
	Mycophenolic Acid			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15835890	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2624737-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Apo-Hydroxyquine			S	Unknown					Not Reported
	Actemra			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15837135	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-997320		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Motor-Sensory Axonal Neuropathy; Muscle Atrophy; Myopathy; Myopathy Toxic	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15837138	EXPEDITED (15-DAY)		OT	US-TEVA-416910USA		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown			Teva
	Azathioprine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15837139	EXPEDITED (15-DAY)		OT	US-TEVA-416909USA		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15837143	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-997317		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15839105	NON-EXPEDITED			US-PFIZER INC-2019023299		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Augmentin [Amoxicillin;Clavulanate Potassium]			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Flomax Relief			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Lodine			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2019	15839181	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-999604			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy	Topiramate			S	Unknown			Teva
	Quensyl			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	12313021	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015019700		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	12717809	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016129658		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Asthenia; Bone Marrow Failure; Fall; Macular Degeneration; Muscle Atrophy; White Blood Cell Count Decreased	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Losartan			C		100 Mg, Unk		Not Reported
	Pantoprazole			C		40 Mg, Unk		Not Reported
	Asa			C		80 Mg, Unk		Not Reported
	Calcium			C		500 Mg, Unk		Not Reported
	Vitamin D2			C		1000 Mg, Unk		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported
	Atorvastatin			C	Oral	40 Mg, Unk		Not Reported

Atenolol	C	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	13575264	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003146			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cortisone			C				Not Reported
	Diclofenac			C				Not Reported
	Xeljanz			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	14186414	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017169925		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide	Enbrel			S	Unknown	50.0 Mg, Unk		Amgen

Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Apo Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Oral	400 Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20.0 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20.0 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25.0 Mg, Qwk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Varenicline Tartrate	S	Oral	1 Df, Qd	Not Reported
	Varenicline Tartrate	S	Oral	Unk Unk, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Unk	Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Rosuvastatin Calcium	C	Oral	Unk	Not Reported
	Rosuvastatin Calcium	C	Oral	Unk	Not Reported
	Valtrex	C	Oral	1000 Mg, Bid	Not Reported
	Valtrex	C	Unknown	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C		Unk	Not Reported

	Naproxen			C	Oral	500 Mg, Bid			Not Reported
	Oxycodone Hydrochloride			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15173243	EXPEDITED (15-DAY)		OT	PHHY2016GB187010			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Diverticulitis; Joint Swelling; Liver Injury; Pain; Peripheral Swelling	Methotrexate			S	Unknown	Unk (Reduced Dose)		Novartis
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cortisone Acetate			C	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported
	Endep			C	Unknown	Unk		Not Reported
	Tapentadol			C	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15372794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15439380	EXPEDITED (15-DAY)		OT	CA-GLENMARK PHARMACEUTICALS-2018GMK037437			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Glenmark
	Folic Acid			S	Unknown	1 Df, Unk (2 Every 1 Weeks)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk (1 Every 1 Week)		Not Reported
	Nexium /01479302/			S	Unknown	40 Mg, Od		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Prednisone			S	Unknown	D5 Mg, Od		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15439387	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2018GMK037485			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium	Gabapentin			S	Oral	100 Mg, Unk		Glenmark
	Actemra			S	Intravenous (not	488 Mg, 1 Every 1 Month		Not Reported

Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure			otherwise specified)		
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Od	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Od	Not Reported
	Trazodone	C	Oral	50 Mg, Unk	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 2 Weeks	Not Reported
	Nasonex	C	Unknown	Unk, Bid (Dosage Form: Spray, Metered Dose)	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Omega 3 /01333901/	C	Unknown	Unk, 1 Every 2 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15546864	EXPEDITED (15-DAY)		OT	CA-GLENMARK PHARMACEUTICALS-2018GMK037854			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anal Incontinence; Back Pain; Constipation; Dyspepsia; Fatigue; Frequent Bowel Movements; Insomnia; Intentional Self-Injury; Muscle Spasms; Nausea; Proctalgia; Pruritus; Scab;	Ursodeoxycholic Acid			S	Oral	750 Mg, Od		Glenmark
	Obeticholic Acid			S	Oral	5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Somnolence; Suicidal Ideation; Thinking Abnormal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15801014	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15840577	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0076		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Product Complaint; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

		Rituxan			S	Unknown					Not Reported
		Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15840638	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001100		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Kidney Infection; Treatment Failure	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15840912	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-999795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Unknown	500 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15840914	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-999806		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid	Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Arthritis; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Barr

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15843780	DIRECT	Y	DE			78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Septic Shock; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2019	15844301	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA009835		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia;	Aclasta			S	Unknown			Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	17.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Arava			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Orencia	S				Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	2 G, Qd		Not Reported
	Tramacet	S	Unknown	Unk		Not Reported
	Metformin	C	Unknown	Unk		Not Reported
	Lorazepam	C	Unknown			Not Reported
	Nortriptyline	C	Unknown			Not Reported
	Vagifem	C	Unknown			Not Reported
	Premarin	C	Unknown			Not Reported
	Vitamin D2	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported
	Tylenol	C	Unknown			Not Reported
	Actonel	C	Unknown			Not Reported
	Methylprednisolone Acetate	C	Unknown			Not Reported
	Depo-Medrol	C	Intramuscular	Unk		Not Reported
	Lyrica	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15636641	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556335-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Miliaria; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	11: 1 Mg		Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

Sleep Disorder; Stomatitis	Methotrexate	S	Subcutaneous	Not Reported
	Celebrex	S	Unknown	Not Reported
	Lorazepam	S	Unknown	Not Reported
	Cyclosporine	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Citalopram	C		Not Reported
	Gold	C		Not Reported
	Prednisone	C		Not Reported
	Pantoloc	C		Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15845561	EXPEDITED (15-DAY)		OT	PHHY2019US009837		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 6.8 Mg/Kg/Day)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15845563	EXPEDITED (15-DAY)		OT	PHHY2019US009854		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 4.5 Mg/Kg/Day)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15845564	EXPEDITED (15-DAY)		OT	PHHY2019US009844		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 5.4 Mg/Kg/Day)			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15845565	EXPEDITED (15-DAY)		OT	PHHY2019US009859		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dosing Based On Actual Body Weight Was 7.1 Mg/Kg/Day)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15845598	EXPEDITED (15-DAY)		OT	PHHY2019US009863			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2019	15845601	EXPEDITED (15-DAY)		OT	DE-TORRENT-00013010			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy	Topiramate			S		Unknown		Unknown
	Quensyl			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2019	10869853	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015017112		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Enbrel		S	Subcutaneous	50 Mg, Qwk		Amgen
	Apo-Prednisone		S	Unknown	5 Mg, Unk		Not Reported
	Cimzia		S	Subcutaneous	400 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Mg, Bid		Not Reported
	Orencia		S	Unknown	125 Mg, Unk		Not Reported
	Plaquenil		S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate		S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate /00113802/		S	Unknown	15 Mg, Qwk		Not Reported
	Prednisone		S	Unknown	Unk		Not Reported
	Arava		S	Unknown	20 Mg, Qd		Not Reported
	Actonel		C	Unknown	35 Mg, Qwk		Not Reported
	Prevacid		C		30 Mg, Qd		Not Reported
	Folate		C		1 Mg, Qd		Not Reported
	Folate		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2019	15087619	NON-EXPEDITED			US-AMGEN-USASP2018087073			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Burning Sensation; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Cellcept			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	11099614	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015044186		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	12342945	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016055450		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; No Adverse Event	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Gold			S	Intramuscular	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

		Azathioprine			S	Unknown	Unk			Not Reported
		Apo-Azathioprine			S	Unknown	Unk			Not Reported
		Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	12488334	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA115157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral			Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold			S		Unk Unk, Unk		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	12671508	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016002463		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	13360740	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA043465		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis;	Arava			S	Oral	20 Mg,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Methotrexate			S	Unknown	17.5 Mg To 25 Mg Every Week		Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown	2 G,Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported

Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure	Methotrexate Sodium	S				Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Orencia	S				Not Reported
	Tramacet	S	Unknown	Unk Unk,Unk		Not Reported
	Actonel	C	Unknown	35 Mg,Qw		Not Reported
	Calcium	C	Unknown	Unk Unk,Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk Unk,Unk		Not Reported
	Lorazepam	C	Unknown	1 Mg,Unk		Not Reported
	Lyrica	C	Oral	150 Mg,Bid		Not Reported
	Metformin	C	Unknown	5 Mg,Qd		Not Reported
	Metformin	C	Unknown	500 Mg,Bid		Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg,Qm		Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg,Qm		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk Unk,Qm		Not Reported
	Nortriptyline	C	Unknown	Unk Unk,Unk		Not Reported
	Nortriptyline	C	Unknown	Unk Unk,Unk		Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Mg,Qd		Not Reported
	Premarin	C	Unknown	.625 Mg,Unk		Not Reported
	Paracetamol	C	Unknown	Unk Unk,Unk		Not Reported
	Vagifem	C	Unknown	Unk Unk,Unk		Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk Unk, Unk		Not Reported
	Depomedrol	C	Unknown	Unk Unk, Unk		Not Reported
	Depomedrol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	14169099	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210781		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Bone Erosion; C-Reactive Protein	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi

Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Plaquenil	S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate	S				Sanofi
	Sulfasalazine	S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk		Not Reported
	Apo-Leflunomide	S				Not Reported
	Actemra	S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk Unk,Unk Solution		Not Reported
	Enbrel	S	Unknown	50 Mg,Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi	S	Unknown	Unk Unk,Unk Solution		Not Reported
	Arava	C	Unknown	Unk Unk,Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]	C				Not Reported
	Cymbalta	C				Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15415983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Mobicox			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15461094	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-088539			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Joint Warmth; Localised Infection; Osteomyelitis; Rheumatoid Arthritis	Abatacept			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15538604	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1078849		5 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Haemoptysis; Product Use In Unapproved Indication; Pulmonary Fibrosis; Pulmonary Haemosiderosis	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15639779	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA131149		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia;	Plaquenil			S		Unk		Sanofi

Cholecystectomy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Sleep Disorder	Arava	S		Unk	Sanofi
	Methotrexate	S	Subcutaneous	25 Mg,Qw	Not Reported
	Celecoxib	S		200 Mg,Bid	Not Reported
	Lorazepam	S		1 Mg	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Cyclosporine	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Dilaudid	S			Not Reported
	Prednisone	C	Unknown	10 Mg,Qd	Not Reported
	Morphine	C	Unknown	Unk Unk,Unk	Not Reported
	Citalopram	C		10 Mg	Not Reported
	Gold	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15693549	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-059153			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy	Topiramate			S	Unknown	Unk, Dosage Form: Unspecified		Aurobindo
	Quensyl			S	Unknown	Unk, Dosage Form: Unspecified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15785823	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397111		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia;	Arava			S	Oral			Sanofi

Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Methotrexate	S			Not Reported
	Plaquenil	S	Oral		Sanofi
	Enbrel	S			Not Reported
	Actemra	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Mobicox	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15838874	NON-EXPEDITED			US-PFIZER INC-2019021841		68 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846732	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Remicade			S	Unknown					Not Reported
	Rituxan			S	Unknown					Not Reported
	Simponi			S	Unknown					Not Reported
	Imuran			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846795	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-100042		25 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	1.5 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846806	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001169		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Rectal			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846811	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-100043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Neuropathy Peripheral	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846814	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001304			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846815	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Treatment Failure; Vasculitis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846912	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1000935		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846913	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1000989		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Cough; Drug Ineffective; Hypoaesthesia; Intraocular Pressure Test Abnormal; Malnutrition; Migraine; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Platelet Count Decreased; Vision Blurred; Visual Impairment; Weight Increased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15846937	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001006			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tocilizumab			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847050	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Finger Deformity; Malaise; Pain; Pulmonary Fibrosis	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847068	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-999883		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Erythro-Base			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Risedronate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847074	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-999879		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide	S	Unknown	20 Milligram Daily;		Barr
	Actemra	S	Unknown			Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Sulfasalazine	C	Oral	1 Gram Daily;		Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847089	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-999893		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847715	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Leflunomide			S	Oral	20 Milligram Daily;		Barr

Ineffective; Joint Swelling; Pain	Methotrexate	S	Oral			Barr
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Lyrica	S	Oral	300 Milligram Daily;		Not Reported
	Tylenol/00020001/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847758	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Plaquenil			S	Oral			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Simponi			C	Unknown	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15847890	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-100022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Eye Disorder; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Nodule	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15848076	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001114			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	2.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15848311	NON-EXPEDITED			US-PFIZER INC-2019026165		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15848676	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014021305		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Diarrhoea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Plaquenil			S	Oral	200 Mg, Unk		Not Reported
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Orencia			S	Unknown	250 Mg, Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported
	Naproxen			C	Oral	500 Mg, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849263	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA012190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported

Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis; Rheumatoid Arthritis	Plaquenil	S	Oral	200 Mg, Bid		Sanofi
	Indometacin	S	Oral	50 Mg, Qid		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk		Not Reported
	Actemra	S		4 Mg/Kg, Q4w		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Q8w		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849499	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001734		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Venlafaxine Hydrochloride			S	Oral	150 Milligram Daily;		Teva
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849531	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001738		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Venlafaxine Hydrochloride			S	Unknown			Teva
	Venlafaxine Hydrochloride			S	Oral	37.5 Milligram Daily;		Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

			Folic Acid		C	Unknown	12.5 Milligram Daily;			Not Reported
			M-Eslon		C		20 Milligram Daily;			Not Reported
			Morphine		C					Not Reported
			Morphine Sulfate		C					Not Reported
			Statex		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849695	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1005001		6 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Pulmonary Haemosiderosis	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2019	15849853	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2019M1005046		47 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective	Mycophenolate Mofetil			S	Unknown	1.5 Gram, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	2 G Per Day		Not Reported
	Mycophenolate Mofetil			S	Unknown	2.5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg Per Day		Not Reported
	Prednisolone			S	Unknown	5 Mg Per Day		Not Reported
	Prednisolone			S	Unknown	1 Milligram/Kilogram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	11604032	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2015103390		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	12313620	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016231208		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Overdose	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Celebrex			S	Unknown	200 Mg, Unk		Pfizer
	Celebrex			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Naprosyn			S	Unknown	500 Mg, Bid		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	12678345	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016008247		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Pain Upper;	Enbrel			S	Unknown	Unk		Pfizer

Arthritis; Chest Pain; Condition Aggravated; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Arava	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	12694526	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016249361		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk (B.I.Wk)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Gold			S	Intramuscular	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

		Hydroxychloroquine			S	Unknown	Unk			Not Reported
		Apo-Hydroxyquine			S	Unknown	Unk			Not Reported
		Apo-Leflunomide			S	Unknown	Unk			Not Reported
		Azathioprine			S	Unknown	Unk			Not Reported
		Apo-Azathioprine			S	Unknown	Unk			Not Reported
		Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	12805351	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Cimzia			S	Subcutaneous	Unk		Ucb
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	13085484	NON-EXPEDITED			US-PFIZER INC-2016598462		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Augmentin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Evoxac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	14185430	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017169884		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Mg, Qd		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Apo Prednison			S	Unknown	10.0 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	14196075	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491474		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50.0 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25.0 Mg, Qwk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Varenicline Tartrate			S	Oral	1 Df, Qd		Pfizer
	Varenicline Tartrate			S	Oral	Unk Unk, Qwk		Pfizer
	Apo Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20.0 Mg, Unk		Not Reported

Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
Plaquenil	S	Oral	400 Unk, Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Esomeprazole Magnesium W/Naproxen	C	Oral	500 Mg, Bid	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
Rosuvastatin Calcium	C	Oral	Unk	Not Reported
Rosuvastatin Calcium	C	Oral	Unk	Not Reported
Valtrex	C	Oral	1000 Mg, Bid	Not Reported
Valtrex	C	Unknown	Unk	Not Reported
Xeljanz	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral	500 Mg, Bid	Not Reported
Naproxen	C		Unk	Not Reported
Naproxen	C	Oral	500 Mg, Bid	Not Reported
Oxycodone Hydrochloride	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	14858510	EXPEDITED (15-DAY)		OT	GB-ORION CORPORATION ORION PHARMA-18_00003584			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Joint Swelling; Liver Injury;	Methotrexate (Trade Name Unknown)			S	Unknown	Reduced Dose		Not Reported

Pain; Peripheral Swelling	Methotrexate (Trade Name Unknown)	S	Unknown	Reduced Dose	Not Reported
	Actemra	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Cortisone Acetate	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Endep	C	Unknown		Not Reported
	Amitriptyline Hydrochloride	C	Unknown		Not Reported
	Tapentadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15046130	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2018M1041894		63 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenocarcinoma Of Colon	Azathioprine			S		100 Mg, Unk		Not Reported
	Azathioprine			S		200 Mg, Unk		Not Reported
	Azathioprine			S		150 Mg, Unk		Not Reported
	Azathioprine			S		50 Mg, Unk		Not Reported
	Azathioprine			S		100 Milligram, Unk		Not Reported
	Azathioprine			S		50 Milligram, Unk		Not Reported
	Azathioprine			S		150 Milligram, Unk		Not Reported
	Azathioprine			S		200 Milligram, Unk		Not Reported
	Azathioprine			S		100 Milligram,Unk		Not Reported
	Azathioprine			S		150 Milligram, Unk		Not Reported
	Azathioprine			S		50 Mg, Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Azathioprine			S		50 Milligram, Unk		Not Reported
	Prednisone			S		5 Mg, Qd		Mylan

Hydroxychloroquine	S	400 Mg, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15804351	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sarilumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15826485	EXPEDITED (15-DAY)		HO	PHHO2018US011260		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Encephalopathy	Gsk2118436			S	Oral	150 Mg, Bid		Not Reported
	Gsk1120212			S	Oral	2 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Not Reported
	Clobazam			S	Oral	10 Mg, Qd		Not Reported
	Clobazam			S	Oral	5 Mg, Qd		Not Reported
	Clobazam			S	Oral	2.5 Mg, Qd		Not Reported
	Lacosamide			S	Oral	250 Mg, Bid		Not Reported
	Lacosamide			S	Oral	200 Mg, Bid		Not Reported
	Lamictal			S	Oral	300 Mg, Bid		Not Reported
	Lamictal			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2019	15851610	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2019-00125		82 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Type Iv Hypersensitivity Reaction	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	200 Mg, Qd (1st Week)		Lupin
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (2nd Week)		Lupin
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	11434208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015075439		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	12578625	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015330946		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Neoplasm; Decreased Immune Responsiveness; Lyme Disease	Enbrel			S	Subcutaneous	Unk			Pfizer
	Methotrexate Sodium			S	Unknown	Unk			Pfizer
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Plaquenil			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	12727015	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1663		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Asthenia; Bone Marrow Failure; Macular Degeneration; Muscle Atrophy; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Losartan			C	Unknown	Strength: 100 Mg		Not Reported
	Pantoprazole			C	Unknown	Strength: 40 Mg		Not Reported
	Acetylsalicylic Acid			C	Unknown	Strength: 80 Mg		Not Reported
	Calcium			C	Unknown	Strength: 500 Mg		Not Reported
	Vitamin D Nos			C	Unknown	Strength: 1000 Mg		Not Reported
	Folic Acid			C	Unknown	Strength: 5 Mg		Not Reported
	Atorvastatin			C	Oral	Strength: 40 Mg		Not Reported
	Atenolol			C	Unknown	Strength: 50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14191101	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490780		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug	Enbrel			S	Subcutaneous	Unk		Pfizer

Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	20.0 Mg, Qd		Not Reported
	Apo Hydroxyquine	S	Unknown	Unk		Not Reported
	Apo Prednison	S	Unknown	10.0 Mg, Qd		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14221809	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017174847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	14236013	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006502		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; C-Reactive Protein Abnormal; Chronic Sinusitis; Drug	Hydroxychloroquine			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Intolerance; Infection; Monocytosis; Nausea; Neutropenia; Pruritus; Psoriasis; Red Blood Cell Sedimentation Rate Abnormal; Sinusitis; Synovitis; Urinary Tract Infection	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15235208	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Product Use Issue	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	1 Every 2 Years		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Arava	S	Oral	2 Times/Wk	Not Reported
Arava	S	Oral	3 Times/Wk	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral	2 Times/Wk	Not Reported
Arava	S	Unknown	2 Times/Wk	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Humira	S	Subcutaneous	Cyclical	Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown	Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported

	Plaquenil			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15661322	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015067667		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Plaquenil			S	Unknown	200 Mg, 2x/Day(2 Every 1 Day)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day (Daily)(1 Every 24 Hours)		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Qwk		Not Reported
	Orencia			S	Unknown	125 Mg, Unk		Not Reported
	Actonel			C	Unknown	35 Mg, Qwk		Not Reported
	Folate			C	Unknown	1 Mg, 1x/Day(Daily)		Not Reported
	Folate			C				Not Reported
	Prevacid			C	Unknown	30 Mg, 1x/Day (Daily) (1 Every 24 Hours)		Not Reported
	Prevacid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15803198	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019009378		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	25 Mg, Weekly		Unknown

Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S		20 Mg, Weekly	Pfizer
	Actemra	S		Unk	Not Reported
	Arava	S		20 Mg, 1x/Day	Not Reported
	Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		200 Mg, Every 2 Weeks	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		200 Mg, Every 2 Weeks	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15846733	EXPEDITED (15-DAY)			CH-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000106			Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Imurek			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2019	15859979	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2019M1005549		38 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pancytopenia; Toxicity To Various Agents; Vasculitis Necrotising	Hydroxychloroquine			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	10392232	EXPEDITED (15-DAY)		OT	BR-ROCHE-1401352		67 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthritis; Asthenia; Back Pain; Blood Pressure Increased; Blood Urea Increased; Body Height Decreased; Bone Disorder; C-Reactive Protein Increased; Choking; Dizziness; Drug Hypersensitivity; Fatigue; Finger Deformity; Gait Disturbance; Hand Deformity; Hand Fracture; Headache; Hepatic Steatosis; Hepatic Steatosis; Hepatomegaly; Influenza; Joint Dislocation; Joint Swelling; Mobility Decreased; Muscular Weakness; Nausea; Pain; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Increased; Spinal Disorder; Spinal Pain; Tenosynovitis; Vein Disorder; Weight Decreased; Weight Decreased	Actemra			S	Intravenous (not otherwise specified)	The Most Recent Infusion Was On 16/Jul2/014. Most Recent Infusion Of Actemra On 02/Jan/2019.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Monthly Dosage: 680mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Recent Infusion Prior To Adverse Event		Not Reported
	Cortisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Half Tablet		Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Chondroitin			C				Not Reported
	Atacand			C				Not Reported
	Harpagophytum Procumbens			C				Not Reported
	Aradois			C				Not Reported
	Ultracet			C				Not Reported
	Methotrexate			C				Not Reported
	Alenia (Brazil)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	13825322	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Chelonae Infection	Prednisone			S	Unknown			Mutual
	Mycophenolate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15860950	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861057	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3429			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rash	Methotrexate (Trade Name Unknown)		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Citalopram Hydrobromide		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Citalopram Hydrobromide W/Mirtazapine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861223	EXPEDITED (15-DAY)		OT	FR-ZYDUS-032693			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication	Mycophenolic Acid			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861231	EXPEDITED (15-DAY)		OT	FR-ZYDUS-032691			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication	Mycophenolic Acid			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861323	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000164			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tubulointerstitial Nephritis	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15861669	EXPEDITED (15-DAY)		OT	CN-IPCA LABORATORIES LIMITED-IPC-2019-CN-000062			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Dexamethasone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15862015	EXPEDITED (15-DAY)		OT	PHHY2018GB198704		63 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Erythema; Oral Discomfort; Periorbital Oedema; Pyrexia; Rash; Scab; Skin Discolouration; Skin Reaction; Swelling Of Eyelid	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15863297	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634377-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Glossodynia;	Humira			S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15864632	NON-EXPEDITED			US-ALLERGAN-1831281US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Concussion; Dyspnoea; Fatigue; Head Injury	Pred Forte			S	Unknown			Allergan
	Enbrel			S		50 Mg, Q Week		Not Reported

	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2019	15865384	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2019002131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Drug Ineffective; Malaise	Cimzia			S	Subcutaneous			Ucb
	Apo-Leflunomide			S		20 Mg, Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S		400 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	12705657	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1514		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

	Anakinra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	13114498	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001489		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Apo-Hydroxyquine			S		400 Mg, Once Daily (Qd)		Not Reported
	Arava			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		400 Mg, Once Daily (Qd)		Not Reported
	Salazopyrin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	13380674	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001979		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure	Aclasta	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Unknown			Not Reported
	Humira	S				Not Reported
	Methotrexate	S	Unknown	17.5 Mg To 25 Mg		Not Reported
	Methotrexate	S				Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Methotrexate Sodium	S				Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported
	Tramacet	S	Unknown			Not Reported
	Actonel	C				Not Reported
	Calcium	C				Not Reported
	Ergocalciferol	C				Not Reported
	Lorazepam	C				Not Reported
	Lyrica	C				Not Reported
	Metformin	C				Not Reported
	Methylprednisolone Acetate	C				Not Reported
	Nortriptyline	C				Not Reported
	Nortriptyline Hydrochloride	C				Not Reported
	Premarin	C				Not Reported
	Paracetamol	C				Not Reported
	Vagifem	C				Not Reported
	Vitamin D2	C				Not Reported
	Depomedrol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	13564686	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1975999-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Drug Ineffective; Hepatic	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Prednisone		C		Not Reported
	Prednisone		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14174009	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006339		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Arava		C		Not Reported
	Aspirin		C		Not Reported
	Cymbalta		C		Not Reported
	Hydromorphone		C		Not Reported
	Synthroid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14234848	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006533		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Anakinra	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported
	Cortisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14309947	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017001278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Pre-Filled Syringe		Not Reported
	Actemra			S				Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tofacitinib Citrate			C	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Folic Acid			C	Oral	5 Mg, Once Daily (Qd)		Not Reported
	Leflunomide			C	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14311700	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050962		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pelvic Fracture; Pneumonitis; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	400 Mg, Unk		Ucb
	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported
	Leflunomide			S		10 Mg, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	Unk, Weekly (Qw)		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Apo-Leflunomide			S		10 Mg, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day (Bid)		Not Reported
	Prednisone			C				Not Reported
	Arava			C				Not Reported
	Tofacitinib Citrate			C	Oral	5 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14311990	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050974		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Cimzia			S	Subcutaneous			Ucb
	Arava			S		20 Mg, Unk		Not Reported
	Azathioprine Sodium			S		25 Mg, Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S		1 G, Unk		Not Reported

Apo-Azathioprine	S	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14313120	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051342		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intracranial Pressure Increased; Meningitis; Meningitis Aseptic	Cimzia			S	Subcutaneous	Unk		Ucb
	Apo-Hydroxyquine			S		Unk		Not Reported
	Salazopyrin			S		1 G, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	14570432	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0515		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Folate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15034325	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15536756	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1078857		365 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication;	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Pulmonary Haemosiderosis; Pulmonary Hypertension

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15605579	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0866		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Palpitations; Stomatitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown	As Needed		Not Reported
	Tylenol With Codeine			C	Unknown			Not Reported
	Mometasone Furoate			C	Unknown			Not Reported
	Metoprolol Tartrate			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; C-Reactive Protein Abnormal; Chronic Sinusitis; Drug Intolerance; Infection; Monocytosis; Nausea; Neutropenia; Pruritus; Psoriasis; Red Blood Cell Sedimentation Rate Abnormal; Sinusitis; Synovitis; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15835219	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000097		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Off Label Use; Pulmonary Embolism; T-Cell Lymphoma	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown	High Dose		Not Reported
	Prednisone			S	Unknown	>20 Mg Daily		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Rituximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15865666	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019002249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

	Orencia			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15865779	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003076		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15865815	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1003852		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Fall; Gait Disturbance; Osteoarthritis; Post Procedural Infection; Spinal Fracture; Upper Limb Fracture	Prednisone			S	Unknown			Actavis
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15865980	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003870		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15866130	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0182		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15866882	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000153		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15867106	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-003		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Blindness; Photopsia; Retinal Toxicity; Visual Field Defect	Hydroxychloroquine			S	Unknown			Hikma
	Levothyroxine			C	Unknown			Not Reported
	Dexlansoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Coenzyme Q10			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15867276	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004023		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Oral			Not Reported

Treatment Failure	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868172	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002157		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rash; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Hydroxychloroquine			S	Oral	300 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	300 Mg, Once Daily (Qd)		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868349	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000152			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Arava	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15868475	NON-EXPEDITED			US-TEVA-2019-US-994528			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Restless Legs Syndrome	Hydroxychloroquine			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2019	15869149	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS-2019M1006668		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ischaemic Stroke; Varicella Zoster Virus Infection; Viral Vasculitis	Prednisolone			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2019	15871107	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004848		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Macular Degeneration; Tuberculin	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Test Positive

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2019	15876675	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004867		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			C				Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	12248144	EXPEDITED (15-DAY)		OT	CA-ROCHE-1710094		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Inflammation; Mouth Ulceration; Pain; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Magic Mouthwash (Nystatin)			S	Unknown			Not Reported
	Magic Mouthwash (Nystatin)			S				Not Reported
	Arava			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Tongue Ulceration; Tooth Infection; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Indocin (United States)	C			Not Reported
	Tramadol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	13870098	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017350904		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	13943098	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017033656		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Reaction; Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use;	Cimzia			S	Subcutaneous	Unk		Ucb
	Plaquenil			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S	Subcutaneous	Pre Filled Syringe		Not Reported

Pain; Rheumatoid Arthritis; Sleep Disorder	Minocin	S		Unk	Not Reported
	Apremilast	S		Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Myochrysine	S	Intramuscular	Solution	Not Reported
	Salazopyrin	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	C		Unk	Not Reported
	Rheumatrex	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	14058071	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182819		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Paracetamol			S		325 Mg		Not Reported
	Tylenol [Paracetamol]			S	Unknown	Unk Unk,Prn		Not Reported
	Apo-Acetaminophen			S				Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S				Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported

Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Orencia		S	Unknown	Unk Unk,Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Simponi		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Sulfasalazine		S	Oral	2000 Mg,Unk	Not Reported
	Meloxicam		C	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate		C	Unknown	25 Mg,Qw	Not Reported
	Synthroid		C	Unknown	Unk Unk,Unk	Not Reported
	Codeine Phosphate		C	Unknown	Unk Unk,Unk	Not Reported
	Celebrex		C	Oral	200 Mg,Bid	Not Reported
	Hydromorph		C	Unknown	Unk Unk,Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	14198916	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3654		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednison			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	14703565	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2018012683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day (Bid)		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15605736	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1042		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Decreased Immune Responsiveness; Lyme Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15669752	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK214712		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Occlusion; Fear	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15754775	EXPEDITED (15-DAY)		OT	US-ROCHE-2232624			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Liver Disorder; Memory Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15857433	NON-EXPEDITED			PHHY2019CN008357		55 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nail Pigmentation; Traumatic Haematoma	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	100 Mg, Qd		Novartis
	Prednisone			C	Oral	40 Mg, Qd		Not Reported
	Prednisone			C		10 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878144	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000169			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity; Pulmonary Fibrosis	Plaquenil			S						Concordia
	Methotrexate			S						Not Reported
	Imuran			S						Not Reported
	Latex			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878195	NON-EXPEDITED			US-PFIZER INC-2019034682		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Albuterol [Salbutamol]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878375	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001527			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Diverticulitis; Joint Swelling; Liver Injury; Pain; Peripheral Swelling	Plaquenil			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cortisone Acetate			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Prednisolone			C				Not Reported
	Endep			C				Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Tapentadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878444	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019012819		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Etanercept			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Qwk		Not Reported
	Prednisone			C	Unknown	30 Mg, Qd		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878491	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight	Cimzia			S	Subcutaneous			Ucb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S		Unk		Not Reported

Increased	Plaquenil	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Ibuprofen	C	600 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15878824	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002453		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Hypersensitivity; Lung Disorder; Pneumonitis; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Ucb
	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Ucb
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day (Bid)		Not Reported
	Leflunomide			S		10 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S				Not Reported
	Methotrexate			S	Oral	Unk, Weekly (Qw)		Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15879010	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002245		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Musculoskeletal Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Unevaluable Event	Cimzia			S	Subcutaneous	200 Mg, Unk		Ucb
	Apo-Hydroxyquine			S	Oral	300 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15879088	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002483		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	400 Mg		Ucb
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Apo-Hydroxyquine			S		400 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Weekly (Qw)		Not Reported
	Sulfasalazine			S		500 Mg 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15880126	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002459			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S		Unk		Ucb
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	Unk Unk, Ev 2 Weeks(Qow)		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S		Unk		Not Reported
	Folic Acid			C	Oral	05 Mg, Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15880886	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004790		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Pain; Pruritus; Rash; Swelling	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15880887	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004791		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Asa			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881078	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1007143			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881459	EXPEDITED (15-DAY)		HO	PHHY2019DE014362			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Humerus Fracture; Mobility Decreased	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	Methotrexate			S	Unknown	10 Mg, Unk		Novartis
	No Treatment Received			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Cimzia			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Unk		Not Reported
	Mabthera			S	Unknown	1000 Mg, Unk		Not Reported
	Simponi			S	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881855	NON-EXPEDITED			US-SA-2019SA022166			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibrinolysis; Hypersensitivity; Limb Discomfort	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15881998	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018432999		64 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Empyema	No Subject Drug			S		No Dose Given		Not Reported
	Lantarel			S		20 Mg, Weekly		Pfizer
	Lantarel			S		15 Unk, Unk		Pfizer
	Lantarel			S		22.5 Mg, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer
	Lantarel			S		22.5 Unk, Unk		Pfizer

Lantarel	S	22.5 Unk, Unk	Pfizer
Sulfasalazine	S	2000 Mg, Unk	Pfizer
Sulfasalazine	S	2000 Mg, Unk	Pfizer
Leflunomid	S	10 Mg, Daily	Not Reported
Leflunomid	S	Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2019	15883362	DIRECT		LT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	12489806	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115394		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Rheumatoid Arthritis; Synovitis	Plaquenil			S		400 Mg,Qd		Sanofi
	Arava			S		20 Mg,Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg,Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg,Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg,Unk		Not Reported
	Methotrexate			S	Oral	15 Mg,Unk		Not Reported
	Methotrexate			S	Oral	20 Mg,Unk		Not Reported
	Methotrexate			S	Oral	25 Mg,Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	12491784	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115274		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Disorder	Plaquenil			S	Oral	400 Mg,Bid		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate Sodium			S	Oral	20 Mg,Qow		Not Reported
	Sulfasalazine			S	Unknown	1 G,Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	12701648	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1486		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	13948093	EXPEDITED (15-DAY)		OT	CA-ROCHE-1708212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15219919	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1012		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15819448	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0048		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea;	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name			S	Intravenous (not			Not Reported

Product Complaint; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Unknown)		otherwise specified)	
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15864417	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019030753		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Etanercept			S	Subcutaneous	Unk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

	Desoximetasone	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	25 Mg, Weekly		Not Reported
	Prednisone	C	Unknown	30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15882441	NON-EXPEDITED		OT	TR-LUPIN PHARMACEUTICALS INC.-2018-08030		55 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15882442	NON-EXPEDITED		OT	AU-GENERIC HEALTH PTY. LTD.-2018-08185		58 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	400 Mg, Qd (7.3 Mg/Kg Actual Body Weight)		Lupin
	Hydroxychloroquine			S	Unknown	200 Mg, Qd (3.7 Mg/Kg Actual Body Weight)		Lupin
	Methotrexate			C	Unknown	Unk		Not Reported
	Fluticasone W/Salmeterol			C	Unknown	Unk		Not Reported
	Tiotropium Bromide			C	Unknown	Unk		Not Reported
	Telmisartan			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15882443	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2018-07745		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15882868	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003927		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			S	Unknown	2.5 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C				Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C	Oral	5 Milligram Daily;		Not Reported
	Humira			C	Unknown			Not Reported
	Indapamide			C	Oral	1.25 Milligram Daily;		Not Reported
	Naprosyn			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Pantoloc			C	Oral	40 Milligram Daily;		Not Reported
	Perindopril			C	Oral	2 Milligram Daily;		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Tylenol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15883075	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2019012223			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk		Amgen
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Penicillin	S	Unknown	Unk		Not Reported
	Entocort	S	Unknown	Unk		Not Reported
	Gentamycin	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Sulfanilamide	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2019	15888821	DIRECT		DS			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Migraine With Aura; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine			S	Oral	Quantity:2 Tablet(S);	13 YR	Amneal
	Pot Chloride			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Azathioprine			C				Not Reported
	Carvedilol			C				Not Reported
	Pantoprazole			C				Not Reported
	Restatis			C				Not Reported
	Ventafaxine			C				Not Reported
	Zolpiden Tartrate			C				Not Reported
	Areds Preser Vision			C				Not Reported
	Multi Vitamin			C				Not Reported
	Citracal			C				Not Reported
	Night Time Lude For Eyes			C				Not Reported
	Systane Ultra Drops			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	13100775	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	08/--/2002 To 05/--/2005		Not Reported
	Enbrel			S	Unknown	Duration 730 Days		Not Reported
	Arava			S	Oral	Dose And Frequency Unknown.		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Dose And Frequency Unknown.		Not Reported
	Imuran			S	Unknown	Dose And Frequency Unknown		Not Reported
	Sulfasalazine			S	Unknown	Dose And Frequency Unknown.		Not Reported
	Ciclosporin			S	Oral	Dose And Frequency Unknown.		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral	Dose And Frequency Unknown		Not Reported

	Certolizumab	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown	Dose And Frequency Unknown.		Not Reported
	Cyclosporine	S	Oral	Dose And Frequency Unknown		Not Reported
	Methotrexate Sodium	S	Unknown	Dose And Frequency Unknown.		Not Reported
	Azathioprine	S	Unknown	Dose And Frequency Unknown.		Not Reported
	Lyrica	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Prednisone	C				Not Reported
	Piroxicam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	13184798	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1856209-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Drug Ineffective; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Acetaminophen			C						Not Reported
	Gabapentin			C						Not Reported
	Reactine (Canada)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	13965959	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020124		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Ml,Qw		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Ml, Qw		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	13989695	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2090540-00		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15323471	EXPEDITED (15-DAY)			US-SA-2018SA236094			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Leflunomide			S				Sanofi
	Plaquenil			S				Sanofi
	Orencia			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15580900	EXPEDITED (15-DAY)		HO, LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003820		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Cellcept			C				Not Reported
	Prednisolone			C				Not Reported
	Nu-Lotan			C				Not Reported
	Magmitt			C				Not Reported
	Atorvastatin			C				Not Reported
	Sodium Rabeprazole			C				Not Reported

	Sodium Rabeprazole			C						Not Reported
	Sennoside A+B			C						Not Reported
	Baktar			C						Not Reported
	Baktar			C						Not Reported
	Onealfa			C						Not Reported
	Polaprezinc			C						Not Reported
	Hyalein			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15805350	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000041		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15860015	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1006034		6 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Product Use In Unapproved Indication; Pulmonary Haemosiderosis	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Cyclophosphamide			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15887225	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3483		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bronchitis; Pneumonia; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15890281	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2636803-00		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Liver Injury; Memory Impairment; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15893342	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000167		58 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basedow'S Disease	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2019	15893347	EXPEDITED (15-DAY)		HO, LT	US-CONCORDIA PHARMACEUTICALS		53 YR	Female	USA

INC.-GSH201901-000170

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Rituximab			S				Not Reported
	Rituximab			S				Not Reported
	Adalimumab			S				Not Reported
	Adalimumab			S				Not Reported
	Prednisone			S		Continues On Lower-Dose		Not Reported
	Prednisone			S				Not Reported
	Azathioprine			S		Continues On Lower-Dose		Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	12216702	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015000517		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Injection Site Reaction; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	13280419	EXPEDITED (15-DAY)		OT	CA-ROCHE-1681465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Years		Not Reported
	Actemra			S	Intravenous (not	Therapy Duration: 4 Years		Not Reported

Failure			otherwise specified)		
	Enbrel	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 9 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 9 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 10 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 21 Years	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 21 Years	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	14069409	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005674		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Arava	S	Oral		Not Reported
	Paracetamol	S	Unknown	As Needed	Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Leflunomide	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Tylenol [Paracetamol]	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Codeine Phosphate	C			Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C			Not Reported
	Synthroid	C			Not Reported
	Celebrex	C			Not Reported
	Hydromorph	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	14740567	EXPEDITED (15-DAY)		HO, OT	PHHY2018MY055787		32 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Urinary Tract Infection	Methylprednisolone			S	Unknown	500 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	250 Mg, Unk		Not Reported
	Prednisolone			S	Oral	1 Mg/Kg, Unk		Not Reported

	Hydroxychloroquine	S	Unknown	200 Mg, Qd		Novartis
	Cardiprin (Acetylsalicylic Acid)	S	Unknown	100 Mg, Qd		Not Reported
	Tinzaparin	S	Subcutaneous	3500 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15732948	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594054-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Gold			C				Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15771543	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018532151		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dupuytren'S Contracture; Limb Injury; Osteoarthritis	Methotrexate Sodium			S	Oral	Up To 25mg Weekly		Pfizer
	Sulfasalazine			S				Pfizer
	Plaquenil [Hydroxychloroquine			S				Not Reported

	Sulfate] Champix			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15893526	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19P-163-2638252-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported

Methotrexate Sodium	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Topicort	S	Subcutaneous	Not Reported
Topicort	S	Other	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Stelara	S	Unknown	Not Reported

	Golimumab	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Salazopyrin	C			Not Reported
	Atasol (Acetaminophen)	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894269	EXPEDITED (15-DAY)		OT	US-SAKK-2019SA025247AA			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Chronic Kidney Disease; Neuropathy Peripheral	Arava			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894484	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2019-00369		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Peripheral Swelling; Transaminases Increased; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin
	Rifampin			S	Unknown	Unk		Not Reported
	Rifampin			S	Unknown	Unk		Not Reported
	Rifampin			S	Unknown	Unk		Not Reported
	Rifampin			S	Unknown	Unk		Not Reported
	Rifampin			S	Unknown	Unk, Resumed		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported

	Ethambutol			S	Unknown	Unk	Not Reported
	Ethambutol			S	Unknown	Unk, Resumed	Not Reported
	Pyrazinamide			S	Unknown	Unk	Not Reported
	Pyrazinamide			S	Unknown	Unk	Not Reported
	Pyrazinamide			S	Unknown	Unk	Not Reported
	Pyrazinamide			S	Unknown	Unk	Not Reported
	Pyrazinamide			S	Unknown	Unk, Resumed	Not Reported
	Isoniazid			S	Unknown	Unk	Not Reported
	Isoniazid			S	Unknown	Unk	Not Reported
	Isoniazid			S	Unknown	Unk	Not Reported
	Isoniazid			S	Unknown	Unk	Not Reported
	Isoniazid			S	Unknown	Unk, Resumed	Not Reported
	Prednisone			S	Unknown	30 Mg, Qd	Not Reported
	Prednisone			S	Unknown	10 Mg, Qd	Not Reported
	Levofloxacin			C	Unknown	Unk	Not Reported
	Trimethoprim Sulfamethoxazole			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894528	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000102			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Peripheral Swelling; Pyomyositis; Transaminases Increased	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Ipca
	Ethambutol			S		Unk		Not Reported
	Prednisone			S	Unknown	30 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Rifampin			S				Not Reported
	Isoniazid			S				Not Reported
	Pyrazinamide			S				Not Reported
	Trimethoprim-Sulfamethoxazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894817	EXPEDITED (15-DAY)		DE, HO, OT	CA-SAKK-2019SA023282AA			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bacteraemia; Clostridium Difficile Infection; Colitis; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Disseminated Strongyloidiasis; Escherichia Infection; Gastrointestinal Haemorrhage; Headache; Htlv-1 Carrier; Nausea; Pyrexia; Seizure; Somnolence; Stress Ulcer; Venous Thrombosis; Vomiting; Weight Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S		Prolonged Course		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15894871	DIRECT	N	HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Shoulder Operation	Hydroxychloroquine			S	Oral			Mylan
	Baclofen/Calcitonin			C				Not Reported
	Celecoxib/Gemfibrozil			C				Not Reported
	Levothyroxin			C				Not Reported
	Irbesartan			C				Not Reported
	Oxycontin			C				Not Reported
	Metformin			C				Not Reported
	Gemfibrozil			C				Not Reported
	Venlafaxine			C				Not Reported
	Lyrica			C				Not Reported

	Topiramate	C	Not Reported
	Pantoprazole	C	Not Reported
	Ranitidine	C	Not Reported
	Methylpred	C	Not Reported
	Oxycod/Apap	C	Not Reported
	Amox/K Clav	C	Not Reported
	Oxybutynin	C	Not Reported
	Fluocinonide	C	Not Reported
	Amoxicillin	C	Not Reported
	Diltiazem	C	Not Reported
	Ketoconazole	C	Not Reported
	Doxycycl Hyc	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2019	15895083	EXPEDITED (15-DAY)		HO	PHHY2019PT020387		40 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Leukoplakia; Pancytopenia; Product Use Issue; Vitamin D Deficiency	Prednisolone			S	Unknown	1 Milligram/Kilogram Per Day		Novartis
	Amlodipine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sildenafil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	12235484	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015002850		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Injection Site Reaction; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day (Freq: 2 Day: Interval:1)		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

	Remicade			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15432732	EXPEDITED (15-DAY)			CH-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003414			Unknown	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dyspnoea	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S				Concordia
	Imurek			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15694039	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0105952			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Tacrolimus			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15707279	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA024549			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported

	Arava	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk;	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15721065	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004112		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Retinal Detachment	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 M/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 M/Day, Alternately		Concordia
	Prednisolone			C				Not Reported
	Gaster D			C				Not Reported
	Lunesta			C				Not Reported
	Halcion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898325	NON-EXPEDITED			US-TEVA-2019-US-999955			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Hydroxychloroquine Sulfate Tablets Teva			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15898429	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000183		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Erythema; Hypotension; Hypoxia; Mycobacterial Infection; Necrosis; Pneumocystis Jirovecii Pneumonia; Pustule; Pyrexia; Rash Erythematous; Respiratory Distress; Telangiectasia	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	Weaned From 60 To 20 Mg/D		Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Pyrazinamide			C				Not Reported
	Trimethoprim Sulfamethoxazole			C				Not Reported
	Rifampin			C				Not Reported
	Isoniazid			C				Not Reported
	Ethambutol			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15899324	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA018385			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

					Orencia	S	Unknown	Unk	Not Reported
					Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Simponi	S	Subcutaneous	Unk	Not Reported
					Tocilizumab	S	Unknown	Unk	Not Reported
					Desoximetasone	C		Unk	Not Reported
					Methotrexate	C		25 Mg, Weekly	Not Reported
					Prednisone	C		30 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2019	15901306	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019038861		31 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pruritus; Pyrexia; Rash	Methylprednisolone			S	Oral	20 Mg, 1x/Day		Pfizer
	Kai Shi			S	Intravenous drip	10 Ug, 2x/Day		Not Reported
	Shenmai Injection			S	Intravenous drip	50 Ml, 1x/Day		Not Reported
	Fen Le [Hydroxychloroquine Sulfate]			S	Oral	0.1 G, 2x/Day		Not Reported
	Acetylcysteine			S	Oral	0.6 G, 2x/Day		Not Reported
	Docusate Sodium			S	Oral	0.1 G, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2019	15903205	NON-EXPEDITED			PHEH2019US005056			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2019	15903245	EXPEDITED (15-DAY)		OT	PHHY2019ES020388			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2019	15903246	EXPEDITED (15-DAY)		OT	PHHY2019KR020397		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2019	15903786	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010554		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Cataract; Cerebrovascular Accident; Crying; Depressed Mood; Disability; Disease Progression; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Fine Motor Skill Dysfunction; Foot Deformity; Gait Disturbance; Hand Deformity; Hepatitis C; Hypokinesia; Impaired Healing; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Muscle Spasms; Musculoskeletal Disorder; Musculoskeletal Pain; Myalgia; Nodule; Peripheral Swelling; Rheumatoid Arthritis;	Plaquenil Tablet			S	Oral			Concordia
	Xeljanz			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Ativan			C				Not Reported
	Senokot			C				Not Reported
	Coversyl			C				Not Reported
	Percocet			C				Not Reported
	Lovastatin			C				Not Reported
	Flexeril			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported

Shoulder Deformity; Sleep Disorder Due To A General Medical Condition; Swelling; Weight Decreased; Wrist Deformity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	13173098	NON-EXPEDITED			US-ABBVIE-16K-163-1592072-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14442334	NON-EXPEDITED			US-ABBVIE-17K-163-2056002-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Joint Swelling; Nausea; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Oral And Injection		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14443147	NON-EXPEDITED			US-ABBVIE-17K-163-2059309-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Dermatitis Allergic; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14445371	NON-EXPEDITED			US-ABBVIE-17K-163-2061219-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Hypersensitivity; Pruritus; Rash; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Nifedipine			S	Subcutaneous			Not Reported
	Leflunomide			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14446191	NON-EXPEDITED			US-ABBVIE-17P-163-2059696-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Nausea; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14447541	NON-EXPEDITED			US-ABBVIE-17K-163-2114625-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14451243	NON-EXPEDITED			US-ABBVIE-17K-163-2178741-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14451393	NON-EXPEDITED			US-ABBVIE-17K-163-2178750-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Exposure During Pregnancy; Eye Disorder; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Leflunomide			C	Unknown				Not Reported
		Enbrel			C					Not Reported
		Xeljanz			C	Oral				Not Reported
		Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	14451871	NON-EXPEDITED		OT	US-ABBVIE-17K-163-2207238-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Gastrointestinal Haemorrhage; Infection; Nausea; Pneumonia; Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15780587	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3953		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dupuytren'S Contracture; Limb Injury; Osteoarthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral	Dose: Up To 25mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Champix			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15795945	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000031		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15904232	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000156		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15904406	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0114		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Pain In Extremity; Peripheral Swelling	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15907166	NON-EXPEDITED			US-PFIZER INC-2019041686		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908043	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA109478		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Methotrexate			S	Oral	25 Mg, Qm		Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg Qw		Not Reported
	Actemra			S	Intravenous (not	8 Mg Qm		Not Reported

							otherwise specified)			
					Cimzia	S				Not Reported
					Orencia	S	Subcutaneous	125 Mg, Qw		Not Reported
					Apo-Hydroxyquine	S	Oral	400 Mg, Qd		Not Reported
					Methotrexate Sodium	S	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908076	NON-EXPEDITED			US-ABBVIE-18K-163-2260557-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pruritus	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908190	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2287912-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Infection; Mouth Ulceration; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908202	NON-EXPEDITED			US-ABBVIE-18K-163-2212390-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gastrointestinal Disorder; Nausea	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908206	NON-EXPEDITED			US-ABBVIE-18K-163-2289518-00		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Immunosuppression; Pneumonia; Pneumonia; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	One Tablet In The Morning, One Tablet At Night		Not Reported
	Xeljanz			S	Oral	One Tablet In The Morning, One Tablet At Night		Not Reported
	Xeljanz			S	Oral	One Tablet In The Morning, One Tablet At Night		Not Reported
	Methotrexate			S	Unknown	Into Stomach		Not Reported
	Methotrexate			S	Unknown	Into Stomach		Not Reported
	Methotrexate			S	Unknown	Into Stomach		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Streptomycin			S	Unknown			Not Reported
	Augmentin			S	Unknown			Not Reported

	Penicillin	S	Unknown			Not Reported
	Keflex	S	Unknown			Not Reported
	Lincocin	S	Unknown			Not Reported
	Sulfa	S	Unknown			Not Reported
	Hyzaar	C	Oral			Not Reported
	Nexium	C	Oral	One To Two Times A Day		Not Reported
	Folic Acid	C	Ophthalmic			Not Reported
	Coreg	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908246	NON-EXPEDITED			US-ABBVIE-18K-163-2254447-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908260	NON-EXPEDITED			US-ABBVIE-18K-163-2252853-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908302	NON-EXPEDITED			US-ABBVIE-18K-163-2213915-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Disorder; Headache; Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908305	NON-EXPEDITED			US-ABBVIE-18K-163-2297426-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Liver Function Test Increased; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908307	NON-EXPEDITED			US-ABBVIE-18K-163-2301633-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908319	NON-EXPEDITED			US-ABBVIE-18K-163-2270666-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Nausea	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908330	NON-EXPEDITED			US-ABBVIE-18K-163-2265283-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pruritus	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908334	NON-EXPEDITED			US-ABBVIE-18K-163-2226507-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Diarrhoea; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Mouth Ulceration	Humira			S	Subcutaneous			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Azathioprine			S	Unknown				Not Reported
		Methotrexate			S	Unknown				Not Reported
		Methotrexate			S	Subcutaneous				Not Reported
		Methotrexate			S	Oral				Not Reported
		Cimzia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908380	NON-EXPEDITED			US-ABBVIE-18K-163-2304633-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908430	NON-EXPEDITED			US-ABBVIE-18K-163-2297428-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Savella			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908435	NON-EXPEDITED			US-ABBVIE-18K-163-2252602-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908522	NON-EXPEDITED			US-ABBVIE-18K-163-2289369-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Ineffective; Drug Intolerance; Lung Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquinol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908548	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2283315-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Rash; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908606	NON-EXPEDITED			US-ABBVIE-18K-163-2258738-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Xeljanz			C	Oral	Daily Once -30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908623	NON-EXPEDITED			US-ABBVIE-18K-163-2282879-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908657	NON-EXPEDITED			US-ABBVIE-18K-163-2267045-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Nausea; Vision Blurred	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908745	NON-EXPEDITED			US-ABBVIE-18K-163-2297424-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908764	NON-EXPEDITED			US-ABBVIE-18K-163-2289304-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Vomiting	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908781	NON-EXPEDITED			US-ABBVIE-18K-163-2231563-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908793	NON-EXPEDITED			US-ABBVIE-18K-163-2282850-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Level Decreased; Drug Level Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908837	NON-EXPEDITED			US-ABBVIE-18K-163-2266773-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Fatigue; Pain; Rash; Tachyphylaxis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908859	NON-EXPEDITED			US-ABBVIE-18K-163-2209565-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Actemra			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908877	NON-EXPEDITED			US-ABBVIE-18K-163-2237795-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Nausea; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908885	NON-EXPEDITED			US-ABBVIE-18K-163-2265111-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug Intolerance; Injection Site Reaction; Therapeutic Product Effect Decreased; Urticaria; Urticaria; Urticaria	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Otezla			S	Unknown			Not Reported
	Otezla			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908887	NON-EXPEDITED			US-ABBVIE-18K-163-2297406-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908903	NON-EXPEDITED			US-ABBVIE-18K-163-2231519-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908917	NON-EXPEDITED			US-ABBVIE-18K-163-2231606-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Glucose-6-Phosphate Dehydrogenase Abnormal; Hepatic Enzyme	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Plaquenil		S	Unknown		Not Reported
	Meloxicam		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908948	NON-EXPEDITED			US-ABBVIE-18K-163-2258816-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Transaminases Increased; Vision Blurred	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15908952	NON-EXPEDITED			US-ABBVIE-18K-163-2215147-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Infection; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909040	NON-EXPEDITED			US-ABBVIE-18K-163-2209532-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hepatic Enzyme Increased; Nausea; Peripheral Swelling; Rash;	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Swelling Face; Vomiting	Plaquenil			S	Unknown			Not Reported
	Aclexa			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909076	NON-EXPEDITED			US-ABBVIE-18K-163-2303723-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pneumonia; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909122	NON-EXPEDITED			US-ABBVIE-18K-163-2294096-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909134	NON-EXPEDITED			US-ABBVIE-18K-163-2251009-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Influenza Like Illness; Paraesthesia; Rash; Urticaria	Humira			S	Subcutaneous	Not Reported
	Arava			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Cimzia			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909167	NON-EXPEDITED			US-ABBVIE-18K-163-2289316-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909191	NON-EXPEDITED			US-ABBVIE-18K-163-2220567-00		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Increased; Blood Urea Increased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dysstasia; Gait Inability; Joint Effusion; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Stiffness; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nodule; Osteoarthritis; Pain; Peripheral Swelling;	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Levothyroxine			C				Not Reported
	Amlodipine			C	Oral			Not Reported
	Tums			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported

Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Toxicity To Various Agents	Tramadol	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909214	NON-EXPEDITED			US-ABBVIE-18K-163-2265276-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909219	NON-EXPEDITED			US-ABBVIE-18K-163-2265042-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909231	NON-EXPEDITED			US-ABBVIE-18K-163-2254455-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Enbrel			S	Unknown					Not Reported
	Xeljanz Xr			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909236	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2265162-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Humira			S	Subcutaneous	> 3 Months		Not Reported
	Methotrexate			S	Unknown	> 3 Months		Not Reported
	Arava			S	Unknown	> 3 Months		Not Reported
	Sulfasalazine			S	Unknown	> 3 Months		Not Reported
	Orencia			S	Unknown	> 3 Months		Not Reported
	Plaquenil			S	Unknown	> 3 Months		Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909270	NON-EXPEDITED			US-ABBVIE-18K-163-2265021-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909280	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2254438-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Gastrointestinal Haemorrhage; Infection; Nausea; Pneumonia; Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

					Methotrexate		S	Unknown		Not Reported
					Methotrexate		S	Oral		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909301	NON-EXPEDITED			US-ABBVIE-18K-163-2258863-00		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Nausea; Neurological Symptom; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909303	NON-EXPEDITED			US-ABBVIE-18K-163-2276336-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909320	NON-EXPEDITED			US-ABBVIE-18K-163-2265078-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira		S			Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909331	NON-EXPEDITED			US-ABBVIE-18K-163-2289515-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909332	NON-EXPEDITED			US-ABBVIE-18K-163-2212427-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909339	NON-EXPEDITED			US-ABBVIE-18K-163-2282900-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909346	NON-EXPEDITED			US-ABBVIE-18K-163-2209559-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909384	NON-EXPEDITED			US-ABBVIE-18K-163-2266814-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909388	NON-EXPEDITED			US-ABBVIE-18K-163-2218802-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909389	NON-EXPEDITED			US-ABBVIE-18K-163-2283321-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Level Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909412	NON-EXPEDITED			US-ABBVIE-18K-163-2234933-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Actemra			C				Not Reported
	Xeljanz			C	Oral	30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909421	NON-EXPEDITED			US-ABBVIE-18K-163-2282962-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Drug Intolerance; Gastrointestinal Disorder; Gastrointestinal Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Arava			C		Not Reported
	Xeljanz			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909455	NON-EXPEDITED			US-ABBVIE-18K-163-2251030-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909464	NON-EXPEDITED			US-ABBVIE-18K-163-2231786-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Injection Site Swelling	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909480	NON-EXPEDITED			US-ABBVIE-18K-163-2209538-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Xeljanz Xr		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909482	NON-EXPEDITED			US-ABBVIE-18K-163-2248803-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909485	NON-EXPEDITED			US-ABBVIE-18K-163-2252860-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909551	NON-EXPEDITED			US-ABBVIE-18K-163-2297268-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous	Not Reported
	Arava			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909558	NON-EXPEDITED			US-ABBVIE-18K-163-2279945-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Eruption; Drug Ineffective; Fatigue; Pain; Tachyphylaxis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909576	NON-EXPEDITED			US-ABBVIE-18K-163-2212434-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909585	NON-EXPEDITED			US-ABBVIE-18K-163-2289475-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hypersensitivity; Skin Hyperpigmentation; Transaminases Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	20 Years		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909615	NON-EXPEDITED			US-ABBVIE-18K-163-2297130-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Liver Function Test Increased; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909623	NON-EXPEDITED			US-ABBVIE-18K-163-2303840-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Mouth Ulceration	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909636	NON-EXPEDITED			US-ABBVIE-18K-163-2289446-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Hydroxychloroquine		S	Unknown	Not Reported
	Remicade		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909645	NON-EXPEDITED			US-ABBVIE-18K-163-2231369-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909648	NON-EXPEDITED			US-ABBVIE-18K-163-2258840-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Pancreatitis; Rash Vesicular	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909672	NON-EXPEDITED			US-ABBVIE-18K-163-2237845-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Drug Intolerance; Fear Of Injection; Headache; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909675	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2283304-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Renal Cell Carcinoma	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909685	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2292171-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Elbow Operation; Injection Site Pain; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909696	NON-EXPEDITED			US-ABBVIE-18K-163-2234968-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909705	NON-EXPEDITED			US-ABBVIE-18K-163-2289354-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Xeljanz Xr			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909719	NON-EXPEDITED			US-ABBVIE-18K-163-2289504-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Headache; Nausea	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909728	NON-EXPEDITED			US-ABBVIE-18K-163-2287831-00		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Range Of Motion Decreased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Lamotrigine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909731	NON-EXPEDITED			US-ABBVIE-18K-163-2282892-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Diarrhoea; Drug Ineffective	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909738	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2289414-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Lyme Disease; Myocardial Infarction; Nervous System Disorder	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909744	NON-EXPEDITED			US-ABBVIE-18K-163-2282977-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909755	NON-EXPEDITED			US-ABBVIE-18K-163-2297397-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported

Arthralgia; Drug Ineffective	Plaquenil			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909785	NON-EXPEDITED			US-ABBVIE-18K-163-2233439-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909806	NON-EXPEDITED			US-ABBVIE-18K-163-2297423-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909821	NON-EXPEDITED			US-ABBVIE-18K-163-2239801-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909841	NON-EXPEDITED			US-ABBVIE-18K-163-2248436-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infectious Mononucleosis; Influenza	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909908	NON-EXPEDITED			US-ABBVIE-18K-163-2233479-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Oral	Quantity 30 (30 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909925	NON-EXPEDITED			US-ABBVIE-18K-163-2343058-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Nausea; Tremor	Humira			S	Unknown			Not Reported
	Vicodin			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909938	NON-EXPEDITED			US-ABBVIE-18K-163-2346226-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909957	NON-EXPEDITED			US-ABBVIE-18K-163-2338870-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Eye Disorder; Headache; Pain	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909963	NON-EXPEDITED			US-ABBVIE-18K-163-2251604-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15909998	NON-EXPEDITED			US-ABBVIE-18K-163-2226618-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Lung Disorder; Pneumonia; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910002	NON-EXPEDITED			US-ABBVIE-18K-163-2305323-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Grip Strength Decreased; Hand Deformity; Loss Of Personal Independence In Daily Activities; Nausea	Humira			S	Subcutaneous			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910007	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2327610-00		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910190	NON-EXPEDITED			US-ABBVIE-18K-163-2341100-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Feeling Abnormal; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910237	NON-EXPEDITED			US-ABBVIE-18K-163-2335456-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ultram			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfa			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910270	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2390640-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Aspartate Aminotransferase Increased; Blood Potassium Decreased; Drug Ineffective; Fatigue; Hair Growth Abnormal; Nasal Ulcer; Pneumonia	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported
	Xeljanz Xr			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910294	NON-EXPEDITED			US-ABBVIE-18K-163-2314134-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dry Mouth; Dyspepsia; Fatigue; Gastrointestinal Disorder; Gastrointestinal Pain; Haematochezia; Haematochezia; Hyperhidrosis; Injection Site Pain; Nasal Congestion; Nausea; Pruritus	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actmera			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910297	NON-EXPEDITED			US-ABBVIE-18K-163-2330863-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug	Adalimumab			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective	Methotrexate			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910353	NON-EXPEDITED			US-ABBVIE-18K-163-2367063-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910407	NON-EXPEDITED			US-ABBVIE-18K-163-2408647-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910415	NON-EXPEDITED			US-ABBVIE-18K-163-2307825-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

		Methotrexate Injection			S	Other				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910448	NON-EXPEDITED			US-ABBVIE-18K-163-2322839-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Depression; Drug Ineffective; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910499	NON-EXPEDITED			US-ABBVIE-18K-163-2381319-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Aspartate Aminotransferase Increased; Blood Potassium Decreased; Drug Ineffective; Drug Ineffective; Fatigue; Nasal Ulcer; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910503	NON-EXPEDITED			US-ABBVIE-18K-163-2387188-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Oedema; Drug Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported

Hypersensitivity; Drug Ineffective; Drug Ineffective; Dysphagia	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910523	NON-EXPEDITED			US-ABBVIE-18K-163-2307797-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910611	NON-EXPEDITED			US-ABBVIE-18K-163-2405292-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ultram			C				Not Reported
	Motrinex			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910629	NON-EXPEDITED			US-ABBVIE-18K-163-2402716-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Adverse Drug Reaction	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910698	NON-EXPEDITED			US-ABBVIE-18K-163-2367047-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance; Fear Of Injection; Injection Site Reaction; Nausea; Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S				Not Reported
	Xeljanz Xr			C	Oral			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910711	NON-EXPEDITED			US-ABBVIE-18K-163-2405829-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Rash	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910718	NON-EXPEDITED			US-ABBVIE-18K-163-2408648-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Fatigue	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910759	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2353565-00		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Coronary Artery Bypass; Depression; Drug Ineffective; Dyspnoea; Osteomyelitis; Paraesthesia; Toe Operation	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910763	NON-EXPEDITED			US-ABBVIE-18K-163-2319431-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous				Not Reported
	Cimzia			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910776	NON-EXPEDITED			US-ABBVIE-18K-163-2308918-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910794	NON-EXPEDITED			US-ABBVIE-18K-163-2343060-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910801	NON-EXPEDITED			US-ABBVIE-18K-163-2349276-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective	Methotrexate			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910822	NON-EXPEDITED			US-ABBVIE-18K-163-2344803-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Synovitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910843	NON-EXPEDITED			US-ABBVIE-18K-163-2314965-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Azulfidine			S	Unknown			Not Reported
	Azulfidine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

	Plaquenil			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910875	NON-EXPEDITED			US-ABBVIE-18K-163-2381321-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Migraine	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910894	NON-EXPEDITED			US-ABBVIE-18K-163-2382842-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Infection; Liver Function Test Increased; Liver Function Test Increased; Malaise; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910897	NON-EXPEDITED			US-ABBVIE-18K-163-2359894-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910921	NON-EXPEDITED			US-ABBVIE-18K-163-2354986-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910925	NON-EXPEDITED			US-ABBVIE-18K-163-2319706-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral	Once Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15910997	NON-EXPEDITED			US-ABBVIE-18K-163-2398434-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Macrobid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911020	NON-EXPEDITED			US-ABBVIE-18K-163-2325643-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911034	NON-EXPEDITED			US-ABBVIE-18K-163-2378477-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel			S						Not Reported
	Remicade			S	Unknown					Not Reported
	Remicade			S						Not Reported
	Cimzia			S	Unknown					Not Reported
	Cimzia			S						Not Reported
	Orencia			S	Unknown					Not Reported
	Orencia			S						Not Reported
	Arava			S	Unknown					Not Reported
	Arava			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911084	NON-EXPEDITED			US-ABBVIE-18K-163-2342489-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Infection; Oral Candidiasis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911118	NON-EXPEDITED			US-ABBVIE-18K-163-2355418-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Rash Macular; Skin Swelling; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911122	NON-EXPEDITED			US-ABBVIE-18K-163-2358330-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911126	NON-EXPEDITED			US-ABBVIE-18K-163-2335406-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911143	NON-EXPEDITED			US-ABBVIE-18K-163-2307833-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulphasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911154	NON-EXPEDITED			US-ABBVIE-18K-163-2341107-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective	Enbrel				S	Unknown				Not Reported
	Plaquenil				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911166	NON-EXPEDITED			US-ABBVIE-18K-163-2306959-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Injection Site Reaction; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911178	NON-EXPEDITED			US-ABBVIE-18K-163-2313141-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Pain; Swelling; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911215	NON-EXPEDITED			US-ABBVIE-18K-163-2327324-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911221	NON-EXPEDITED			US-ABBVIE-18K-163-2382815-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Liver Function Test Increased; Therapy Non-Responder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911263	NON-EXPEDITED			US-ABBVIE-18K-163-2306989-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Sulfa			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911287	NON-EXPEDITED			US-ABBVIE-18K-163-2382847-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911323	NON-EXPEDITED			US-ABBVIE-18K-163-2389201-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911332	NON-EXPEDITED			US-ABBVIE-18K-163-2325667-00		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Depression; Drug Ineffective; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911375	NON-EXPEDITED			US-ABBVIE-18K-163-2310670-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contusion; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Actemra			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911391	NON-EXPEDITED			US-ABBVIE-18K-163-2313175-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911409	NON-EXPEDITED			US-ABBVIE-18K-163-2337217-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911416	NON-EXPEDITED			US-ABBVIE-18K-163-2314918-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug	Humira			S	Subcutaneous			Not Reported

Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911490	NON-EXPEDITED			US-ABBVIE-18K-163-2394781-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Respiratory Tract Infection; Sinusitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sst			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911536	NON-EXPEDITED			US-ABBVIE-18K-163-2322861-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911553	NON-EXPEDITED			US-ABBVIE-18K-163-2415718-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911577	NON-EXPEDITED			US-ABBVIE-18K-163-2305143-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspnoea; Fatigue; Nausea; Tachycardia; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911614	NON-EXPEDITED			US-ABBVIE-18K-163-2367071-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911620	NON-EXPEDITED			US-ABBVIE-18K-163-2330899-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Headache; Liver Function Test Abnormal; Malaise; Nausea; Palmoplantar Pustulosis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911626	NON-EXPEDITED			US-ABBVIE-18K-163-2318166-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Inflammatory Marker Increased; Mouth Ulceration; Rash	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911703	NON-EXPEDITED			US-ABBVIE-18K-163-2310638-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatic Enzyme Increased; Injection Site Reaction; Transaminases Increased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911714	NON-EXPEDITED			US-ABBVIE-18K-163-2314878-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Azulfidine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911724	NON-EXPEDITED			US-ABBVIE-18K-163-2378471-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911738	NON-EXPEDITED			US-ABBVIE-18K-163-2319724-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Atena			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Cellcept				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911763	NON-EXPEDITED			US-ABBVIE-18K-163-2415700-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug Intolerance; Hepatitis B Virus Test Positive; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911820	NON-EXPEDITED			US-ABBVIE-18K-163-2363847-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911841	NON-EXPEDITED			US-ABBVIE-18K-163-2310626-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911860	NON-EXPEDITED			US-ABBVIE-18K-163-2308241-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911867	NON-EXPEDITED			US-ABBVIE-18K-163-2306962-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Infection; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Quality Of Life Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911904	NON-EXPEDITED			US-ABBVIE-18K-163-2305318-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911907	NON-EXPEDITED			US-ABBVIE-18K-163-2330730-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911938	NON-EXPEDITED			US-ABBVIE-18K-163-2389206-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911980	NON-EXPEDITED			US-ABBVIE-18K-163-2308916-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fine Motor Skill Dysfunction; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15911993	NON-EXPEDITED			US-ABBVIE-18K-163-2307798-00		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Headache; Herpes Zoster; Hypokalaemia; Injection Site Reaction; Joint Swelling; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Arthritis; Syncope; Synovitis; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Mtx			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912024	NON-EXPEDITED			US-ABBVIE-18K-163-2365663-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspnoea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912130	NON-EXPEDITED			US-ABBVIE-18K-163-2469258-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912236	NON-EXPEDITED		OT	US-ABBVIE-18K-163-2447736-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Deformity; Drug Eruption; Grip Strength Decreased; Loss Of Personal	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil		S	Unknown	Not Reported
	Azulfidine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912259	NON-EXPEDITED			US-ABBVIE-18K-163-2426543-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Colitis Microscopic; Inflammation; Intestinal Ulcer; Joint Swelling; Limb Discomfort; Mouth Ulceration; Peripheral Swelling; Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Mtx			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912298	NON-EXPEDITED			US-ABBVIE-18K-163-2494988-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Epistaxis; Paraesthesia	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicaide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912391	NON-EXPEDITED			US-ABBVIE-18K-163-2426546-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blister; Drug Hypersensitivity; Drug Hypersensitivity; Rash; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912462	NON-EXPEDITED			US-ABBVIE-18K-163-2420640-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Injection Site Pain; Leukopenia; Mouth Ulceration; Retinal Disorder; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912473	NON-EXPEDITED			US-ABBVIE-18K-163-2447780-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912632	NON-EXPEDITED			US-ABBVIE-18K-163-2427859-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nodule	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912649	NON-EXPEDITED			US-ABBVIE-18K-163-2425054-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912695	NON-EXPEDITED			US-ABBVIE-18K-163-2467929-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Latent Tuberculosis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912796	NON-EXPEDITED			US-ABBVIE-18K-163-2475753-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15912942	NON-EXPEDITED			US-ABBVIE-18K-163-2463172-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913082	NON-EXPEDITED			US-ABBVIE-18K-163-2463178-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913140	NON-EXPEDITED			US-ABBVIE-18K-163-2499511-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Retinal Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913419	NON-EXPEDITED			US-ABBVIE-18K-163-2514544-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913499	NON-EXPEDITED			US-ABBVIE-18K-163-2501960-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913650	NON-EXPEDITED			US-ABBVIE-18K-163-2417650-00		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclobenzaprin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Enbrel			S	Unknown	50mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913739	NON-EXPEDITED			US-ABBVIE-18K-163-2496436-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Fatigue; Liver Function Test Increased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913752	NON-EXPEDITED			US-ABBVIE-18K-163-2424766-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea	Humira			S	Subcutaneous			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Arava			S	Unknown				Not Reported
		Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913760	NON-EXPEDITED			US-ABBVIE-18K-163-2429262-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Rash; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913771	NON-EXPEDITED			US-ABBVIE-18K-163-2446795-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Gastrointestinal Disorder; Musculoskeletal Pain; Osteoarthritis; Osteopenia; Pain; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cymbalta			C				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913838	NON-EXPEDITED			US-ABBVIE-18K-163-2439075-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Remicade			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913850	NON-EXPEDITED			US-ABBVIE-18K-163-2500260-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913867	NON-EXPEDITED			US-ABBVIE-18K-163-2484810-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Infection; Liver Function Test Increased; Product Use In Unapproved Indication	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Etanercept			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15913899	NON-EXPEDITED			US-ABBVIE-18K-163-2499522-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz Xr	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914123	NON-EXPEDITED			US-ABBVIE-18K-163-2516587-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Infection; Infection; Poor Venous Access; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Vascular Device Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914341	NON-EXPEDITED			US-ABBVIE-18K-163-2455587-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914449	NON-EXPEDITED			US-ABBVIE-18K-163-2500258-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914518	NON-EXPEDITED			US-ABBVIE-18K-163-2484502-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914572	NON-EXPEDITED			US-ABBVIE-18K-163-2469493-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Sulfasalazine				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914629	NON-EXPEDITED			US-ABBVIE-18K-163-2508113-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Hcq			S	Oral			Not Reported
	Enbrel			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914631	NON-EXPEDITED			US-ABBVIE-18K-163-2507410-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Skin Discolouration	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914744	NON-EXPEDITED			US-ABBVIE-18K-163-2490231-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Influenza Like Illness	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914887	NON-EXPEDITED			US-ABBVIE-18K-163-2548257-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Somnolence	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15914955	NON-EXPEDITED			US-ABBVIE-18K-163-2538155-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15915127	NON-EXPEDITED			US-ABBVIE-18K-163-2541431-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Drug Ineffective; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15915136	NON-EXPEDITED			US-ABBVIE-18K-163-2556176-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Infection; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15915268	NON-EXPEDITED			US-ABBVIE-18K-163-2541357-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rash; Rash	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2019	15915735	NON-EXPEDITED			US-ABBVIE-18K-163-2596450-00		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Liver Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Decreased; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	12885274	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2015-0006005		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Dilaudid			S	Unknown	Unk		Purdue
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	13123627	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1835547-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

					Remicade	S	Intravenous (not otherwise specified)			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Rituxan	S	Intravenous (not otherwise specified)			Not Reported
					Apo-Hydroxyquine	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	13579085	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-002033		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	13968430	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005234		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15526638	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2522484-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Fatigue; Hyperhidrosis; Intervertebral Disc	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Poor Quality Sleep; Temperature Intolerance; Therapeutic Product Effect Incomplete; Vomiting	Xeljanz	S	Oral		Not Reported
	Hydromorphone	S	Oral		Not Reported
	Percocet	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15762266	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-119565		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Liver Disorder; Memory Impairment; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15916733	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000202		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Peripheral Swelling; Pneumonia; Pyomyositis; Transaminases Increased	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S		Tapered		Not Reported
	Rifampicin			S	Unknown			Not Reported

	Rifampicin	S			Not Reported
	Rifampicin	S			Not Reported
	Rifampicin	S			Not Reported
	Isoniazid	S	Unknown		Not Reported
	Isoniazid	S			Not Reported
	Isoniazid	S			Not Reported
	Pyrazinamide	S	Unknown		Not Reported
	Ethambutol	S	Unknown		Not Reported
	Ethambutol	S			Not Reported
	Ethambutol	S			Not Reported
	Ethambutol	S			Not Reported
	Trimethoprim Sulfamethoxazole	C			Not Reported
	Levofloxacin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15916997	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007237		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15916998	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1007711		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Impaired Work Ability; Loss Of Personal Independence In Daily Activities	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15917140	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15917144	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007214		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Drug Hypersensitivity; Drug Ineffective; Hepatitis	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown	1 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15918679	NON-EXPEDITED			US-SA-2019SA030009			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glucose-6-Phosphate Dehydrogenase Abnormal; Hepatic Enzyme Increased; Therapeutic Response Decreased	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Meloxicam			S		Unk Unk, Unk		Not Reported

	Sulfasalazine			S		Unk Unk, Unk			Not Reported
	Plaquenil			S		Unk Unk, Unk			Sanofi
	Enbrel			S		Unk Unk, Unk			Not Reported
	Xeljanz			S		Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15920389	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1007407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15920424	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007501		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15920484	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007272		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Methotrexate		S	Subcutaneous	Barr
	Methotrexate		S	Oral	Barr
	Actemra		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15920787	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007742		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15921180	EXPEDITED (15-DAY)		OT	CA-ROCHE-2258823		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported

Arthritis; Rheumatoid Factor Positive	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi		S	Subcutaneous	Solution	Not Reported
	Arthrotec		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Imuran		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15928082	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000207			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Chronic Kidney Disease; Neuropathy Peripheral	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2019	15928162	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1008137		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous	20 Mg		Barr
	Methotrexate			S	Oral	20 Mg		Barr
	Methotrexate			S	Oral	20 Mg		Barr

Leflunomide	S	Unknown		Barr
Neoral	S	Subcutaneous		Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous		Not Reported
Apo-Hydroxyquine	S	Subcutaneous		Not Reported
Rituxan	S	Unknown		Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Mg	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	11449567	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-15K-028-1454383-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	11925927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1411809-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate			S	Unknown	Variable Doses 10 To 20 Mg		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Dexamethasone			C				Not Reported
	Cortisone Infiltration			C				Not Reported
	Acetaminophen			C				Not Reported

		Gabapentin			C					Not Reported
		Reactine [Cetirizine Hydrochloride]			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	12262173	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1600077-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Drug Ineffective; Joint Stiffness; Joint Swelling; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Gold (198 Au)			S	Unknown			Not Reported
	Indocid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Cymbalta	C	Oral		Not Reported
	Folic Acid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	12918918	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-16K-028-1771095-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Oral				Not Reported
		Hydroxychloroquine			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13112057	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876559		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous	Therapy Duration: 8 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Therapy Duration: 6 Months		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13157219	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1846768-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Product Effect Decreased	Actemra		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Apo Hydroxyquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Lyrica		C	Oral	Not Reported
	Prednisone		C		Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13191146	EXPEDITED (15-DAY)		DS	CA-ROCHE-1888720		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Indometacin			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	Frequency: Every 1 Day		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Prednisone		S	Unknown		Not Reported
	Prednisone		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution For Injection	Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Actemra		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Cymbalta		C	Oral		Not Reported
	Folic Acid		C	Oral		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13195504	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 365.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Apo-Hydroxyquine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13229065	EXPEDITED (15-DAY)		OT	CA-ROCHE-1892565		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Therapy Duration: 2.0 Year(S)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration 505.0 Day(S)		Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13242895	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1876032-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Ill-Defined Disorder; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13248252	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001133		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Cortisone	C		Not Reported
	Dexamethasone	C		Not Reported
	Desoximetasone	C		Not Reported
	Acetaminophen	C		Not Reported
	Gabapentine	C		Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13606666	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity;	Actemra			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Rituxan			S	Intravenous (not	Therapy Duration: 9		Not Reported

Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Treatment Failure			otherwise specified)	Months	
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Therapy Duration: 2 Years	Not Reported
	Enbrel	S	Unknown	Therapy Duration: 730 Not Otherwise Specified	Not Reported
	Enbrel	S	Unknown	Therapy Duration: 4 Years	Not Reported
	Enbrel	S	Unknown	Therapy Duration: 731 Not Otherwise Specified	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 5 Months	Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 5 Months	Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 1 Month	Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years	Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 2 Months	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Imuran	C			Not Reported
	Vitamin D3	C			Not Reported
	Arthrotec	C	Unknown		Not Reported
	Clindamycin	C			Not Reported
	Cloxacillin	C			Not Reported
	Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	13692484	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003792		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	14899274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1570719-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Zostavax	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Voltaren	C		Not Reported
	Cortisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15631783	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1541702-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported

Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo Mycophenolate	S	Unknown	Not Reported
Kineret	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15736047	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2244219-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

Ineffective; Hypertensive Crisis; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope; Presyncope	Plaquenil	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15923250	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2650232-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Voltarene (Diclofenac Sodium)			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15923280	EXPEDITED (15-DAY)		HO, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-198214		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basilar Artery Stenosis; Headache; Ischaemic Stroke; Ivth Nerve	Prednisolone			S	Unknown	Unk		Taro
	Methotrexate			S	Unknown	Unk		Sun

Paralysis; Nausea; Pyrexia; Varicella Zoster Virus Infection	Tacrolimus			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15923845	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007265		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bladder Prolapse	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15923975	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007397		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Localised Infection; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15924091	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007364		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported

Swelling; Tongue Ulceration; Tooth Infection	Orencia			S	Unknown				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Indometacin			C					Not Reported
	Prednisone			C					Not Reported
	Tramadol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15924095	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007369		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15925154	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-005710			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Leukoplakia; Pancytopenia; Product Use Issue; Vitamin D Deficiency	Amlodipine			S	Unknown	Unk		Aurobindo
	Sildenafil			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	1 Milligram/Kilogram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15925931	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653343-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15928223	EXPEDITED (15-DAY)		OT	US-SA-2019SA031966			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Neuropathy Peripheral; Rheumatoid Arthritis	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15928883	EXPEDITED (15-DAY)		OT	PHHY2018ES171074		37 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Pregnancy; Coagulation Test Abnormal; Complement Factor C3 Decreased; Complement Factor C4 Decreased; Hyponatraemia; Maternal Exposure During Pregnancy; Postpartum Haemorrhage; Proteinuria; Thrombocytopenia	Prednisone			S	Oral	2.5 Mg, Qd		Novartis
	Prednisone			S	Oral	5 Unk, Unk		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Not Reported
	Bemiparin Sodium			S	Unknown	2500 U/L, Qd		Not Reported
	Aspirin			S	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929079	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832232		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929525	NON-EXPEDITED			US-SA-2019SA031917			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Arava			S	Unknown	Unk, Unk		Sanofi
	Pregabalin			S	Unknown	200 Mg, Bid		Not Reported
	Amoxicillin			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Ciprofloxacin Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Levofloxacin			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929536	NON-EXPEDITED			US-SA-2019SA032139			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Peripheral Swelling	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929544	NON-EXPEDITED			US-SA-2019SA032095			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Arava			S		20 Mg		Sanofi
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Bid		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929551	NON-EXPEDITED			US-SA-2019SA032075			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Drug Ineffective; Drug Intolerance; Unevaluable Event	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929912	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007871		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C		200 Milligram Daily;		Not Reported
	Esomeprazole Magnesium			C				Not Reported

	Trihydrate		
	Hydroxychloroquine	C	Not Reported
	L-Thyroxine	C	Not Reported
	Tylenol Arthritis Pain	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2019	15929934	EXPEDITED (15-DAY)		OT	PHHY2019AU025047		17 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cholecystitis; Cryoglobulinaemia; Disease Progression; Fatigue; Haematochezia; Malaise; Mood Swings; Nephrocalcinosis; Neuropathy Peripheral; Neutropenia; Palindromic Rheumatism; Paraproteinaemia; Polyarthritis; Purpura; Recrudescent Typhus; Sjogren'S Syndrome; Stomatitis; Tenosynovitis; Tubulointerstitial Nephritis; Vasculitis	Methotrexate			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	11620575	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1477924-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Vaginal	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Abatacept	C		Not Reported
	Anakinra	C		Not Reported
	Ativan	C		Not Reported
	Benadryl	C		Not Reported
	Cortisone Drops	C	Oral	Not Reported
	Cortisone Drops	C	Intramuscular	Not Reported
	Darifenacin	C		Not Reported
	Dilaudid	C		Not Reported
	Dilaudid	C		Not Reported

	Dilaudid	C		Not Reported
	Lasix	C		Not Reported
	Leflunomide	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C		Not Reported
	Pantoloc	C		Not Reported
	Synthroid	C		Not Reported
	Vagifem	C	Vaginal	Not Reported
	Enablex	C		Not Reported
	Dyclone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	13674362	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003657		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

	Methotrexate Sodium			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	14151596	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164332			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C	Unknown	1 Df, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	14279525	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2189895-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	7.5 Mg To 22.5 Mg		Not Reported
	Plaquenil			S	Oral			Not Reported

Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Prednisone	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Metronidazole	C			Not Reported
	Pregabalin	C			Not Reported
	Deflazacort	C			Not Reported
	Tylenol	C			Not Reported
	Dilaudid	C			Not Reported
	Risedronate	C			Not Reported
	Salbutamol	C			Not Reported
	Nitroglycerin	C			Not Reported
	Crestor	C			Not Reported
	Hydromorph	C			Not Reported
	Januvia	C			Not Reported
	Pantoloc	C			Not Reported
	Calcium	C			Not Reported
	Vitamin D2	C			Not Reported
	Acidophilus	C			Not Reported
	Aspirin	C			Not Reported
	Triamcinolone	C			Not Reported
	Lidocaine	C			Not Reported
	Kenalog	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	14328907	EXPEDITED (15-DAY)		OT	CA-SA-2017SA262937		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg To 22.5 Mg		Not Reported

Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Methotrexate	S		Unk Unk, Qow	Not Reported
	Azathioprine	S	Unknown	Unk Unk,Unk	Not Reported
	Remicade	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
	Prednisone	S	Unknown	Unk Unk,Unk	Not Reported
	Infliximab	S		Unk Unk, Unk	Not Reported
	Xeljanz	C	Unknown	Unk Unk,Unk	Not Reported
	Metronidazole	C	Unknown	Unk Unk,Unk	Not Reported
	Pregabalin	C	Unknown	Unk Unk,Unk	Not Reported
	Deflazacort	C	Unknown	Unk Unk,Unk	Not Reported
	Paracetamol	C	Unknown	Unk Unk,Unk	Not Reported
	Dilaudid	C	Unknown	Unk Unk,Unk	Not Reported
	Risedronate	C	Unknown	Unk Unk,Unk	Not Reported
	Salbutamol	C	Unknown	Unk Unk,Unk	Not Reported
	Nitroglycerin	C	Unknown	Unk Unk,Unk	Not Reported
	Crestor	C	Unknown	Unk Unk,Unk	Not Reported
	Hydromorph	C	Unknown	Unk Unk,Unk	Not Reported
	Januvia	C	Unknown	Unk Unk,Unk	Not Reported
	Pantoprazole	C	Unknown	Unk Unk,Unk	Not Reported
	Calcium	C	Unknown	Unk Unk,Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk,Unk	Not Reported
	Acidophilus [Lactobacillus Acidophilus]	C	Unknown	Unk Unk,Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk Unk,Unk	Not Reported
	Triamcinolone	C	Unknown	Unk Unk,Unk	Not Reported
	Lidocaine	C	Unknown	Unk Unk,Unk	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unk Unk, Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Unk Unk,Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	14631842	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115349		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Delayed	Plaquenil			S	Unknown	400 Mg,Qd		Sanofi
	Sulfasalazine			S				Not Reported
	Leflunomide			S				Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qcy		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg,Qcy		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Prednisone			C	Oral	5 Mg,Qd		Not Reported
	Cortisone			C	Unknown	Unk Unk,Unk		Not Reported
	Tylenol 8 Hour			C				Not Reported
	Naproxen			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15026702	EXPEDITED (15-DAY)		OT	CA-SA-2016SA115342		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea;	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	200 Mg,Biw		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	10 Mg,Biw		Sanofi

Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava	S	Unknown	10 Mg,Tiw	Sanofi
	Arava	S	Unknown	10 Mg,Qod	Sanofi
	Arava	S	Unknown	10 Mg,Qod	Sanofi
	Arava	S	Unknown	10 Mg,Qd	Sanofi
	Arava	S	Unknown	200 Mg,Biw	Sanofi
	Hydroxychloroquine	S			Sanofi
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg,Qcy	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg,Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg,Qw	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg,Qd	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Intramuscular	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Qcy	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Qcy	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Qcy	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15121893	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-BAUSCH-BL-2018-018616			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Salbutamol Sulfate			S	Transplacental	From Gestational Week 0-14		Bausch And Lomb
	Salbutamol Sulfate			S	Unknown			Bausch And Lomb
	Ramipril			S	Transplacental	Exposure Duration 0-13 Plus 6 Weeks		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Tacrolimus			S				Not Reported
	Prednisolone			S	Transplacental			Not Reported
	Dalteparin Sodium			S	Transplacental			Not Reported
	Metamizole Sodium			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	Rom Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported

	Ezetimibe		S	Transplacental	From Gestational Week 0-14	Not Reported
	Ezetimibe		S	Transplacental		Not Reported
	Torasemide		S	Transplacental	From Gestational Week 0-14	Not Reported
	Torasemide		S	Transdermal		Not Reported
	Pantoprazole Sodium		S	Transplacental		Not Reported
	Pantoprazole Sodium		S	Transplacental	Gestational Week 0-14	Not Reported
	Clexane		S	Transplacental		Not Reported
	Rituximab		S	Transplacental		Not Reported
	Heparin (Salt Not Specified)		S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15368641	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2477338-00		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Benzalkonium Chloride W/Diphenhydra	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Celebrex	C			Not Reported
	Ibuprofen	C			Not Reported
	Lipitor	C			Not Reported
	Prednisone	C			Not Reported
	Benzalkonium Chloride W/Diphenhydra/03049201/	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15376977	EXPEDITED (15-DAY)		OT	US-ABBVIE-18P-163-2477508-00		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Aspartate Aminotransferase Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Diarrhoea; Fatigue; Gait Disturbance; Hypersensitivity; Inflammatory Marker Increased; Influenza; Injection Site Pain; Musculoskeletal Stiffness; Pain In Extremity; Pain In Jaw; Peripheral Swelling; Rheumatoid Arthritis; Rheumatoid Nodule; Sjogren'S Syndrome; Splenomegaly; Therapeutic Product Effect Decreased; Tinnitus; Vertigo	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Rasuvo			S	Subcutaneous			Not Reported
	Aspirin			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Lipitor			C				Not Reported
	Meloxicam			C				Not Reported
	Proair Hfa			C				Not Reported
	Tofacitinib			C				Not Reported
	Flu Vaccine Vii			C				Not Reported
	Pneumococcal Vaccine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15697307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2055186-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Cyclosporine			S	Oral			Not Reported
	Cyclosporine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

							otherwise specified)			
					Apo-Cyclosporine	S	Oral			Not Reported
					Lyrica	S	Unknown			Not Reported
					Rituxan	S	Unknown			Not Reported
					Mycophenolate Mofetil	S	Unknown			Not Reported
					Orencia	S	Unknown			Not Reported
					Simponi	S	Unknown			Not Reported
					Certolizumab Pegol	S	Unknown			Not Reported
					Remicade	S	Intravenous (not otherwise specified)			Not Reported
					Prednisone	C				Not Reported
					Piroxicam	C				Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
07-Feb-2019	15721651	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263002-00		67 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira			S	Subcutaneous			Not Reported		
	Actemra			S	Unknown			Not Reported		
	Arava			S	Unknown			Not Reported		
	Cimzia			S	Subcutaneous			Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported		
	Methotrexate			S	Unknown			Not Reported		
	Plaquenil			S	Unknown			Not Reported		
	Remicade			S	Intravenous (not otherwise specified)			Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported		
	Simponi			S	Subcutaneous			Not Reported		

	Apo-Leflunomide			S	Unknown					Not Reported
	Arthrotec			C						Not Reported
	Ergocalciferol			C						Not Reported
	Imuran			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15796432	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000034		53 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Compression Fracture; Pneumonia	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Every Other Day		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Every Other Day		Concordia
	Prednisolone			C				Not Reported
	Prograf			C				Not Reported
	Rinderon-Vg			C				Not Reported
	Revolade			C				Not Reported
	Warfarin [Warfarin Potassium]			C				Not Reported
	Alfacalcidol			C				Not Reported
	Pariet			C				Not Reported
	Sennoside A+B			C				Not Reported
	Ursodeoxycholic Acid			C				Not Reported
	Bayaspirin			C				Not Reported
	Rebamipide			C				Not Reported
	Benet			C				Not Reported
	Unasyn [Sultamicillin Tosilate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15840379	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1463071-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Ineffective; Infection;	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Insomnia; Joint Swelling; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Methotrexate	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15850805	EXPEDITED (15-DAY)		HO, OT	SE-MYLANLABS-2019M1004959		40 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Appendicitis; Drug Abuse; Intentional Product Misuse; Intentional Product Use Issue; Off Label Use	Prednisolone			S	Unknown	5 Milligram, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	2000 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Unk		Not Reported
	Belimumab			C	Intravenous (not otherwise specified)	800 Milligram, Unk (As Maintenance Dose)		Mylan
	Cyclophosphamide			C	Unknown	800 Milligram, Unk		Mylan
	Rituximab			C	Intravenous (not otherwise specified)	1000 Milligram, Unk (Two Weeks Apart)		Mylan
	Bortezomib			C	Unknown	Unk		Mylan
	Dexamethasone			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930239	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007382		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930616	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007516		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930632	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007492		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Shoulder Operation;	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported

Therapeutic Response Decreased	Enbrel		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930661	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007524		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930800	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007812			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Neutropenia	Methotrexate Sodium			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown	200 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930805	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007507		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Infection; Eye Inflammation; Rheumatoid Arthritis; Vulvovaginal Mycotic Infection	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15930941	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655659-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15932350	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA030298		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Atrioventricular Block; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Ambien			S				Sanofi
	Nifedipine			S				Not Reported
	Metoclopramide Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Loperamide			S				Not Reported
	Gabapentin			S				Not Reported
	Esomeprazole Magnesium			S				Not Reported
	Isosorbide Mononitrate			S				Not Reported
	Plavix			S	Unknown			Sanofi
	Famotidine			S				Not Reported
	Rosuvastatin Calcium			S				Not Reported
	Potassium			S				Not Reported
	Glyceryl Trinitrate			S				Sanofi
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Doxycycline			S				Not Reported
	Trandolapril			S				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Flomax			S				Sanofi
	Furosemide			S				Sanofi
	Victoza			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15932580	EXPEDITED (15-DAY)		DE, OT	PHHY2019US027099			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hellp Syndrome; Premature Baby	Hydroxychloroquine			S	Transplacental			Novartis
	Low Molecular Weight Heparin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15932714	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1042751		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Hypoxia; Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia; Respiratory Distress; Respiratory Failure	Prednisone			S	Unknown	60 Milligram		Not Reported
	Prednisone			S	Unknown	Gradually Weaned		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Adalimumab			S	Unknown	Unk		Mylan
	Adalimumab			S				Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Rituximab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15933571	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1010833		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S		Unk		Not Reported
	Aciclovir			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15933821	NON-EXPEDITED			US-SA-2018SA019699		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15933997	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008088		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Inflammation; Rheumatoid Arthritis; Vulvovaginal Mycotic Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15933998	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008079		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Sarcoidosis; Drug Ineffective;	Methotrexate			S	Subcutaneous			Barr

Rheumatoid Arthritis	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Plaquenil /00072602/		C	Unknown	Not Reported
	Salazopyrin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934027	EXPEDITED (15-DAY)		OT	PHHY2019US027072		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Novartis
	Low Molecular Weight Heparin			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934064	EXPEDITED (15-DAY)		OT	PHHY2019US027081		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934451	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007290		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported

	Orencia			S	Unknown					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934465	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15934814	EXPEDITED (15-DAY)		HO, OT	JP-TEVA-2019-JP-1007470		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection; Viral Vasculitis	Prednisolone			S	Unknown			Actavis
	Tacrolimus			S	Unknown			Actavis
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2019	15935155	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656851-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira	S	Subcutaneous	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported
	Leflunomide	C	Oral	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported
	Tylenol W/Codeine No. 3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	11705579	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015115425		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Feeling Hot; Gait Inability; Immunisation Reaction; Knee Arthroplasty; Loss Of Personal Independence	Enbrel			S	Unknown	Unk		Amgen
	Cymbalta			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported

In Daily Activities; Ocular Vascular Disorder; Off Label Use; Ophthalmic Vein Thrombosis; Pain; Pain In Extremity; Pyrexia; Therapeutic Response Decreased; Thrombosis; Vaccination Complication	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate	S	Oral	20 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	12109663	EXPEDITED (15-DAY)		OT	CA-SA-2016SA033659		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Plaquenil			S		400 Mg,Qd		Sanofi
	Leflunomide			S		10 Mg,Qd		Sanofi
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S		15 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	12130379	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717281			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Lymphoma; Off Label Use; Onychoclasis; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Voltaren			C	Unknown			Not Reported
	Cortisone			C	Oral	Drops		Not Reported
	Zostavax			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	12309292	EXPEDITED (15-DAY)		HO	CA-ROCHE-1746971			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 6 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous	Therapy Duration: 581 Days	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Oral	Therapy Duration: 581 Days	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine		S	Oral		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	12967628	EXPEDITED (15-DAY)		DS	CA-ROCHE-1857523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Simponi			S	Subcutaneous				Not Reported
		Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	13165940	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017014229		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Subcutaneous	50 Mg, Qmo		Amgen
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	13564000	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1773116-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil Sulfate	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Gold	C	Other	Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	13670307	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105919		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Hydroxychloroquine Sulfate			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Qow		Not Reported
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Qow		Not Reported
	Sulfasalazine			S	Oral	1 G,Bid		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk			Not Reported
	Stelara			S	Subcutaneous	Unk Unk,Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	14382896	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-15K-028-1473055-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)			Not Reported
	Human Immunoglobulin			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Respiratory (inhalation)			Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg/Kg	Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Abatacept	S	Intravenous (not otherwise specified)		Not Reported
	Abatacept	S	Intravenous (not		Not Reported

					otherwise specified)	
	Naproxen			S	Unknown	Not Reported
	Naproxen			S		Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Apo-Naproxen			S	Unknown	Not Reported
	Apo-Prednisone			S	Oral	Not Reported
	Apo-Prednisone			S	Oral	Not Reported
	Apo Triamcinolone Aq			S	Unknown	Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Not Reported
	Triamcinolone Acetonide			S		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	Not Reported
	Folic Acid			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	14557924	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262325-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15042947	NON-EXPEDITED			US-PFIZER INC-2018179059		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Rash; Rash Macular; Skin Swelling; Vomiting	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15263425	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15480085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2194166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown	Not Reported
	Xeljanz			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			C		Not Reported
	Prednisone			C		Not Reported
	Naproxen			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15635152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105933			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15635174	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105580			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15713718	EXPEDITED (15-DAY)		CA, OT	DE-BAYER-2015-390037		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Contraindicated Product Administered; Drug Ineffective; Maternal Exposure During Pregnancy; Premature Baby; Product Monitoring Error; Renal Vascular Thrombosis; Vena Cava Thrombosis	Xarelto			S		Gestational Week 0-5		Johnson And Johnson
	Acetylsalicylic Acid(<=100 Mg)			S		100 Mg, Qd, From Gestational Week 0-14		Bayer
	Simvastatin			S		Gestational Week 0-14		Not Reported
	Ramipril			S		20 Mg, Gestational Week 0-13+6		Not Reported
	Tacrolimus			S		6 Mg, Qd, Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd, Gestational Week 0-14		Not Reported

Prednisolone	S		10 Mg, Bid, Gestational Week 0-14	Not Reported
Pantoprazole	S	Oral	40 Mg, Qd, From Gestational Week 0-14	Not Reported
Torasemide	S		100 Mg, Qd, Gestational Week 0-14	Not Reported
Ezetimibe	S		Gestational Week 0-14	Not Reported
Salbutamol	S		Gestational Week 0-14	Not Reported
Metamizole	S		Gestational Week 0-14	Not Reported
Aliskiren	S		300 Mg, Gestational Week 0-5	Not Reported
Nicotine	S		Gestational Week 0-14	Not Reported
Enoxaparin	S		Gestational Week 0-14	Not Reported
Dalteparin Sodium	S		Gestational Week 6-14	Not Reported
Low Molecular Weight Heparin	S			Not Reported
Novaminsulfon	S		Unk, Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Heparin Lmw	S			Not Reported
Clexane	S		100 Mg, Bid	Not Reported
Rituximab	S		Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Cytotec	C	Oral	Unk, Gestational Week 13.6	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)	3000 [Mg Cumulative]; Preconceptional 3000 Mg Cumulative (Preconceptional)	Not Reported
Mifegyne	C	Oral	Unk, 13.6 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15713752	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-BAYER-2015-390046			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Xarelto			S	Transplacental	Gestational Week 0-5		Johnson And Johnson
	Acetylsalicylic Acid(<=100 Mg)			S	Transplacental	100 Mg, Qd, Gestational Week 0-14		Bayer
	Aliskiren			S		300 Mg, Qd, Gestational Week 0-5		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd, Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg, Qd, Gestational Week 0-13+6		Not Reported
	Ezetimibe			S	Transplacental	Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	6 Mg, Qd, Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental	100 Mg, Qd, Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental	Gestational Week 0-14		Not Reported
	Metamizole			S		Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	10 Mg, Bid, Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 Mg, Qd, Gestational Week 0-14		Not Reported
	Nicotine			S		Gestational Week 0-14		Not Reported
	Dalteparin Sodium			S		Gestational Week 6-14		Not Reported
	Low Molecular Weight Heparin			S	Transplacental	Unk		Not Reported
	Novaminsulfon			S	Transplacental	, Trimester: First; Probably Only In Hospital In Week 5unk		Not Reported
	Dalteparin Sodium			S	Transplacental	Unk		Not Reported
	Clexane			S	Transplacental	200 Mg, Bid		Not Reported
	Rituximab			S	Transplacental	Unk, Last Time In December 2011, Pre Or		Not Reported

					Periconceptional	
	Cytotec		C	Transplacental	Unk, Gestational Week 13.6	Not Reported
	Mifegyne		C	Transplacental	Unk, Gestational Week 13.6	Not Reported
	Cyclophosphamide		C	Transplacental	Unk, 3000 Mg Cumulative; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15777795	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181229915		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)	Strength = 100 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Asa			C	Oral			Not Reported
	Premarin			C	Oral			Not Reported
	Rosuvastatin			C	Oral			Not Reported
	Naproxen			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Duloxetine			C	Oral			Not Reported
	Quetiapine			C	Oral			Not Reported
	Quetiapine			C	Oral			Not Reported
	Lamotrigine			C	Oral			Not Reported
	Lamotrigine			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported
	Lansoprazole			C	Oral			Not Reported
	B12-Vitamin			C	Intramuscular			Not Reported

	Coversyl	C	Oral		Not Reported
	Flovent	C	Unknown		Not Reported
	Trazodone	C	Oral		Not Reported
	Zopiclone	C	Oral		Not Reported
	Ventolin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15929675	EXPEDITED (15-DAY)		OT	CA-009507513-1902CAN001547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Fosamax			S	Oral	Unk, Unknown		Merck
	Prednisone			S	Unknown	Unk, Unknown		Merck
	Methotrexate			S	Unknown	Unk, Unknown		Not Reported
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Prednisone			S	Oral	Unk, Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unknown		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk, Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

					Simponi		S	Intravenous (not otherwise specified)	Unk			Not Reported
					Simponi		S	Subcutaneous	Unk, Subcutaneous			Not Reported
					Sulfasalazine		S	Unknown	500 Milligram, Unk			Not Reported
					Arava		S	Oral	Unk, Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15934009	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655411-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15935514	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657195-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Arava	C		Not Reported
	Calcium Carbonate	C		Not Reported
	Cymbalta	C		Not Reported
	Elavil	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Imitrex	C		Not Reported
	Lyrica	C		Not Reported
	Premarin	C		Not Reported
	Tenormin	C		Not Reported
	Xeljanz	C		Not Reported
	Sumatriptan Succinate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15935967	EXPEDITED (15-DAY)		OT	FR-ROCHE-2260104		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Inflammation; Vulvovaginal Inflammation	Cellcept			S	Oral	Voir Commentaire		Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936039	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010090		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936105	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2019-CA-1008117		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Lung Neoplasm Malignant; Pneumonia; Product Use Issue; Pulmonary Embolism	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936153	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Prednisone				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936155	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastric Disorder; Leukopenia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936164	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013326			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936168	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010006			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936419	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657843-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15936464	EXPEDITED (15-DAY)		OT	US-SA-2019SA035524			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Endocarditis; Lung Disorder	Arava	S	Unk	Sanofi
	Hydroxychloroquine	S	Unk	Sanofi
	Methotrexate	S	Unk	Not Reported
	Sulfasalazine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15938872	NON-EXPEDITED			US-SA-2019SA037702			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Sanofi
	Atabrine			S				Sanofi
	Rifampicin			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15939793	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15940302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658219-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities;	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Somnolence; Visual Impairment	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Acetaminophen		C		Not Reported
	Codeine Phosphate		C		Not Reported
	Meloxicam		C		Not Reported
	Methotrexate		C		Not Reported
	Synthroid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2019	15941635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2261498		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	13015664	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865625		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

					Anakinra		S	Unknown		Not Reported
					Azathioprine		S	Unknown		Not Reported
					Enbrel		S	Unknown		Not Reported
					Enbrel		S	Subcutaneous		Not Reported
					Enbrel		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Oral		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Arava		S	Unknown		Not Reported
					Arava		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Imuran		S	Unknown		Not Reported
					Cimizia		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	13062914	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Prednisone		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Inflectra		S	Intravenous (not otherwise specified)	300 Mg On Week 0, Week 2, Week 6 Then Every 8 Weeks For 12 Months	Not Reported
	Inflectra		S	Unknown		Not Reported
	Plaquenil		C	Unknown		Not Reported
	Pantoloc		C	Unknown		Not Reported
	Atorvastatin		C	Unknown		Not Reported
	Atorvastatin		C	Unknown		Not Reported
	Pantoprazole Sodium		C	Unknown		Not Reported
	Pantoprazole Sodium		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15342319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2174048			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab			C	Unknown	Not Reported
	Xeljanz			C	Unknown	Not Reported
	Prednisone			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15941746	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653100-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Dose Decreased		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported
	Mtx			S	Unknown	Dose Reduced		Not Reported
	Mtx			S	Unknown	Dose Increased		Not Reported

	Xeljanz			C						Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
09-Feb-2019	15941832	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658429-00			Female	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

						Rituxan		S	Intravenous (not otherwise specified)	Not Reported
						Simponi		S	Subcutaneous	Not Reported
						Sulfasalazine		S	Unknown	Not Reported
						Diclofenac Sodium		S	Unknown	Not Reported
						Plaquenil		S	Unknown	Not Reported
						Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
						Hydroxychloroquine		S	Unknown	Not Reported
						Methotrexate Sodium		S	Unknown	Not Reported
						Reactine		S	Unknown	Not Reported
						Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15941963	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1774322-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15942012	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010761		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance;	Methotrexate			S	Unknown			Barr

Hypersensitivity; Lung Disorder	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15942210	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010009		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate			S	Unknown			Barr
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15942220	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral	25 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Barr
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15942230	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Treatment Failure	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2019	15942234	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010012		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	11457282	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1626689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Nail Operation; Onychomadesis; Onychomycosis	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Xeljanz			S					Not Reported
	Apo-Hydroxyquine			S	Unknown				Not Reported
	Hydroxychloroquine			C	Unknown				Not Reported
	Arava			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	15313916	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2018115640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Surgery; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Orencia			S	Unknown	125 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	15941698	DIRECT		DS, OT			63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blindness; Impaired Driving Ability; Retinal Disorder; Toxicity To Various Agents	Hydroxychloroquine 200 Mg Tab. Generic For Plaquenil	S	Oral	Quantity:2 Tablet(S);		Sandoz
	Tramadol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	15942431	EXPEDITED (15-DAY)		OT	PHHY2019US027094			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental			Novartis
	Low Molecular Weight Heparin			S	Transplacental			Not Reported
	Aspirin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	15942685	EXPEDITED (15-DAY)		OT	PHHY2019US027085			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Hydroxychloroquine			S	Transplacental			Novartis
	Low Molecular Weight Heparin			S	Transplacental			Not Reported
	Aspirin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	15942779	EXPEDITED (15-DAY)		OT	PHHY2019US027090			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Hydroxychloroquine			S	Transplacental			Novartis
	Low Molecular Weight Heparin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2019	16056453	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain	Soliris 10 Mg/Ml			S	Intravenous (not otherwise specified)	Other Frequency:Every 2 Weeks ;		Alexion
	Zolpidem			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Junel			C				Not Reported
	Clonazepam			C				Not Reported
	Diphenhydramine			C				Not Reported
	Epinephrine			C				Not Reported
	Heparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	8790063	EXPEDITED (15-DAY)		CA	DE-SANOFI-AVENTIS-2012SA065845			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Delix (Ramipril)			S	Transplacental	20 [Mg/D]		Sanofi
	Quensyl			S	Transplacental	Unk Unk,Unk		Sanofi
	Ezetimibe/Simvastatin			S	Transplacental	40 [Mg/D] / 10 [Mg/D]		Not Reported
	Torasemide			S	Transplacental	100 Mg, Qd		Not Reported
	Tacrolimus			S	Transplacental	6 Mg,Unk		Not Reported
	Rituximab			S	Transplacental	Last Time In December 2011: Pre Or Periconceptional		Not Reported
	Advagraf			S	Transplacental	6 [Mg/D]		Not Reported
	Cyclophosphamide			C	Transplacental	3000 [Mg Cumulative]/ April -August 2011		Not Reported
	Clexane			C	Transplacental	200 [Mg/D (2x100)]		Not Reported
	Prednisolone			C	Transplacental	10 Mg Milligram(S) Every 2 Day		Not Reported
	Acetylsalicylic Acid			C	Transplacental	100 [Mg/D]		Not Reported
	Pantoprazole			C	Transplacental	40 Mg, Qd		Not Reported
	Aliskiren			C	Transplacental	300 Mg, Unk		Not Reported
	Salbutamol			C	Transplacental	Unk Unk, Unk		Not Reported

	Novaminsulfon			C	Transplacental	Unk Unk, Unk		Not Reported
	Mifegyne			C	Transplacental	Unk Unk, Unk		Not Reported
	Cytotec			C	Transplacental	Unk Unk, Unk		Not Reported
	Xarelto			C	Transplacental	Not Known, If Treatment Started Before Or After Missed Abortion.		Not Reported
	Albuterol [Salbutamol]			C	Transplacental	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	12349395	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016057769		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	13210436	EXPEDITED (15-DAY)		OT	US-SA-2016SA235895		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Arava			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg,Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg,Bid		Not Reported

	Methotrexate Sodium		S	Subcutaneous	20 Mg,Qw	Not Reported
	Prednisone		S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone		S	Unknown	5 Mg,Qd	Not Reported
	Rituxan		S	Unknown	Unk Unk,Unk	Not Reported
	Rituxan		S	Unknown	Unk Unk,Unk	Not Reported
	Infliximab		S	Unknown	300 Mg,Qd	Not Reported
	Pantoprazole		C	Unknown	Unk Unk,Unk	Not Reported
	Pantoprazole		C		Unk	Not Reported
	Pantoprazole		C		Unk	Not Reported
	Pantoprazole		C		Unk	Not Reported
	Atorvastatin		C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	14109381	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017157043			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Tiaprofenic			C		300 Mg, Qd		Not Reported

	Plaquenil			C	Unknown	Unk			Not Reported
	Aspirin			C		81 Mg, Qd			Not Reported
	Aspirin			C	Unknown	Unk			Not Reported
	Acetylsalicylic Acid			C		81 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	14343927	EXPEDITED (15-DAY)		HO, OT	CA-SA-2016SA036595		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; No Adverse Event; Respiratory Arrest; Visual Impairment	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	1 G,Bid		Not Reported
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported
	Celecoxib			S	Oral	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Orencia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg,Qcy		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qw		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	14652750	NON-EXPEDITED			US-AMGEN-USASP2018036228			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Sulfasalazine		S	Unknown	Unk		Not Reported
	Cimzia		S	Unknown	Unk		Not Reported
	Penicillin		S	Unknown	Unk		Not Reported
	Xeljanz		C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15369821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182488		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Lyrica			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15505712	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014007688		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Enbrel	S	Unknown	50 Mg, Unk	Amgen
	Penicillin	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Penicillin G	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	17.5 Unk, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	1.5 G, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Plaquenil	C		Unk	Not Reported
	Plaquenil	C	Unknown	300 Mg, Unk	Not Reported
	Vitamin D2	C	Unknown	Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Tylenol	C	Unknown	Unk, As Necessary	Not Reported
	Hydroxychloroquine	C		300 Mg, Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15530124	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018147274		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability; Herpes Zoster; Hiatus Hernia; Insomnia; Muscle	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Spasms; Pain In Extremity; Rheumatoid Arthritis; Sarcoidosis; Skin Cancer; Sleep Disorder Due To General Medical Condition, Insomnia Type	Humira			S	Unknown	Unk			Not Reported
	Cimzia			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Leflunomide			C		Unk			Not Reported
	Sulfasalazine			C		Unk			Not Reported
	Xeljanz			C		Unk			Not Reported
	Plaquenil			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15555911	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018148917		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Pain; Drug Intolerance; Eye Disorder; Impaired Healing; Localised Infection; Mobility Decreased; Musculoskeletal Disorder; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hepatitis A Vaccine Inact W/Hepatitis B Vacci			C		Unk		Not Reported
	Hepatitis B Surface Antigen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15800542	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000043		60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Simplex; Off Label Use; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported

	Isotretinoin			S	Unknown		Not Reported
	Isotretinoin			S			Not Reported
	Acitretin			S	Unknown		Not Reported
	Acitretin			S			Not Reported
	5-Fluorouracil			S	Unknown		Not Reported
	5-Fluorouracil			S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15941983	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007505		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

	Methotrexate	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Paroxetine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Simvastatin	C	Unknown		Not Reported
	Statex	C	Unknown		Not Reported
	Telmisartan	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15944183	EXPEDITED (15-DAY)		HO, LT, OT	NL-STRIDES ARCOLAB LIMITED-2019SP001185		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Drug Ineffective; Drug Ineffective For Unapproved Indication; Lupus Nephritis; Myocarditis; Renal Tubular Necrosis; Respiratory Failure	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Low Dose		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	1000 Mg, Bid		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Immunoglobulin /00025201/			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945087	EXPEDITED (15-DAY)		OT	CA-SA-2019SA033545			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Desoximetasone			S	Oral			Sanofi
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945129	EXPEDITED (15-DAY)		OT	CA-SA-2018SA288302		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Hydromorphone Hydrochloride			S	Oral	12 Mg, Qd		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			S	Oral	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945443	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010113		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Rash; Red Cell Distribution Width Increased; Swelling Face	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945499	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Depo-Medrol			C	Intramuscular			Not Reported
	Prednisone			C		5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945764	EXPEDITED (15-DAY)		OT	CA-ROCHE-2260720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Reactine (Canada)			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945827	EXPEDITED (15-DAY)		OT	ES-APPCO PHARMA LLC-2062476			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myasthenia Gravis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2260747		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Remicade			S	Unknown				Not Reported
		Sodium Aurothiomalate			S	Unknown				Not Reported
		Cephalexin			C					Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15945994	NON-EXPEDITED			PHEH2019US006191			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15946089	EXPEDITED (15-DAY)		HO	US-ABBVIE-19K-163-2650028-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; Dysstasia; Gait Inability; Pain	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Otezla			S	Unknown			Not Reported
	Otezla			S				Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Stelara			S	Unknown			Not Reported
	Stelara			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15948005	EXPEDITED (15-DAY)		OT	PHHY2019CA031446		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Methotrexate	S	Unknown	Unk (More Than 20 Mg)	Novartis
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15948176	NON-EXPEDITED			US-SA-2019SA037128			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Peripheral Swelling	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Enbrel			C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15948542	NON-EXPEDITED			US-SA-2019SA038005			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15948653	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000230			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Neuropathy Peripheral; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15949240	EXPEDITED (15-DAY)		HO	US-CELGENEUS-USA-20190200338			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Cholesterol Increased; Dysstasia; Gait Inability; Pain	Otezla			S	Unknown			Celgene
	Otezla			S				Celgene
	Etanercept			S	Unknown			Celgene
	Methotrexate Sodium			S	Unknown			Celgene
	Adalimumab			S	Unknown			Celgene
	Certolizumab Pegol			S	Unknown			Celgene
	Ustekinumab			S	Unknown			Celgene
	Lyrica			S	Unknown			Celgene
	Plaquenil			S	Unknown			Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15951459	NON-EXPEDITED			PHEH2019US006138			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Paraesthesia	Cosentyx			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

		Leflunomide			S	Unknown	Unk			Not Reported
		Humira			S	Unknown	Unk			Not Reported
		Celebrex			S	Unknown	Unk			Not Reported
		Enbrel			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15952152	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010767		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Decreased Appetite; Delirium; Drug Ineffective; Fall; Insomnia; Seizure; Skin Disorder; Somnolence; Tinnitus	Methotrexate			S	Oral			Barr
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	11583330	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA052515		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 G,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	1 Mg,Qw		Not Reported
	Celecoxib			S	Unknown	2 Df, Qd		Not Reported
	Sulfasalazine			S	Rectal	1 G,Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Xeljanz			C	Unknown	Unk Unk,Unk		Not Reported

	Methotrexate Sodium			C		Unk			Not Reported
	Methotrexate Sodium			C		Unk			Not Reported
	Hydroxychloroquine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	11760631	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015371834		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Feeling Hot; Gait Inability; Immunisation Reaction; Loss Of Personal Independence In Daily Activities; Ocular Vascular Disorder; Off Label Use; Ophthalmic Vein Thrombosis; Pain; Pain In Extremity; Pain In Extremity; Pyrexia; Therapeutic Response Decreased; Thrombosis; Vaccination Complication	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Cymbalta			S	Unknown	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	13096603	EXPEDITED (15-DAY)		OT	CA-ROCHE-1632312			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Single Dose		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Due To General Medical Condition, Insomnia Type	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	13123664	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1659162-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	More Than 20 Mg		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	14625084	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown	750 Mg, Q4wk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q4wk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15103996	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-059500			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Herpes Zoster; Injection Site Reaction; Paralysis; Transaminases Increased; Treatment Failure	Orencia	S	Unknown		Bristol Myers Squibb
	Enbrel	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Imuran /00001501/	S	Unknown		Not Reported
	Kevzara	S	Unknown		Not Reported
	Xeljanz Xr	S	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15499099	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018414005		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Disorder; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Venlafaxine Hcl			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Naproxen			S		500 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15567890	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018445527		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Pain; Drug Intolerance; Eye Disorder; Impaired Healing; Localised Infection; Mobility Decreased;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Musculoskeletal Disorder; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira		S	Subcutaneous	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Hepatitis A Vaccine Inact W/Hepatitis B Vacci		C		Unk		Not Reported
	Hepatitis B Surface Antigen		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15855309	EXPEDITED (15-DAY)		DE, OT	PHEH2019US003152		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bile Duct Obstruction; Blood Calcium Decreased; Metastases To Liver; Product Use In Unapproved Indication	Mekinist			S	Oral	2 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15945728	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1010752			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard Liquid			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine/00072603/			S	Oral	5 Mg/Kg Daily;		Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User			otherwise specified)			
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone Acetonide	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15946264	EXPEDITED (15-DAY)		OT	CA-SA-2019SA033391		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cephalexin [Cefalexin]			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15946793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011292			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Q4wk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	17 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Enbrel			S	Unknown	25 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15947106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15947191	EXPEDITED (15-DAY)		OT	CA-SA-2019SA033456		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Ml, Qw		Not Reported
	Plaquenil			S	Oral	Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15948270	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA147266		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Celecoxib			S	Unknown	2 Df, Qd		Not Reported
	Leflunomide			S	Oral	20 G		Sanofi
	Sulfasalazine			S	Rectal	1 G,Bid		Not Reported
	Arava			S	Oral	Unk		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Methotrexate			S		1 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported

	Xeljanz	C	Oral	5 Mg,Bid			Not Reported
	Xeljanz	C	Unknown	5 Mg,Bid			Not Reported
	Methotrexate Sodium	C	Unknown	Unk			Not Reported
	Hydroxychloroquine	C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949193	EXPEDITED (15-DAY)		OT	CA-BAXTER-2019BAX002794		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole 5mg/Ml Injection			S	Unknown	Dosage Form: Not Specified		Baxter
	Apo-Leflunomide			S	Unknown	Dosage Form: Tablet		Not Reported
	Arava			S	Unknown	Dosage Form: Tablet		Not Reported
	Arthrotec			S	Unknown	Dosage Form: Tablet		Not Reported
	Bisoprolol			S	Unknown	Dosage Form: Tablet		Not Reported
	Ceclor			S	Unknown	Dosage Form: Not Specified		Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown	Dosage Form: Not Specified		Not Reported
	Erythro-Base			S	Unknown	Dosage Form: Tablet		Not Reported
	Humira			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral	Dosage Form: Tablet		Not Reported
	Prednisone			S	Unknown	Dosage Form: Not Specified		Not Reported
	Sulfasalazine			S	Unknown	Dosage Form: Not		Not Reported

						Specified			
	Meperidine Hydrochloride		S	Unknown					Not Reported
	Erythromycin Estolate		S	Unknown		Dosage Form: Not Specified			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949376	EXPEDITED (15-DAY)		OT	PHHY2019US027075		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hellp Syndrome; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S				Novartis
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Aspirin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15952935	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011504		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15953131	EXPEDITED (15-DAY)		OT	PHHY2019GB030304		52 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomegaly; Congestive Cardiomyopathy; Lymphadenopathy Mediastinal; Product Use In Unapproved Indication; Right Atrial Enlargement	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15953653	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011931		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Pain; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Barr
	Folic Acid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	13118536	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1777062-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

	Arava	S	Unknown	Not Reported
	Meloxicam	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	14528256	EXPEDITED (15-DAY)		HO, OT	DE-ABBVIE-18K-062-2250819-00		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer Female; Deep Vein Thrombosis; Foot Fracture; Foot Fracture; Hypogammaglobulinaemia; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Radiculopathy; Rotator Cuff Syndrome; Secondary Immunodeficiency; Spinal Osteoarthritis; Stenosis; Stomatitis; Vitamin D Deficiency	Humira			S	Subcutaneous			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mtx			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Quensyl			S	Unknown	Given 2017,2018		Not Reported
	Sulfasalazin			S	Unknown			Not Reported
	Sulfasalazin			S	Unknown			Not Reported
	Cyanocobalamin W/Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Celecoxib			C				Not Reported
	Cotrimoxazole			C				Not Reported
	Folinic Acid			C				Not Reported
	Tapentadol			C				Not Reported
	Anastrozol			C				Not Reported
	Prednisolone			C				Not Reported

	Pantozol			C						Not Reported
	Colecalciferol			C						Not Reported
	Leflunomide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15454692	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2044289		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Gastritis; Hypokalaemia; Hyponatraemia; Renal Failure; Urinary Tract Infection	Rituximab			S	Unknown	Last Cycle Of Rituximab Was Administered On 06/Sep/2016		Not Reported
	Methotrexat			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tilidin			C				Not Reported
	Prednisolone			C				Not Reported
	Omeprazol			C				Not Reported
	Dytide			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15518489	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014037808		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Daily		Pfizer
	Methotrexate Sodium			S		17.5 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	1.5 G, 2x/Day		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

					Rituximab		S	Unknown	Unk	Not Reported
					Penicillin G [Benzylpenicillin]		S	Unknown		Not Reported
					Plaquenil		C		300 Mg, Unk	Not Reported
					Vitamin D2		C		Unk	Not Reported
					Calcium		C		Unk	Not Reported
					Tylenol		C		Unk, As Necessary	Not Reported
					Prednisone		C		10 Mg, Daily	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
13-Feb-2019	15524413	EXPEDITED (15-DAY)		OT		CA-PFIZER INC-2017447535			Male	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Back Pain; Drug Ineffective; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Mg, Twice Weekly		Pfizer		
	Methotrexate Sodium			S	Subcutaneous	Unk, Up To 25 Mg Weekly		Unknown		
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown		
	Methotrexate Sodium			S	Unknown	Unk		Unknown		
	Sulfasalazine			S		Unk		Pfizer		
	Orencia			S		Unk		Not Reported		
	Azathioprine			S	Unknown	Unk		Not Reported		
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported		
	Imuran			S		Unk		Not Reported		
	Gold			S		Unk		Not Reported		
	Plaquenil			S		200mg, Bid		Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported		
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported		
	Arava			S		Unk		Not Reported		
	Actemra			S	Unknown	Unk		Not Reported		
	Tiaprofenic			C		300 Mg, Daily		Not Reported		
	Aspirin 81			C		81 Mg, Daily		Not Reported		

	Aspirin 81			C		Unk				Not Reported
	Acetylsalicylic Acid			C		81 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15580508	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017038118		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Subcutaneous	50 Mg, Qmo		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Every 2 Weeks		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Esomeprazole Magnesium/Naproxen			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk		Not Reported
	Naproxen			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15894437	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011435		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Myalgia	Plaquenil Tablet			S	Oral			Concordia

	Cortancyl	S	Oral	Diminution Progressive Posologie		Not Reported
	Mycophenolate Mofetil	S	Oral	Cellcept 1g X 2		Not Reported
	Triatec	C				Not Reported
	Plaquenil Tablet	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15954588	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011482		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Gastrointestinal Disorder; Headache; Irritable Bowel Syndrome; Malaise	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15954602	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011653		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Piroxicam			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15954879	EXPEDITED (15-DAY)		OT	US-ROCHE-2261122			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955012	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011527			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Erythematosus	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine /00884302/	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955322	EXPEDITED (15-DAY)		OT	BR-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000267		30 DAY	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Haematochezia	Plaquenil Tablet			S	Transmammary			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955341	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000261		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Atrioventricular Block; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Hydroxychloroquine			S	Unknown			Concordia
	Ambien			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Metoclopramide Hydrochloride			S	Unknown			Not Reported
	Trazodone Hydrochloride			S	Unknown			Not Reported
	Loperamide			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Esomeprazole Magnesium			S	Unknown			Not Reported
	Isosorbide Mononitrate			S	Unknown			Not Reported
	Plavix			S	Unknown			Not Reported
	Famotidine			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Potassium			S	Unknown			Not Reported
	Glyceryl Trinitrate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Trandolapril			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Flomax			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Victoza			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15955346	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000259			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Retinal Disorder	Plaquenil			S						Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957311	EXPEDITED (15-DAY)		OT	DE-UCBSA-2019004670			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Foot Fracture	Cimzia			S	Unknown	200 Mg, Unk		Ucb
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	150 Mg, Unk		Not Reported
	Roactemra			S	Unknown	600 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	17.5 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957514	NON-EXPEDITED			US-SA-2018SA034555			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Ill-Defined Disorder; Rash	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			C	Unknown			Not Reported
	Humira			C	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957573	NON-EXPEDITED			US-SA-2019SA039090			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Enzyme Increased; Pain	Leflunomide	S	Unk		Sanofi
	Methotrexate	S	Unk		Not Reported
	Plaquenil	S	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957577	NON-EXPEDITED			US-SA-2019SA039028			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Headache	Arava			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz Xr			C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957609	NON-EXPEDITED			US-SA-2019SA039072			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957682	NON-EXPEDITED			US-SA-2019SA039577			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Arava			S		Unk		Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957692	NON-EXPEDITED			US-SA-2019SA039167			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dizziness; Drug Ineffective; Nausea; Urticaria	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Humira			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957714	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011560		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957715	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011716		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Infected Skin Ulcer; Lung Disorder; Night Sweats; Productive Cough; Therapeutic Product Effect Incomplete	Methotrexate		S	Subcutaneous	Barr
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957718	NON-EXPEDITED			US-SA-2019SA039578			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957722	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011561		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15957759	NON-EXPEDITED			US-SA-2019SA039696			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Intolerance	Arava			S	Unknown				Sanofi
	Methotrexate			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Sanofi
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15958200	EXPEDITED (15-DAY)		HO, OT	PHHY2019BR033250		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cytomegalovirus Infection; Pyrexia; Sepsis	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15958252	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1012377		61 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Mylan
	Sulfasalazine			S	Unknown			Mylan
	Etanercept			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15958650	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201904752			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Gammagard Liquid			S	Intravenous (not	70 Gram		Shire

Arthritis; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User			otherwise specified)		
	Enbrel	S	Subcutaneous	12.5 Milligram, 1x/Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2x A Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Cyclical	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, 1x/Day:Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1x/2wks	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Orencia	S		250 Milligram, 1x A Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Not Reported
	Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Prednisone	S	Unknown	Unk, 50	Not Reported

	Prednisone	S	Oral	1.3 Unk, 2 Every 1 Day	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Anakinra	S	Unknown	50 Milligram	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Apo Triamcinolone Aq	S	Unknown		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15958842	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262863		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatitis	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 214.0		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

		Sulfasalazine			C	Unknown					Not Reported
		Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2019	15958883	EXPEDITED (15-DAY)		HO	GR-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000250		42 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Muscular Weakness; Pupils Unequal; Raynaud'S Phenomenon	Plaquenil Tablet			S	Oral			Concordia
	Adalat			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	12368812	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016252047		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	12913274	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-035678		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Contraindicated Product	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported

Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel	S	Unknown		Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo Leflunomida	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Baclofen	C	Unknown	Unk	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk	Not Reported
	Estradiol	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Levaquin	C	Unknown	Unk	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	13266618	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895852			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate Sodium		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Kineret		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	13871021	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895127		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Therapy Duration: 175 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14384298	NON-EXPEDITED			US-PFIZER INC-2018016136		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Codeine			S		Unk		Not Reported
	Gabapentin			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer

Minocin	S	Unk	Pfizer
Tetracycline Hcl	S	Unk	Pfizer
Iodine	S	Unk	Not Reported
Ioversol	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Darvocet	S	Unk	Not Reported
Ultram	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14721080	NON-EXPEDITED		OT	PHEH2018US013109			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Nausea; Product Use In Unapproved Indication; Psoriatic Arthropathy; Pustule; Vomiting	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Novartis
	Cosentyx			S				Novartis
	Plaquenil			S	Unknown			Not Reported
	Enstilar			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	14979357	EXPEDITED (15-DAY)		DE, OT	PHHY2018IT015150		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Montelukast Sodium			S	Unknown	Unk		Novartis
	Lorazepam			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk		Not Reported

	Warfarin			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15050250	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1042649		68 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infected Seroma; Intervertebral Disc Protrusion	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	10-15 Mg		Mylan
	Hydroxychloroquine			S	Unknown	10-15 Mg		Mylan
	Hydroxychloroquine			S	Oral	Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15617649	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-103140			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Episcleritis; Herpes Zoster; Hypersensitivity; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported

	Leflunomide	S	Unknown			Not Reported
	Kevzara	S	Unknown	200 Mg, Unk		Not Reported
	Actemra	S	Unknown	162 Mg, Qwk		Not Reported
	Arava	S	Unknown			Not Reported
	Celebrex	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Xeljanz Xr	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15789842	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-001340		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Aspirin			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Motrin [Naproxen]			S	Unknown	Unk		Not Reported
	Naprosyn [Naproxen]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfamethoxazole			S	Unknown	Unk		Not Reported
	Trimethoprim			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15929542	NON-EXPEDITED		OT	US-SA-2019SA031994			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15938881	NON-EXPEDITED			US-SA-2019SA037762			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Unevaluable Event	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Meloxicam			S		Unk Unk, Unk		Not Reported
	Etodolac			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959206	EXPEDITED (15-DAY)		OT	PHHY2019US033249		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Toxicity; Vision Blurred	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959264	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959626	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1012335		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Methotrexate			S	Unknown			Barr
	Cellcept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959631	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1012360		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Methotrexate			S	Unknown			Barr
	Cellcept			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
					Sodium Aurothiomalate Injection Bp	S	Parenteral			Not Reported
					Sulfasalazine	S	Unknown			Not Reported
					Tacrolimus	S	Unknown			Not Reported
					Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959643	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012931		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15959648	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012943			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15961030	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1011842		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Torasemide			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Prednisolone			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Ramipril			S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Mylan
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Mylan
	Metamizole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Mylan
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Mylan
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Mylan
	Enoxaparin			C	Unknown	Unk Unk, Unknown Freq.		Mylan

(0-14 Gw)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15961110	NON-EXPEDITED			US-PFIZER INC-2019063055		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15961384	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-008		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia; Respiratory Failure	Azathioprine			S	Unknown			Westward
	Prednisone			S	Unknown			Westward
	Prednisone			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Hikma
	Adalimumab			S	Unknown			Not Reported
	Trimethoprim Sulfamethoxazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15962855	NON-EXPEDITED			PHEH2019US006800		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15962910	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013634			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15962957	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Cimzia	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15963721	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1014215			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15963724	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1014212			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15963726	EXPEDITED (15-DAY)		HO	BR-MYLANLABS-2019M1014217		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cytomegalovirus Infection; Hepatosplenomegaly; Proteinuria; Renal Vein Thrombosis; Urosepsis	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Mylan
	Dapsone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15963728	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1014231			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15963817	EXPEDITED (15-DAY)		HO, OT	DK-MYLANLABS-2019M1012757		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Mycoplasmal	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Mylan
	Insulin			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2019	15964218	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1014224			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	12815439	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2015027945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache;	Cimzia			S	Subcutaneous	Solution Subcutaneous		Ucb
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported

Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Enbrel	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Tofacitinib	S		5 Mg, 2x/Day (Bid)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine	S			Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Arava	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	13078214	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006568		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

		Rituxan			S	Unknown				Not Reported
		Infliximab			S	Unknown				Not Reported
		Pantoloc			C					Not Reported
		Atorvastatin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	13124556	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000487			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	14235972	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3852		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Esomeprazole Magnesium;Naproxen	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15314336	NON-EXPEDITED			US-PFIZER INC-2018341513		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Grisol			S		Unk		Not Reported
	Mercaptopurine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15366139	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082883			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Hypersensitivity; Oropharyngeal Pain; Sinusitis	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15400195	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185480			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15449468	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0912		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Plaquenil			S	Unknown	Not Reported
	Apo-Hydroxyquine			S	Unknown	Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Codeine			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15505504	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-2906		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Disorder; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15531784	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2949		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name			S	Unknown			Not Reported

Administration; X-Ray Abnormal	Unknown)				
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Penicillin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Penicillin G	S	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15699379	EXPEDITED (15-DAY)		HO, LT, OT	CA-BIOVITRUM-2015CA0570		11 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia;	Kineret			S	Subcutaneous			Not Reported
	Kineret			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin Intravenous			S	Intravenous (not			Not Reported

Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	(Human)		otherwise specified)		
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Apo-Triamcinolone Aq	S	Intra-articular		Not Reported
	Apo-Triamcinolone Aq	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Naproxen	S			Not Reported
	Methotrexate Sodium	S			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15752221	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-JNJFOC-20150801224			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Xarelto			S	Transplacental			Not Reported
	Ramipril			S	Transplacental	20 Mg, Qd, Gestational Week 0-13+6		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd, Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental	300 Mg, Qd, Gestational Week 0-5		Not Reported

Hydroxychloroquine	S	Transplacental	400 Mg, Qd, Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental		Not Reported
Metamizole	S	Transplacental		Not Reported
Pantoprazole	S	Transplacental	40 Mg, Qd, Gestational Week 0-14	Not Reported
Prednisolone	S	Transplacental	10 Mg, Bid, Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental		Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Tacrolimus	S	Transplacental	6 Mg, Qd, Gestational Week 0-14	Not Reported
Torasemide	S	Transplacental	100 Mg, Qd, Gestational Week 0-14	Not Reported
Salbutamol	S	Transplacental		Not Reported
Heparin	S	Transplacental		Not Reported
Novaminsulfon	S	Transplacental	, Trimester: First; Probably Only In Hospital In Week 5unk	Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Clexane	S	Transplacental		Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011, Pre Or Periconceptional	Not Reported
Cytotec	C	Transplacental	Unk, Gestational Week 13.6	Not Reported
Mifegyne	C	Transplacental	Unk, Gestational Week 13.6	Not Reported
Cyclophosphamide	C	Transplacental	Unk, 3000 Mg Cumulative; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15781465	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-242755			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Ow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Ml, Ow		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Ow		Not Reported
	Infliximab			S	Unknown	5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Ow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Q1mon		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013829		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Sleep Disorder						otherwise specified)				
	Sodium Aurothiomalate				S	Unknown				Not Reported
	Sulfasalazine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964486	EXPEDITED (15-DAY)		OT	BR-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000275		55 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964501	EXPEDITED (15-DAY)		OT	CA-AMCO LTD-GSH201706-003730		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964502	EXPEDITED (15-DAY)		OT	CA-AMCO LTD-GSH201706-003770		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964503	EXPEDITED (15-DAY)		OT	CA-AMCO LTD-GSH201712-006723		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer;	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	7.5 Mg To 22.5 Mg;		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Staphylococcal Infection; Therapeutic Product Effect Incomplete	Remicade	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Metronidazole	C		Not Reported
	Pregabalin	C		Not Reported
	Deflazacort	C		Not Reported
	Paracetamol	C		Not Reported
	Dilaudid	C		Not Reported
	Risedronate	C		Not Reported
	Salbutamol	C		Not Reported
	Nitroglycerin	C		Not Reported
	Crestor	C		Not Reported
	Hydromorph	C		Not Reported
	Januvia	C		Not Reported
	Pantoprazole	C		Not Reported
	Calcium	C		Not Reported
	Ergocalciferol	C		Not Reported
	Acidophilus	C		Not Reported
	Aspirin	C		Not Reported
	Triamcinolone	C		Not Reported
	Lidocaine	C		Not Reported
	Kenalog	C		Not Reported
	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964504	EXPEDITED (15-DAY)		OT	CA-AMCO LTD-GSH201803-000988		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance;	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Delayed	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Cortisone	C		Not Reported
	Tylenol L 8 Hour	C		Not Reported
	Naproxen	C		Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964506	EXPEDITED (15-DAY)		OT	CA-AMCO LTD-MAPI_00010609		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate Sodium		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964518	EXPEDITED (15-DAY)		HO, OT	PHEH2019US006390			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne; Arthralgia; Blister; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Infusion Site Reaction; Pain; Pain In Extremity; Rash; Rheumatoid Arthritis; Tongue Oedema; Toothache; Ulcer Haemorrhage	Ciclosporin			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qw		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qw		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Unknown	40 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, For 8 Weeks		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15964521	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2019-00767			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Congestive Cardiomyopathy; Oedema	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

Peripheral; Pulmonary Hypertension; Rales; Venous Pressure Jugular Increased	Ramipril		C	Unknown	Unk			Not Reported
	Bisoprolol		C	Unknown	Unk			Not Reported
	Frusemide /00032601/		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15965274	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15965852	NON-EXPEDITED			US-PFIZER INC-2019057079		73 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Rocuronium Bromide			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15965987	NON-EXPEDITED			US-PFIZER INC-2019065330			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15966293	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-009		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Drug-Disease Interaction; Pyomyositis	Hydroxychloroquine			S	Unknown			Hikma
	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Trimethoprim Sulfamethoxazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15966755	EXPEDITED (15-DAY)		OT	AU-NOVAST LABORATORIES, LTD-AU-2019NOV000044		77 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Butalbital, Acetaminophen, And Caffeine			S		Unk		Novast
	Tapentadol			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Citalopram			S		Unk		Not Reported
	Temazepam			S		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15966958	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1012932		75 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Wound	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram		Mylan
	Humira			S	Subcutaneous	40 Milligram, Biweekly		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967120	NON-EXPEDITED			US-SA-2019SA039616			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967123	NON-EXPEDITED			US-SA-2019SA040152			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Treatment Failure	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Prednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967155	NON-EXPEDITED			US-SA-2019SA040058			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity	Arava			S				Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967167	NON-EXPEDITED			US-SA-2019SA040153			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967174	NON-EXPEDITED			US-SA-2019SA040160			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dyspnoea; Gastrointestinal Disorder; Rash	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967184	NON-EXPEDITED			US-SA-2019SA040101			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967198	NON-EXPEDITED			US-SA-2019SA040662			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Retinal Disorder	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967209	NON-EXPEDITED			US-SA-2019SA041284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Therapeutic Response Decreased	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967215	NON-EXPEDITED			US-SA-2019SA041287			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea;	Arava			S		Unk		Sanofi

Therapeutic Response Decreased	Plaquenil		S		Unk		Sanofi
	Methotrexate		S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967222	NON-EXPEDITED			US-SA-2019SA040000			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967225	NON-EXPEDITED			US-SA-2019SA041282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Liver Function Test Increased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz			S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967230	NON-EXPEDITED			US-SA-2019SA041293			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contusion; Cough; Drug Ineffective; White Blood Cell Count Decreased	Arava			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Celecoxib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967302	NON-EXPEDITED			US-SA-2019SA041289			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967325	NON-EXPEDITED			US-SA-2018SA044844			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fear Of Disease; Liver Function Test Abnormal; Malaise; Skin Toxicity	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S				Not Reported
	Enbrel			C				Not Reported
	Rituxan			C				Not Reported
	Xeljanz			C	Oral	11 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967347	NON-EXPEDITED			US-SA-2019SA041776			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967380	NON-EXPEDITED			US-SA-2019SA041286			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Drug Ineffective; Unevaluable Event	Arava			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			C	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967381	NON-EXPEDITED			US-SA-2019SA042015			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967388	NON-EXPEDITED		OT	US-SA-2019SA041914			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Hepatic Enzyme Abnormal; Pancreatitis	Arava			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Imovane			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967500	NON-EXPEDITED			US-SA-2019SA041759			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Lipids Abnormal	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Infliximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15967575	NON-EXPEDITED			US-SA-2019SA042122			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15968116	NON-EXPEDITED			US-SA-2019SA042865			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Stomatitis; Therapeutic Response Decreased; Treatment Failure	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S		Unk		Sanofi
	Humira			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15968126	NON-EXPEDITED		OT	US-SA-2019SA042898			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Ocular Toxicity; Rash; Therapeutic Product Effect Decreased	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S				Not Reported
	Simponi Aria			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15968140	NON-EXPEDITED			US-SA-2019SA042853			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Celecoxib			S				Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15968217	NON-EXPEDITED		OT	US-SA-2019SA043141			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Hyperpigmentation	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz Xr			C	Oral	11 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15969054	EXPEDITED (15-DAY)		OT	PHHY2019US034984			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2019	15971255	EXPEDITED (15-DAY)		DE, LT, OT	PHHY2018AU179222		31 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Face Oedema; Lymphadenopathy; Pyrexia; Rash Morbilliform; Shock; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2019	12427477	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2013056563		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Oral	37.5 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Morphine	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	M-Eslon	C		10 Mg, Bid		Not Reported
	Statex	C		5 Mg, 4-6 Hours		Not Reported
	Hydrodiuril	C	Unknown	12.5 Mg, Once Daily		Not Reported
	Arava	C		Unk		Not Reported
	Cimzia	C		Unk		Not Reported
	Actemra	C		Unk		Not Reported
	Effexor	C	Oral	37.5 Mg, Once Daily		Not Reported
	Orencia	C		Unk		Not Reported
	Morphine Sulfate	C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2019	15973018	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1013544		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2019	15973612	NON-EXPEDITED		OT	PHEH2019US006409			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Disorder; Condition Aggravated; Pain	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	14236021	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006532		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine Tablet			S	Oral			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	14361160	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000052		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Drug Ineffective; Drug Ineffective; Drug	Hydroxychloroquine Tablet			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported

Intolerance; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Methotrexate Sodium			S	Oral	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Xeljanz			C		Not Reported
	Meloxicam			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	14361872	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000055		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; No Adverse Event; Respiratory Arrest; Visual Impairment	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15034337	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010703		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Hydroxychloroquine Tablet		S	Unknown	Concordia
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone		S	Oral	Not Reported
	Desoximetasone		S	Oral	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	Not Reported
	Cortisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15759193	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004185		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported

Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Methotrexate Sodium	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Sulfasalazine	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15974066	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000282		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydromorphone Hydrochloride			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Percocet			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15974067	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000290		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine 200 Mg Tablet			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Cimzia			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Celebrex			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15974068	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000302		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cefalexin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15974074	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000303		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion;	Plaquenil Tablet			S	Oral			Concordia

C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Arava		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Remicade		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15974075	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000313		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Plaquenil			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2019	15974076	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000281			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	8180854	EXPEDITED (15-DAY)		CA, HO, OT	DE-PFIZER INC-2011240717			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fallot'S Tetralogy; Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent	Delix (Ramipril)			S	Transplacental	20 Mg, 1x/Day		Pfizer
	Falithrom			S	Transplacental	3 Mg, 2x/Day		Not Reported
	Cyclosporine A			S	Transplacental	150 Mg, 2x/Day		Not Reported
	Torem [Torasemide]			S	Transplacental	10 Mg, 1x/Day		Not Reported
	Torem [Torasemide]			S	Transplacental	100 Mg, Unk		Not Reported
	Quensyl			S	Transplacental	400 Mg, Daily (Every Days)		Not Reported
	Inegy			S	Transplacental	Unk (40 [Mg/D] / 10 [Mg/D)		Not Reported
	Rituximab			S	Transplacental	Unk (Last Time In December 2011: Pre Or Periconceptional)		Not Reported
	Tacrolimus			S	Transplacental	6 Mg, Unk		Not Reported
	Advagraf			S	Transplacental	6 Mg, Unk (6 Mg, Unk 6 [Mg/D])		Not Reported
	Clexane			C	Transplacental	60mg And 80 Mg, 140 Mg, 1x/Day		Not Reported
	Clexane			C	Transplacental	Unk		Not Reported
	Prednisolone			C	Transplacental	7.5 Mg, 1x/Day		Not Reported
	Prednisolone			C	Transplacental	Unk		Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			C	Transplacental	Unk		Not Reported
	Albuterol [Salbutamol]			C	Transplacental	Unk		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Cyclophosphamid			C	Transplacental	Unk		Not Reported
	Xarelto			C	Transplacental	10 Mg, Unk		Not Reported
	Novaminsulfon			C	Transplacental	Unk		Not Reported

	Aliskiren	C	Transplacental	Unk		Not Reported
	Mifegyne	C	Transplacental	Unk		Not Reported
	Rasilez	C	Transplacental	Unk		Not Reported
	Salbutamol	C	Transplacental	Unk		Not Reported
	Ass	C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	11567356	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1638076		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis;	Naproxen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 153 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral	Therapy Duration: 10 Years		Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 63 Days, Therapy Duration: 3 Months		Not Reported
	Orencia			S	Respiratory (inhalation)			Not Reported

Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)	Qmo	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 3 Months Therapy Duration: 62 Days	Not Reported
	Kineret	S	Subcutaneous	Therapy Duration: 700 Days, Therapy Duration: 3 Years	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 8.0 Month(S)	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 4 Months	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Months	Not Reported
	Infliximab	S	Unknown	Therapy Duration: 62 Days	Not Reported
	Sulfasalazine	S	Oral	500 Mg Tablet	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Ivig	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
	Ivig	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Abatacept	S	Intravenous (not		Not Reported

			otherwise specified)		
	Abatacept	S	Intravenous drip	Therapy Duration: 3 Months	Not Reported
	Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous	Cyclic Therapy Duration: 4 Months	Not Reported
	Immune Globulin Nos	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	12723166	EXPEDITED (15-DAY)		OT	CA-ROCHE-1827234		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Tendon Disorder	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	12914293	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091894		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous	250 Mg, Unk		Bristol Myers Squibb
	Celebrex			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	13519794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown			Not Reported
	Reactine /00884302/	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	13851383	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070652		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	13854687	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	14502121	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010645		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling; Product Dose Omission	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	14632417	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038313		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia	S	Unknown	12.5 Mg, Q2wk	Bristol Myers Squibb
	Orencia	S	Unknown	125 Mg, Qwk	Bristol Myers Squibb
	Orencia	S	Unknown	12.5 Mg, Unk	Bristol Myers Squibb
	Celebrex	S	Oral	200 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Leflunomide	S	Oral	10 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	5 Mg, Q2wk	Not Reported
	Methotrexate	S	Unknown	7.5 Mg, Q2wk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q2wk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Q2wk	Not Reported
	Methotrexate	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	7.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	7.5 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	10.0 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Enbrel	S	Unknown	1.0 Ml, Qwk	Not Reported
	Enbrel	S	Unknown	25 Mg, Q2wk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Qwk	Not Reported

Enbrel	S	Unknown	25 Mg, Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	300 Mg, Qd	Not Reported
Prednisone	C	Oral	5 Mg, Tid	Not Reported
Prednisone	C	Unknown	15 Mg, Qd	Not Reported
Prednisone	C	Oral	5 Mg, Unk	Not Reported
Shark Liver Oil	C	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Mg, Unk	Not Reported
Taro-Mupirocin	C	Topical		Not Reported
Tramacet	C	Oral		Not Reported
Tramadol Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Unk	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Unk, Unk	Not Reported
Altace	C	Unknown	5 Mg, Unk	Not Reported
Altace	C	Unknown	10 Mg, Unk	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, Q2wk	Not Reported
Atorvastatin Calcium	C	Oral	40 Mg, Qd	Not Reported
Cipralex /01588501/	C	Unknown	10 Mg, Unk	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Mg, Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
Apo-Gabapentin	C	Unknown	300 Mg, Unk	Not Reported
Apo-Gabapentin	C	Oral	100 Mg, Unk	Not Reported
Apo-Prednisone	C	Oral	15 Mg, Qd	Not Reported
Apo-Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Conjugated Estrogens	C	Oral	0.625 Mg, Unk	Not Reported
Cymbalta	C	Unknown	60 Mg, Unk	Not Reported

Cymbalta	C	Unknown	120 Mg, Qd		Not Reported
Cymbalta	C	Unknown	30 Mg, Qid		Not Reported
Escitalopram	C	Unknown	10 Mg, Unk		Not Reported
Estrace	C	Unknown	0.5 Mg, Unk		Not Reported
Gabapentin	C	Unknown	300 Mg, Unk		Not Reported
Gabapentin	C	Oral	100 Mg, Unk		Not Reported
Pantoloc /01263201/	C	Unknown	20 Mg, Qd		Not Reported
Mupirocin	C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	14922041	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044305		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	14923972	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Methotrexate	S	Unknown	25 Mg, Unk		Not Reported
	Mirtazapine	S	Unknown	15 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15943391	EXPEDITED (15-DAY)		OT	PHHY2019CA026884			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15946651	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011535		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

				Rituximab		S	Unknown	1 G, Unk	Not Reported
				Tocilizumab		S	Unknown	Unk	Not Reported
				Actemra		S	Unknown	Unk	Not Reported
				Leflunomide		C	Unknown	20 Mg, Qd	Not Reported
				Methotrexate		C	Subcutaneous	20 Mg, Qd	Not Reported
				Methotrexate		C	Unknown	0.8 Ml, Qd	Not Reported
				Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974252	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2666576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindicated Product Administered; Hepatic Steatosis; Squamous Cell Carcinoma; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra Iv			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974274	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000292			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974275	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Unknown	USA

						INC.-GSH201902-000293				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974276	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000274			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974852	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1013976		61 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974876	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1208		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Feeding	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Disorder; Gait Disturbance; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Joint Swelling; Pain In Extremity; Weight Decreased	Enbrel			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Voltaren			S	Unknown	Not Reported
	Diclofenac Sodium			S	Unknown	Not Reported
	Arava			C	Unknown	Not Reported
	Dexilant			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15974881	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0467		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15975431	EXPEDITED (15-DAY)		OT	US-SA-2019SA043761		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Blood Glucose Increased; Cystitis; Diarrhoea; Drug Intolerance; Insomnia; Osteopenia; Rash; Rheumatoid Arthritis;	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Stomatitis; Swelling; Visual Impairment	Enbrel	S		Unk	Not Reported
	Xeljanz Xr	S	Oral	1 Df, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		Unk	Not Reported
	Gold	S		Unk	Not Reported
	Acthar [Corticotropin]	C		Unk	Not Reported
	Latanoprost	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15976385	EXPEDITED (15-DAY)		HO, OT	US-NOVOPROD-646440		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Victoza			S	Subcutaneous	Unk		Novo Nordisk
	Humira			S	Subcutaneous	40 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Biw		Not Reported
	Humira			S				Not Reported
	Ambien			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Effexor			S		Unk		Not Reported
	Famotidine			S		Unk		Not Reported
	Flomax /01280302/			S		Unk		Not Reported
	Furosemide			S		Unk		Not Reported
	Gabapentin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Imdur			S		Unk		Not Reported
	Loperamide			S		Unk		Not Reported
	Nexium /01479302/			S		Unk		Not Reported
	Nifedipine			S		Unk		Not Reported

	Nitroglycerin	S	Unk	Not Reported
	Plavix	S	Unk	Not Reported
	Potassium	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Reglan /00041901/	S	Unk	Not Reported
	Trandolapril	S	Unk	Not Reported
	Trazodone	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15977195	EXPEDITED (15-DAY)		HO, OT	PHHY2019BR033243		18 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Blood Fibrinogen Decreased; Cytomegalovirus Infection; Erythema; Haemophagocytic Lymphohistiocytosis; Hypertriglyceridaemia; Injury; Lymphadenopathy; Sepsis; Skin Lesion; Splenomegaly	Prednisone			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978038	NON-EXPEDITED			US-SA-2019SA042608			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Liver Function Test Abnormal; Psoriasis; Rash	Sulfasalazine			S				Not Reported
	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978040	NON-EXPEDITED			US-SA-2019SA041959			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Migraine	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978080	NON-EXPEDITED			US-SA-2019SA044064			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Arava			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978117	NON-EXPEDITED			US-SA-2019SA043974			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Humira			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978123	NON-EXPEDITED			US-SA-2019SA043962			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Diarrhoea; Drug Ineffective; Rash	Arava	S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate	S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil	S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone	S	Unknown	Unk Unk, Unk		Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk Unk, Unk		Not Reported
	Humira	S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978127	NON-EXPEDITED			US-SA-2019SA044242			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective	Arava			S				Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978160	NON-EXPEDITED			US-SA-2019SA044986			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Therapeutic Response Decreased	Arava			S				Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978166	NON-EXPEDITED			US-SA-2019SA044282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Arava			S				Sanofi

	Methotrexate			S	Oral	Unk			Not Reported
	Plaquenil			S		Unk			Sanofi
	Sulfasalazine			S					Not Reported
	Enbrel			S		Unk			Not Reported
	Humira			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978169	NON-EXPEDITED			US-SA-2019SA044773			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hepatic Enzyme Increased; Tongue Oedema	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Cyclosporin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978199	NON-EXPEDITED			US-SA-2019SA044243			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Dyspnoea; Fatigue; Ill-Defined Disorder	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978202	NON-EXPEDITED			US-SA-2019SA046102			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S				Sanofi
	Plaquenil			S				Sanofi

	Enbrel	S				Not Reported
	Humira	S				Not Reported
	Methotrexate	C		25 Mg, Qw		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2019	15978211	NON-EXPEDITED			US-SA-2019SA045911			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscular Weakness; Myalgia	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	11057721	EXPEDITED (15-DAY)		OT	CA-ROCHE-1233662		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Most Recent Dose Of Rituximab: 12/Jun/2017		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported

Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Sulfasalazine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Etanercept			S	Unknown				Not Reported
	Kineret			S	Unknown				Not Reported
	Infliximab			S	Unknown				Not Reported
	Diphenhydramine Hcl			C	Oral				Not Reported
	Acetaminophen			C	Oral				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)				Not Reported
	Oxycontin			C					Not Reported
	Folic Acid			C					Not Reported
	Ferrous Gluconate			C					Not Reported
	Lasix			C					Not Reported
	Oxyneo			C					Not Reported
	Naprosyn			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	14456326	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2236724-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Hypersensitivity; Injection Site Pain; Injection Site Reaction; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15478389	NON-EXPEDITED			US-SA-2018SA277368			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Dyspnoea; Liver Function Test Increased; Phobia	Arava			S	Unknown	Unk, Unk		Sanofi
	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978243	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978279	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013823			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Mg, Unk		Not Reported

Ineffective; Rheumatoid Arthritis; Weight Increased	Humira		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil /00072602/		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Levothyroxine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978299	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013830			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20.0 Mg, Qwk		Not Reported
	Prednisone			S	Oral	5.0 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978454	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013947		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported

Intolerance; Finger Deformity; Headache; Macular Degeneration; Pain In Extremity; Peripheral Swelling; Synovitis; Wrist Deformity	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	25 Mg, Qd		Not Reported
	Asacol			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Endocervical	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013866		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept /01275102/			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978806	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Cetirizine		S	Unknown	10 Mg, Unk	Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Cortisone Acetate		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown	5 Mg, Unk	Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978829	EXPEDITED (15-DAY)		OT	CA-ROCHE-2265540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
		Sulfasalazine			S		Unknown			Not Reported
		Methotrexate			S		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978833	EXPEDITED (15-DAY)		OT	CA-ROCHE-2261460		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Oxycodone Cr			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15978852	NON-EXPEDITED			PHEH2019US007070			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Cosentyx			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15979009	EXPEDITED (15-DAY)		DE, OT	AU-IPCA LABORATORIES LIMITED-IPC-2019-AU-000199			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15979729	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010573		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Plaquenil			S	Oral	Unknown		Not Reported
	Celecoxib			S	Unknown			Not Reported
	Sulfasalazine			S	Rectal			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15979898	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-033718		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Dyspnoea; Hypotension; Hypoxia; Mycobacterial	Azathioprine			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Zydus Pharm

Infection; Nodular Rash; Peripheral Swelling; Pneumocystis Jirovecii Pneumonia; Pneumonia; Pustule; Pyrexia; Rash; Rash Erythematous; Respiratory Distress; Respiratory Failure; Skin Exfoliation; Tenderness	Rituximab	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15980026	EXPEDITED (15-DAY)		HO, LT, OT	NL-ALKEM LABORATORIES LIMITED-NL-ALKEM-2019-01502		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Drug Ineffective; Myocarditis; Renal Tubular Necrosis; Respiratory Failure	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Alkem
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Low Dose		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Cyclophosphamide			S	Unknown	Unknown		Not Reported
	Methylprednisolone			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15980078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2264569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Lupus Erythematosus	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Reactine (Canada)		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15981882	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1014875		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Lisinopril			S	Oral	1 Dosage Form, Total		Not Reported
	Diltiazem			S	Oral	1 Dosage Form, Total		Not Reported
	Plaquenil /00072603/			S	Oral	1 Dosage Form, Total		Mylan
	Hydrochlorothiazide			S	Oral	1 Dosage Form, Total		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15982619	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015104366		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Drug Ineffective; Eye Disorder;	Methotrexate Sodium			S	Oral	Superior Or Equal To 20mg/Week, Minimum Of 12 Weeks Of Continuous		Pfizer

Fatigue; Malaise; Musculoskeletal Stiffness; Night Sweats; Peripheral Swelling; Temperature Intolerance; Vomiting				Treatment	
	Plaquenil	S		Unk	Not Reported
	Arava	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15984007	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1015665		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Visual Impairment	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		7.5 Mg, Qw		Not Reported
	Etanercept			C		Unk		Mylan
	Rituximab			C		Unk		Mylan
	Adalimumab			C		Unk		Mylan
	Prednisone			C		5 Mg, Qd		Mylan
	Tocilizumab			C		8 Mg/Kg, Q4w		Mylan
	Infliximab			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2019	15984234	NON-EXPEDITED			US-AMGEN-USASP2019025155			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Azulfidine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	13372544	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001950		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Certolizumab			S	Subcutaneous			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

		Rituximab			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Simponi			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	14173093	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3466		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	14931907	EXPEDITED (15-DAY)		OT	US-ROCHE-2123843			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Chronic Kidney Disease; Epistaxis; Fall; Joint Swelling; Leukopenia; Rash; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cholestyramine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution For Injection		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15133247	EXPEDITED (15-DAY)		DE, DS, HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002251		49 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Infection; Antiphospholipid Antibodies; Hypersensitivity; Musculoskeletal Stiffness; Pain; Product Dose Omission; Product Use Issue; Therapeutic Response Decreased	Plaquenil			S	Unknown			Concordia
	Kevzara			S	Subcutaneous			Not Reported
	Kevzara			S	Subcutaneous			Not Reported
	Sarilumab Pre-Filled Syringe			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15523908	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018416313		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability;	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

Herpes Zoster; Hiatus Hernia; Insomnia; Muscle Spasms; Sarcoidosis; Skin Cancer	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk		Not Reported
	Humira	S	Unk		Not Reported
	Cimzia	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15716710	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004107		61 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Juvela			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15955633	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000299			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15983307	EXPEDITED (15-DAY)		HO	CA-ROCHE-2261481		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Anakinra		S	Subcutaneous	Not Reported
	Apo-Hydroxyquine		S	Oral	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Infliximab		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15983661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2209		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Drug Ineffective; Eye Disorder; Fatigue; Malaise; Musculoskeletal Stiffness; Night Sweats; Peripheral Swelling; Temperature Intolerance; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral	Dose Superior Or Equal To 20mg/Week, Minimum Of 12 Weeks Of Continuous Treatment		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15983837	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015008		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Thrombosis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15983927	EXPEDITED (15-DAY)		OT	DE-AMGEN-DEUNI2019025967			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Foot Fracture	Etanercept			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984926	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017576			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15984940	EXPEDITED (15-DAY)		OT	US-SA-2019SA045229			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance; Nephrotic Syndrome; Oedema; Rash	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported

	Sodium Aurothiomalate	S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil	S	Unknown	Unk Unk, Unk		Sanofi
	Penicillamine	S	Unknown	Unk Unk, Unk		Not Reported
	Humira	S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk		Not Reported
	Orencia	S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan	S	Unknown	Unk Unk, Unk		Not Reported
	Actemra	S	Unknown	Unk Unk, Unk		Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985333	DIRECT		DS, OT			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Nausea; Product Substitution Issue; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Watson

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985531	NON-EXPEDITED			US-AMGEN-USASP2019025883			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985875	EXPEDITED (15-DAY)		HO	PHHY2019FR034330		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nail Disorder; Nail Pigmentation	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15985897	EXPEDITED (15-DAY)		OT	US-ABBVIE-19S-163-2659840-00		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dyspnoea; Fatigue; Renal Function Test Abnormal; Renal Pain; Systemic Lupus Erythematosus; Weight Increased	Synthroid			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Triamterene/Hydrocholothiazide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15986090	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2673017-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15986319	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017592			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Injection Site Reaction; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15987993	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000316			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15987995	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000312			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Syncope	Plaquenil			S				Concordia
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15987996	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000331			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Pancreatitis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Imovane			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2019	15987997	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000387			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Pancreatitis; Skin Hyperpigmentation	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	10653444	EXPEDITED (15-DAY)		DS	FR-009507513-1412FRA006146		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Fosamax			S	Oral	Unk		Merck
	Lasilix			S	Oral	Unk		Not Reported

	Plaquenil	S	Oral	Unk	Not Reported
	Lexomil	S	Oral	Unk	Not Reported
	Cacit Vitamine D3	S	Oral	Unk	Not Reported
	Rivotril	S	Oral	Unk	Not Reported
	Avodart	S	Oral	Unk	Not Reported
	Cymbalta	S	Oral	Unk	Not Reported
	Inexium (Esomeprazole Magnesium)	S	Oral	Unk	Not Reported
	Salazopyrine	S	Oral	Unk	Not Reported
	Salazopyrine	S	Oral		Not Reported
	Tahor	S	Oral	Unk	Not Reported
	Forlax	S	Oral	Unk	Not Reported
	Skenan	S	Oral	Unk	Not Reported
	Cortancyl	S	Oral	Unk	Not Reported
	Metoject	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	13931734	EXPEDITED (15-DAY)		HO	CA-ROCHE-1836871		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Dosage Form: Kit Nos		Not Reported
	Plaquenil			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	14763773	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107864		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Calcium Gluconate			C				Not Reported
	Dorzolamide Hydrochloride			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C				Not Reported
	Furosemide			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15495062	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2018141634			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Fatigue; Feeling Abnormal; Psoriasis; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15693232	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004071		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 M/Day On Alternate Days		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 M/Day On Alternate Days		Concordia
	Lansoprazole			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15988868	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262888		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15989630	NON-EXPEDITED			US-PFIZER INC-2019068405		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15989684	NON-EXPEDITED			US-PFIZER INC-2019080497			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15990049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2264604		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15990074	EXPEDITED (15-DAY)		OT	CA-ROCHE-2268505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported

Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Prednisolone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15990186	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2673015-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15990263	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674821-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Methotrexate			C						Not Reported
	Prednisolone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15991854	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019035465		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Sulfasalazine			S		2 G, Unk		Pfizer
	Plaquenil S			S		Unk		Not Reported
	Arava			C		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2268502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992666	EXPEDITED (15-DAY)		OT	CA-ROCHE-2268511		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992668	EXPEDITED (15-DAY)		OT	CA-ROCHE-2264580		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain;	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: -59.0		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 4.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Diclofenac			C				Not Reported

Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Pantoprazole Magnesium	C	Unknown			Not Reported
	Plaquenil	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Depo-Medrol	C	Intra-articular	Therapy Duration: 1.0 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992675	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992699	EXPEDITED (15-DAY)		DS	CA-ROCHE-2267302		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992705	EXPEDITED (15-DAY)		OT	CA-ROCHE-2267298		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15992822	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016048		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Swelling; Weight Decreased	Chloroquine			S	Unknown	250 Milligram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown	20 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	250 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15003690	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001573			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Rash; Skin Lesion; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Oedema; Toothache; Ulcer Haemorrhage	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	(3 Times),		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S				Not Reported
	Cyclosporin			S				Not Reported
	Doxycycline			S				Not Reported
	Xeljanz			C				Not Reported
	Candex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15535216	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2966		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Herpes Zoster; Hiatus Hernia; Insomnia; Knee Arthroplasty; Muscle Spasms; Pain; Pain In Extremity; Sarcoidosis; Skin Cancer	Plaquenil			S	Unknown	Not Reported
	Humira			S	Unknown	Not Reported
	Cimzia			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15978164	NON-EXPEDITED			US-SA-2019SA044284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Hypersensitivity; Liver Function Test Abnormal; Rash	Arava			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Azathioprine			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15981867	EXPEDITED (15-DAY)		HO	US-JNJFOC-20190218067			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; Gait Inability; Pain	Stelara			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

	Cimzia		S	Subcutaneous	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15988757	EXPEDITED (15-DAY)		DS, OT	GR-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000361		70 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Optic Neuropathy; Visual Impairment	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15993447	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001105		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fatigue; Malaise; Nausea; Pain In Extremity; Rash; Systemic Lupus Erythematosus	Plaquenil			S	Unknown	Unknown		Not Reported
	Plaquenil			S				Not Reported
	Cerezyme			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15993877	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016193			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15993956	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015569		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cellulitis; Drug Ineffective; Drug Intolerance; Myalgia; Nausea; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Leflunomide			S	Oral	10 Milligram Daily;		Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15994008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2268536		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Lyrica			C	Oral				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15994010	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000411			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance; Nephrotic Syndrome; Oedema; Rash	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15994013	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015074			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15994131	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000410			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Throat Cancer	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15994320	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2676438-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15994957	EXPEDITED (15-DAY)		HO, LT	US-APPCO PHARMA LLC-2063055		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine Sulfate			S				Appco Pharma
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15995130	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0299		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15997319	NON-EXPEDITED			US-SA-2019SA044075			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15997760	NON-EXPEDITED			US-SA-2019SA044279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Toxicity To Various Agents	Arava			S				Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	14559962	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2263188-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15467737	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018136082		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing;	Etanercept			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	624 Mg, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	680 Mg, Q4wk		Not Reported

Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Anakinra	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	680 Mg, Q4wk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	624 Mg, Q4wk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Lasix	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported
	Oxycontin	C	Unknown	Unk	Not Reported
	Oxyneo	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2019	15998676	NON-EXPEDITED		OT	PHEH2019US007723			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2019	15157435	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2417624-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Fear Of Injection; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mtx			S	Intramuscular			Not Reported
	Mtx			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	12248361	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1737509		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Dysphonia; Gait Disturbance; Joint	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Spinal Operation; Sputum Discoloured; Thrombosis	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Warfarin		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Apo-Prednisone		S	Unknown	Not Reported
	Amitriptyline		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	12511500	EXPEDITED (15-DAY)		OT	CA-ROCHE-1784162			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	14203933	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3711		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Arthritis; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Advil	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Mefenamic Acid	S	Unknown	Not Reported

		Mefenamic Acid			S	Unknown				Not Reported
		Apo-Leflunomide			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	14630967	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2082164		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer; Deep Vein Thrombosis; Foot Fracture; Fracture; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Radiculopathy; Rotator Cuff Syndrome; Secondary Immunodeficiency; Spinal Osteoarthritis; Stenosis; Stomatitis; Vitamin D Deficiency	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazin			S	Unknown			Not Reported
	Sulfasalazin			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Most Recent Dose: /Jan/2015		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Mtx Support			S	Unknown			Not Reported
	Pantozol (Germany)			C	Unknown			Not Reported
	Cotrimoxazole			C	Unknown			Not Reported
	Colecalciferol			C	Unknown			Not Reported
	Tapentadol			C	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Prednisolon			C	Unknown			Not Reported

	Anastrozol			C	Unknown					Not Reported
	Celecoxib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	14800900	EXPEDITED (15-DAY)		HO	DE-ROCHE-2111044		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Granulosa Cell Tumour	Tocilizumab			S	Unknown			Not Reported
	Methotrexat			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	15693452	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2067131-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Cosopt	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Codeine Phosphate	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
	Methotrexate Sodium	C	Subcutaneous	Not Reported
	Tylenol No.2	C		Not Reported
	Plaquenil	C		Not Reported
	Tylenol	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Acetaminophen W/Codeine Phosphate	C		Not Reported
	Acetaminophen W/Caffeine/Dihydrocodeine	C		Not Reported
	Methylprednisolone	C		Not Reported
	Diphenhydramine	C		Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen W/Caffeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	15773654	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2018-036647			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Ramipril			S	Unknown	20 Milligram, Exposure Duration: 0-13+6 Weeks At 1 {Trimester}		Aurobindo
	Pantoprazole			S	Unknown	Gestational Week 0-14		Aurobindo
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw) ()		Aurobindo
	Ezetimibe			S	Unknown	Exposure Duration: 0-14		Aurobindo

			Weeks	
Acetylsalicylic Acid	S	Unknown	Unk, Exposure Duration: 0-14 Weeks	Not Reported
Metamizole	S	Intracardiac	Exposure Duration: 0-14 Weeks	Not Reported
Salbutamol	S	Unknown	Exposure Duration: 0-14 Weeks	Not Reported
Rivaroxaban	S	Unknown	Exposure Duration: 0-5 Weeks	Not Reported
Prednisolone	S	Unknown	Exposure Duration: 0-14 Weeks	Not Reported
Nicotine	S	Unknown	Exposure Duration: 0-14 Weeks	Not Reported
Tacrolimus	S	Unknown	Unk, Exposure Duration: 0-14 Weeks	Not Reported
Torasemide	S	Unknown	Unk, Exposure Duration: 0-14 Weeks	Not Reported
Hydroxychloroquine	S	Unknown	Exposure Duration: 0-14 Weeks	Not Reported
Aliskiren	S	Unknown	Unk, Exposure Duration: 0-5 Weeks	Not Reported
Enoxaparin	C	Intracardiac	Unk, Exposure Duration: 0-14 Weeks	Not Reported
Metamizole	C	Intracardiac	Exposure Duration: 0-14 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	15935490	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2656873-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000172	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019006376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Cimzia			S	Subcutaneous			Ucb
	Acetaminophen			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S		50 Mg, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day (Bid)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Acetaminophen W/Codeine Phosphate			C				Not Reported

	Celebrex	C	Not Reported
	Hydromorphone Hydrochloride	C	Not Reported
	Meloxicam	C	Not Reported
	Methotrexate	C	Not Reported
	Synthroid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000225	EXPEDITED (15-DAY)		HO	US-CELGENEUS-USA-20190204369			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; Dysstasia; Gait Inability; Pain	Otezla			S	Oral			Celgene
	Otezla			S				Celgene
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Stelara			S	Unknown			Not Reported
	Stelara			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000317	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018003258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

	Actemra			S						Not Reported
	Tofacitinib			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000583	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016555		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Naprosyn			C	Unknown			Not Reported
	Folic Acid			C	Unknown	5 Milligram Daily;		Not Reported
	Citalopram			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16000632	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Sodium Aurothiomalate			C	Unknown			Not Reported
	Sodium Aurothiomalate			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

	Naproxen	C	Unknown	250 Milligram Daily;		Not Reported
	Naproxen	C	Unknown			Not Reported
	Lyderm	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Hydrocortisone Valerate	C	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16001169	NON-EXPEDITED			PHEH2019US007851			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16001993	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019079161			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Arthralgia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective For Unapproved Indication; Dysstasia; Gait Inability	Lyrica			S		Unk		Pfizer
	Lyrica			S				Pfizer
	Cimzia			S		Unk		Not Reported
	Cimzia			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Stelara			S		Unk		Not Reported
	Stelara			S				Not Reported
	Otezla			S		Unk		Not Reported
	Otezla			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002107	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002136	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269336		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid	Actemra			S	Subcutaneous			Not Reported

Arthritis; Therapeutic Product Effect Decreased	Apo-Hydroxyquine			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Meloxicam			C	Oral	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002138	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269371			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002142	EXPEDITED (15-DAY)		LT	CA-ROCHE-2269298		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis	Rituxan	S	Unknown	Not Reported
	Rituxan	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002153	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown	Not Reported
	Apo-Hydroxyquine			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Tofacitinib			S	Subcutaneous	Not Reported
	Tofacitinib			S	Unknown	Not Reported
	Celebrex			C	Oral	Not Reported
	Ibuprofen			C	Oral	Not Reported
	Lipitor			C	Oral	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002154	EXPEDITED (15-DAY)		OT	CA-ROCHE-2270112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002170	EXPEDITED (15-DAY)		OT	US-ROCHE-2271634			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dizziness; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Headache; Herpes Zoster; Neuropathy Peripheral; Stomatitis	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002225	EXPEDITED (15-DAY)		OT	CA-ROCHE-2266504		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 132.0		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Aspirin	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002553	NON-EXPEDITED			US-SA-2019SA045245			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hypersensitivity; Infection	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002582	NON-EXPEDITED			US-SA-2019SA046572			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002595	NON-EXPEDITED			US-SA-2019SA046825			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Fexofenadine Hydrochloride			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002620	NON-EXPEDITED			US-SA-2019SA045819			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002621	NON-EXPEDITED			US-SA-2019SA049525			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Simponi Aria			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002665	NON-EXPEDITED			US-SA-2019SA045235			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Drug Intolerance; Hypersensitivity; Liver Function Test Increased	Arava	S	Unk		Sanofi
	Hydroxychloroquine Sulfate	S	Unk		Sanofi
	Methotrexate	S	Unk		Not Reported
	Humira	S			Not Reported
	Orencia	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002666	NON-EXPEDITED			US-SA-2019SA045227			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002705	NON-EXPEDITED			US-SA-2019SA047255			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Arava			S				Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002716	NON-EXPEDITED			US-SA-2019SA047096			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported

	Plaquenil			S		Unk Unk, Unk			Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002732	NON-EXPEDITED			US-SA-2019SA047991			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Nausea; Vomiting	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002737	NON-EXPEDITED			US-SA-2019SA047316			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk Unk, Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002820	NON-EXPEDITED			US-SA-2019SA047992			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002823	NON-EXPEDITED			US-SA-2019SA047242			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Arava			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S				Sanofi
	Enbrel			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002835	NON-EXPEDITED			US-SA-2019SA050820			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Arava			S				Sanofi
	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002839	NON-EXPEDITED			US-SA-2019SA047986			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Arava	S	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unk	Sanofi
	Methotrexate	S	Unk	Not Reported
	Diclofenac Sodium	S	Unk	Not Reported
	Sulfasalazine	S	Unk	Not Reported
	Humira	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002846	NON-EXPEDITED			US-SA-2019SA047995			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Simponi Aria			S		Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002862	NON-EXPEDITED			US-SA-2019SA050633			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Intolerance; Rash	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Humira			S		Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Rituxan			S		Unk Unk, Unk		Not Reported
	Imuran [Azathioprine]			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002867	NON-EXPEDITED			US-SA-2019SA050739			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Kevzara			S		Unk		Sanofi
	Humira			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002910	NON-EXPEDITED			US-SA-2019SA050849			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Ascorbic Acid			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd (30 Days)		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd (14 Days)		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd (28 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002915	NON-EXPEDITED			US-SA-2019SA050834			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Disorder; Injection Site	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported

Reaction; Unevaluable Event	Arava	S	Unknown	Unk, Unk		Sanofi
	Plaquenil	S	Unknown	Unk Unk, Unk		Sanofi
	Humira	S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Xeljanz Xr	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002919	NON-EXPEDITED			US-SA-2019SA047994			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Prednisone			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002975	NON-EXPEDITED			US-SA-2019SA050582			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002985	NON-EXPEDITED			US-SA-2019SA050727			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Therapeutic Response Decreased;	Arava			S	Unknown	Unk Unk, Unk		Sanofi

Treatment Failure	Plaquenil		S	Unknown	Unk Unk, Unk	Sanofi
	Plaquenil		S	Unknown	Unk Unk, Unk	Sanofi
	Methotrexate		S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel		S	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002990	NON-EXPEDITED			US-SA-2019SA050561			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Ulcer; Lung Disorder; Rash	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002992	NON-EXPEDITED			US-SA-2019SA050759			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Response Decreased	Arava			S	Unknown	Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16002997	NON-EXPEDITED			US-SA-2019SA050709			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

	Prednisone			S	Unknown	Unk Unk, Unk			Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk Unk, Unk			Not Reported
	Lisinopril			S					Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16003001	NON-EXPEDITED			US-SA-2019SA050669			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Arava			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16003004	NON-EXPEDITED			US-SA-2019SA050823			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Response Decreased	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16008222	EXPEDITED (15-DAY)		OT	CA-009507513-1902CAN008263			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In	Lisinopril			S	Unknown			Merck
	Diclofenac Potassium			S	Oral	75.0 Milligram		Not Reported
	Folic Acid			S	Unknown			Not Reported

Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Methotrexate		S	Subcutaneous	20.0 Milligram, 1 Every 1 Week	Not Reported
	Pantoprazole Magnesium		S	Oral	Unk	Not Reported
	Plaquenil		S	Oral	200.0 Milligram, 1 Every 24 Hours	Not Reported
	Gold Sodium Thiomalate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	500.0 Milligram, 1 Every 24 Hours	Not Reported
	Synthroid		S	Unknown		Not Reported
	Xeljanz		S	Unknown	Unk, 2 Every 1 Day	Not Reported
	Depo-Medrol		C	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16008466	EXPEDITED (15-DAY)		OT	PHHY2019US039764			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Product Use In Unapproved Indication; Pyomyositis; Tuberculosis	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16009047	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016701			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

Vomiting	Rituxan	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Bifidobacterium Bifidum	C	Unknown			Not Reported
	Loperamide	C	Oral			Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16009264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269303		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16009403	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate		S	Unknown		Barr
	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16009405	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017385		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Discomfort; Drug Ineffective; Erythema; Joint Swelling; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16010011	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2269297			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16010016	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017550		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16010291	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1016928		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	6 Dosage Forms Daily;		Not Reported
	Tacrolimus			S	Unknown	5 Dosage Forms Daily;		Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16010299	EXPEDITED (15-DAY)		OT	US-ROCHE-2269883			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatic Steatosis; Squamous Cell Carcinoma; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Ongoing: No		Not Reported
	Rituxan			S	Unknown	Ongoing: No		Not Reported
	Humira			S	Subcutaneous	Ongoing : Unknown		Not Reported
	Orencia			S	Unknown	Ongoing: No		Not Reported
	Hydroxychloroquine			S	Unknown	Ongoing:No		Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2019	16010649	EXPEDITED (15-DAY)		DS	CA-ELI_LILLY_AND_COMPANY-CA201902009585			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Arava			S	Unknown	Unk, Unknown		Not Reported
	Baclofen			S	Unknown	Unk, Unknown		Not Reported
	Humira			S	Subcutaneous	Unk, Unknown		Not Reported
	Lyrica			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unknown		Not Reported
	Celebrex			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	13122656	EXPEDITED (15-DAY)		OT	CA-SA-2016SA086812		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi

Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Oral	15 Mg,Unk	Not Reported
	Methotrexate	S	Oral	15 Mg,Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Oral	20 Mg,Unk	Not Reported
	Methotrexate	S	Oral	20 Mg,Qw	Not Reported
	Methotrexate	S	Oral	20 Mg,Unk	Not Reported
	Methotrexate	S	Oral	15 Mg,Unk	Not Reported
	Methotrexate	S	Oral	10 Mg,Unk	Not Reported
	Methotrexate	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg,Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	592 Mg,Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Infliximab	C	Unknown	Unk Unk,Unk	Not Reported
	Infliximab	C	Unknown	Unk Unk,Unk	Not Reported
	Desoximetasone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	13129006	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1835080-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase	Humira			S	Subcutaneous			Not Reported

Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Ulcer	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Parenteral	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Alendronic Acid	S	Unknown	Not Reported

	Ciclosporin			C						Not Reported
	Prednisone			C						Not Reported
	Prednisone			C						Not Reported
	Xeljanz			C						Not Reported
	Prednisolone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	13303877	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1902159		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	13953535	NON-EXPEDITED			US-PFIZER INC-2017386820		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer

Oxycodone Hcl	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported
Humira	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	14968981	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE011520		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer; Deep Vein Thrombosis; Foot Fracture; Fracture; Hypogammaglobulinaemia; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Radiculopathy; Rotator Cuff Syndrome; Secondary Immunodeficiency; Spinal Osteoarthritis; Stenosis; Stomatitis; Vitamin D Deficiency	Methotrexate			S	Unknown	25 Mg, Unk		Novartis
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Mtx			S	Unknown	Unk		Not Reported
	Mtx			S	Unknown	25 Mg, Unk		Not Reported
	Quensyl			S	Unknown	400 Mg, Unk (Given In 2017, 2018)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (Most Recent Dose: Jan 2015)		Not Reported
	Sulfasalazin			S	Unknown	3000 Df, Unk		Not Reported
	Sulfasalazin			S	Unknown	2000 Df, Unk		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, Unk		Not Reported
	Celecoxib			C	Unknown	200 Mg, Unk		Not Reported
	Cotrimoxazole			C	Unknown	960 Mg, Unk		Not Reported
	Folinic Acid			C	Unknown	5 Mg, Unk		Not Reported
	Tapentadol			C	Unknown	50 Mg, Unk		Not Reported
	Anastrozol			C	Unknown	1 Mg, Unk		Not Reported
	Pantozol			C	Unknown	20 Mg, Unk		Not Reported
	Prednisolone			C	Unknown	20 Mg, Unk		Not Reported
	Cholecalciferol			C	Unknown	1000 Iu, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	15501334	EXPEDITED (15-DAY)		HO, OT	PHHY2017DE200479		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Gastritis; Hypokalaemia; Hyponatraemia; Renal Failure; Urinary Tract Infection	Rituximab			S	Unknown	1000 Mg, Unk (Last Cycle Of Rituximab Was Administered On 06 Sep 2016)		Not Reported
	Methotrexat			S	Unknown	25 Mg, Unk		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Dytide			C	Unknown			Not Reported
	Tilidin			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Omeprazol			C	Unknown			Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	15699565	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2017SA019845		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Prednisone	C		Unk		Not Reported
	Methotrexate Sodium	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	15946255	EXPEDITED (15-DAY)		OT	CA-SA-2017SA106140		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	1.2 Ml,Qw		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	15987079	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019067882		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic	Amlor			S	Oral	5 Mg, 1x/Day		Pfizer

Symptoms; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16003828	NON-EXPEDITED			US-AMGEN-USASP2019029000			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C		25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16003883	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2678572-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16004114	EXPEDITED (15-DAY)		CA, OT	TW-SA-2019SA050416			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Eyelid Malformation; Congenital Nose Malformation; External Auditory Canal Atresia; Foetal Exposure	Mycophenolate Mofetil			S	Transplacental	Maintenance Therapy		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	30 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Transplacental			Sanofi

During Pregnancy; Hypertelorism Of Orbit; Micrognathia; Microtia	Hydroxychloroquine		S	Transplacental	200 Mg, Qd	Sanofi
	Irbesartan		S	Transplacental	150 Mg, Qd	Sanofi
	Felodipine		S	Transplacental	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16005011	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA139124		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

	Humira			C	Subcutaneous	Unk Unk,Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16005953	EXPEDITED (15-DAY)		DE, HO	CA-MYLANLABS-2019M1016935		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Strongyloidiasis	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	Various Doses		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16006735	EXPEDITED (15-DAY)		DS, OT	CA-ICU MEDICAL, INC.-ICU2019CA00036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Morphine Sulfate Injection			S	Unknown	Unk		Icu Medical
	Acetaminophen			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	12.5 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16006794	EXPEDITED (15-DAY)		DE, HO	AU-HERITAGE PHARMACEUTICALS-2019HTG00040		31 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Shock; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Sulfasalazine			S	Unknown			Heritage
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16006910	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018418756			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Fatigue; Feeling Abnormal; Psoriasis; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16008223	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269299			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Azathioprine		S	Unknown		Not Reported
					Ciclosporin		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2019	16008350	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269296		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	13254141	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895758			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Treatment Failure; Urticaria; Wrist Surgery	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	13687628	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003730		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Humira			S	Subcutaneous	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Stelara			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Methotrexate			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	13984193	EXPEDITED (15-DAY)		OT	CA-ROCHE-1993146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	14353365	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000021			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia Foetal; Foetal Disorder; Foetal Exposure During Pregnancy	Plaquenil 200 Mg Tablet	S	Transplacental		Concordia
	Heparin Calcium	C			Not Reported
	Cefazolin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	14898765	EXPEDITED (15-DAY)		HO, OT	US-SA-2018SA133315			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Rash; Skin Lesion; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Tongue Oedema; Tongue Oedema; Toothache; Ulcer Haemorrhage	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Doxycycline			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	17.5 Mg,Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg,Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg,Qw		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg,Unk		Not Reported
	Cyclosporin			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	14912352	NON-EXPEDITED			US-AMGEN-USASP2018066143			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dermatitis Allergic; Nausea; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Reglan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown	Unk		Not Reported

	Orencia	C	Unknown	Unk		Not Reported
	Humira	C	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Diclofenac	C		Unk		Not Reported
	Leflunomide	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	15296301	EXPEDITED (15-DAY)		OT	ES-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002988		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			C				Not Reported
	Lornoxicam			C				Not Reported
	Paracetamol			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	15483542	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018377028		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		500 Mg, 2x/Day		Pfizer

Humira	S	40 Mg, 2x/Week	Not Reported
Plaquenil	S	200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	15721216	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3731		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ferric Hydroxide Polymaltose			S	Unknown			Not Reported
	Mtx			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Cyclosporine			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Acetazolamide			C	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Alendronate			C	Unknown			Not Reported
	Cyclosporine A			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	15737952	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-988039		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Leflunomide			S	Unknown			Barr
	Etanercept			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Dolquine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported
	Paracetamol			C				Not Reported
	Lornoxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16009719	NON-EXPEDITED			US-SA-2019SA051669			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16009770	NON-EXPEDITED			US-SA-2019SA051553			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Abnormal; Liver Function Test Abnormal	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16009889	NON-EXPEDITED			US-SA-2019SA050758			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Risk Factor; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Treatment Failure	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16010816	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1018611		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8 Hour			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16011872	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201902009622		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme	Cymbalta			S	Unknown	Unk, Unknown		Not Reported
	Metformin Hcl			S	Unknown	Unk, Unknown		Not Reported
	Metformin Hcl			S				Not Reported
	Plaquenil S			S	Unknown	Unk, Unknown		Not Reported

Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Prednisone			S	Unknown	Unk, Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unknown		Not Reported
	Warfarin Sodium			S	Unknown	Unk, Unknown		Not Reported
	Xarelto			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16012503	EXPEDITED (15-DAY)		DS	FR-ROCHE-2270472		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Lexomil			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported
	Avodart			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Salazopyrine			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Forlax			S	Oral			Not Reported
	Skenan			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16013677	NON-EXPEDITED			US-SA-2019SA052668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16013685	NON-EXPEDITED			US-SA-2019SA054236			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Arava			S				Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16013775	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019084056		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Ibrance			S		100 Mg, Daily		Pfizer
	Faslodex			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16014237	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019082340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Sulfasalazine			S		2 G, Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine	S		400 Mg, Unk		Not Reported
	Otezla	S		Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16014994	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000423			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown	(Started Prior To 2013)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Humira			S	Unknown	Started Prior To 2013		Not Reported
	Azathioprine			S	Unknown	Started Prior To 2013-Jul/2017		Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Pamidronate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Tenoxicam			C				Not Reported
	6-Mercaptopurine Monohydrate			C				Not Reported
	Dilaudid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	12606526	EXPEDITED (15-DAY)		DE, HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-061028		69 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Cardiac Failure; Invasive Lobular Breast Carcinoma; Surgery	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Bristol Myers Squibb
	Methotrexate			S	Unknown	2.5 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Carvedilol			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Quensyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	13771722	NON-EXPEDITED			US-PFIZER INC-2017315631		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Aricept			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Asa			S		Unk		Not Reported
	Carafate			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

	Revlimid			S		Unk				Not Reported
	Oxycontin			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	14606940	EXPEDITED (15-DAY)		DE, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000747		62 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Function Abnormal; Hypertension; Psoriasis; Sepsis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Voriconazole			S	Oral			Not Reported
	Rinderon (Betamethasone Sodium Phosphate)			C				Not Reported
	Furosemide			C				Not Reported
	Rabeprazole			C				Not Reported
	Rabeprazole			C				Not Reported
	Thyradin			C				Not Reported
	Micardis			C				Not Reported
	Denosine [Ganciclovir]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15119332	EXPEDITED (15-DAY)		OT	ES-ROCHE-2147319		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Tocilizumab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Dolquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Paracetamol			C	Unknown	Dosage Form: Unspecified		Not Reported

Pantoprazole	C	Unknown	Dosage Form: Unspecified	Not Reported
Enbrel	C	Unknown	Dosage Form: Unspecified	Not Reported
Lornoxicam	C	Unknown	Dosage Form: Unspecified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15313539	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/18/0103266		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Ramipril			S		20 Mg, Unknown Freq. (0-13+6 Gw)		Not Reported
	Ezetimibe			S		Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Torasemide			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Prednisolone			S	Unknown	0-14 Gw		Not Reported
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Metamizole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported

Salbutamol	S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
Enoxaparin Sodium	C	Unknown	Unk Unk, Unknown Freq. (0-14 Gw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15627723	EXPEDITED (15-DAY)			CA-PFIZER INC-2018106494		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Condition Aggravated; Depressed Mood; Diarrhoea; Hyperhidrosis; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Panic Reaction; Product Dose Omission; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		Unk		Not Reported
	Advil			C		Unk, As Needed		Not Reported
	Advil			C	Unknown	8 Df, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	15987994	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000358			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Plaquenil Tablet			S		By Mouth		Concordia
	Methotrexate			S	Oral			Not Reported
	Rasuvo			S		15mg Per 0.30 Ml Injections		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16015193	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2676119-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Pamidronate			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Ustekinumab			C	Unknown			Not Reported
	6-Mercaptopurine Monohydrate			C				Not Reported
	Tenoxicam			C				Not Reported
	Dilaudid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16015854	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019030919		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure; Visual Impairment	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16016369	EXPEDITED (15-DAY)		OT	CA-SA-2019SA054112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Sarilumab			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16017033	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1017176			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16018792	NON-EXPEDITED			US-SA-2019SA055164			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Toxicity To Various Agents	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16018839	NON-EXPEDITED			US-SA-2019SA055167			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

			Plaquenil		S	Unknown				Sanofi
			Humira		S	Subcutaneous	Unk			Not Reported
			Enbrel		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16018849	NON-EXPEDITED			US-SA-2019SA055032			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Rash; Sinusitis; Urinary Tract Infection	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16018867	NON-EXPEDITED			US-SA-2019SA055270			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz Xr			C	Oral	11 Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16018883	NON-EXPEDITED			US-SA-2019SA055189			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective;	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi

Gastrointestinal Disorder	Sulfasalazine			S	Unknown	Unk Unk, Unk				Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16019080	EXPEDITED (15-DAY)		HO	BR-TEVA-2019-BR-1017258		40 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cytomegalovirus Infection; Hepatosplenomegaly; Proteinuria; Renal Vein Thrombosis; Urosepsis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Dapsone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16019741	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1017178			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16019800	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS-2019M1018723			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Sepsis	Prednisone			S		20 Milligram, Qd		Not Reported
	Mycophenolate Mofetil			S		2 Gram, Qd		Not Reported
	Hydroxychloroquine			S		20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16019859	NON-EXPEDITED			PHEH2019US008853			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2019	16157088	DIRECT	Y					Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Sleep Disorder	Hydroxychloroquine Tablet 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	14737423	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA097770		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Warfarin Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Warfarin Sodium			S				Not Reported
	Warfarin Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

		Rituxan		S	Unknown	Unk Unk,Unk				Not Reported
		Rituxan		S	Intravenous (not otherwise specified)	Unk				Not Reported
		Amitriptyline		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	15005310	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-068218		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Off Label Use; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Mycophenolic Acid			S	Unknown	2 G, Qd		Accord
	Azathioprine			S	Unknown			Not Reported
	Prednisolone			S	Unknown	15 Mg, Qd		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16020394	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000432			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16021468	EXPEDITED (15-DAY)		OT	CA-SA-2018SA341020		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi

	Hydroxychloroquine	S	Unknown	Unk	Sanofi
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S		Unk Unk, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Anakinra	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Apo-Azathioprine	S	Oral		Not Reported
	Enbrel	S	Subcutaneous	Unk, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Gold	S	Unknown		Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
	Prednisone	C	Unknown		Not Reported
	Kineret	S	Unknown	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16021720	NON-EXPEDITED		OT	US-SA-2019SA055166			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Benzylpenicillin			S				Not Reported
	Budesonide			S				Not Reported
	Gentamicin Sulfate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported

	Orencia			S						Not Reported
	Sulfanilamide			S						Not Reported
	Enbrel			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16021768	EXPEDITED (15-DAY)		DE, HO, OT	CA-AUROBINDO-AUR-APL-2019-009954			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Aspiration; Electrolyte Imbalance; Hypotension; Leukocytosis; Loss Of Consciousness; Muscle Rigidity; Neuroleptic Malignant Syndrome; Renal Failure; Septic Shock; Serotonin Syndrome; Syncope	Alendronic Acid Tablets			S	Unknown	70 Milligram, Every Week		Aurobindo
	Cyclobenzaprine Tablets			S	Unknown	10 Milligram,As Required		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	400 Milligram, Once A Day		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	487 Milligram		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	1800 Milligram		Aurobindo
	Quetiapine Film-Coated Tablet			S	Unknown	142 Milligram		Aurobindo
	Bactrim			S	Unknown	Unk, Once A Day		Not Reported
	Budesonide			S		200 Milligram, Two Times A Day		Not Reported
	Celebrex			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Desipramine			S	Unknown	25 Milligram, Two Times A Day		Not Reported
	Fluconazole			S	Unknown	150 Milligram, Once A Day		Not Reported
	Furosemide			S	Unknown	40 Milligram, Once A Day		Not Reported
	Haloperidol			S	Intramuscular	20 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Hydroxyzine			S	Unknown	25 Milligram, Two Times A Day		Not Reported
	Levothyroxine			S	Unknown	50 Milligram, Once A Day		Not Reported
	Loperamide			S	Unknown	2 Milligram, As Required		Not Reported
	Mometasone Furoate			S	Unknown	2 Dosage Form, Two Times A Day		Not Reported

	Mometasone Furoate	S	Unknown	0.05 Percent, Four Times/Day	Not Reported
	Omeprazole	S	Unknown	20 Milligram, Two Times A Day	Not Reported
	Prednisone	S	Unknown	7.5 Milligram, Once A Day	Not Reported
	Risperidone	S	Unknown	5 Milligram, Once A Day	Not Reported
	Risperidone	S	Unknown	2 Milligram	Not Reported
	Risperidone	S	Unknown	3 Milligram	Not Reported
	Salbutamol	S	Unknown	100 Microgram, As Required	Not Reported
	Sulfamethoxazole;Trimethoprim	S	Unknown	Unk Unk, Once A Day	Not Reported
	Trazodone	S	Unknown	200 Milligram, Once A Day	Not Reported
	Venlafaxine Xr	S	Unknown	75 Milligram, Two Times A Day	Not Reported
	Sumatriptan	S	Unknown	50 Milligram, As Required	Not Reported
	Lorazepam	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16022028	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-010353			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Pneumonia	Cyclobenzaprine Tablets			S	Unknown	Unk		Aurobindo
	Mirtazapine Tablet			S	Unknown	Unk		Aurobindo
	Venlafaxine Extended Release Capsule			S		Unk		Aurobindo
	Bupropion			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pristiq			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16022189	EXPEDITED (15-DAY)		DS, OT	CA-009507513-1902CAN009041		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Prinivil			S	Unknown	Unk		Merck
	Prinivil			S	Unknown	Unk		Merck
	Diclofenac			S	Oral	1 Dosage Form		Not Reported
	Diclofenac			S	Oral	2 Dosage Forms, 1 Every 1 Day(S)		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, 1 Every 1 Week (S)		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	1 Dosage Form, 1 Every 1 Day(S)		Not Reported
	Sulfasalazine			S	Oral	1 Gram, 2 Every 1 Day(S)		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 1 Every 1 Day(S)		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Milligram, 2 Every 1 Day(S)		Not Reported
	Voltaren Sr			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	2 Dosage Form, 1 Every 1 Day(S)		Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16022884	NON-EXPEDITED			US-PFIZER INC-2019090307		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Amlodipine Besilate	S	Unk	Pfizer
	Ibuprofen	S	Unk	Pfizer
	Sulfasalazine	S	Unk	Pfizer
	Actemra	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Tocilizumab	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024275	EXPEDITED (15-DAY)		OT	CA-SA-2019SA050248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024947	NON-EXPEDITED			US-SA-2019SA052647			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024948	NON-EXPEDITED			US-SA-2019SA054209			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Arava			S	Unknown	Unk		Sanofi

Drug Ineffective; Injection Site Reaction; Liver Function Test Increased; Rash	Methotrexate		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Sanofi
	Azathioprine		S	Unknown	Unk		Not Reported
	Enbrel		S	Unknown	Unk		Not Reported
	Humira		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024950	NON-EXPEDITED			US-SA-2019SA054227			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024971	NON-EXPEDITED			US-SA-2019SA054985			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024975	NON-EXPEDITED			US-SA-2019SA054228			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Arava			S	Unknown			Sanofi

	Methotrexate		S	Unknown	Unk				Not Reported
	Methotrexate		S	Oral	Unk				Not Reported
	Hydroxychloroquine Sulfate		S	Unknown					Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16024977	NON-EXPEDITED			US-SA-2019SA055192			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025005	NON-EXPEDITED			US-SA-2019SA055480		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Extra Dose Administered	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Xeljanz			S				Not Reported
	Folic Acid			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025035	NON-EXPEDITED			US-SA-2019SA055384			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi

	Humira		S	Subcutaneous	Unk Unk, Unk			Not Reported
	Enbrel		S	Unknown	Unk Unk, Unk			Not Reported
	Orencia		S	Unknown	Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025073	NON-EXPEDITED			US-SA-2019SA054689			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Remicade			S				Not Reported
	Orencia			S				Not Reported
	Rituxan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025110	NON-EXPEDITED			US-SA-2019SA055932			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025116	NON-EXPEDITED			US-SA-2019SA055855			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug	Arava			S	Unknown	Unk Unk, Unk		Sanofi

Intolerance; Local Reaction; Pain	Methotrexate		S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel		S	Unknown	Unk Unk, Unk		Not Reported
	Humira		S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025124	NON-EXPEDITED			US-SA-2019SA055929			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Nausea	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025211	NON-EXPEDITED			US-SA-2019SA058006			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Osteoporosis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2019	16025341	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2019M1017441		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Infection Reactivation; Pneumonia;	Prednisone			S	Unknown	30 Milligram, Qd		Not Reported
	Prednisone			S				Not Reported

Pyomyositis; Septic Shock; Vomiting	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Trimethoprim Sulfamethoxazole	C	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2019	16029291	DIRECT					45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Eye Swelling; Eyelid Disorder; Eyelids Pruritus; Lip Pain; Skin Irritation; Skin Sensitisation; Swollen Tongue; Visual Impairment	Hydroxychlor 200 Mg			S	Oral	Quantity:30 Tablet(S);		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	14214446	NON-EXPEDITED			US-PFIZER INC-2017497470			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Lidocaine Hcl			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Minocycline			S		Unk		Pfizer
	Macrobid			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Nitrofurantoin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	14229216	EXPEDITED (15-DAY)		HO, LT, OT	US-AMGEN-USASP2017176922		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Anxiety; Aortic Valve Stenosis; Carpal Tunnel Syndrome; Constipation; Cushingoid; Deafness; Depression; Drug Hypersensitivity; Drug Intolerance; Dry Eye; Feeling Jittery; Ill-Defined Disorder; Increased Appetite; Injury; Interstitial Lung Disease; Intervertebral Disc Degeneration; Neuropathy Peripheral; Ocular Hyperaemia; Organising Pneumonia; Osteoarthritis; Pain In Jaw; Pelvic Fracture; Peripheral Nerve Lesion; Pneumonitis; Pruritus; Pulmonary Arterial Hypertension; Pulmonary Mass; Respiratory Failure; Rheumatoid Arthritis; Road Traffic Accident; Rotator Cuff Syndrome; Sleep Disorder; Spinal Stenosis; Syncope; Therapeutic Procedure; Treatment Failure; Upper Respiratory Tract Infection; Urinary Tract Infection; Weight Decreased	Enbrel	S	Subcutaneous	50 Mg, Qwk	Amgen
	Enbrel	S	Subcutaneous	50 Mg, Unk	Amgen
	Fosamax	S	Unknown	Unk	Not Reported
	Ursodiol	S	Oral	1500 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	600 Mg, Qd	Not Reported
	Mtx	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Prednisone	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C		15 Mg, Qd	Not Reported
	Xeljanz Xr	C	Oral	11 Mg, Qd	Not Reported
	Zyrtec	C		Unk	Not Reported
	Welchol	C	Oral	1875 Mg, Bid	Not Reported
	Trazodone	C	Oral	75 Mg, Qhs	Not Reported
	Nasonex	C		Unk	Not Reported
	Nexium	C		Unk	Not Reported
	Skelaxin	C		1 Df, Bid/ Prn	Not Reported
	Cytotec	C		Unk	Not Reported
	Etodolac	C	Oral	500 Mg, Bid	Not Reported
	Aspirin	C		81 Mg, Qd	Not Reported
	Calcium	C		Unk	Not Reported
	Vitamin B12	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported
	Benicar Hct	C		40/12.5	Not Reported
	Arava	C		Unk	Not Reported
	Synvisc One	C		Unk	Not Reported

Synvisc One	C		Unk	Not Reported
Synvisc One	C		Unk	Not Reported
Synvisc	C		Unk	Not Reported
Synvisc	C		Unk	Not Reported
Synvisc	C		Unk	Not Reported
Estrace Vaginal	C	Vaginal	1 G, Qwk	Not Reported
Zinc Sulfate	C		220 Mg, Unk	Not Reported
Refresh Liquigel	C		Unk	Not Reported
Allergy Relief	C		10 Mg, Unk	Not Reported
Mometasone	C	Nasal	100 Mug, Bid	Not Reported
Polyethylene Glycol 3350	C	Oral	17 G, Qd	Not Reported
Milk Of Magnesia	C	Oral	2400 Mg, Qd	Not Reported
Miconazole Nitrate	C	Topical	Unk Unk, Bid	Not Reported
Compazine	C	Oral	10 Mg, Tid	Not Reported
Compazine	C	Oral	10 Mg, Bid	Not Reported
Alprazolam	C		0.25 Mg, Unk	Not Reported
Toprol Xl	C	Oral	25 Mg, Qd	Not Reported
Lisinopril	C	Subcutaneous	5 Mg, Qd	Not Reported
Aspir 81	C	Oral	81 Mg, Qd	Not Reported
Calcium + Vitamin D	C		600 Mg, Unk	Not Reported
Prilosec	C	Oral	40 Mg, Qd	Not Reported
Tylenol Extra Strength	C	Oral	Unk Unk, Q6h	Not Reported
Cranberry Extract	C		300 Mg, Unk	Not Reported
Misoprostol	C	Oral	100 Mug, Bid	Not Reported
Arthrotec	C		Unk	Not Reported
Lidocaine	C		Unk Unk, As Necessary	Not Reported
Azor	C		10/40 Mg, As Necessary	Not Reported
Mvi	C		Unk	Not Reported
Citracal	C		Unk	Not Reported

	Asa	C		Unk		Not Reported
	Glucosamine Chondroitin	C		Unk		Not Reported
	Vesicare	C	Oral	Unk		Not Reported
	Percocet	C		Unk		Not Reported
	Vicoprofen	C		Unk		Not Reported
	Vioxx	C		Unk		Not Reported
	Flexeril	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	15165390	NON-EXPEDITED			US-SA-2018SA178530		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gastrointestinal Disorder; White Blood Cell Count Decreased	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S		Unk		Sanofi
	Prednisone			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	15967226	NON-EXPEDITED			US-SA-2019SA040100			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Hypersensitivity	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Actemra			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported
	Interimmun			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029082	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-198268			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029083	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-198095			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029165	NON-EXPEDITED			US-SA-2019SA055031			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029275	NON-EXPEDITED			US-SA-2019SA058426			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi

		Methotrexate			S	Unknown	Unk			Not Reported
		Plaquenil			S	Unknown	Unk			Sanofi
		Enbrel			S	Unknown	Unk			Not Reported
		Humira			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029302	NON-EXPEDITED			US-SA-2019SA058020			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029303	NON-EXPEDITED			US-SA-2019SA058427			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Insomnia; Mouth Ulceration; Nausea; Rash	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029437	NON-EXPEDITED			US-SA-2019SA059708			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Skin Infection	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Remicade			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029477	NON-EXPEDITED			US-SA-2019SA059709			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029493	NON-EXPEDITED			US-SA-2019SA059714			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Xeljanz			C	Oral	11 Mg, Qd		Not Reported
	Prednisone			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16029504	NON-EXPEDITED			US-SA-2019SA059712		60 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Humira			C				Not Reported
	Enbrel			C				Not Reported
	Remicade			C				Not Reported
	Xeljanz			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16031987	EXPEDITED (15-DAY)		OT	PHHY2019US048347		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisynthetase Syndrome; Arthritis; Interstitial Lung Disease; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Mycophenolate Mofetil			S	Unknown			Novartis
	Mycophenolate Mofetil			S				Novartis
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S				Not Reported
	Abatacept			S	Unknown			Not Reported
	Abatacept			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	10655276	EXPEDITED (15-DAY)		DS	FR-PFIZER INC-2014339628		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Peripheral Sensorimotor Neuropathy; Polyneuropathy	Salazopyrine			S	Oral			Pfizer
	Tahor			S	Oral	Unk		Pfizer
	Plaquenil			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Skenan			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Inexium [Esomeprazole Magnesium]			S	Oral			Not Reported

	Fosamax			S	Oral			Not Reported
	Avodart			S	Oral			Not Reported
	Cacit D3			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Lexomil Roche			S	Oral			Not Reported
	Forlax			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Actiskenan			C	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	13128865	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201701-000497		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel		S	Subcutaneous	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Cortisone		C		Not Reported
	Infliximab		C		Not Reported
	Desoximetasone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	13680958	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706-003601		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Oral			Not Reported

Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Ciclosporin	C		Not Reported
	Prednisolone	C		Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	14607766	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2018088790		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer; Deep Vein Thrombosis; Foot Fracture; Foot Fracture; Hypogammaglobulinaemia ; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Radiculopathy; Rotator Cuff Syndrome; Spinal Osteoarthritis; Stenosis; Stomatitis; Vitamin D Deficiency	No Subject Drug			S		No Dose Given		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	3000 Mg, Unk		Pfizer
	Mtx Support			S		Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	15 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S		1000 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Quensyl			S		400 Mg, Given 2017,2018		Not Reported
	Quensyl			S		400 Mg, Given 2017,2018		Not Reported
	Cyanocobalamin W/Folic Acid			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Celecoxib			C		200 Mg, Unk		Not Reported
	Cotrimoxazole			C		960 Mg, Unk		Not Reported
	Folinic Acid			C		5 Mg, Unk		Not Reported
	Anastrozol			C		1 Mg, Unk		Not Reported

	Prednisolone	C	20 Mg, Unk		Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]	C	20 Mg, Unk		Not Reported
	Colecalciferol	C	1000 Iu, Unk		Not Reported
	Tapentadol	C	50 Mg, Unk		Not Reported
	Leflunomide	C	15 Mg, Unk		Not Reported
	Hydroxychloroquine	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15386469	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018357548		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intellectual Disability	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Prednisone			S		5 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, 1x/Day		Not Reported
	Euro Sulfate			C		Unk		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15748473	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Prednisone			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Up To 20 Mg Weekly		Not Reported
	Methotrexate			S	Oral			Not Reported

Naproxen	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	15792246	EXPEDITED (15-DAY)		HO	TR-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000012		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pruritus; Rash; Skin Lesion; Skin Swelling	Plaquenil Tablet			S	Oral	Dose: 2*1		Concordia
	Glifor			C				Not Reported
	Cortisol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16032631	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000459		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Neuromyopathy; Weight Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16032632	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000460			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Orencia			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16032928	NON-EXPEDITED			US-AMGEN-USASP2019034269			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Reaction; Pain	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16033252	EXPEDITED (15-DAY)		OT	CA-SA-2019SA054729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Muscle Strain; Nasopharyngitis; Nephrolithiasis; Urinary Tract Infection	Plaquenil			S		200 Mg, Bid		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate [Methotrexate Sodium]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16033411	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019338			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16034448	NON-EXPEDITED			US-PFIZER INC-2019090046			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16034452	NON-EXPEDITED			US-PFIZER INC-2019089978		54 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fatigue; Infection	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035167	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK034719			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dysphagia; Sleep Disorder	Arnuity Ellipta Inhalation Powder			S	Respiratory (inhalation)	Unk		Glaxosmithkline
	Prednisone			S		Unk Unk, Qd		Not Reported
	Leflunomide			S		Unk, Qd		Not Reported

	Plaquenil			S		2 Df, Qd				Not Reported
	Plaquenil			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035225	NON-EXPEDITED			US-SA-2019SA059246			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Plaquenil			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035243	NON-EXPEDITED			US-SA-2019SA058352			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035244	NON-EXPEDITED			US-SA-2019SA057794			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Visual Impairment	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035298	NON-EXPEDITED			US-SA-2019SA058364			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hypoaesthesia; Pruritus	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035339	NON-EXPEDITED			US-SA-2019SA060012			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Latent Tuberculosis; Nightmare; Pain	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035362	NON-EXPEDITED			US-SA-2019SA059702			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Rash	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Humira			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035368	NON-EXPEDITED			US-SA-2019SA061402			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Arava	S	Unk		Sanofi
	Plaquenil	S	Unk		Sanofi
	Gabapentin	S	Unk		Not Reported
	Folic Acid	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035404	NON-EXPEDITED			US-SA-2019SA059707			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035462	NON-EXPEDITED		OT	US-SA-2019SA059704			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Gastrointestinal Disorder; Pneumonia; Unevaluable Event	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035475	NON-EXPEDITED		OT	US-SA-2019SA059687			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Arava			S		Unk		Sanofi

Dyspepsia; Leukopenia; Off Label Use	Methotrexate	S	Oral			Not Reported
	Prednisone	S		Unk		Not Reported
	Plaquenil	S				Sanofi
	Enbrel	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035725	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019926		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Granuloma; Headache; Hepatic Enzyme Increased; Insomnia	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Otezla			S	Oral	60 Milligram Daily;		Not Reported
	Clonazepam			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Metformin			C	Unknown			Not Reported
	Rabeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16035744	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA059096		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S				Sanofi
	Prednisone			S				Not Reported
	Naproxen Sodium			S				Not Reported
	Naproxen			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Xeljanz			S	Oral	10.0 Mg, Bid		Not Reported

	Folic Acid			C						Not Reported
	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038525	EXPEDITED (15-DAY)		OT	US-SA-2019SA058430			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Neoplasm Malignant; Pulmonary Mass	Arava			S				Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Prednisone			S		Unk Unk, Prn		Not Reported
	Cyclosporin			S		Unk Unk, Unk		Not Reported
	Rituxan			S		Unk Unk, Unk		Not Reported
	Humira			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038650	NON-EXPEDITED			US-AMGEN-USASP2019032641			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Infection; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038680	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020317		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr
	Actemera			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

Intolerance; Glaucoma; Synovitis	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Estrogel	C	Unknown			Not Reported
	Furosemide	C	Unknown	40 Milligram Daily;		Not Reported
	Morphine	C	Unknown			Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan	C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan	C	Unknown	50 Microgram Daily;		Not Reported
	Zingiber Officinale	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038779	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000486		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Tachycardia	Hydroxychloroquine 200 Mg			S		Low Dose		Concordia
	Hydroxychloroquine 200 Mg			S		Doubled Dose		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2019	16038780	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000487			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	13367400	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201703-001913		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Plaquenil Tablet			S	Oral	Unknown		Concordia
	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unknown		Not Reported
	Benzylpenicillin			S	Unknown	Unknown		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	14762090	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001267		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Thrombosis	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Warfarin Sodium			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	15394543	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2642		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intellectual Disability	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Euro Sulfate			C	Unknown				Not Reported
		Folic Acid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	15556623	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018148882		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	15759195	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004188		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Oral			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Kineret	S	Unknown	Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16038368	NON-EXPEDITED		OT	US-SA-2019SA060033			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Leukopenia; Paraesthesia	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16039822	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020535		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

	Sulfasalazine			S	Oral	2 Gram Daily;				Not Reported
	Naprosyn /00256201/			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16040049	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1018837		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Type 1 Diabetes Mellitus	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Apremilast			C	Oral	30 Milligram		Mylan
	Mycophenolate Mofetil			C	Unknown			Mylan
	Mycophenolate Mofetil			C				Mylan
	Azathioprine			C	Unknown			Mylan
	Azathioprine			C				Mylan
	Methotrexate			C	Unknown			Mylan
	Methotrexate			C				Mylan
	Acitretin			C	Unknown			Mylan
	Acitretin			C				Mylan
	Immune Globulin Nos			C	Intravenous (not otherwise specified)			Mylan
	Immune Globulin			C				Mylan
	Tacrolimus			C	Unknown			Mylan
	Tacrolimus			C				Mylan
	Chlorambucil			C	Unknown			Mylan
	Chlorambucil			C				Mylan
	Infliximab			C	Unknown			Mylan
	Infliximab			C				Mylan
	Rituximab			C	Unknown			Mylan
	Rituximab			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16040416	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Systemic		Concordia
	Colchicine			S	Unknown	Systemic		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Sodium Thiosulfate			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16040417	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Abnormal; Condition Aggravated; Drug Ineffective; End Stage Renal Disease; Proteinuria	Plaquenil			S	Unknown	Unknown		Concordia
	Humira			S	Unknown	Unknown		Not Reported
	Xeljanz			C				Not Reported
	Infliximab			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16040629	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-023021			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16040850	EXPEDITED (15-DAY)		OT	US-SA-2019SA060030			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Drug Ineffective	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Rasuvo			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16041968	NON-EXPEDITED			US-PFIZER INC-2019100936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Reaction; Pain	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16043043	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S		20 Mg, Unk		Sanofi
	Hydroxychloroquine			S		400 Mg, Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Actemra			S		8 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported

					Orencia	S		750 Mg, Unk		Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
					Sulfasalazine	C		Unk Unk, Unk		Not Reported
					Meloxicam	C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16043065	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2015GSK066918		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure	Belimumab			S				Glaxosmithkline
	Methylprednisolone			S		4 Mg, Qd		Not Reported
	Hydroxychloroquine			S		300 Mg, Qd		Not Reported
	Lomotil			C		20 Mg, 1d		Not Reported
	Synthroid			C		Unk		Not Reported
	Lasix			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16043876	NON-EXPEDITED			US-SA-2019SA058428			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16043950	NON-EXPEDITED			US-SA-2019SA061406			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Oral	Unk Unk, Unk		Sanofi

	Plaquenil			S	Unknown	Unk Unk, Unk			Sanofi	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16043963	NON-EXPEDITED			US-SA-2019SA061219			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dysgeusia; Nausea; Vision Blurred	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16044038	NON-EXPEDITED			US-SA-2019SA061608			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Vomiting	Arava			S	Unknown	Unk		Sanofi
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2019	16044412	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Plaquenil	S	Unknown		Not Reported
	Depo-Medrol	C	Unknown	80 Milligram Daily;	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Humira	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	14766853	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018050461		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Etanercept			S	Unknown	25 Mg, Qwk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cyclosporin A			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	400 Mg, One Dose (Total)		Not Reported
	Rituximab			S	Unknown	2 Doses		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

				Naprosyn	S	Unknown	Unk		Not Reported
				Prednisone	S	Unknown	Unk		Not Reported
				Hydroxychloroquine	C	Unknown	Unk		Not Reported
				Amitriptyline	S	Unknown	Unk		Not Reported
				Oxycodone	S	Unknown	Unk		Not Reported
				Folic Acid	S	Unknown	Unk		Not Reported
				Ciclosporin	S	Unknown	Unk		Not Reported
				Medroxyprogesterone Acetate	S	Unknown	Unk		Not Reported
				Anakinra	C		Unk		Not Reported
				Cyclosporine	C	Unknown	Unk		Not Reported
				Depo-Provera	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	15978402	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2666218-00		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Macular Degeneration	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Valsartan			C				Not Reported
	Duloxetine			C				Not Reported
	Duloxetine			C				Not Reported
	Spiriva			C				Not Reported
	Advair			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin D3			C				Not Reported
	Vitamin B12			C				Not Reported
	Folic Acid			C				Not Reported
	Norco			C				Not Reported
	Fenofibrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16045602	EXPEDITED (15-DAY)		DE, HO	AU-APPCO PHARMA LLC-2063646		31 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Shock; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046577	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046584	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058690		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Prednisone			S		5 Mg, Unk		Not Reported

	Prednisone		S		Unk Unk, Unk	Not Reported
	Methotrexate		S	Unknown	Unk Unk, Unk	Not Reported
	Arava		S	Unknown	Unk Unk, Unk	Sanofi
	Cimzia		S	Subcutaneous	Unk Unk, Unk	Not Reported
	Enbrel		S	Unknown	Unk Unk, Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046593	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046594	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057698		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

		Rituxan			S	Unknown	Unk			Not Reported
		Methotrexate			C	Unknown	0.8 Ml, Qw			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046595	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057730		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Salazopyrin			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046596	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057625		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Arava			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Leflunomide			S		200 Mg, Qd		Sanofi
	Orencia			S		Unk Unk, Unk		Not Reported
	Actemra			S		Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Naproxen			C		Unk Unk, Unk		Not Reported
	Advil [Ibuprofen]			C		Unk Unk, Unk		Not Reported
	Folic Acid			C		Unk Unk, Unk		Not Reported
	Ketorolac			C		Unk Unk, Unk		Not Reported
	Methotrexate			C		20 Mg, Qw		Not Reported
	Prednisone			C		Unk Unk, Unk		Not Reported

	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046597	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Mg, Unk		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16046942	NON-EXPEDITED			US-PFIZER INC-2019101328			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Infection; Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16047221	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058764		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava	S	Oral	10 Mg		Sanofi
	Hydroxychloroquine	S	Oral	400 Mg		Sanofi
	Methotrexate	S	Oral	25 Mg, Qiw		Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetylsalicylic Acid	C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg		Not Reported
	Asa	C	Unknown	81 Mg		Not Reported
	Lantus	C	Subcutaneous			Not Reported
	Lozide [Indapamide]	C				Not Reported
	Metformin	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Ramipril	C	Unknown			Not Reported
	Naprosyn [Naproxen]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16047223	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058618		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Arava			S		20 Mg, Qd		Sanofi
	Plaquenil			S		200 Mg, Qow		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Actemra			S		5 Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Methotrexate Sodium			S		25 Mg, Qw		Not Reported
	Methotrexate Sodium			S		20 Mg, Qw		Not Reported

Arthritis	Remicade			S						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048337	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058541		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Enbrel			S		50 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048553	NON-EXPEDITED			US-SA-2019SA060156			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Gastritis; Headache	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Remicade			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048664	NON-EXPEDITED			US-SA-2019SA062602			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Arava			S				Sanofi

Methotrexate	S	Unk Unk, Unk	Not Reported
Plaquenil	S	Unk Unk, Unk	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048704	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020499		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown	2.5 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	5 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Coversyl/00790702/			C	Oral	2 Milligram Daily;		Not Reported
	Enbrel			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Indapamide			C	Oral	1.25 Milligram Daily;		Not Reported
	Naprosyn			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Pantoloc			C	Oral	40 Milligram Daily;		Not Reported
	Rituxan			C	Unknown			Not Reported
	Tylenol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048737	NON-EXPEDITED			US-SA-2019SA063532			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Humira			S		Unk		Not Reported
	Gold			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048763	NON-EXPEDITED			US-SA-2019SA063429			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048784	NON-EXPEDITED			US-SA-2019SA064275			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Muscle Fatigue; Muscular Weakness; Peripheral Swelling; Peripheral Swelling	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048875	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Leflunomide			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S		2 G, Qd		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16048920	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Cosentyx			S		Unk Unk, Unk		Not Reported
	Orencia			S		Unk Unk, Unk		Not Reported
	Otezla			S		Unk Unk, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Stelara			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Xeljanz			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16049472	EXPEDITED (15-DAY)		DS, OT	CA-MYLANLABS-2019M1021331		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Synthroid			S		Unk		Mylan
	Diclofenac			S	Oral	1 Dosage Form		Mylan
	Diclofenac			S	Oral	2 Dosage Form, Qd		Mylan
	Folic Acid			S		Unk		Mylan
	Lisinopril			S		Unk		Mylan
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw		Mylan
	Pantoprazole			S		Unk		Mylan
	Pantoprazole Magnesium			S		Unk		Mylan
	Plaquenil /00072602/			S	Oral	1 Dosage Form, Qd		Mylan
	Sulfasalazine			S	Oral	1 Gram, Bid		Mylan
	Sulfasalazine			S		500 Milligram, Qd		Mylan
	Voltaren Sr			S	Oral	75 Milligram, Bid		Mylan
	Voltaren Sr			S	Oral	Unk		Mylan
	Xeljanz			S	Oral	2 Dosage Form, Qd		Mylan
	Gold			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2019	16049839	EXPEDITED (15-DAY)		OT	US-ZYDUS-034515		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Oedema Peripheral; Pneumonia; Pyomyositis	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	13056558	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP015782		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Ibuprofen Tab 200mg			S	Unknown	Unk		Not Reported
	Apo Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Ibuprofen			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	14485343	NON-EXPEDITED			US-PFIZER INC-2018050090		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

	Vioxx			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	15201714	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002531			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fear Of Injection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular	25 Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Kevzara			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	15600879	EXPEDITED (15-DAY)		OT	US-ROCHE-2208819			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Episcleritis; Herpes Zoster; Hypersensitivity; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Celebrex	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Xeljanz Xr	C	Unknown	Ongoing: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	15739429	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018DE188813		69 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Cardiac Failure; Invasive Lobular Breast Carcinoma; Myocardial Infarction	Methotrexate			S	Unknown	2.5 Mg, Qw		Novartis
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Q4w		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Quensyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16010805	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1018469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16010819	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1018592		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not	2000 Milligram Daily;		Not Reported

						otherwise specified)			
	Orencia			S		Unknown			Not Reported
	Orencia			S		Unknown			Not Reported
	Sulfasalazine			S		Unknown			Not Reported
	Ciclosporin			C					Not Reported
	Prednisone			C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16049886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2277562		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050154	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000501		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400		Concordia

							Mg/Day, Alternately			
		Prednisolone			C					Not Reported
		Actonel			C					Not Reported
		Actonel			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050269	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059268		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050298	NON-EXPEDITED			PHEH2019US009746			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050508	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020347		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fine Motor Skill Dysfunction; Finger Deformity; Hand	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Deformity; Impaired Healing; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling					otherwise specified)				
	Plaquenil			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Warfarin			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050521	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050531	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Silfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

		Ibuprofen			C	Unknown				Not Reported
		Morphine			C	Unknown				Not Reported
		Pertussis Vaccine			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050550	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1020973		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050619	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023434		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema;	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Rheumatoid Arthritis	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Sodium Aurothiomalate Injection Bp		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16050706	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023435		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Joint Swelling; Knee Operation; Musculoskeletal Stiffness; Psoriasis; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Alprazolam			C	Oral	.5 Milligram Daily;		Not Reported
	Celebrex			C	Oral			Not Reported
	Levothyroxine Sodium			C	Oral	50 Microgram Daily;		Not Reported
	Prednisone			C				Not Reported
	Salmeterol/Fluticason			C		4 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051263	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Sulfasalazine			S	Unknown	1000 G, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

			Humira		S	Unknown	20 Mg, Unk			Not Reported
			Orencia		S	Unknown				Not Reported
			Xeljanz		C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051536	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA051785		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

			Sodium Aurothiomalate		S	Unknown				Not Reported
			Sodium Aurothiomalate		S					Not Reported
			Sulfasalazine		S	Unknown				Not Reported
			Sulfasalazine		S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2019	16054368	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2696830-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Skin Erosion; Synovitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	Once In A Day Or Twice In A Day		Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2019	16054757	NON-EXPEDITED		OT	PHEH2019US008895			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Pancreatitis	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Entyvio			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	15182750	EXPEDITED (15-DAY)		OT	US-SAKK-2018SA198721AA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Fear Of Injection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Plaquenil	S	Unknown			Sanofi
	Prednisone	S	Unknown			Not Reported
	Methotrexate	S	Intramuscular	25 Unk, Qw		Not Reported
	Leflunomide	S	Unknown			Sanofi
	Enbrel	S		Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Simponi Aria	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Kevzara	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	15850280	NON-EXPEDITED			US-PFIZER INC-2019018037		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg/Ml, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	0.6 Ml, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	15881000	EXPEDITED (15-DAY)		HO, OT	GR-MYLANLABS-2019M1007066		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia;	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported

Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Citalopram	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qw		Not Reported
	Alprazolam	S	Unknown	Unk		Not Reported
	Adalimumab	S	Unknown	Unk		Not Reported
	Captopril	S		Unk		Not Reported
	Etanercept	S	Unknown	Unk		Mylan
	Etanercept	S				Mylan
	Folic Acid	S	Unknown	5 Milligram, Qw		Mylan
	Folate Sodium	S	Unknown	5 Milligram, Qw		Mylan
	Valsartan	C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16010828	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1018860		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Nerve Injury; Renal Function Test Abnormal; Tuberculin Test Positive	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16010836	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1018869		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Arthralgia; Diarrhoea	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr

Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16055855	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Muscle Strain; Nasopharyngitis; Nephrolithiasis; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16055947	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057819		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction;	Arava			S	Oral	20 Mg, Qd		Sanofi
	Gabapentin			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	100 Mg, Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q3w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S	Intravenous (not	488 Mg, Qm		Not Reported

Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)		
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Qm	Not Reported
	Omega 3 [Fish Oil]	C	Oral	1200 Mg, Bid	Not Reported
	Omega 3 [Fish Oil]	C	Unknown	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Actonel	C	Unknown	36 Mg, Qw	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
	Genteal [Hypromellose]	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
	Nicotinamide	C	Unknown	Unk Unk, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Qcy	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Unk	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	400 Mg, Qd	Not Reported

	Pantoprazole Magnesium	C	Unknown	40 Mg, Qd		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk		Not Reported
	Sodium	C	Unknown	Unk		Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
	Trazodone [Trazodone Hydrochloride]	C	Oral	50 Mg, Qcy		Not Reported
	Tylenol [Paracetamol]	C	Unknown	50 Mg, Qcy		Not Reported
	Vit D3	C	Unknown	Unk		Not Reported
	Vitamin A [Retinol]	C	Unknown	Unk		Not Reported
	Vitamin B12 [Vitamin B12 Nos]	C	Unknown	Unk		Not Reported
	Vitamin D [Vitamin D Nos]	C	Unknown	400 Df, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057413	NON-EXPEDITED			US-PFIZER INC-2019103272		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate Sodium			S				Unknown
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057550	NON-EXPEDITED			US-SA-2019SA062601			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi

	Methotrexate			S	Unknown	Unk Unk, Unk				Not Reported
	Rituxan			S	Unknown	Unk Unk, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057571	NON-EXPEDITED		OT	US-SA-2019SA063006			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pancreatitis	Arava			S				Sanofi
	Plaquenil			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057583	NON-EXPEDITED			US-SA-2019SA063432			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Osteoporosis	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Prednisone			S		Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057682	NON-EXPEDITED			US-SA-2019SA065464			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oral Pain; Rash	Arava			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Sulfasalazine			S		Unk Unk, Unk		Not Reported
	Methotrexate			S		20 Mg, Unk		Not Reported

Prednisone	S	15 Mg, Qd	Not Reported
Prednisone	S	10 Mg, Qd	Not Reported
Ustekinumab	S	Unk Unk, Unk	Not Reported
Secukinumab	S	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057888	EXPEDITED (15-DAY)		OT	PHEH2019US009133			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Lupus-Like Syndrome	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057902	EXPEDITED (15-DAY)		OT	PHEH2019US009913			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Cancer; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16058129	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021310		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16058143	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021057		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16059885	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020726		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Arava	C	Unknown		Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Elavil (Amitriptyline Hydrochloride)	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Sumatriptan Succinate	C			Not Reported
	Tenormin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	14681312	NON-EXPEDITED			US-PFIZER INC-2018124568		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Etanercept			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Pfizer
	Infliximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	15680044	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-178698		62 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Daily (5.6 Mg/Kg)		Sun
	Hydroxychloroquine			S	Unknown	600 Milligram, Daily (8.3 Mg/Kg)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	15747037	EXPEDITED (15-DAY)		DE	GB-MYLANLABS-2018M1095314		15 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Prednisolone			S	Unknown	Unk Unk, Biweekly		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Dosage Form, Qw		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S		Unk		Mylan
	Human Immunoglobulin (Immunoglobulin Human Normal)			S		Unk		Mylan
	Human Immunoglobulin (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	Unk		Mylan
	Rituximab			S		Unk		Mylan
	Privigen			S	Intravenous (not otherwise specified)	20 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	20 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	20 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	20 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	5 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	20 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	10 Gram		Mylan

	Privigen			S	Intravenous (not otherwise specified)	20 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	10 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	10 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	10 Gram		Mylan
	Privigen			S	Intravenous (not otherwise specified)	5 Gram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16059936	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000594		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatocellular Injury	Plaquenil			S	Unknown			Concordia
	Ibrance			S	Unknown			Not Reported
	Faslodex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16059938	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000526			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Gastrointestinal Disorder; Pneumonia; Unevaluable Event	Plaquenil			S	Unknown	Unknown		Concordia
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Xeljanz Xr			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16060353	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000559			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Drug Ineffective	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Rasuvo			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16060465	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024052			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16060479	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024074		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait	Methotrexate			S	Oral			Barr

Inability; Hypogammaglobulinaemia ; Therapeutic Product Effect Incomplete	Apo-Leflunomide		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16060792	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024059		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16061813	NON-EXPEDITED			US-PFIZER INC-2019104066		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Furosemide			S		Unk		Unknown
	Lasix			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hctz			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16061933	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2019-0009744		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Oxycodone Hydrochloride			S	Unknown	Unk		Purdue
	Amitriptyline			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclosporin A			S	Unknown	Unk		Not Reported
	Depo-Provera			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	25 Mg, Weekly		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	400 Mg, Total		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16062146	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021192			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16062151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020996		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16063214	NON-EXPEDITED			US-SA-2019SA066465			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Thyroid Antibody Positive; Immunoglobulins Abnormal	Arava			S	Unknown	Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16063375	EXPEDITED (15-DAY)		HO, OT	DE-SA-2018SA044549		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer	Leflunomide			S	Unknown	15 Mg,Unk		Sanofi

Female; Deep Vein Thrombosis; Foot Fracture; Foot Fracture; Fracture; Hypogammaglobulinaemia; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Radiculopathy; Rotator Cuff Syndrome; Secondary Immunodeficiency; Spinal Osteoarthritis; Stenosis; Stomatitis; Vitamin D Deficiency	Leflunomide	S		15 Unk	Sanofi
	Hydroxychloroquine Sulfate	S		400 Mg	Sanofi
	Hydroxychloroquine Sulfate	S		400 Unk	Sanofi
	Methotrexate	S		25 Mg	Not Reported
	Methotrexate	S		25 Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Sulfasalazine	S		2000 Df	Not Reported
	Sulfasalazine	S		3000 Unk	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Mabthera	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg,Unk	Not Reported
	Cyanocobalamin W/Folic Acid	S			Not Reported
	Folinic Acid	C		5 Mg	Not Reported
	Colecalciferol	C		1000 Iu	Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]	C		20 Mg	Not Reported
	Cotrimoxazole	C		960 Mg	Not Reported
	Tapentadol	C		50 Mg	Not Reported
	Prednisolone	C		20 Mg	Not Reported
	Anastrozol	C		1 Mg	Not Reported
	Celecoxib	C		200 Mg	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064773	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab		S	Unknown	Unknown	Not Reported
	Actemra		S	Unknown	Unknown	Not Reported
	Anakinra		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	Unknown	Not Reported
	Humira		S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Unknown	Not Reported
	Orencia		S	Unknown	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi		S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine		S	Oral	Unknown	Not Reported
	Desoximetasone		C	Unknown	Unknown	Not Reported
	Methotrexate		C	Oral		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064779	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05686		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported

	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064786	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064793	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)		Not Reported
	Actemra			S	Unknown		Not Reported
	Arava			S	Oral	Unknown	Not Reported
	Ciclosporin			S	Unknown	Unknown	Not Reported
	Cimzia			S	Subcutaneous		Not Reported
	Enbrel			S	Unknown		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown	Not Reported
	Imuran			S	Unknown	Unknown	Not Reported
	Methotrexate			S	Unknown	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2019	16064794	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	12931174	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201538		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Abatacept			S	Unknown	Unk Unk,Unk		Not Reported
	Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	13210307	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006358		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Gastrooesophageal Reflux Disease; Malaise; Movement Disorder; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased	Apo-Prednisone			S	Unknown	1 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Apo-Diclo			S	Unknown			Apotex
	Amitriptyline			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported

	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Voltaren /00372301/			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	15620122	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2018AP024518			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hypertransaminasaemia; Proteinuria	Mycophenolate			S	Unknown	1 G, Per Day		Apotex
	Prednisone			S	Unknown	1 Mg/Kg, Per Day		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16066206	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20190307277		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol		Y	S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Serevent			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16067748	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1023023			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Urinary Tract Infection	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16068312	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16068364	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate		S	Unknown	Barr
	Cimzia		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16068365	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16068370	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021453		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Off Label Use; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069005	NON-EXPEDITED			US-SA-2019SA068501			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069181	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021925		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069183	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022112		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Intellectual Disability	Methotrexate		S	Oral		Barr
	Prednisone		S	Unknown	5 Milligram Daily;	Actavis
	Hydroxychloroquine Sulfate		S	Unknown	20 Milligram Daily;	Not Reported
	Euro Sulfate		C			Not Reported
	Folic Acid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069355	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021607			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069359	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16069393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2702973-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2019	16208290	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Mass	Hydroxychloroquine 200 Mg Tab			S	Oral			Unknown
	Orencia 125 Mg/Ml Pfs Ng			S	Subcutaneous			Bristol Myers Squibb

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	12918639	EXPEDITED (15-DAY)		OT	CA-SA-2015SA061409		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported
	Actemra			S	Unknown	8 Mg/Kg,Unk		Not Reported
	Abatacept			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg,Unk		Not Reported
	Avara			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Amitriptyline Hydrochloride			C		Unk		Not Reported
	Hydrochlorothiazide			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Premarin			C		Unk		Not Reported
	Sumatriptan Succinate			C		Unk		Not Reported
	Tenormin			C		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	13590617	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017236091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	14194419	NON-EXPEDITED			US-PFIZER INC-2017490937		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Gabapentin			S		Unk		Pfizer

Gastrointestinal Disorder	Acetaminophen	S	Unk		Not Reported
	Arava	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Oxycodone	S	Unk		Not Reported
	Tylenol	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15188634	NON-EXPEDITED			US-PFIZER INC-2018294560		46 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15559343	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP023370			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Irritation	Imiquimod			S	Unknown	Three Times A Week		Apotex
	Imiquimod			S				Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	5 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	15 Mg, Weekly		Not Reported
	Pimecrolimus			S	Topical	Unk, Bid		Not Reported
	Pimecrolimus			S				Not Reported
	Triamcinolone			S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15640793	EXPEDITED (15-DAY)		OT	CA-SA-2015SA051602		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Arava	S	Unknown	20 Mg,Qd	Sanofi
	Methotrexate	S	Unknown	25 Mg,Qw	Not Reported
	Plaquenil	S	Unknown	200 Mg,Bid	Sanofi
	Hydroxychloroquine	S	Unknown	40 Mg, Bid	Sanofi
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
	Xeljanz	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S		25 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg,Qm	Not Reported
	Enbrel	S	Unknown	25 Mg,Biw	Not Reported
	Abatacept	S		750 Mg Every Mouth	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Gold	S			Not Reported
	Apo-Hydroxyquine	S	Unknown	40 Mg, Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk, Unk	Not Reported
	Kineret	C			Not Reported
	Orphenadrine Citrate	C		Unk Unk,Bid	Not Reported
	Dyclone	C			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Unk Unk,Prn	Not Reported
	Synthroid	C		Unk	Not Reported
	Furosemide	C		40 Mg,Tid	Not Reported
	Darifenacin	C		Unk Unk,Prn	Not Reported
	Ativan	C		1 Mg,Hs	Not Reported
	Loperamide Hydrochloride	C		Unk Unk,Bid	Not Reported

Omnaris	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Vagifem	C	Unk	Not Reported
Dilaudid	C	4 Mg,Q6h	Not Reported
Cortisone	C	Unk	Not Reported
Darifenacin Hydrobromide	C		Not Reported
Desoximetasone	C		Not Reported
Acetaminophen	C		Not Reported
Codeine	C		Not Reported
Hydromorphone	C		Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C		Not Reported
Oxyneo	C		Not Reported
Restasis	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Morphine Sulfate	C		Not Reported
Diphenhydramine	C		Not Reported
Desoximetasone	C		Not Reported
Dyclone	C		Not Reported
Anakinra	C		Not Reported
Pantoprazole Sodium Anhydrous	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	15919109	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2019M1008884			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryopyrin Associated Periodic Syndrome; Foetal Exposure During Pregnancy; Fragile X Syndrome; Medium-Chain Acyl-Coenzyme A Dehydrogenase Deficiency; Microcephaly; Trisomy 8	Paracetamol			S	Transplacental	Gestational Week Of Exposure- 17-21		Not Reported
	Diclofenac			S	Transplacental	100 Milligram, Prn Geststional Week Of Exposure 0-19 + 4		Not Reported
	Hydroxychloroquine			S	Transplacental	Gestational Week Of Exposure- 0-13		Not Reported
	Sulfasalazine			S	Transplacental	Gestational Week Of		Mylan

Exposure- 0-17

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16070052	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022401			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Sodium			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16070070	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022667		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Methotrexate			S	Unknown			Barr
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16070438	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022446		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Swelling	Hydroxychloroquine			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16070497	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071269	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate	Infliximab			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Abnormal; Shoulder Arthroplasty; Treatment Failure	Simponi	S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unknown		Not Reported
	Actemra	S	Unknown	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Subcutaneous Solution		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown		Not Reported
	Methotrexate	C	Oral			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071448	NON-EXPEDITED			US-PFIZER INC-2019107190			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071533	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported

	Ciclosporin	S	Unknown	Unknown		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Imuran	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071538	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16072718	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2019108692		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Granulosa Cell Tumour	No Subject Drug			S		No Dose Given		Not Reported

	Methotrexate Sodium	S	Unknown	15 Mg, Weekly		Pfizer
	Tocilizumab	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	250 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073128	EXPEDITED (15-DAY)		OT	IND-CA-009507513-1903CAN005401		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Rocuronium Bromide			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous(Dosage Form)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073218	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1021452		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported

Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Oral	200 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021344		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			C	Unknown	2.5 Milligram Daily;		Not Reported
	Gabapentin			C	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073556	EXPEDITED (15-DAY)		OT	PHHY2019DE050703		30 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During	Betamethasone			S	Intravenous (not	12 Mg, Unk (Two		Not Reported

Pregnancy; Premature Delivery				otherwise specified)	Applications Overe 24 Hours)			
	Hydroxychloroquine		S	Unknown	200 Mg, Qd			Not Reported
	Prednisolone		S	Unknown	5 Mg, Qd			Novartis
	Partusisten		S	Intravenous (not otherwise specified)	25 Ug, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073566	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE075777			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Chondrocalcinosis; Deep Vein Thrombosis; Femur Fracture; Foot Deformity; Intentional Self-Injury; Mobility Decreased; Osteomyelitis	Erelzi			S	Subcutaneous	50 Mg, Qw		Not Reported
	Erelzi			S	Subcutaneous	50 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15.0 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15.0 Mg, Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Unk		Novartis
	Methotrexate			S	Unknown	5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	7.5 Mg, Unk		Novartis
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Lodotra			C	Unknown			Not Reported
	L-Thyrox			C	Unknown			Not Reported
	Cholecalciferol			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

		Hydromorphone			C	Unknown				Not Reported
		Amineurin			C	Unknown				Not Reported
		Pantozol			C	Unknown				Not Reported
		Clexane			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073738	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05807		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Triamcinolone Hexacetonide			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073764	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073770	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018158350		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Thrombosis	Methotrexate Sodium			S	Oral	6 Df(Tablets), Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073810	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021357		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram Daily;		Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen/ Codeine			C	Unknown			Not Reported
	Caffeine/Dihydrocodeinebitartrate/Paracetamol			C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Ophthalmic			Not Reported
	Plaquenil			C	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073811	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Rheumatoid Arthritis	Methotrexate	S	Unknown			Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unknown		Not Reported
	Atorvastatin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073857	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2019-0009773		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Increased; Stomatitis; Urticaria	Oxycodone Hydrochloride			S	Unknown	10 Mg, Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Lyrica			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16074113	EXPEDITED (15-DAY)		OT	CA-SA-2019SA065746			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Oedema;	Hydroxychloroquine			S		400 Mg, Qd		Sanofi

Retinopathy	Methotrexate	C	Subcutaneous	12.5 Mg		Not Reported
	Sulfasalazine	C				Not Reported
	Tylenol [Paracetamol]	C		2 Df, Qd		Not Reported
	Nexium [Esomeprazole Sodium]	C		Unk		Not Reported
	Vitamins Nos	C		Unk		Not Reported
	Leflunomide	S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	12921888	EXPEDITED (15-DAY)		OT	CA-SA-2015SA091037		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Abatacept			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	15647248	EXPEDITED (15-DAY)		HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-191666		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	45 Dosage Form, Single [45 Tablets Of 200mg (A Total Of 9 G)]		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	15664642	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-MAPI_00010560		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported
	Leflunomide			S				Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Kineret			S	Unknown	Unknown		Not Reported
	Kineret			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S				Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S				Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Simponi			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S				Not Reported
	Cellcept			S	Unknown	Unknown		Not Reported
	Cellcept			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S				Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S				Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S				Not Reported
	Gold			S	Unknown	Unknown		Not Reported

		Gold			S					Not Reported
		Celebrex			C					Not Reported
		Methotrexate			C					Not Reported
		Prednisone			C					Not Reported
		Humira			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	15978702	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014031		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous	Unk Mg, Unk		Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg, Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Folic Acid			C	Unknown	10 Milligram, Qd		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075012	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS			Unknown	USA

INC.-GSH201903-000612

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pancreatitis	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075026	EXPEDITED (15-DAY)		OT	IND-CA-009507513-1903CAN005407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Tenosynovitis; Urticaria; Wrist Surgery	Rocuronium Bromide			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Penicillin (Unspecified)			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

					otherwise specified)				
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Sulfamethoxazole (+) Trimethoprim			S	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075154	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1023044		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Off Label Use; Pruritus; Type 1 Diabetes Mellitus	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Oral			Actavis
	Apremilast			S	Oral	60 Milligram Daily;		Not Reported
	Mycophenolate -Mofetil			C	Unknown			Not Reported
	Mycophenolate -Mofetil			C				Not Reported
	Azathioprine			C	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Acitretin			C	Unknown			Not Reported
	Acitretin			C				Not Reported
	Immune-Globulin			C	Intravenous (not otherwise specified)			Not Reported
	Immune-Globulin			C				Not Reported
	Tacrolimus			C	Unknown			Not Reported
	Tacrolimus			C				Not Reported
	Chlorambucil			C	Unknown			Not Reported
	Chlorambucil			C				Not Reported
	Infliximab			C	Unknown			Not Reported
	Infliximab			C				Not Reported
	Rituximab			C	Unknown			Not Reported
	Rituximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075439	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012890			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075446	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012901			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling;	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported

Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S		25.0 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1.0 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075696	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013217			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Rheumatoid Arthritis	Meloxicam			S	Unknown	15 Milligram		Aurobindo
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Gabapentin			C	Unknown	100 Milligram		Not Reported

					Lansoprazole	C	Unknown	30 Milligram	Not Reported
					Plaquenil	C	Unknown	Unk	Not Reported
					Plaquenil	C	Unknown	200 Milligram	Not Reported
					Symbicort	C	Unknown	Unk	Not Reported
					Atorvastatin	C	Unknown	20 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16075899	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16076009	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024334		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16076078	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2064041		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pyomyositis; Tuberculosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisone			S	Unknown			Not Reported
	Cotrimoxazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16076636	EXPEDITED (15-DAY)		OT	PHHY2019CA056631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16077294	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023088		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Incorrect Route Of Product Administration; Tuberculin Test Positive; Tuberculosis	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

	Folic Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16077866	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022876			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079039	EXPEDITED (15-DAY)		OT	US-SA-2019SA071589			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Sjogren'S Syndrome	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079496	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1023279		15 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Coeliac Disease	Hydroxychloroquine Sulfate Tablets	S	Unknown		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079690	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024270		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079719	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024401		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Xeljanz			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported
	Prevacid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079727	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024260			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079882	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported

	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atorvastatin Calcium			C	Unknown	Unknown		Not Reported
	Pantoloc			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079886	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-05747			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079889	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2019-05816			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079919	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05850		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Contraindicated	Infliximab			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Product Administered; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079932	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079964	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05852			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Rituxan			S	Unknown	Unknown		Not Reported
	Atorvastatin			C	Unknown	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079967	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06102		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2019	16079972	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16046627	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-2019-US-1019698		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis; Disseminated Tuberculosis; Infection Reactivation; Pneumonia; Pyomyositis; Septic Shock; Vomiting	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Hydroxychloroquine			S				Teva
	Trimethoprim/Sulfamethoxazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080795	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013881			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	488 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Celebrex			S	Occlusive dressing technique	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Once A Day		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Actonel			C	Oral	36 Milligram, Every Week		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Biotin			C	Unknown	Unk		Not Reported
	D-Alpha Tocopherol			C	Unknown	1200 Milligram, Two Times A Day		Not Reported
	Diphenoxylate			C	Unknown	2.5 Milligram, Once A Day		Not Reported
	Diphenoxylate			C	Unknown	Unk, Once A Day		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C	Unknown	1200 Milligram, Two Times A Day		Not Reported

Ergocalciferolum	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferolum	C	Unknown	Unk, Once A Day	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C		300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080821	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012977			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib Capsules			S	Unknown	200 Milligram, Once A Day		Aurobindo
	Citalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Sertraline			S	Unknown	25 Milligram		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Indomethacin			S	Unknown	50 Milligram, Every 8 Hours		Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Temazepam			S	Unknown	Unk		Not Reported
	Toradol			S	Intramuscular	10 Milligram		Not Reported
	Toradol			S				Not Reported
	Zopiclone			S	Unknown	7.5 Milligram		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Lidocaine			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Milligram		Not Reported
	Naproxen			C	Unknown	500 Milligram, Two Times A Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	50000.0 International Unit, Every Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080824	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013652			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib Capsules	S	Unknown	200.0 Milligram, Once A Day	Aurobindo
	Citalopram	S	Unknown	20.0 Milligram, Once A Day	Aurobindo
	Sertraline	S	Unknown	25.0 Milligram	Aurobindo
	Methotrexate	S	Oral	10.0 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Indomethacin	S	Unknown	50.0 Milligram, 3 Times A Day	Not Reported
	Indomethacin	S			Not Reported
	Leflunomide	S	Unknown	20.0 Milligram	Not Reported
	Toradol	S	Intramuscular	10.0 Milligram	Not Reported
	Toradol	S			Not Reported
	Temazepam	S	Unknown	Unk	Not Reported
	Zopiclone	S	Unknown	7.5 Milligram	Not Reported
	Lidocaine	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Methylprednisolone Acetate	C	Unknown	80.0 Milligram	Not Reported
	Naproxen	C	Unknown	500.0 Milligram, Two Times A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Vitamin D Nos	C	Unknown	50000 International Unit, Every Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16080825	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012975			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Drug Ineffective;	Celecoxib Capsules			S	Unknown	200 Milligram, Two Times A Day		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported

Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Sleep Disorder	Dilaudid		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Lorazepam		S	Unknown	1 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Citalopram		C	Unknown	Unk	Not Reported
	Gold		C	Unknown	Unk	Not Reported
	Morphine		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	10 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081358	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

	Sulfasalazine			S	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081402	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013392			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Meperidine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081403	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013366			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin	S	Unknown	Unk		Aurobindo
	Metronidazole	S	Unknown	Unk		Aurobindo
	Arava	S	Unknown	Unk		Not Reported
	Arthrotec	S	Unknown	Unk		Not Reported
	Bisoprolol	S	Unknown	Unk		Not Reported
	Ceclor	S	Unknown	Unk		Not Reported
	Celebrex	S	Oral	200 Milligram, Daily		Not Reported
	Demerol	S	Unknown	Unk		Not Reported
	Erythromycin	S	Unknown	Unk		Not Reported
	Erythromycin	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Norfloxacin	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	400 Milligram		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Pethidine Hydrochloride	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081459	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023055			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Tofacitinib			S	Unknown					Not Reported
	Tofacitinib Citrate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081465	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022884		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081513	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022912		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Arthrotec		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Imuran		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081523	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022860		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	1dosage Forms, 1every 1weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081542	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022788		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081560	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2019-CA-1022789			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate	S			Not Reported
					Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
					Ilaris Single-Use Vial	S			Not Reported
					Orencia	S	Intravenous (not otherwise specified)		Not Reported
					Orencia	S	Unknown		Not Reported
					Plaquenil	S	Unknown		Not Reported
					Plaquenil	S			Not Reported
					Remicade	S	Intravenous (not otherwise specified)		Not Reported
					Remicade	S			Not Reported
					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Rituxan	S			Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081561	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081571	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024810			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2019	16081669	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2019GMK040164			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, (1 Every 1 Month)		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Od		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, (1 Every 1 Month)		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2.5 Mg, Od		Not Reported
	Acetaminophen W/Oxycodone			C	Unknown	Unk		Not Reported

	Hydrochloride				
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, (1 Every 1 Month)	Not Reported
	Actonel	C	Unknown	36 Mg, Qw	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Od	Not Reported
	Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Od	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	2 Df, Bid (Spray, Metered Dose)	Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Mg, Od	Not Reported
	Prednisone	C	Unknown	5 Mg, Od	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2019	16082138	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06062			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)			Not Reported
	Immune Globulin Nos			S				Not Reported

In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2019	16082152	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06021		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2019	16082157	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2019	16082161	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

	Apo-Azathioprine	S	Unknown	Unknown		Not Reported
	Arava	S	Unknown	Unknown		Not Reported
	Azathioprine	S	Unknown	Unknown		Not Reported
	Ciclosporin	S	Oral	Unknown		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Gold	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	9843376	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20140114429		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec			S	Oral			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Prednisone			S	Unknown					Not Reported
		Serevent			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	14069408	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005673		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			C				Not Reported
	Tylenol			C				Not Reported
	Tylenol With Codein			C				Not Reported

	[Caffeine;Codeine Phosphate;Paracetamol]		
	Caffeine	C	Not Reported
	Levothyroxine	C	Not Reported
	Acetaminophen;Caffeine	C	Not Reported
	Plaquenil	C	Not Reported
	Acetaminophen	C	Not Reported
	Diphenhydramine	C	Not Reported
	Methylprednisolone	C	Not Reported
	Acetaminophen;Caffeine;Dihydrocodeine	C	Not Reported
	Acetaminophen And Codeine Phosphate	C	Not Reported
	Hydroxychloroquine Sulfate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	14339866	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1083144		17 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis; Product Use In Unapproved Indication; Respiratory Tract Infection; Therapeutic Response Decreased; Transient Hypogammaglobulinaemia Of Infancy	Mycophenolate Mofetil			S	Unknown	2 Gram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	15 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	25 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	15684194	EXPEDITED (15-DAY)		OT	CA-ICU MEDICAL, INC.-ICU2018CA00150			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Rheumatoid	Morphine Sulfate Injection			S	Unknown			Icu Medical
	Apo-Hydroxyquine			S	Unknown			Not Reported

Arthritis; Sarcoidosis	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1/Week		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	15922009	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011317			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Pain; Pain	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported
	Vitamins /00067501/			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16082359	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000651		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypoaesthesia; Musculoskeletal Stiffness; Pain; Seronegative Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16082361	EXPEDITED (15-DAY)		HO	US-ROCHE-2281333		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis; Skin Infection	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16083945	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019047900			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Voltaren Actigo Gel			S	Unknown	Unk		Glaxosmithkline
	Lantus			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Byetta			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085045	EXPEDITED (15-DAY)		OT	IND-CA-009507513-1903CAN005033		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb	Rocuronium Bromide			S	Unknown			Merck
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported

Operation; Peripheral Swelling; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Arava	S	Oral			Not Reported
	Codeine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Route: Intravenous (Not Otherwise Specified)		Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Route: Intravenous (Not Otherwise Specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Route: Intravenous (Not Otherwise Specified)		Not Reported
	Gold Sodium Thiomalate	S	Parenteral			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085086	EXPEDITED (15-DAY)		OT	PHHY2019CA056309			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085215	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06150		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Oral	Unknown		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	Unknown		Not Reported
	Ferrous Gluconate			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported

	Lasix			C	Unknown	Unknown		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Unknown		Not Reported
	Naprosyn			C	Unknown	Unknown		Not Reported
	Oxycontin			C	Unknown	Unknown		Not Reported
	Oxyneo			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085229	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06157		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Oral	Unknown		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	Unknown		Not Reported
	Ferrous Gluconate			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported
	Lasix			C	Unknown	Unknown		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Unknown		Not Reported

	Naprosyn			C	Unknown	Unknown			Not Reported
	Oxycontin			C	Unknown	Unknown			Not Reported
	Oxyneo			C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085231	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085271	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

		Humira			S	Subcutaneous				Not Reported
		Hydroxychloroquine			S	Unknown	Unknown			Not Reported
		Methotrexate			S	Unknown	Unknown			Not Reported
		Sulfasalazine			S	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16085615	EXPEDITED (15-DAY)		OT	IND-CA-009507513-1903CAN005427			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Rocuronium Bromide			S	Unknown			Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	12136391	NON-EXPEDITED			US-PFIZER INC-2016067782		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Levothyroxine Sodium			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Estrace			S		Unk		Not Reported
	Plaquenil Sulfate			S		Unk		Not Reported
	Lovastatin-Niacin			S		Unk		Not Reported
	Ezetimibe/Simvastatin			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	12954041	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005804		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Unknown	2 Unk		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Sodium Aurothiomalate	S	Intramuscular			Not Reported
	Prednisone	C				Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	14241987	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021746		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Valtrex			C	Oral	1000 Mg, Bid		Not Reported
	Valtrex			C				Not Reported
	Rosuvastatin Calcium			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium			C	Oral	500 Mg, Bid		Not Reported

	W/Naproxen Acetaminophen W/Oxycodone Hydrochloride			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	15677346	EXPEDITED (15-DAY)		OT	CA-SAKK-2018SA324569AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Arava			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Gold			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16018874	NON-EXPEDITED			US-SA-2019SA054229			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16033819	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-011488			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective	Amoxicillin Capsule			S	Unknown	Unk		Aurobindo
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Probenecid			S	Unknown			Not Reported
	Flagyl			S		Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16070034	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA019314			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	400 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	25 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Medroxyprogesterone Acetate			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naprosyn [Naproxen]			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16079892	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05929			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin Iv			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16082163	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06030			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S	Unknown			Not Reported
	Adalimumab	S	Subcutaneous	Unknown		Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gamastan	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16087032	EXPEDITED (15-DAY)		OT	ES-IPCA LABORATORIES LIMITED-IPC-2019-ES-000286			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Ipca
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16087059	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000662		55 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Ocular Hypertension	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately;		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately;		Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Unknown	Unknown		Concordia
	Prednisolone			C				Not Reported
	Prograf			C				Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16087061	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000705			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16088406	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1027087			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16089641	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06229			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Triamcinolone Acetonide			S	Unknown	Unknown		Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16090050	NON-EXPEDITED			US-SA-2019SA071514			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity	Lantus	S	Unknown	Unk		Sanofi
	Arava	S	Unknown	Unk		Sanofi
	Plaquenil	S	Unknown	Unk		Sanofi
	Humira	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Voltaren [Diclofenac]	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16090242	NON-EXPEDITED			US-SA-2019SA073956			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Stomatitis	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16091459	NON-EXPEDITED			US-SA-2019SA071591			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dry Skin; Pruritus; Swelling Of Eyelid	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16092464	EXPEDITED (15-DAY)		OT	PHHY2019CA056804			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity;	Neoral			S	Unknown	125 Mg, Bid		Novartis
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Imuran	S	Unknown	150 Mg, Tid		Not Reported
	Plaquenil	S	Unknown	200 Mg, Qd		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1.0 G, Unk		Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Prednisone	C	Unknown	10.0 Mg, Unk		Not Reported
	Citalopram Hydrobromide	C	Unknown	40.0 Mg, Unk		Not Reported
	Citalopram Hydrobromide	C	Unknown	1 Df, Qd (40 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2019	16094531	DIRECT					63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Dizziness; Drug Hypersensitivity; Fatigue; Headache; Myalgia; Peripheral Coldness	Hydroxychloroquine			S	Oral	Quantity:2 Tablet(S);		Not Reported
	Atenolol			C				Not Reported
	Lisinopril			C				Not Reported
	Aspirin			C				Not Reported
	Vitamn D3			C				Not Reported
	Apple Cider Vinegar			C				Not Reported
	Turmeric			C				Not Reported
	Ginger Powder			C				Not Reported
	Aleve			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	12932037	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005715		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported

Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Leflunomide	S		Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Abatacept	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Avara	C			Not Reported
	Paracetamol	C			Not Reported
	Calcium Carbonate	C			Not Reported
	Cymbalta	C			Not Reported
	Elavil	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Lyrica	C			Not Reported
	Premarin	C			Not Reported
	Sumatriptan Succinate	C			Not Reported
	Tenormin	C			Not Reported
	Tofacitinib	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	12944853	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005802		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	12963014	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201611-005836		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	15230450	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-180264		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Histoplasmosis Disseminated	Methotrexate			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Infliximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	15722903	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004086		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Plaquenil Tablet	S	Unknown		Concordia
	Hydroxychloroquine	S	Unknown		Concordia
	Hydroxychloroquine	S	Unknown		Concordia
	Arava	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Abatacept	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	C			Not Reported
	Benadryl	C			Not Reported
	Synthroid	C			Not Reported
	Lasix	C			Not Reported
	Darifenacin	C			Not Reported
	Ativan	C			Not Reported
	Loperamide Hydrochloride	C			Not Reported
	Orphenadrine Citrate	C			Not Reported
	Omnaris	C			Not Reported
	Pantoprazole	C			Not Reported
	Vagifem	C			Not Reported
	Dilaudid	C			Not Reported

	Cortisone	C	(Intermittent Intra-Auricular And Intramuscular To Keep Her Comfortable)	Not Reported
	Rituxan	C		Not Reported
	Darifenacin Hydrobromide	C		Not Reported
	Desoximetasone	C		Not Reported
	Acetaminophen	C		Not Reported
	Codeine	C		Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog	C		Not Reported
	Oxyneo	C		Not Reported
	Restasis	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Morphine Sulfate	C		Not Reported
	Diphenhydramine	C		Not Reported
	Dyclone	C		Not Reported
	Desoximetasone	C		Not Reported
	Anakinra	C		Not Reported
	Pantoprazole Sodium Anhydrous	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	15989272	EXPEDITED (15-DAY)		OT	JP-GLAXOSMITHKLINE-JP2018JPN126664		37 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Pyrexia	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 2 Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 4 Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 4 Weeks		Glaxosmithkline
	Predonine			S	Oral	Unk		Not Reported
	Predonine			S	Oral	9 Mg, Qd		Not Reported
	Cellcept			S	Oral	1500 Mg, Qd		Not Reported
	Cellcept			S				Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Oral	200 Mg, Qd		Not Reported
	Evolocumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16092842	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000693			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Plaquenil			S	Unknown			Concordia
	Pantoloc			C				Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16094459	NON-EXPEDITED			US-PFIZER INC-2019118807		76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Zosyn			S		Unk		Pfizer
	Lovenox			S		Unk		Not Reported
	Niaspan			S		Unk		Not Reported
	Plaquenil Sulfate			S		Unk		Not Reported
	Sulphur			S		Unk		Not Reported
	Zocor			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16094961	NON-EXPEDITED			US-PFIZER INC-2019118365			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16095085	EXPEDITED (15-DAY)		DE	CA-JNJFOC-20190321907		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Tylenol		Y	S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16098167	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1026302		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Polyneuropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown	Therapy Duration 16 Years		Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration 17 Years		Not Reported
	Hydroxychloroquine 00072603			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Atorvastatin			C	Oral	40 Milligram Daily;		Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16099948	DIRECT		OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Injury	Hydroxychloroquine (Generic For Plaquenil)			S	Oral	Quantity:1 Tablet(S);	15 YR	Mylan
	Anastrozole (Generic For Arimidex) 1mg Tab			S	Oral	Quantity:1 Tablet(S);		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	12335889	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015080712		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1 Every 1 Day, 16 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Qd		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

					Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
					Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
					Methotrexate	S	Unknown	Unk	Not Reported
					Methotrexate	S	Unknown	Unk	Not Reported
					Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	12353299	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016056591		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	12499091	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016080246		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported

Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	500 Milligram, Qwk	Not Reported
	Methotrexate Sodium		S	Oral	25 Mg, Qwk	Not Reported
	Methotrexate Sodium		S	Oral	17.5 Mg, Qweek	Not Reported
	Methotrexate Sodium		S	Oral	15 Mg, Qwk	Not Reported
	Methotrexate		S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate		S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate		S	Oral	17.5 Milligram, Qwk	Not Reported
	Leucovorin		C		Unk	Not Reported
	Vitamin D2		C		2000 Iu, Unk	Not Reported
	Coversyl		C	Unknown	4 Milligram, Qd	Not Reported
	Ergocalciferol		C		2000 International Unit, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	13358180	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017042979		42 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			C	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	13849414	EXPEDITED (15-DAY)		OT	GB-ACCORD-056755		39 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Anaphylactic Reaction; Drug Ineffective; Lethargy; Leukopenia; Off Label Use	Methotrexate	S	Over 2 Years	Accord
	Mycophenolic Acid	S	Over 2 Years	Accord
	Prednisolone	S	Over 2 Years	Not Reported
	Azathioprine	S	Over 2 Years	Not Reported
	Hydroxychloroquine	S	Over 2 Years	Not Reported
	Dapsone	S	Over 2 Years	Not Reported
	Colchicine	S	Over 2 Years	Not Reported
	Rituximab	S	Over 2 Years	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	14156192	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165071			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	14157858	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Investigation Abnormal; Joint Swelling; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Myochrysine			C	Intramuscular	Unk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	14169090	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	50 Mg,Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S	Unknown	8 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

					Methotrexate		S	Unknown	20 Mg,Qd		Not Reported
					Orencia		S	Unknown	750 Mg,Unk		Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
					Meloxicam		C	Unknown			Not Reported
					Sulfasalazine		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	14869768	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2018US021237		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Tacrolimus			S	Unknown	Unk Unk, Unknown Freq.		Astellas
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	15573921	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018153600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Pain In Extremity; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Sulfasalazine			C	Unknown				Not Reported
	Asa			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	15707761	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174006		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101533	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-HQWYE016205SEP07			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative; Erysipelas; Face Oedema; Lupus-Like Syndrome; Malaise	Cordarone			S	Oral	Dose And Frequency Not Specified		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg Tablet, Dose And Frequency Not Specified		Not Reported
	Flecaine			S	Unknown	Unk		Not Reported
	Olmetec			S	Oral	Dose And Frequency Not Specified		Not Reported

		Fenofibrate			C	Oral	Unk			Not Reported
		Ginkor			C	Oral	Unk			Not Reported
		Aprovel			C	Oral	Unk			Not Reported
		Cervoxan			C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16101600	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-050925		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Avelox			S	Unknown	Unk		Bayer
	Ciprofloxacin			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hctz			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	8.5 Mg, Qd			Not Reported
	Cipro [Ciprofloxacin]			C	Unknown	Unk			Not Reported
	Iron Sucrose			C	Unknown	Unk			Not Reported
	Esomeprazole			C	Unknown	Unk			Not Reported
	Gold			C		Unk			Not Reported
	Hydroxychloroquine Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16102075	EXPEDITED (15-DAY)		DE	US-LANNETT COMPANY, INC.-US-2019LAN000279		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Isoniazid			S	Oral	Unk		Lannett
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Ethanol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2019	16102310	EXPEDITED (15-DAY)		DS	PHHY2019CA062343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Ciclosporin			S	Unknown	Unk		Novartis
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Declofenac			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	12368813	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016257109		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Stress At Work; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Unk		Pfizer
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	12625274	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016100343		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Anxiety; Condition Aggravated; Drug Ineffective; Drug Intolerance; Palpitations; Rash; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	12913898	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091693			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine /00884302/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Cetrizine			S	Unknown			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	12933958	EXPEDITED (15-DAY)		OT	CA-SA-2016SA201465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Herpes Zoster; Herpes Zoster; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Pneumonia Viral; Rheumatoid Arthritis; Swelling; Synovitis; Tenderness	Arava			S	Unknown	20 Mg,Qd		Sanofi
	Plaquenil			S	Unknown	200 Mg,Bid		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg,Biw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg,Qm		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg,Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg,Qm		Not Reported
	Ativan			C	Unknown	1 Mg,Qd		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown	Unk Unk,Unk		Not Reported
	Dilaudid			C	Unknown	4 Mg,Q6h		Not Reported
	Darifenacin			C	Unknown	Unk Unk,Unk		Not Reported
	Furosemide			C	Unknown	40 Mg,Qid		Not Reported
	Loperamide			C	Unknown	Unk Unk,Bid		Not Reported
	Orphenadrine Citrate			C	Unknown	Unk Unk,Bid		Not Reported
	Omnaris			C	Unknown	Unk Unk,Unk		Not Reported
	Pantoprazole Sodium			C	Unknown	Unk Unk,Unk		Not Reported
	Synthroid			C	Unknown	Unk Unk,Unk		Not Reported
	Vagifem			C	Vaginal	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	14185631	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017170118		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Warfarin Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	14312115	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006671		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Aortic Valve Stenosis; Carpal Tunnel Syndrome; Constipation; Cushingoid; Deafness; Depression; Drug Hypersensitivity; Drug Intolerance; Dry Eye; Feeling Jittery; Ill-Defined	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Disorder; Increased Appetite; Injury; Interstitial Lung Disease; Intervertebral Disc Degeneration; Neuropathy Peripheral; Ocular Hyperaemia; Organising Pneumonia; Osteoarthritis; Pain In Jaw; Pelvic Fracture; Peripheral Nerve Lesion; Pneumonitis; Pruritus; Pulmonary Arterial Hypertension; Pulmonary Mass; Respiratory Failure; Rheumatoid Arthritis; Road Traffic Accident; Rotator Cuff Syndrome; Sleep Disorder; Spinal Stenosis; Syncope; Therapeutic Procedure; Treatment Failure; Upper Respiratory Tract Infection; Urinary Tract Infection; Weight Decreased	Fosamax (Alendronate Sodium)	S	Unknown	Unknown	Not Reported
	Ursodiol	S	Oral		Not Reported
	Mtx	C			Not Reported
	Remicade	C			Not Reported
	Humira	C			Not Reported
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported
	Xeljanz Xr	C			Not Reported
	Zyrtec	C			Not Reported
	Welchol	C			Not Reported
	Trazodone	C			Not Reported
	Nasonex	C			Not Reported
	Nexium	C			Not Reported
	Skelaxin	C			Not Reported
	Cytotec	C			Not Reported
	Etodolac	C			Not Reported
	Aspirin	C			Not Reported
	Calcium	C			Not Reported
	Vitamin B12	C			Not Reported
	Fish Oil	C			Not Reported
	Benicar Hct	C			Not Reported
	Arava	C			Not Reported
	Synvisc One	C			Not Reported
	Synvisc One	C			Not Reported
	Synvisc One	C			Not Reported
	Synvisc (Hylan G-F 20)	C			Not Reported
	Synvisc (Hylan G-F 20)	C			Not Reported
	Synvisc (Hylan G-F 20)	C			Not Reported
	Estrace Vaginal	C			Not Reported
	Zinc Sulfate	C			Not Reported
	Refresh Liquigel	C			Not Reported
	Allergy Relief	C			Not Reported
	Mometasone	C			Not Reported
	Polyethylene Glycol 3350	C			Not Reported
	Milk Of Magnesia	C			Not Reported
	Miconazole Nitrate	C			Not Reported
	Compazine	C			Not Reported
	Compazine	C			Not Reported
	Alprazolam	C			Not Reported
	Toprol Xl	C			Not Reported

	Lisinopril	C	Not Reported
	Aspir 81	C	Not Reported
	Calcium + Vitamin D	C	Not Reported
	Prilosec	C	Not Reported
	Tylenol Extra Strength	C	Not Reported
	Cranberry Extract	C	Not Reported
	Misoprostol	C	Not Reported
	Arthrotec	C	Not Reported
	Lidocaine	C	Not Reported
	Azor	C	Not Reported
	Mvi	C	Not Reported
	Citracal	C	Not Reported
	Asa	C	Not Reported
	Glucosamine Chondroitin	C	Not Reported
	Vesicare	C	Not Reported
	Percocet	C	Not Reported
	Vicoprofen	C	Not Reported
	Vioxx	C	Not Reported
	Flexeril	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	14444350	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018006324		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Simponi			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			C	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	14633661	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019429		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	1 Df, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Codeine			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15249735	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-072052		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Pulmonary Mass; Sinusitis	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Oral	1 Tab, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15360042	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018123317		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Spleen Disorder; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Bid		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported
	Cimzia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15362364	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1082367		68 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Maculopathy; Off Label Use; Retinal Toxicity; Visual Acuity Reduced; Visual Field Defect	Hydroxychloroquine			S	Unknown	Unk Unk, Qd, (More Than 1500 G On Varying Doses Over Time 200-400mg Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15505159	NON-EXPEDITED			US-AMGEN-USASP2018142956			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Malaise	Enbrel			S	Unknown	Unk		Amgen
	Hcq			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

Xeljanz Xr	C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15555303	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016047247		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil S			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Multivitamin			C	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15578883	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018153609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15633223	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105382		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15652205	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018166512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	500 Mg, Unk		Not Reported
	Oxycodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15964290	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS		60 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	15978212	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013645		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported

Synovitis	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	400.0 Mg, Unk	Not Reported
	Xeljanz		S	Oral	5.0 Mg, Bid	Not Reported
	Naproxen Sodium		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Leflunomide		S	Oral		Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16103369	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000759			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Sjogren'S Syndrome	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2019	16105299	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP009483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Apotex
	Meloxicam			S	Unknown			Apotex
	Methotrexate			S	Unknown			Not Reported
	Abatacept			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2019	15583124	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018153705		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine			C	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2019	16108605	EXPEDITED (15-DAY)		DS	GB-ACCORD-113837		31 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Mood; Drug Ineffective; Intentional Self-Injury; Suicidal Ideation	Sertraline			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2019	16108789	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA064197			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Novartis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2019	16108796	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA064190			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous			Not Reported
	Humira	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2019	16108797	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA064199			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported

	Humira		S	Subcutaneous		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine		S			Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S			Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2019	16108858	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1029420			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	11449663	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2013082462		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Unknown	25 Milligram, Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Oral	200 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis	Humira	S	Subcutaneous	Unk		Not Reported
	Ibuprofen	S	Unknown	Unk		Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, Unk		Not Reported
	Apo-Ibuprofen	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Prednisone	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	12573117	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2016091153		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	12898922	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016150362		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	750 Milligram, Q2wk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Sulfasalazine			C	Unknown	1 G, Twice Daily		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	12913901	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091816		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	750. Mg, Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Naproxen Sodium	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Reactine /00884302/	C	Unknown		Not Reported
	Venlafaxine Hydrochloride	C	Unknown		Not Reported
	Benadryl /00000402/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	12983622	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016166963		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	50 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	40 Mg, Cyclic		Not Reported
	Humira			S	Unknown	40 Mg, Cyclic		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	50 Milligram, Q2wk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported

Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
Leflunomide	S	Oral	10 Mg, Qd	Not Reported
Leflunomide	S	Oral	20 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Mg, Qd	Not Reported
Methotrexate	S	Unknown	25 Mg, Q2wk	Not Reported
Methotrexate	S	Unknown	10 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	7.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	7.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	5 Mg, Qwk(Every Tuesday)	Not Reported
Methotrexate	S	Unknown	5 Mg, Q2wk	Not Reported
Methotrexate	S	Unknown	10 Mg, Q2wk	Not Reported
Methotrexate	S	Unknown	7.5 Mg, Q2wk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
Celebrex	S	Oral	200 Mg, Unk	Not Reported
Orencia	S	Unknown	125 Mg, Qwk	Not Reported
Orencia	S	Unknown	12.5 Mg, Q2wk	Not Reported
Gabapentin	C	Unknown	300 Mg, Unk	Not Reported
Gabapentin	C	Oral	100 Mg, Unk	Not Reported
Gabapentin	C	Oral	100 Mg, Unk	Not Reported
Gabapentin	C	Unknown	100 Mg, Unk	Not Reported
Atorvastatin	C	Oral	40 Mg, 2 Times/Wk	Not Reported
Atorvastatin	C	Oral	40 Mg, Qd	Not Reported
Altace	C		5 Mg And 10 Mg Unk	Not Reported
Estrogens Conjugated	C	Oral	0.625 Mg, Unk	Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Unk	Not Reported
Hydromorphone Hcl	C	Oral	3 Mg, Bid	Not Reported
Prednisone	C	Oral	15 Mg, Qd	Not Reported

Intolerance; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Orencia		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		C	Subcutaneous	25 Milligram	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	13290430	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016121051		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14159126	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165285		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen

	Etanercept	S	Unknown	Unk	Amgen
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	65 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	65 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14181934	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017170136		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Amgen
	Humira			S	Subcutaneous	40 Mg, Unk (Solution Subcutaneous)		Not Reported
	Apo Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk Intravenous (Not Otherwise Specified)		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14217561	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017174921		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Apo-Minocycline			S	Unknown	50 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	3 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Unknown	3 Dosage Form		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14233427	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015262989		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Hydroxychloroquine			S	Unknown	200 Mg, 1 Every 1 Day, 16 Years		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1 Every 1 Day, 119 Days		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	200 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 1x/Day	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
	Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14415190	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000253		72 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Eye Burns; Visual Field Defect; Visual Impairment; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral	1 Tablet Per Day (1 Df, Every Morning),		Concordia
	Lanzor			C				Not Reported
	Kardegic			C				Not Reported
	Coaprovel			C				Not Reported
	Ventoline			C				Not Reported
	Rosuvastatine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Rosuvastatine			C				Not Reported
	Irbesartan			C				Not Reported
	Bisoprolol			C				Not Reported
	Seretide			C				Not Reported
	Salbutamol			C				Not Reported

	Lansoprazole			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14491493	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007150		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Piroxicam			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14629723	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018033444			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Abatacept			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	750 Milligram, Qd		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Rituxan			C		Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Lisinopril Hct			C		Unk		Not Reported
	Lisinopril And Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Tylenol Extra Strength			C	Unknown	Unk Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	14917941	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15554016	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018148309			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15583659	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018451470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Pain In Extremity; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram, Qwk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15591682	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018153859		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15652183	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018167291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15666191	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018166204			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk				Not Reported
	Leflunomide			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15849374	EXPEDITED (15-DAY)		OT	CA-SAKK-2019SA011855AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S		200 Mg Alternating With 400mg Per Day		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Gold			C				Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported
	Sulfasalazine			C				Not Reported
	Naproxen			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	15946971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased; Bronchitis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

Calcium Carbonate	C	Oral	1500 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hydromorphone	C	Oral	1 Milligram, 4 Every 1 Day	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qd	Not Reported
Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
Naproxen	C	Unknown	500 Milligram, Bid	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Tylenol Arthritis	C	Unknown	Unk	Not Reported
Vitamin D /00107901/	C	Oral	10000 Milligram, Qwk	Not Reported
Vitamin D /00107901/	C	Oral	20000 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16030388	EXPEDITED (15-DAY)		HO	NL-PFIZER INC-2019090979		62 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Diarrhoea; Headache; Laryngitis; Myalgia; Nausea; Oral Candidiasis; Upper Respiratory Tract Infection; Vomiting	Salazopyrine			S	Unknown	Unk		Pfizer
	Abatacept			S	Subcutaneous	125 Mg/Ml, Weekly		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16109971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported

	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16110226	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025845			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16110292	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2019049642		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Lactulose			S	Oral	1 Df, Qd		Glaxosmithkline
	Dulcolax			S	Oral	5 Mg, Qd		Glaxosmithkline
	Ranitidine			S	Oral	300 Mg, Qd		Glaxosmithkline
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported

Zolpidem	S	Oral	10 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16111255	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000773		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Toxicity To Various Agents; Vitreous Floaters	Hydroxychloroquine			S	Unknown	Mean Daily Dose Of 5.33 Mg/Kg Rbw , Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16111906	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetrizine			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16112469	NON-EXPEDITED			US-PFIZER INC-2019120437		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Mirtazapine			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Nitrofurantoin Monohydrate/Macrocrystals			S		Unk		Not Reported
	Cefaclor			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2019	16114426	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019124608		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Ibrance			S	Oral	100 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Faslodex			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	12088348	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2016018659		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; No Adverse Event; Respiratory Arrest; Visual Impairment	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclical		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	12373877	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016061705		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Remicade			S	Unknown	Unk				Not Reported
	Methotrexate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	12576358	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016093347		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Latent Tuberculosis; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	50 Milligram		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram And Then 4 Times/Wk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Four Every One Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	14165461	EXPEDITED (15-DAY)		HO	CA-AMGEN-CANSP2017166856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Malaise; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

	Rituxan			C	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	14191056	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490913		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Warfarin Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	14918715	NON-EXPEDITED			US-PFIZER INC-2018203350		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Infliximab			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported

	Codeine	S	Unk	Not Reported
	Duloxetine	S	Unk	Not Reported
	Leflunomide	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15233606	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016546889		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly (4 Tablets Once A Week)		Pfizer
	Methotrexate Sodium			S	Oral	7.5 Mg, Weekly (3 Tablets Once A Week)		Pfizer
	Methotrexate Sodium			S	Oral	7.5 Mg, Weekly (3 Tablets Once A Week)		Pfizer
	Methotrexate Sodium			S	Oral	5 Mg, Weekly (2 Tablets Every Tuesday)		Pfizer
	Methotrexate Sodium			S		25 Mg/Ml, Vial		Unknown
	Celebrex			S	Oral	200 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg, Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Orencia			S	Unknown	125 Mg, Weekly		Not Reported
	Humira			S		40 Mg, Cyclic (Every Other Week)		Not Reported
	Humira			S		40 Mg, Cyclic (Every Other Week)		Not Reported

Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic (Every Other Week)	Not Reported
Humira	S		40 Mg, Cyclic	Not Reported
Humira	S		40 Mg, Cyclic	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic (Every Two Weeks)	Not Reported
Humira	S	Subcutaneous	50 Milligram, Cyclic (Every Two Weeks)	Not Reported
Leflunomide	S	Oral	20 Mg, Once Daily	Not Reported
Leflunomide	S	Unknown	10 Mg, Once Daily	Not Reported
Hydroxychloroquine	S		200 Mg, Once Daily (1.5 Tablet)	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day	Not Reported
Altace	C		10 Mg, Unk	Not Reported
Altace	C		5 Mg	Not Reported
Estrogens Conjugated	C	Oral	0.625 Mg, Unk	Not Reported
Hydrochlorothiazide	C	Oral	12.5 Mg, Unk	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Mg, Twice A Day	Not Reported

Taro-Mupirocin	C		2 %, Unk	Not Reported
Tramadol	C	Oral	50 Mg, Unk	Not Reported
Tramacet	C	Oral	37.5/325 Mg, 1-2 Tablets Every 6 Hours	Not Reported
Celexa	C		20 Mg, Unk	Not Reported
Cipralex	C		10 Mg, Unk	Not Reported
Cymbalta	C	Unknown	30 Mg, 4x/Day	Not Reported
Cymbalta	C	Unknown	60 Mg, Unk	Not Reported
Estrace	C	Unknown	0.5 Mg, Unk	Not Reported
Nucynta	C		50 Mg, Unk	Not Reported
Atorvastatin Calcium	C	Oral	40 Mg, Once Daily	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Q2wk	Not Reported
Apo-Prednisone	C		5 Mg, Unk	Not Reported
Apo-Prednisone	C		15 Mg, 1x/Day	Not Reported
Prednisone	C	Oral	5 Mg	Not Reported
Prednisone	C	Oral	5 Mg	Not Reported
Prednisone	C	Oral	5 Mg, Three Times Daily	Not Reported
Prednisone	C	Oral	5 Mg, Unk	Not Reported
Pantoloc	C		20 Mg, 1 Tablet Once Daily	Not Reported
Pantoloc	C			Not Reported
Ratio-Emtec	C		1-2 Tablets Taken Every 4-6	Not Reported
Ratio-Emtec	C		1-2 Tablets Taken Every 4-6	Not Reported
Gabapentin	C	Oral	100 Mg, Unk	Not Reported
Gabapentin	C	Unknown	100 Mg, Unk	Not Reported
Apo-Gabapentin	C		300 Mg, Unk	Not Reported
Apo-Gabapentin	C		5 Unk, Unk	Not Reported
Citalopram Hydrobromide	C	Unknown	Unk	Not Reported
Citalopram Hydrobromide	C	Oral	Unk	Not Reported

		Shark-Liver Oil			C		Unk			Not Reported
		Tapentadol			C	Unknown	50 Mg, Unk			Not Reported
		Mupirocin			C	Topical	Unk			Not Reported
		Escitalopram Oxalate			C	Unknown	10 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15238168	EXPEDITED (15-DAY)		OT	ES-SA-2018SA177098		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Leflunomide			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Adalimumab			S		Unk Unk, Unk		Not Reported
	Abatacept			S		Unk Unk, Unk		Not Reported
	Tocilizumab			S		Unk Unk, Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			C	Unknown	50 Mg, Unk		Not Reported
	Lornoxicam			C				Not Reported
	Paracetamol			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15438012	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-090258			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Infection; Liver Function Test Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

		Hcq			S	Unknown	Unk			Not Reported
		Etanercept			C	Unknown	Unk			Not Reported
		Hydroxychloroquine			C	Unknown	Unk			Not Reported
		Xeljanz Xr			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15555436	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016303412		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Headache; Hyperhidrosis; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qwk		Not Reported
	Arava			S		20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Coversyl			C	Oral	4 Milligram, Qd		Not Reported
	Vitamin D2			C		2000 Iu, Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Ergocalciferol			C		2000 International Unit, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15592333	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018455625		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness	Enbrel			S	Unknown	Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15595175	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016207943		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Motor Dysfunction; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence	Enbrel			S	Unknown	50 Mg, Milligram, Qwk (4 Times/Wk)		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Leflunomide			S		20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil S			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Multivitamin			C	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15646735	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018166372		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15654793	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018166521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contraindicated Product Administered; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Sinusitis; Treatment Failure; Vertigo	Desoximetasone		S	Unknown	Unk	Not Reported
	Desoximetasone		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Prednisone		C		7.5 Milligram	Not Reported
	Xeljanz		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15662209	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018486633			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	500 Mg, Unk		Not Reported
	Oxycodone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15663720	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018166363		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis;	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported

Road Traffic Accident; Therapeutic Product Effect Decreased	Arava	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15689903	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA325600AA			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Triamcinolone Acetonide			S				Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Immune Globulin Nos			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Unk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Unknown	12.5 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Infliximab			S	Unknown	5 Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	250 Mg, Qd		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16115835	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Ill-Defined Disorder; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Qd		Not Reported
	Synthroid			C	Unknown			Not Reported
	Losec /00661201/			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Betaloc /00376902/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16116308	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025987		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported

Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Sulfasalazine	S	Unknown		Not Reported
	Benadryl /00000402/	C	Unknown		Not Reported
	Naproxen Sodium	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Reactine /00884302/	C	Unknown		Not Reported
	Venlafaxine	C	Unknown		Not Reported
	Cetirizine Hcl	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16117392	EXPEDITED (15-DAY)		HO	ES-ACCORD-114946		29 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Off Label Use	Mycophenolic Acid			S	Oral	1000 Mg In The Morning And 500 Mg In The Evening,		Accord
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16117781	EXPEDITED (15-DAY)		OT	CA-SA-2017SA208672			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S		0.5 Df, Unk		Sanofi
	Kevzara			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			C	Oral	3 G,Qd		Not Reported
	Meloxicam			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16118575	EXPEDITED (15-DAY)		HO	PHHY2019FR061845		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Lactulose			S	Oral	1 Df, Qd		Not Reported
	Zolpidem			S	Oral	10 Mg, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported
	Dulcolax			S	Oral	5 Mg, Qd		Not Reported
	Ranitidine			S	Oral	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16118609	EXPEDITED (15-DAY)		LT	PHHY2019NO067351		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	11062402	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2011045864		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported

Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium	S	Oral	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Naprelan	C	Unknown	Unk		Not Reported
	Effexor	C	Unknown	Unk		Not Reported
	Plaquenil	C	Unknown	Unk		Not Reported
	Naproxen Sodium	C		Unk		Not Reported
	Venlafaxine Hydrochloride	C	Unknown	Unk		Not Reported
	Benadryl	C	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Unk		Not Reported
	Venlafaxine	C		Unk		Not Reported
	Cetirizine Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	12582919	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016353843		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

			Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
			Leflunomide		S	Unknown	Unk			Not Reported
			Orencia		S	Unknown	Unk			Not Reported
			Apo-Leflunomide		S	Unknown	Unk			Not Reported
			Hydroxychloroquine		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	12685824	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016396262		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Drug Ineffective; Hepatic Enzyme Increased; Lymphadenopathy	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, Unk		Pfizer
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Arava			S		10 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Monthly		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	12912721	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra		S	Unknown			Not Reported
	Arava		S	Unknown			Not Reported
	Cimzia		S	Subcutaneous			Not Reported
	Enbrel		S	Subcutaneous			Not Reported
	Fosamax		S	Unknown			Not Reported
	Humira		S	Subcutaneous			Not Reported
	Hydroxychloroquine		S	Unknown			Not Reported
	Methotrexate		S	Unknown			Not Reported
	Prednisone		S	Unknown			Not Reported
	Reactine /00884302/		S	Unknown			Not Reported
	Remicade		S	Intravenous (not otherwise specified)			Not Reported
	Rituxan		S	Intravenous (not otherwise specified)			Not Reported
	Simponi		S	Subcutaneous			Not Reported
	Sulfasalazine		S	Unknown			Not Reported
	Folic Acid		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	12914260	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093132		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Angiopathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Venous Injury; Visual	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown	8 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	13057913	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Codeine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	360 Mg, Q.M.T.		Not Reported
	Tocilizumab			S	Unknown	680 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown	380 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown	360 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Orencia			S	Unknown	780 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	760 Mg, Q.Wk.		Not Reported
	Rituximab			S	Unknown	1000 Mg, Bid		Not Reported
	Humira			S	Unknown	40 Mg, 2 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	12 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	70 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Q.Wk.		Not Reported

	Methotrexate			S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Remicade			S	Unknown	Unk	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Actemra			S	Unknown	360 Mg, Q.M.T.	Not Reported
	Actemra			S	Unknown	680 Mg, Every Four Week	Not Reported
	Myochrysine			S	Unknown	50 Mg, Q.M.T.	Not Reported
	Ciclosporin			C	Unknown	150 Mg, Qd	Not Reported
	Ciclosporin			C	Unknown	Unk	Not Reported
	Prednisone			C	Unknown	20 Mg, Unk	Not Reported
	Prednisone			C	Unknown	10 Mg, Qd	Not Reported
	Prednisone			C	Unknown	Unk	Not Reported
	Xeljanz			C	Unknown	Unk	Not Reported
	Prednisolone			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	13153727	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005397		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	577 Milligram		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Simponi		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	577 Milligram	Not Reported
	Desoximetasone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	13216871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-009735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	13519876	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037935			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive	Abatacept			S	Intravenous (not otherwise specified)	125 Mg, Qwk		Bristol Myers Squibb

Protein Increased; Contraindicated Product Administered; Drug Ineffective; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Thrombocytosis	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Naprosyn /00256201/	S	Unknown	500 Mg, Bid	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	5 Mg, Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Lovastatin	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	50 Mg, Unk	Not Reported
	Naproxen Sodium	C	Unknown	1000.0 Mg, Qd	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Rosuvastatin /01588602/	C	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D 3	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	14007308	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017144074		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis;	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Rituxan		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Leflunomide		C		1 Tab, Qd		Not Reported
	Leflunomide		C		Unk		Not Reported
	Arava		C		20 Milligram, Qd		Not Reported
	Xeljanz Xr		C	Oral	11 Milligram, Qd		Not Reported
	Xeljanz Xr		C	Unknown	Unk		Not Reported
	Xeljanz		C	Oral	11 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	14187023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490474		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease	Enbrel			S	Subcutaneous	25 Mg, 2 Times/Wk		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk (Solution Subcutaneous)		Not Reported
	Apo Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	14528316	NON-EXPEDITED			US-AMGEN-USASP2018019166			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Injection Site Reaction; Pain	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	Unk				Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	14632449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	200 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	14921464	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044371		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	2.0 G, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Prednisone			C	Unknown					Not Reported
	Xeljanz			C	Oral	5.0 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15560469	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018442155			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15602283	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016371889		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Anxiety; Condition Aggravated; Drug Ineffective; Drug Intolerance; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day (Bid)		Pfizer
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil			S	Unknown	400 Mg, 1x/Day (Qd)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Prednisone			C	Unknown	5 Mg, 1x/Day (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15631788	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105288		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15635424	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Reactine /00884302/	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15664774	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018487473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contraindicated Product Administered; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sinusitis; Treatment Failure; Vertigo	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S				Not Reported
	Desoximetasone			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C		7.5 Mg, Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15667697	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018491587		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis;	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported

Road Traffic Accident; Therapeutic Product Effect Decreased	Plaquenil			S	Oral	200 Mg, 2 Every 1 Day		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15669579	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018492640			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15781548	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3981		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Endocervical			Not Reported
	Rituximab			S	Unknown	2 Doses		Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Azathioprine	S	Unknown		Not Reported
	Cyclosporine A	S	Unknown		Not Reported
	Cyclosporine A	S	Unknown		Not Reported
	Cyclosporine A	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Infliximab	S	Unknown	1 Dose	Not Reported
	Medroxyprogesterone Acetate	S	Unknown		Not Reported
	Amitriptyline	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Oxycodone	C	Unknown		Not Reported
	Depo-Provera	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15964334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported

	Enbrel	S	Unknown	25 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Qwk		Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Wellbutrin	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15978140	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25.0 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15978256	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15978705	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown	400 Mg, Unk			Not Reported
		Methotrexate			S	Subcutaneous	15 Mg, Unk			Not Reported
		Sulfasalazine			S	Oral	1 G, Qd			Not Reported
		Xeljanz			C	Oral	5 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15978774	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013890		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Not Reported
	Prednisone			C	Endocervical	50 Mg, 1 Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16016350	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1017195		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16025701	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-ACCORD-108696			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	From Gestational Week 0-14, Also Received Unk Dose Additionally		Not Reported
	Pantoprazole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Accord
	Ramipril			S	Transplacental	Maternal Dose 20 Mg, Unk,20 Mg Unk From Gestational Week 0-113+6		Accord
	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Not Reported
	Metamizole/Metamizole Magnesium/Metamizole Sodium/Metamizole Sodium Monohydrate			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Enoxaparin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Rivaroxaban			S	Transplacental	From Gestational Week 0-5		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported

	Aliskiren	S	Transplacental		Not Reported
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Dalteparin	S			Not Reported
	Rituximab	S			Not Reported
	Heparin Lmw	S	Transplacental	Unk	Not Reported
	Clexane	S			Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
	Ezetimibe	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16101730	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190316870		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16121157	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-028385			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16121489	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported

	Simponi		C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Xeljanz		C	Oral	5.0 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16121820	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16122395	EXPEDITED (15-DAY)		OT	DE-APOTEX-2019AP010097		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Exposure During Pregnancy; Premature Delivery	Pantoprazole			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Apotex
	Pantoprazole			S	Unknown	Unk		Apotex
	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Apotex
	Ezetimibe			S	Unknown			Apotex
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Tacrolimus			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

Prednisolone	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Prednisolone	S	Unknown		Not Reported
Salbutamol	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Salbutamol	S	Unknown	Unk	Not Reported
Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
Rivaroxaban	S	Unknown		Not Reported
Ramipril	S	Unknown	20 Mg, Unknown Freq. (0-13+6 Gw)	Not Reported
Ramipril	S	Unknown	20 Mg Per Day	Not Reported
Torasemide	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Torasemide	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Metamizole	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Metamizole	S	Unknown		Not Reported
Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
Aliskiren	S	Unknown	Unk	Not Reported
Simvastatin	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Simvastatin	S	Unknown		Not Reported
Nicotine	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
Nicotine	S	Unknown	Unk	Not Reported
Enoxaparin Sodium	S	Unknown		Not Reported
Enoxaparin	C	Unknown	Unk Unk, Unknown Freq.	Not Reported

(0-14 Gw)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16122679	EXPEDITED (15-DAY)		HO	FR-SA-2019SA075555		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Zolpidem Tartrate			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	400 Mg		Sanofi
	Lactulose			S	Oral	1 Df, Qd		Sanofi
	Dulcolax			S	Oral	5 Mg, Qd		Sanofi
	Ranitidine			S	Oral	300 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16123788	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019011508		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Ucb
	Actemra			S				Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124578	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019011766		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Cimzia	S	Subcutaneous			Ucb
	Actemra	S		Unk		Not Reported
	Bactrim	S		Unk		Not Reported
	Enbrel	S		Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S		200 Mg, 2x/Day (Bid)		Not Reported
	Leflunomide	S		Unk		Not Reported
	Methotrexate	S		Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124663	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018287118		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		25 Weekly		Pfizer
	Plaquenil /00072603/			S		200 Mg, 2x/Day		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16124986	EXPEDITED (15-DAY)		LT	NO-BAUSCH-BL-2019-008987		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab			S	Unknown					Not Reported
	Plaquenil			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	12898332	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016501067		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Every 2 Weeks		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	13063419	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0803		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hypersensitivity; Hypertension; Pneumonia; Synovitis; Thyroid Disorder; Treatment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Failure; Vomiting	Plaquenil	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Dorzolamide Hcl/Timolol Maleate	C	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Zingiber Officinale	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Atasol (Acetaminophen)	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	13074347	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0539		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Fluctuation; Depression; Drug Intolerance; Nausea; Night Sweats; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)		S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)		S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)		S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Arava		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Cyclic	Not Reported
	Cimzia		S	Subcutaneous	Cyclic	Not Reported
	Leucovorin		C	Unknown		Not Reported
	Vitamin D Nos		C	Unknown		Not Reported
	Coversyl		C	Oral		Not Reported
	Ergocalciferol		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	13157841	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Intolerance; Off Label Use; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Unk		Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	13215892	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020086		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Cortisone			C	Oral	Drops		Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	13330713	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017036139		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	15 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qod		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid (2 Every 1 Day)		Not Reported
	Xeljanz			C		Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	14167629	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3392		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	14198960	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3659		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	14242119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3933		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Inappropriate Schedule Of Product Administration; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Overdose; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	4 Times		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Multivitamin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	14788669	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Myochrysine			S	Intramuscular				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Sodium Aurothiomalate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	14922187	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044307		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Coversyl /00790702/			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leucovorin /00566701/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15230256	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2453		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate (Trade Name			S	Oral	Strength: 2.5 Mg, 4		Not Reported

Rheumatoid Arthritis; Therapeutic Response Decreased	Unknown)			Tablets	
	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg, 3 Tablets	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg, 3 Tablets	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg, 2 Tablets Every Tuesday	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	25 Mg/Ml, Vial	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Twice A Week	Not Reported
	Enbrel	S	Unknown	50 Mg/Ml	Not Reported
	Enbrel	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Unknown	Cyclic	Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported

Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	1.5 Tablet	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Estrogens Conjugated	C	Oral		Not Reported
Hydrochlorothiazide	C	Oral		Not Reported
Hydromorphone Hydrochloride	C	Oral		Not Reported
Taro-Mupirocin	C	Unknown	Strength: 2%	Not Reported
Tramadol	C	Oral		Not Reported
Tramacet	C	Unknown	37.5/325mg, 1-2 Tablets Every 6 Hours	Not Reported
Celexa	C	Unknown	Strength: 20 Mg	Not Reported
Cipralex	C	Unknown	Strength: 10 Mg	Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Estrace	C	Unknown	Strength: 0.5 Mg	Not Reported
Nucynta	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Apo-Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Pantoloc	C	Unknown	1 Tablet Once Daily	Not Reported
Ratio-Emtec	C	Unknown	1-2 Tablets Taken Every 4-6	Not Reported

		Ratio-Emtec			C	Unknown				Not Reported
		Gabapentin			C	Oral				Not Reported
		Apo-Gabapentin			C	Unknown				Not Reported
		Citalopram Hydrobromide			C	Unknown				Not Reported
		Shark-Liver Oil			C	Unknown				Not Reported
		Tapentadol Hydrochloride			C	Unknown				Not Reported
		Mupirocin			C	Unknown				Not Reported
		Mupirocin Calcium Dihydrate			C	Unknown				Not Reported
		Escitalopram Oxalate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15535263	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2969		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15568781	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1032		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Intolerance; Hepatitis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Kineret			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15605744	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3230		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Potassium Chloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15605750	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3223			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Pain In Extremity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15664772	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018483899		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported

	Roactemra	S	Unknown	620 Mg, Unk	Not Reported
	Roactemra	S	Unknown	634 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	15893341	EXPEDITED (15-DAY)		DS	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000161		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Visual Acuity Reduced; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Nivaquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16025229	NON-EXPEDITED			US-SA-2019SA058865			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16125593	EXPEDITED (15-DAY)		LT	NO-ROCHE-2290721		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent	Rituximab			S	Unknown	Used For Two Periods In 2010 And 2012, But Withdrawn Due To Lack Of Drug Effect		Not Reported

					Rituximab	S	Unknown		Not Reported
					Prednisolon	S	Oral		Not Reported
					Prednisolon	S	Oral		Not Reported
					Plaquenil	S	Oral		Not Reported
					Methotrexate	S	Unknown	Used Low-Dose Methotrexate Over Long Periods (Not Further Stated), But Eventually Withdrawn	Not Reported
					Infliximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126110	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126163	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019011954			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Cimzia			S		400 Mg, Ev 2 Weeks(Qow)		Ucb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Ev 4 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Infliximab			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126634	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000785		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Fibrosis	Plaquenil 200 Mg Tablet			S	Oral	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126782	EXPEDITED (15-DAY)		OT	DE-ACCORD-115264			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy	Topiramate			S				Accord
	Quensyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16126991	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-APOTEX-2019AP010106			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect; Ventricular Septal Defect	Ezetimibe	S	Transplacental	From Gestational Week 0-14	Apotex
	Pantoprazole	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Apotex
	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week, 300 Mg, Qd	Not Reported
	Tacrolimus	S	Transplacental	6 Mg, Qd (From Gestational Week 0-14)	Not Reported
	Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
	Salbutamol	S	Transplacental	Unk Unk, Qd	Not Reported
	Ramipril	S	Transplacental	20 Mg Unk From Gestational Week 0-113+6	Not Reported
	Torasemide	S	Transplacental	From Gestational Week 0-14, 100 Mg, Qd	Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Rivaroxaban	S	Transplacental		Not Reported
	Hydroxychloroquine	S	Transplacental	400 Mg, Qd, From Gestational Week 0-14	Not Reported
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14 (100 Mg Qd)	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
	Enoxaparin Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported

	Heparin Lmw	S	Transplacental	Unk	Not Reported
	Dalteparin Sodium	S	Unknown		Not Reported
	Clexane	S	Transplacental	200 Mg/D (2x100), 200 Mg, Qd	Not Reported
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
	Cytotec	C	Transplacental	Unk, Qd	Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16127212	EXPEDITED (15-DAY)		OT	PHHY2019CA064251		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported

	Remicade		S	Unknown	3 Mg, Unk	Not Reported
	Sulfasalazine		S	Oral	Unk	Not Reported
	Xeljanz		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16127788	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0848			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16128008	EXPEDITED (15-DAY)		OT	PHHY2019CA064559		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported

	Leflunomide		S	Unknown		Not Reported
	Actemra		S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk	Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	50.0 Mg, Qw	Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Subcutaneous	125.0 Mg, Unk	Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3.0 Mg/Kg, Unk	Not Reported
	Rituxan		S	Endocervical		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		C	Oral	5.0 Mg, Bid (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16128011	EXPEDITED (15-DAY)		OT	PHHY2019CA064269		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Oral	Unk	Not Reported
	Xeljanz Xr		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	12111071	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016052445		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Respiratory Arrest; Visual Impairment	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk, Unk (Injectable)		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Remicade			S		3 Mg/Kg, Every 8 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Arava			S				Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	13215841	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020034		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Unevaluable Event	Plaquenil			S	Unknown	400 Mg,Unk		Sanofi
	Arava			S	Unknown	20 Mg, Unk		Sanofi
	Sulfasalazine			S	Oral	1 G,Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg,Unk		Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg,Qw		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg,Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	13976070	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005259		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Autoimmune Thyroiditis; Conjunctivitis; Cough; Depression; Dry Eye; Fatigue; Fear Of Injection; Fibromyalgia; Hypoaesthesia; Insomnia; Lacrimation Decreased; Ocular Hyperaemia;	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Oral	400 Mg, Qd (200 Mg 2 Tablets)		Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported

Paraesthesia; Rash; Rheumatoid Arthritis; Therapeutic Response Decreased; Tinnitus; Weight Increased	Methotrexate	S		25 Mg, Qwk (2.5 Mg 10 Tablets)	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qwk (2.5 Mg 10 Tablets)	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Rheumate	C	Oral	500 Mg, Qd	Not Reported
	Rheumate	C	Oral	500 Mg, Qd	Not Reported
	Synthroid	C	Oral	75 Mug, Qd	Not Reported
	Restasis	C	Ophthalmic	0.05 % 1 Instill Drop, Q12h	Not Reported
	Restasis	C	Ophthalmic	0.05 % 1 Instill Drop, Q12h	Not Reported
	Meloxicam	C		15 Mg, Qod	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	100 Mg, Qwk	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd (200 Mg 2 Tablets)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14037298	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2995		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Naprosyn	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Apo-Folic Acid	S	Unknown		Not Reported
	Apo-Ibuprofen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14167611	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3385		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14193906	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3578		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease	Enbrel	S	Subcutaneous	2 Times/Week		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14198690	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3643		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14204133	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3713		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Joint Swelling; Pulmonary Fibrosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14227328	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506248		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Unk	Pfizer
	Methotrexate Sodium		S	Unknown	20 Mg, Qwk	Pfizer
	Apo-Minocycline		S	Unknown	50 Mg, Unk	Not Reported
	Apo-Prednisone		S	Unknown	3 Mg, Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride		S	Unknown	50 Mg, Unk	Not Reported
	Prednisone		S	Unknown	3 Dosage Form	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14235947	NON-EXPEDITED		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3884		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported

Clonazepam	C	Unknown		Not Reported
Desipramine	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported
Nitroglycerin	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	14631814	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020036		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Desoximetasone			S	Oral	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Cortisone			S	Oral			Not Reported
	Methotrexate			C		Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	15451998	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018389916		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased;	Etanercept			S		Unk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	616 Mg One Every Four Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	680 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	624 Mg, 1 Every 4 Weeks	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, On Day 1 And 15	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg Day 1 And 15	Not Reported
	Acetaminophen	C	Oral	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Unk	Not Reported
	Ferrous Gluconate	C		Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Lasix [Furosemide]	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Naprosyn [Naproxen]	C		Unk	Not Reported
	Oxycontin	C		Unk	Not Reported
	Oxyneo	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	15569637	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3074			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Methotrexate (Trade Name Unknown)		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	15675152	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3494			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contraindicated Product Administered; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sinusitis; Treatment Failure; Vertigo	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S				Not Reported
	Desoximetasone			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	15985540	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2656340-00		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Macular Degeneration;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Nasopharyngitis	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16029358	NON-EXPEDITED			US-SA-2019SA058002			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diarrhoea; Drug Hypersensitivity; Oral Pain; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Rituxan			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16131868	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-203261		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Zolpidem			S	Oral	10 Milligram, Daily		Sun
	Lactulose			S	Oral	1 Dosage Form, Daily		Not Reported
	Dulcolax			S	Oral	5 Milligram, Daily		Not Reported
	Ranitidine			S	Oral	300 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16131933	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000774			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Eye Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16132518	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1030308		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Lactulose			S	Oral	1 Dosage Forms Daily;		Actavis
	Ranitidine Base			S	Oral	300 Milligram Daily;		Actavis
	Zolpidem			S	Oral	10 Milligram Daily;		Teva
	Plaquenil			S	Oral			Not Reported
	Dulcolax			S	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16132915	NON-EXPEDITED			US-SA-2019SA084336			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Treatment Failure	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133084	EXPEDITED (15-DAY)		OT	PHHY2019CA064352		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To	Neoral			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25.0 Mg, Unk		Not Reported
	Arava			S	Unknown	20.0 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Humira		S	Subcutaneous	Unk	Not Reported
	8-Hydroxyquinoline Sulfate		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Prograft		S	Oral	2.0 Mg, Bid	Not Reported
	Prograft		S	Oral	3.0 Mg, Bid	Not Reported
	Rapamune		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Unknown	1.0 G, Unk	Not Reported
	Imuran		C	Unknown	25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133115	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-015757			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Bisacodyl			S	Oral	5 Milligram, Daily		Not Reported
	Lactulose			S	Oral	1 Dosage Form, Daily		Not Reported
	Ranitidine			S	Oral	300 Milligram, Daily		Aurobindo
	Zolpidem			S	Oral	10 Milligram, Daily		Aurobindo
	Plaquenil			S	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16133494	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2877		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fungal Infection; Hepatic Enzyme Increased; Mycobacterium Tuberculosis Complex Test Positive; Urinary Bladder Suspension	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

		Hydrochlorothiazide			C	Unknown				Not Reported
		Atorvastatin			C	Unknown				Not Reported
		Telmisartan			C	Unknown				Not Reported
		Arava			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16134374	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020135		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Synovitis	Hydroxychloroquine			S	Unknown	250 Mg,Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	250 Mg,Unk		Sanofi
	Arava			S		750 Mg,Unk		Sanofi
	Xeljanz			S		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16134510	EXPEDITED (15-DAY)		CA, OT	DE-APOTEX-2019AP010383			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin			S	Transplacental	Unknown		Not Reported
	Ezetimibe			S	Transplacental	Unknown		Apotex
	Pantoprazole			S	Transplacental	Unknown		Apotex
	Torasemide			S	Transplacental	Unknown		Not Reported
	Hydroxychloroquine			S	Transplacental	Unknown		Not Reported
	Metamizole			S	Transplacental	Unknown		Not Reported
	Rivaroxaban			S	Transplacental	Unknown		Not Reported
	Enoxaparin Sodium			S	Transplacental	Unknown		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unknown		Not Reported
	Aliskiren			S	Transplacental	Unknown		Not Reported
	Nicotine			S	Transplacental	Unknown		Not Reported
	Tacrolimus			S	Transplacental	Unknown		Not Reported

	Salbutamol Sulfate			S	Transplacental	Unknown			Not Reported
	Prednisolone			S	Transplacental	Unknown			Not Reported
	Ramipril			S	Transplacental	20 Mg, Unk (Maternal Dose 20 Mg, Unk)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16135166	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1030716		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection Bacterial	Methotrexate Sodium			S	Subcutaneous			Barr
	Plaquenil			S	Oral	200 Milligram Daily;		Not Reported
	Salazopyrin En			S	Oral	1000 Milligram Daily;		Not Reported
	Duloxetine Hydrochloride			C				Not Reported
	Dibase			C				Not Reported
	Cardirene			C				Not Reported
	Domperidone			C				Not Reported
	Folina [Folic Acid]			C				Not Reported
	Omeprazole			C				Not Reported
	Prednisone			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16136072	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019139288		56 YR	Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16136580	EXPEDITED (15-DAY)		DS, OT	US-ASSERTIO THERAPEUTICS, INC.-CA-2019DEP000309		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Diclofenac Potassium		S	Unknown	Unk		Assertio Therapeutics
	Actemra		S	Unknown	Unk		Not Reported
	Celebrex		S	Unknown	Unk		Not Reported
	Cimzia		S	Unknown	Unk		Not Reported
	Codeine		S	Unknown	Unk		Not Reported
	Dilaudid		S	Unknown	Unk		Not Reported
	Enbrel		S	Unknown	Unk		Not Reported
	Humira		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Plaquenil /00072602/		S	Unknown	Unk		Not Reported
	Rituxan		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2019	16269883	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Rheumatoid Nodule	Plaquenil (Hydroxychloroquine) 200mg			S	Oral			Prasco

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	15605682	EXPEDITED (15-DAY)		OT	GB-ACCORD-091469			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Diverticulitis; Joint Swelling; Liver Injury; Pain; Peripheral Swelling	Methotrexate			S		Unk Reduced Dose		Accord
	Actemra			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Certolizumab Pegol			S		Unk		Not Reported
	Endep			C		Unk		Not Reported
	Prednisolone			C				Not Reported

Cortisone	C	Unk		Not Reported
Tramadol	C	Unk		Not Reported
Tapentadol	C			Not Reported
Methotrexate	S	Reduced Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16132152	EXPEDITED (15-DAY)		OT	FR-ACCORD-116180		4 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Disease Recurrence; Dyspnoea; Haemoptysis; Off Label Use; Product Use Issue; Pulmonary Haemosiderosis	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16138807	EXPEDITED (15-DAY)		OT	PHHY2019CA071181		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Hidroxicloroquina			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Unk		Not Reported

	Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2019	16139181	EXPEDITED (15-DAY)		DS, OT	PHHY2019CA071272			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	11558953	EXPEDITED (15-DAY)		DE, OT	CA-SA-2015SA145632		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Death; Drug Ineffective; Drug Intolerance; Feeling Jittery; Joint Swelling; Limb Discomfort; Localised Infection; Malaise; Musculoskeletal Disorder; Nausea; Neck Pain; Night Sweats; Pain;	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg,Qd		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	81 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Qw		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported

Peripheral Swelling; Purulent Discharge; Pustular Psoriasis; Synovitis; Tachycardia; Treatment Failure; Vomiting	Enbrel	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Actemra	S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Xeljanz	S	Oral	10 Mg, Bid		Not Reported
	Prednisone	C	Unknown	10 Mg, Qd		Not Reported
	Calcium	C	Oral	500 Mg, Unk		Not Reported
	Celebrex	C	Unknown	Unk Unk, Unk		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	10 Mg		Not Reported
	Ergocalciferol	C	Oral	Unk		Not Reported
	Leucovorin Calcium	C	Oral	5 Mg, Unk		Not Reported
	Lorazepam	C	Oral	0.5 Mg, Unk		Not Reported
	Pantoprazole	C	Unknown	40 Mg, Qd		Not Reported
	Magnesium	C	Unknown			Not Reported
	Valtrex	C	Unknown	500 Mg, Qd		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	12911509	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2169		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	12948187	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2016-2294		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Joint Destruction; Nausea; Obesity; Rheumatoid Arthritis; Septic Shock; Synovitis; Vomiting	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Etanercept			S	Subcutaneous	Cyclic, 2 Per Week		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Immune Globulin Iv			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	13199435	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019851		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Intra-arterial	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	13199450	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019929		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	13199491	EXPEDITED (15-DAY)		OT	CA-SA-2017SA019948		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cellulitis; Drug Intolerance; Myalgia; Nausea	Plaquenil		S	Unknown	Unk Unk,Unk	Sanofi
	Arava		S	Unknown	Unk Unk,Unk	Sanofi
	Methotrexate		S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone		S	Unknown	Unk Unk,Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk Unk,Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	13199652	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020243		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	.6 Ml,Qw		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	13519382	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038196		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported

					Methotrexate	S	Subcutaneous	25 Mg, Unk	Not Reported
					Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
					Methotrexate	S	Subcutaneous	10 Mg, Unk	Not Reported
					Prednisone	S	Unknown		Not Reported
					Prednisone	S	Unknown		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
					Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
					Plaquenil /00072602/	S	Unknown	300 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	14163219	EXPEDITED (15-DAY)		OT	CA-ROCHE-2014798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown	Discontinued		Not Reported
	Leflunomide			C	Unknown	Half Tablet, Frequency Unknown		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	14725904	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1039		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Contraindicated Product Administered; Drug Intolerance	Methotrexate (Trade Name Unknown)		S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown	10-20 Mg	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Prolia		S	Unknown		Not Reported
	Cymbalta		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	14765115	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018049525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Q3mo (Every 12 Weeks)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Gold			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	15297992	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015139			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Infliximab Pfizer (Unknown)			S	Intracardiac	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	15964948	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Erythematosus	Folic Acid		S	Unknown	1 Mg, Unk	Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Reactine /00884302/		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16138845	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0947		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)	
	Orencia		S	Unknown	Not Reported
	Humira		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported
	Arava		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16138972	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0924		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16139404	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000849		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Ulcer	Plaquenil 200 Mg Tablet			S	Oral	Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16139476	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Unknown	Unknown		Concordia
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C				Not Reported
	Zopiclone			C				Not Reported
	Amitriptyline			C				Not Reported
	Vitamin D3			C				Not Reported
	Ralivia			C				Not Reported
	Micardis			C				Not Reported
	Cymbalta			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16140299	EXPEDITED (15-DAY)		OT	PHEH2019US013184			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Hydroxychloroquine Sulphate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16140574	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2173		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16140758	EXPEDITED (15-DAY)		OT	CA-009507513-1903CAN012953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Zenhale			S	Unknown	400 Microgram, 2 Every 1 Day		Merck
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Lipitor			S	Unknown	40 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	300 Milligram, 1 Every 1 Day		Not Reported
	Spiriva			S	Unknown	2.5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16140830	EXPEDITED (15-DAY)		OT	FR-INTERCEPT-PM2019000499		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythromelalgia; Prurigo; Rash Pruritic	Ocaliva			S	Oral			Intercept Pharmaceuticals
	Plaquenil			S	Oral			Not Reported
	Cerazette			C		()		Not Reported
	Delursan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16142291	NON-EXPEDITED			US-SA-2019SA087721			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16142621	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	5.0 Milligram, Q12h	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Arava		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16142642	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027732		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16143603	NON-EXPEDITED			US-NEOPHARMA INC-000058			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Augmentin			S	Unknown			Not Reported
	Methotrexate/Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Advair			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Lisinopril/Lisinopril Dihydrate			S	Unknown			Not Reported
	Symbicort			S	Unknown			Not Reported
	Anacin			S	Unknown			Not Reported
	Astelin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tofacitinib			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16143608	NON-EXPEDITED			US-NEOPHARMA INC-000073			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Hypersensitivity	Augmentin			S				Not Reported
	Septra			S				Not Reported
	Mobic			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16144159	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025525			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk				Not Reported
	Methotrexate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2019	16274052	DIRECT	N	OT			42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Nodule	Plaquenil (Hydroxychloroquine) 200mg			S	Oral			Prasco

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	12701988	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1484		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Intolerance; Internal Haemorrhage; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	13215809	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA020031		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angiopathy; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Unevaluable Event; Visual Impairment	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	8 Mg,Qd		Not Reported
	Anakinra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Sulfathalidine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	14236345	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3848		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Minocycline Hydrochloride		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	15133021	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002361		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematoma	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Cortancyl			S	Oral			Not Reported
	Actonel Oam			S	Oral	30mg Saturday Morning		Not Reported
	Calcium Carbonate/Colecalciferol			S	Oral	500mg + 400iu In The Morning		Not Reported
	Lercanidipine Hydrochloride			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	15764819	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3830			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine			S	Oral					Not Reported
	Hydroxychloroquine			S	Oral					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported
	Simponi			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	15848987	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016279710		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Off Label Use; Pain; Product Use In Unapproved Indication	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S		More Than 3 Months		Pfizer
	Effexor			S	Oral	37.5 Mg, Daily		Pfizer
	Venlafaxine Hcl			S	Oral	37.5 Mg, Qd		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	More Than 3 Months		Not Reported
	Hydroxychloroquine			S	Unknown	More Than 3 Months		Not Reported
	Simponi			S	Subcutaneous	More Than 3 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	M-Eslon			C		10 Mg, 2x/Day		Not Reported
	Statex			C		5 Mg, Every 4 To 6 Hours		Not Reported
	Hydrodiuril			C	Unknown	12.5 Mg, 1x/Day		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Morphine Sulfate			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	15964487	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Hydroxychloroquine			S	Unknown			Concordia
	Plavix			S	Unknown			Not Reported
	Famotidine			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Trandolapril			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Loperamide			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Nexium			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Potassium Acetate			S	Unknown			Not Reported
	Nitroglycerin			S	Unknown			Not Reported
	Victoza			S	Unknown			Not Reported
	Humira 40 Mg/0.8 Ml			S	Subcutaneous			Not Reported
	Humira 40 Mg/0.8 Ml			S	Subcutaneous			Not Reported
	Flomax			S	Unknown			Not Reported
	Reglan			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Imdur			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16144545	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083360		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Arava			S		20 Mg, Qd		Sanofi
	Plaquenil			S		200 Mg, Bid		Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145338	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083321		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Arava			S		10 Mg		Sanofi
	Arava			S		20 Mg		Sanofi
	Hydroxychloroquine			S		300 Mg		Sanofi
	Celebrex			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145406	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083057		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Leflunomide			S		10 Unk, Qd		Sanofi
	Methotrexate Sodium			S	Oral	25 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16145668	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000875			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Parkinson'S Disease	Plaquenil			S	Unknown	Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16146104	EXPEDITED (15-DAY)		HO	CN-SA-2019SA085231		53 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Hydroxychloroquine Sulfate			S	Oral	0.2 G, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Calcium Carbonate			C	Oral	0.3 G, Qd		Not Reported
	Prednisone Acetate			C	Intraocular	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16148350	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083213		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S	Oral	2 Df, Qd (200 Mg)		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Folic Acid	C	Oral	5 G, Qd	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd	Not Reported
	Leflunomide	C	Oral	20 Mg, Qd	Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral	2 Df, Qd (5 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16148390	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083762		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Dizziness; Gastrointestinal Disorder; Headache; Irritability; Nausea; Perioral Dermatitis; Rash; Urticaria	Hydroxychloroquine Sulfate			S		400 Mg, Qw		Sanofi
	Chloroquine (Salt Not Specified)			S		400 Mg, Qw		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S		10 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydrocortisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16149422	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083883			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision	Hydroxychloroquine			S				Sanofi
	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Abatacept			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	50.0 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Mg, Qw		Not Reported

Blurred	Simponi			S					Not Reported
	Sulfasalazine			S					Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16150813	NON-EXPEDITED			US-SA-2019SA088014			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Humira			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2019	16285685	DIRECT	Y				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasal Congestion	Hydroxychloroquine 200 Mg Tab			S	Oral			Not Reported
	Prednisone 5 Mg Tablet Actavis Pharma			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	11233909	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015064426		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

		Orencia		S	Intravenous (not otherwise specified)	Unk			Not Reported
		Methotrexate Sodium		S	Oral	Unk			Not Reported
		Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
		Xeljanz		C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	12343872	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2013017550		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Humira			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apo-Warfarin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	14096656	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005823		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Plaquenil 200 Mg Tablet			S	Oral	200 Mg Daily And 400 Mg		Concordia

					Daily, Alternately	
	Plaquenil 200 Mg Tablet	S	Oral	200 Mg Daily And 400 Mg Daily, Alternately		Concordia
	Prograf	S	Oral			Not Reported
	Mycophenolate Mofetil	S	Oral			Not Reported
	Prednisolone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	14391367	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000196			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Plaquenil			S	Unknown	Unknown		Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Kevzara			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	14657812	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0826		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Multiple System Atrophy; Rheumatoid Arthritis	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz	S	Intravenous (not otherwise specified)	Alternate Day (Qod)		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown	Cyclic (At 0, 2, 6 Weeks, Then Every 8)		Not Reported
	Remicade	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil S	S	Unknown			Not Reported
	Remicade	C	Unknown			Not Reported
	Enbrel	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15243574	NON-EXPEDITED			US-PFIZER INC-2018311231		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Decreased Appetite; Fatigue; Myalgia; Pain; Somnolence	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		200 Mg, Unk		Not Reported
	Prednisone			S		2.5 Mg, Unk		Not Reported
	Prednisone			S		2 Mg, Unk		Not Reported
	Minocycline			S		50 Mg, Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Leflunomide			C		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15463201	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab Hospira			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	On Day 1 And 15		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 And 15th Day		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Oxycontin			C	Unknown			Not Reported

	Oxyneo			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15677347	EXPEDITED (15-DAY)		OT	CA-SA-2018SA325606		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Plaquenil			S		Unk		Sanofi
	Arava			S				Sanofi
	Myochrysine			S	Intramuscular			Not Reported
	Actemra			S				Not Reported
	Cimzia			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Otezla			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Sirukumab			S				Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Ustekinumab			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Orencia			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15693230	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP026141		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Dolquine			S	Unknown	Unk		Not Reported
	Lornoxicam			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	50 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15878374	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown	200 Mg Alternating With 400mg Per Day		Concordia
	Plaquenil			S	Unknown	200 Mg Alternating With 400mg Per Day		Concordia
	Arava			S	Unknown			Not Reported

	Gold	C		Not Reported
	Methotrexate	C		Not Reported
	Sulfasalazine	C		Not Reported
	Naproxen	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	15936350	EXPEDITED (15-DAY)		HO, OT	CN-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000219		32 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Transaminases Increased; Vision Blurred	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16043968	NON-EXPEDITED			US-SA-2019SA061307			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Sulfasalazine			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Humira			S		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16139672	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1213		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Intravenous (not otherwise specified)		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16150154	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP010560		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Apotex
	Ibuprofen			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Naproxen			S	Unknown			Apotex

Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Trimethoprim/Sulfamethoxazole	S	Unknown				Apotex
	Arava	S	Oral	Unk			Not Reported
	Arava	S	Unknown	Unk			Not Reported
	Enbrel	S	Subcutaneous				Not Reported
	Gold	S	Unknown				Not Reported
	Humira	S	Subcutaneous				Not Reported
	Methotrexate	S	Unknown				Not Reported
	Plaquenil /00072602/	S	Oral				Not Reported
	Sodium Aurothiomalate	S	Oral				Not Reported
	Tramadol Hydrochloride	C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16151095	EXPEDITED (15-DAY)		LT	NO-TEVA-2019-NO-1032266		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent	Methotrexate			S				Barr
	Prednisolon			S	Oral			Actavis
	Prednisolon			S	Oral			Actavis
	Infliximab			S				Not Reported
	Rituximab			S				Not Reported
	Rituximab			S				Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16151896	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000904			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hypophagia; Influenza Like Illness; Myalgia;	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Nausea; Pain; Shoulder Operation	Humira		S	Subcutaneous		Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16152130	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2730074-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16152581	EXPEDITED (15-DAY)		HO	DE-GLAXOSMITHKLINE-DE2019GSK056659		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Exposure During Pregnancy; Live Birth; Premature Rupture Of Membranes; Pyrexia; Tachycardia; Twin Pregnancy	Azathioprine			S		Unk		Glaxosmithkline
	Prednisolone			S		Unk		Glaxosmithkline
	Folic Acid			S		Unk		Not Reported
	Cyclophosphamide			S		Unk		Not Reported
	Cyclophosphamide			S				Not Reported
	Hcq			S		Unk		Not Reported
	Low Molecular Weight Heparin			S		Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported
	Aspirin			S		Unk		Not Reported
	Belimumab			S		Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16154189	NON-EXPEDITED			PHEH2019US013836			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dry Mouth; Erythema; Feeling Jittery; Rash Erythematous; Skin Exfoliation	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Novartis
	Fluoxetine			C	Unknown	Unk		Not Reported
	Fish Oil			C	Unknown	Unk		Not Reported
	Coenzyme Q10			C	Unknown			Not Reported
	Vitamin D2			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Glucosamine			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	12764912	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007837		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia	Plaquenil Tablet			S	Unknown			Concordia
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	12893100	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016503723			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Disorder; Chest Pain; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Gabapentin			S	Unknown	Unk		Pfizer
	Folic Acid			S	Unknown	1 Df, 2x/Week		Pfizer
	Prednisone			S	Unknown	5 Mg, 1x/Day		Not Reported
	Nexium /01479302/			S	Unknown	40 Mg, 1x/Day		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, 2x/Day		Not Reported
	Actemra			C		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Golden Seal /01446501/			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	13246578	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000999		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal	Plaquenil			S	Oral			Concordia
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported

Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Methotrexate	C		Not Reported
	Remicade	C		Not Reported
	Simponi	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	14174008	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006337			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo Lefunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	14817980	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001406		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Uveitis	Plaquenil 200 Mg Tablet	S	Oral		Concordia
	Predonine	C			Not Reported
	Edirol	C			Not Reported
	Edirol	C			Not Reported
	Actonel	C			Not Reported
	Actonel	C			Not Reported
	Pariet	C			Not Reported
	Pariet	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	15856541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0968		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Insomnia; Off Label Use; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Effexor			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	M-Eslom			C	Unknown			Not Reported
	Statex			C	Unknown	Every 4-6 Hours		Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16004023	EXPEDITED (15-DAY)		OT	DE-ACCORD-109195		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Contraindicated Product Administered; Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Pantoprazole			S	Unknown	Gestational Week 0-14		Not Reported
	Ramipril			S	Unknown	20 Mg, Unknown Freq		Accord
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Accord
	Tacrolimus			S	Unknown	Gestational Week 0-14		Accord
	Acetylsalicylic Acid			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Prednisolone			S		0-14 Gw		Not Reported
	Enoxaparin			S	Unknown	Unknown Freq. (0-14 Gw)		Not Reported
	Rivaroxaban			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Metamizole Sodium			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Nicotine			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported
	Torasemide			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported
	Enoxaparin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16061680	NON-EXPEDITED			US-PFIZER INC-2019107176		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Daypro	S	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16136306	EXPEDITED (15-DAY)			FR-009507513-1903FRA011412		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Betamethasone Dipropionate			S	Topical	Unk		Merck
	Hydroxychloroquine Sulfate			S		400 Mg/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16155666	EXPEDITED (15-DAY)		OT	CA-009507513-1903CAN012940		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Zenhale			S	Unknown	200 Milligram, 2 Every 1 Day(S), Aerosol, Metered Dose(Dosage Form)		Merck
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Lipitor			S	Unknown	40 Milligram, 1 Every 1 Day(S)		Not Reported
	Plaquenil			S	Oral	300 Milligram, 1 Every 1 Day(S)		Not Reported
	Spiriva			S	Unknown	2.5 Milligram, 2 Every 1 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16156149	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Cetirizine Hydrochloride		S	Unknown		Not Reported
	Cimzia		S	Unknown		Not Reported
	Cortisone Acetate		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16156164	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1034404		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not	Solution Intravenous		Not Reported

					otherwise specified)				
	Bupropion			C					Not Reported
	Esomeprazole			C					Not Reported
	Folic Acid			C					Not Reported
	Levothyroxine Sodium			C					Not Reported
	Naproxen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16156394	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16157526	NON-EXPEDITED			US-PFIZER INC-2019136105		79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Minoxidil			S		Unk		Pfizer
	Septra			S		Unk		Pfizer
	Spironolactone			S		Unk		Pfizer
	Fluoxetine			S		Unk		Not Reported
	Cialis			S		Unk		Not Reported

Versed	S	Unk	Not Reported
Cipro	S	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Catapres	S	Unk	Not Reported
Restasis	S	Unk	Not Reported
Augmentin [Amoxicillin;Clavulanic Acid]	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	11221771	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015104261		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bone Erosion; Bronchitis; Condition Aggravated; Condition Aggravated; Fatigue; Herpes Zoster; Inflammation; Lower Respiratory Tract Infection; Lyme Disease; Memory Impairment; Musculoskeletal Pain; Plantar Fasciitis; Rash; Rheumatoid Arthritis; Sciatica; Tendon Rupture; Tendonitis	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Celebrex			S	Oral	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Tylenol Extra Strength			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	12213098	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016035723		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling; Product Dose Omission	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen

	Methotrexate Sodium		S	Oral	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	12341424	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2011259822		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Every 4 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Naprelan			C	Unknown	Unk		Not Reported

	Effexor	C	Unknown	Unk		Not Reported
	Plaquenil	C		Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)	C		Unk		Not Reported
	Benadryl	C		Unk		Not Reported
	Naproxen Sodium	C		Unk		Not Reported
	Venlafaxine Hydrochloride	C	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Unk		Not Reported
	Venlafaxine	C		Unk		Not Reported
	Cetirizine Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	13233382	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001018		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Guillain-Barre Syndrome	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Humira			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Simponi			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	13234105	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000981		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Chloroquine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	14165048	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017476855		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	592 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16060335	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2019035834		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Humira			S	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram (1 Every Four Week)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)	5 Milligram 1 Every 2 Days		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Oral	Unk Unk, Qwk		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Remicade			S	Unknown	3 Milligram/Kilogram		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16148443	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019CH074396		80 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bronchiectasis; Cough; Decreased Appetite; Dyspnoea; Pulmonary Alveolar	Methotrexate			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown			Not Reported

Haemorrhage

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161245	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035465		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	25milligram		Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown	100milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161262	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034443		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

	Align	C	Unknown			Not Reported
	Loperamide	C	Oral			Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161345	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1035440		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine / 00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161348	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

	Rituxan			S	Unknown	Solution Intravenous				Not Reported
	Celebrex			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16161624	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16162160	EXPEDITED (15-DAY)		OT	CA-SA-2019SA090851			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Plaquenil			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine Gf			C		2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16162284	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16162317	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-02163		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Apr-2019	16165679	EXPEDITED (15-DAY)		OT	PHHY2019US077321			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective For Unapproved Indication; Hypertension; Leukopenia; Osteonecrosis; Osteopenia; Pulmonary Fibrosis; Pulmonary Function Test Decreased	Prednisone			S	Unknown	5-7 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	5 Mg, Qw		Not Reported
	Minocycline			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Novartis
	Adalimumab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tocilizumab			C	Unknown	162 Mg, Qw		Not Reported
	Tocilizumab			C	Unknown	8 Mg/Kg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2019	16165788	NON-EXPEDITED			US-ALEXION PHARMACEUTICALS INC.-A201905082			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Soliris			S	Unknown	Unk		Alexion
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2019	16169580	DIRECT		HO			30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depressed Mood; Diarrhoea; Mood Altered; Suicidal Ideation; Vision Blurred	Hydroxychloroquinine, Plaquenil			S	Oral	Quantity:1.5 Tablet(S);		Prasco

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	11212100	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014346897		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Viral Infection	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Celebrex			S		Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	11291893	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015225222			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Cell Carcinoma	Methotrexate Sodium			S	Subcutaneous	30 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	3000 Mg, Daily		Pfizer
	Arava			S		20 Mg, Daily		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	12140309	NON-EXPEDITED			US-PFIZER INC-2016108311		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celecoxib			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Cefalexin			S		Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported
	Cefixime			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Rofecoxib			S		Unk		Not Reported

	Vioxx			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13229516	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000960		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Eye Disorder; Herpes Zoster; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Intra-arterial	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233190	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Larynx Irritation; Nausea; Rheumatoid Arthritis; Weight Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233193	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233194	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000983		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Arthropathy; Bedridden; Crying; Depressed Mood; Drug Ineffective; Joint Swelling	Plaquenil Tablet			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown	50 Mg/1.0ml		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Calcium			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folinic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Arava			C				Not Reported
	Naproxen			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233380	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001017		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Hypersensitivity; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Unknown			Concordia
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233489	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000984		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233495	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001013		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Intolerance; Myalgia; Nausea	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

	Prednisone			S	Unknown	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unknown			Not Reported
	Xeljanz			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13233624	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000978		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Rheumatoid Arthritis	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Unknown			Concordia
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13234423	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001039		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Tolerance; Fatigue; Hyperhidrosis; Influenza; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil Tablet			S	Unknown			Concordia
	Plaquenil Tablet			S	Subcutaneous			Concordia
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Celebrex			C				Not Reported

	Ergocalciferol			C						Not Reported
	Folic Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13237824	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001006		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Malaise; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Hydroxychloroquine Tablet			S	Unknown	Unknown		Concordia
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Arava			C				Not Reported
	Ibuprofen			C				Not Reported
	Plaquenil Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13237825	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001014		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Pruritus	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

		Sulfasalazine			S	Unknown						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13238097	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001080		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cystitis; Drug Ineffective; Guillain-Barre Syndrome; Micturition Disorder; Walking Aid User	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	13500356	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015206233		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Guillain-Barre Syndrome	Methotrexate Sodium			S		Unk		Pfizer
	Hcq			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	14775501	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018156628			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Mg, 2x/Week (2 Every 1 Week(S))		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	300 Mg,Cyclical (Once		Not Reported

							Every 6 Weeks)		
		Rituxan		S		Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
		Rituxan		S		Intravenous (not otherwise specified)	1000 Mg, Q3mo (Every 12 Weeks)		Not Reported
		Hydroxychloroquine Sulfate		S		Unknown	Unk		Not Reported
		Methotrexate		C		Unknown	Unk		Not Reported
		Prednisone		C		Unknown	Unk		Not Reported
		Gold		C		Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	15465541	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2507541-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Mycobacterium Tuberculosis Complex Test Positive; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	15707267	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2018CA019464			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Unk (4 Every 1 Week(S))		Not Reported

Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Unk (1 Every 2 Week(S))	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Sulfasalazine	S	Oral	250 Mg, 1x/Day	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day	Not Reported
	Immunglobulin	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunglobulin	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
	Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Q2wk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Other	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1 Every 2week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Gamastan	S	Intramuscular	70 G, Unk	Not Reported
	Gammagard	S	Unknown	Unk	Not Reported

	Gammagard			S	Intravenous (not otherwise specified)	70 G, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	15852369	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2628454-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Entocort			S	Unknown			Not Reported
	Sulfanilamide			S	Unknown			Not Reported
	Gentamycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16068610	NON-EXPEDITED			US-SA-2019SA064771			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Stomatitis; Therapeutic Product Effect Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Oral	Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			C	Unknown	Unk Unk, Unk		Not Reported

	Orencia			C	Unknown	Unk Unk, Unk				Not Reported
	Actemra			C	Unknown	Unk Unk, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16167645	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034921		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	40 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16167900	EXPEDITED (15-DAY)		OT	CA-SA-2019SA082965		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Thyroid Disorder; Treatment Failure; Vomiting	Plaquenil	S	Unknown			Sanofi
	Orencia	S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate	S	Unknown	Unk Unk, Unk		Not Reported
	Arava	S	Unknown	Unk Unk, Unk		Sanofi
	Actemra	S		Unk Unk, Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk		Not Reported
	Estradiol	C	Unknown	Unk Unk, Unk		Not Reported
	Furosemide	C	Unknown	Unk Unk, Unk		Not Reported
	Valsartan	C	Unknown	Unk Unk, Unk		Not Reported
	Xalatan	C	Unknown	Unk Unk, Unk		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16170017	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015170195		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Diarrhoea; Drug Ineffective; Dysgeusia; Dyspepsia; Epistaxis; Headache; Sinus Congestion; Sinusitis; Synovitis; Urinary Tract Infection	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Leflunomide			S		Unk		Not Reported
	Humira			S	Subcutaneous	90 Mg, Every 2 Weeks		Not Reported
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16170190	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019AU078850		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bone	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

Abscess; Cachexia; Calcinosis; Delirium; Dermal Sinus; Disseminated Mycobacterium Avium Complex Infection; Enterobacter Infection; Peptostreptococcus Infection; Sepsis	Prednisolone	S	Unknown	8 Mg, Qd		Novartis
	Methotrexate	S	Oral	10 Mg, Q2w		Not Reported
	Rivaroxaban	C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2019	16170986	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-3024651		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Depressed Mood; Drug Ineffective; Influenza; Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Sulfasalazine			S				Pfizer
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13229515	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000953		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Haemorrhage; Eye Infection	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Prednisone			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13233360	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000988		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis; Unevaluable Event	Plaquenil Tablet	S	Oral	Unknown		Concordia
	Cimzia	S	Subcutaneous	Unknown		Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Ergocalciferol	C				Not Reported
	Folic Acid	C				Not Reported
	Gabapentin	C				Not Reported
	Lovastatin	C				Not Reported
	Metoprolol	C				Not Reported
	Naprosyn	C				Not Reported
	Naproxen Sodium	C				Not Reported
	Pantoprazole	C				Not Reported
	Prednisone	C				Not Reported
	Rosuvastatin Calcium	C				Not Reported
	Tramadol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13233551	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001019		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Plaquenil Tablet			S	Unknown			Concordia
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Metoprolol Salt Not Specified			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

					Prednisone		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Crestor		C			Not Reported
					Folic Acid		C			Not Reported
					Naprelan		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13233636	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001040		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haematocrit Decreased; Haemoglobin Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Atenolol			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13233926	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000982		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Angiopathy; Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis;	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

Unevaluable Event; Visual Impairment	Enbrel	S	Subcutaneous	Unknown		Not Reported
	Prednisone	S	Unknown			Not Reported
	Anakinra	S	Unknown	Unknown		Not Reported
	Sulfathalidine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13250499	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001116		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Joint Swelling; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Plaquenil Tablet			S	Unknown			Concordia
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Arava			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	13250617	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001197		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Plaquenil Tablet			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	14235956	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3888		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Embolism; Fear; Fine Motor Skill	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete	Celebrex	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Humira	S	Unknown	Discontinued After Four Injection		Not Reported
	Warfarin	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Apo-Warfarin	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	14566069	NON-EXPEDITED			US-PFIZER INC-2018077514		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Cosentyx			S		Unk		Not Reported
	Cosentyx			S				Not Reported
	Prednisone			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	15650378	EXPEDITED (15-DAY)		HO	DE-ROCHE-2218273			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Haematoma Infection	Tocilizumab	S	Intravenous (not otherwise specified)	Last Recent Dose Given Prior To The Events Was Given On 03/May/2018	Not Reported
	Sulfasalazin	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Eliquis	C			Not Reported
	Bisoprolol	C			Not Reported
	Xipamid	C			Not Reported
	Torem	C			Not Reported
	Pantozol (Germany)	C			Not Reported
	Lodotra	C			Not Reported
	Lyrica	C			Not Reported
	Allopurinol	C	Unknown		Not Reported
	Vitamin B12	C			Not Reported
	Ibuprofen	C			Not Reported
	Spiro Comp	C			Not Reported
	Wobenzym	C			Not Reported
	Clexane	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	15856328	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA018107			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile	Infliximab Pfizer (Unknown)			S	Unknown	5 Mg, Unk		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4 Times/Wk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, 2x/Week		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Weekly		Not Reported

Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Sulfasalazine	S	Oral	250 Mg, 1x/Day	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Other	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 2x/Week	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, 1x/Day	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg, 1x/Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
	Prednisone	S	Unknown	1.3 Mg, 2x/Day	Not Reported
	Prednisone	S	Unknown	3 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Ug/Kg. 1x/Day	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Immune Globulin Iv	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	15940125	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2657252-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16016752	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-019775			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Metotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16055856	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000528			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Neoplasm Malignant; Pulmonary Mass	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Cyclosporin			S	Unknown	Unknown		Not Reported
	Rituxan			S	Unknown	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16148591	EXPEDITED (15-DAY)		OT	PHHY2019CA073512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Cosentyx			S	Oral	300 Mg, Qmo		Novartis
	Pantoprazole			S	Oral	1 Df, Qd(7.5 Mg)		Not Reported
	Leucovorin Calcium			S	Oral	5 Mg, Qw		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Diclofenac			S	Oral	Unk Unk, Tid		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Meloxicam			S	Oral	7.5 Mg, Qd(1-2 Tab)		Not Reported
	Tecta			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Tramadol Hcl			C	Oral	Unk Unk, Q24h (Biphasic 25-75)		Not Reported

	Salbutamol Sulfate	C	Respiratory (inhalation)			Not Reported
	Mar-Pantoprazole	C	Unknown			Not Reported
	Taro-Mometasone	C	Unknown			Not Reported
	Fluticasone Propionate	C	Respiratory (inhalation)			Not Reported
	Premarin	C	Unknown	Unk		Not Reported
	Diltiazem Hcl	C	Oral	240 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16174485	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035666		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16174487	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035727		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Anakinra	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16174518	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035670		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16176330	NON-EXPEDITED			US-SA-2019SA097073			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S		Unk		Sanofi

	Humira	S	Unk	Not Reported
	Metotrexate	S	Unk	Not Reported
	Enbrel	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	13250265	EXPEDITED (15-DAY)		DE, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001025		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Death; Drug Ineffective; Drug Intolerance; Feeling Jittery; Ill-Defined Disorder; Joint Swelling; Limb Discomfort; Localised Infection; Musculoskeletal Disorder; Nausea; Neck Pain; Night Sweats; Pain; Peripheral Swelling; Purulent Discharge; Pustular Psoriasis; Synovitis; Tachycardia; Treatment Failure; Vomiting	Plaquenil Tablet			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Calcium			C				Not Reported
	Celebrex			C				Not Reported
	Elavil			C				Not Reported
	Ergocalciferol			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Lorazepam			C				Not Reported
	Pantoprazole			C				Not Reported

	Magnesium			C						Not Reported
	Valtrex			C						Not Reported
	Rituxan			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	14198982	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3611			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Sulfasalazine			C	Unknown					Not Reported
	Wellbutrin			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	14649308	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018104779		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Multiple System Atrophy	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Intravenous (not otherwise specified)	5 Mg, Alternate Day (Qod)		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Remicade			S		3 Mg/Kg, Cyclic (At 0, 2, 6 Weeks, Then Every 8)		Not Reported
	Remicade			S	Oral	3 Mg/Kg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Two Weeks		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15283756	EXPEDITED (15-DAY)		OT	ES-ROCHE-2169023		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Tocilizumab	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Etanercept	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Adalimumab	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Abatacept	S	Unknown			Not Reported
	Lornoxicam	C	Unknown			Not Reported
	Paracetamol	C	Unknown			Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Enbrel	C	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15313579	EXPEDITED (15-DAY)		LT, OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003017		14 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chalazion; Electrocardiogram Qt Prolonged; Eyelid Ptosis; Hypotension; Pupils Unequal; Swelling; Vertigo; Vomiting	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15404748	NON-EXPEDITED			US-SA-2018SA260146			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Drug Ineffective	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15474256	NON-EXPEDITED			US-SA-2018SA277191			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Humira			S				Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15486250	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003442		33 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Bronchitis; Nasopharyngitis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Edirol			C				Not Reported
	Nexium			C				Not Reported
	Benet			C				Not Reported
	Diquas			C				Not Reported
	Hirudoid			C				Not Reported
	Shimbuto [Aconitum Spp. Processed Root;Atractylodes			C				Not Reported

	Lancea Rhizome;Pae			
	Choyoto	C		Not Reported
	Sansoninto	C		Not Reported
	Calcium Lactate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15568788	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0804		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Feeling Abnormal; Memory Impairment	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprelan			C	Unknown			Not Reported
	Effexor			C	Unknown			Not Reported

	Reactine (Cetirizine Hydrochloride)			C	Unknown				Not Reported
	Benadryl			C	Unknown				Not Reported
	Plaquenil			C	Unknown				Not Reported
	Naproxen			C	Unknown				Not Reported
	Venlafaxine Hydrochloride			C	Unknown				Not Reported
	Venlafaxine			C	Unknown				Not Reported
	Reactine			C	Unknown				Not Reported
	Cetirizine Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15622272	EXPEDITED (15-DAY)		OT	IL-PFIZER INC-2018466575		60 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphoma; Malignant Melanoma; Skin Lesion	Xeljanz			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15763575	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004201		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Emergency; Nocturia; Rash	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Eve (Ibuprofen)			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Neoral			C				Not Reported
	Ciclosporin			C				Not Reported
	Levothyroxine Na			C				Not Reported
	Lochol			C				Not Reported

			Forteo		C	Subcutaneous				Not Reported
			Urepearl		C					Not Reported
			Mohrus		C					Not Reported
			Vanarl N		C					Not Reported
			Calonal O		C					Not Reported
			Alfacalcidol		C					Not Reported
			Amlodipine		C					Not Reported
			Neriproct		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15764816	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3828		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15792302	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-		34 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delivery; Exposure During Pregnancy; Oropharyngeal Pain	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prograf			C				Not Reported
	Prednisolone			C				Not Reported
	Menatetrenone			C				Not Reported
	Magmitt			C				Not Reported
	Miya Bm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15796433	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000045		33 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oesophageal Candidiasis; Periodontal Inflammation; Rash Papular; Stomatitis	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Predonine			C				Not Reported
	Prednisolone			C				Not Reported
	Nexium 1-2-3			C				Not Reported
	Magmitt			C				Not Reported
	Sennoside A+B			C				Not Reported
	Bilanoa			C				Not Reported
	Hirudoid			C				Not Reported
	Alfarol			C				Not Reported
	Alfarol			C				Not Reported
	Menatetrenone			C				Not Reported
	Topsym			C				Not Reported
	Ferrous Citrate Na			C				Not Reported
	Benet			C				Not Reported
	Dermovate			C				Not Reported
	Belimumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15809425	EXPEDITED (15-DAY)		DE, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000078			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Exposure During Pregnancy	Plaquenil 200 Mg Tablet			S	Oral	Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15936882	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656805-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Synovitis; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo Folic	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16077254	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025766			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatic Enzyme Increased; Injection Site Reaction	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16144376	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA019969			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	3 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	250 Milligram, Qd		Not Reported
	Actemra			S		280 Milligram, Qd		Not Reported
	Anakinra			S	Unknown	50 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram, Qd		Not Reported
	Orencia			S	Unknown	250 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram, 2 Times/Wk		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16168017	EXPEDITED (15-DAY)		OT	US-SA-2019SA094868			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Leukopenia; Off Label Use; Osteonecrosis; Osteopenia; Pulmonary Sarcoidosis; Rebound Effect	Prednisone			S		15 Mg, Qd		Not Reported
	Prednisone			S		Tapered Dose;Attempts To Taper Prednisone Below 15 Mg/Day		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Leflunomide			S				Sanofi
	Azathioprine			C				Not Reported
	Adalimumab			C				Not Reported
	Infliximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177319	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177342	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea;	Leflunomide			S	Unknown			Barr

Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate	S	Unknown			Barr
	Mirtazapine	S	Unknown			Teva
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Mirtazapine	S	Unknown	15.0 Milligram		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177476	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000978			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Fungal Infection; White Blood Cell Count Decreased	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177559	EXPEDITED (15-DAY)		OT	GH-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-204467		22 YR	Male	GHA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Enterobacter Infection; Odynophagia; Ophthalmic Herpes Zoster; Oropharyngeal Candidiasis; Pathogen Resistance; Post Herpetic Neuralgia	Prednisolone			S	Unknown	60 Milligram, Daily		Taro
	Methotrexate			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Sun
	Mycophenolate Mofetil			S	Unknown	1.5 Gram, Bid		Not Reported
	Furosemide			C	Unknown	80 Milligram, Tid		Not Reported
	Nifedipine			C	Unknown	30 Milligram, Daily		Not Reported
	Carvedilol			C	Unknown	12.5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177595	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035665		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Restasis			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	2000 Milligram Daily;		Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177744	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2019-1033		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177750	NON-EXPEDITED			US-TEVA-2019-US-1031859			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gluten Sensitivity; Rash;	Hydroxychloroquine			S	Unknown			Teva

Rash

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177965	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035612			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177970	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035668			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr

Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177992	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035686		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178057	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036655			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Wellbutrin	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178560	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-02087		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Anastrozole			S	Unknown	Unk		Not Reported
	Docetaxel			S	Unknown	Unk, Four 21-Day Cycles		Not Reported
	Cyclophosphamide			S	Unknown	Unk, Four 21-Day Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16178609	EXPEDITED (15-DAY)		OT	PHHY2018ES080199		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Methotrexate			S	Unknown	Unk		Novartis
	Adalimumab			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Leflunomide			S	Unknown	Unk			Not Reported
	Lornoxicam			C	Unknown	Unk			Not Reported
	Paracetamol			C	Unknown	Unk			Not Reported
	Pantoprazole			C	Unknown	Unk			Not Reported
	Enbrel			C	Unknown	50 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16179517	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019150172		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Lyrica			S	Oral	50 Mg, 2x/Day (1-0-1)		Pfizer
	Contramal			S	Oral	2 Df, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2 Df, Daily		Not Reported
	Imovane			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Rhinofluimucil			S	Nasal	A Spray 2 To 3 Times / Day		Not Reported
	Cortancyl			C		Unk		Not Reported
	Orocal [Calcium Carbonate]			C				Not Reported
	Sulfarlem S			C				Not Reported
	Movicol			C				Not Reported
	Fosavance			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16180155	NON-EXPEDITED			US-PFIZER INC-2019153865		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Metronidazole			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Propoxyphene Hcl			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Phenazopyridine Hcl			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16181683	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001023			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Coumadin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	12211103	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016168430		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling; Product Dose Omission	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	12359545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2013088765		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug	Enbrel			S		Unk		Pfizer
	Enbrel			S				Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Celebrex			S				Pfizer

Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine	S		Unk		Pfizer
	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Humira	S	Unknown	Discontinued After Four Injection		Not Reported
	Warfarin	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Apo-Warfarin	S		Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	14169339	NON-EXPEDITED			US-AMGEN-USASP2017166721		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	15419253	NON-EXPEDITED			US-PFIZER INC-2018380664		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported

	Remicade	S	Unk	Not Reported
	Leflunomide	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	15576655	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016348229		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Latent Tuberculosis; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			S	Endocervical	40 Mg, Unk, 'Ir'		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			C	Intramuscular	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, 4 Times/Wk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Four Every One Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	15703550	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174073		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Simponi			S	Unknown	Unk				Not Reported
	Sulfasalazine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	15899320	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2019CA018379			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab Pfizer (Unknown)			S	Unknown	200 Mg, Monthly		Not Reported
	Etanercept			S		Unk		Not Reported
	Etanercept			S		15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	15908463	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1904623US			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Gentamicin Unk			S	Unknown	Unk		Allergan
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Entocort			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfanilamide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	15927259	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019019180			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Cough; Injection Site Pain; Insomnia; Multiple Drug Therapy; Pain In Extremity; Peripheral Swelling; Restlessness; Visual Impairment	Benlysta Solution For Injection In Pre-Filled Pen			S	Subcutaneous	200 Mg, Unk		Glaxosmithkline
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16160471	NON-EXPEDITED			US-AMGEN-USASP2019053493			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Gastrooesophageal Reflux Disease	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16183623	EXPEDITED (15-DAY)		HO, LT, OT	AU-ORION CORPORATION ORION PHARMA-19_00006018		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bone Abscess; Cachexia; Calcinosis; Delirium; Dermal Sinus; Disseminated Mycobacterium Avium Complex Infection; Enterobacter Test Positive; Immunosuppression; Peptostreptococcus Test Positive; Sepsis	Methotrexate			S	Oral	Twice Weekly		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Low Dose		Not Reported
	Rivaroxaban			C	Unknown			Not Reported
	Rivaroxaban			C				Not Reported
	Immune Globulin Nos			C	Subcutaneous	Received Regular Infusions		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16183839	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011188		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use	Alendronate			S	Unknown	Unk		Apotex
	Acetazolamide			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Azathioprine			S				Apotex
	Cyclosporine			S	Unknown	Unk		Apotex

	Cyclosporine			S					Apotex
	Leflunomide			S	Unknown	Unk			Apotex
	Leflunomide			S					Apotex
	Infliximab			S	Unknown	Unk, Q.M.T.			Not Reported
	Infliximab			S					Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Methotrexate			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184516	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1034448			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Off Label Use; Osteopenia	Prednisone			S	Unknown	15 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline			S				Not Reported
	Minocycline			S				Not Reported
	Adalimumab			S	Unknown			Mylan
	Adalimumab			S				Mylan
	Adalimumab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184558	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr

Intolerance; Rheumatoid Arthritis	Actemra		S	Unknown	640 Mg,	Not Reported
	Arava		S	Oral		Not Reported
	Cimzia		S	Subcutaneous	200 Mg, 1 Every 1 Week,Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown	50 Mg, 1 Every1 Week,	Not Reported
	Humira		S	Subcutaneous	40 Mg, Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Imuran		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	300 Mg,Powder For Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184823	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2018180327		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cystitis; Diarrhoea; Feeding Disorder; Gait Disturbance; Hepatic Enzyme Increased; Hypertension; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Urinary Tract Infection; Weight Decreased; Wound	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Oral	11 Milligram, Qd		Not Reported
	Xeljanz Xr			S	Oral	11 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Arava			C		Unk		Not Reported
	Humira			C				Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Voltaren [Diclofenac			C		Unk, Prn		Not Reported

	Diethylamine]								
	Vitamin D [Colecalciferol]			C		400 Unit			Not Reported
	Acidophilus [Lactobacillus Acidophilus]			C		Unk			Not Reported
	Azathioprine			C		Unk			Not Reported
	Naproxen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16184932	EXPEDITED (15-DAY)		HO, LT, OT	AU-BAUSCH-BL-2019-010331		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bone Abscess; Cachexia; Calcinosis; Delirium; Dermal Sinus; Disseminated Mycobacterium Avium Complex Infection; Enterobacter Infection; Peptostreptococcus Infection; Sepsis	Prednisolone			S	Unknown	Low Dose		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rivaroxaban			C				Not Reported
	Immune Globulin Nos			C	Subcutaneous	Received Regular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16186537	EXPEDITED (15-DAY)		OT	CA-PURDUE-CAN-2019-0009896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Body Height Decreased; Deep Vein Thrombosis; Depressed Mood; Drug Ineffective; Drug Ineffective; Emotional Distress; Feeling Abnormal; Gait Inability; Impaired Quality Of Life; Osteoporosis; Osteoporotic Fracture; Pelvic Fracture; Pruritus	Dilaudid			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	20 Mg, Weekly		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Unk		Not Reported

Allergic; Psoriasis; Psoriasis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Prednisone	C	Unknown	Unk		Not Reported
	Vioxx	C	Unknown	Unk		Not Reported
	Warfarin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16186574	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2019155123		20 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adenovirus Infection	Hydrocortisone Sodium Succinate			S	Intravenous (not otherwise specified)	50 Mg, 3x/Day (Stress Dose Levels, Q8h))		Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day (High Dose)		Pfizer
	Plaquenil Sulfate			S		500 Mg, Daily (Maintenance Therapy)		Not Reported
	Prednisone			S		20 Mg, 2x/Day (Maintenance Therapy)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2019	16186744	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018522265		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		12.5 Mg, Unk		Pfizer
	Cortisone			S		13 Mg,Tapering Every 2 Weeks		Not Reported
	Prednisone			S		15 Mg For 2 Weeks And Will Go Down To 10 Mg		Not Reported
	Folic Acid			S		5 Mg, Unk		Not Reported
	Plaquenil Sulfate			S		200 Mg, Unk		Not Reported
	Meloxicam			S		15 Mg, Unk		Not Reported
	Rabeprazole			S		20 Mg, Unk		Not Reported

Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	9863335	NON-EXPEDITED		OT	US-PFIZER INC-2014026149		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Bextra			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Depo-Medrol			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Solu-Medrol			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported
	Zyrtec			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	12568761	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2016091121		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Fracture	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Procytox		S	Unknown	2000 Milligram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	13634008	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017086092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Stress	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Celebrex			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Domperidone			C	Unknown	10 Mg, Qd		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	13859279	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017119779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthritis; Back Pain; Bone Pain; Chest	Enbrel			S	Unknown	500 Mg, Qwk		Amgen
	Amitriptyline			S	Unknown	Unk		Not Reported

Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Joint Swelling; Kyphoscoliosis; Laboratory Test Abnormal; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Sacroiliitis; Somnolence; Spinal Osteoarthritis; Spinal X-Ray Abnormal; Spondyloarthropathy; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Apo Meloxicam	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Mobicox	S	Unknown	Unk		Not Reported
	Meloxicam	S	Unknown	Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Methotrexate	C		Unk		Not Reported
	Naproxen	C		Unk		Not Reported
	Pantoprazole	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	15494534	NON-EXPEDITED			US-PFIZER INC-2018404368		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Enbrel			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	15792322	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000023		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia

	Plaquenil 200 Mg Tablet	S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Prednisolone	S	Oral			Concordia
	Onealfa	C				Not Reported
	Onealfa	C				Not Reported
	Takepron	C				Not Reported
	Takepron	C				Not Reported
	Persantin	C				Not Reported
	Epadel T	C				Not Reported
	Bonalon	C				Not Reported
	Bonalon	C				Not Reported
	Loxonin	C				Not Reported
	Selbex	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16021494	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000419		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage	Hydroxychloroquine			S	Unknown			Concordia
	Rimatil			C				Not Reported
	Selbex			C				Not Reported
	Celecox			C				Not Reported
	Predonine			C				Not Reported
	Careram			C				Not Reported
	Clarith			C				Not Reported
	Rifadin			C				Not Reported
	Esanbutol			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16096073	NON-EXPEDITED			US-SA-2019SA076499			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Leflunomide			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16175285	EXPEDITED (15-DAY)		DE	PHHY2019NL080046		67 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Neoplasm Malignant; Product Use In Unapproved Indication	Methotrexate			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Novartis
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188264	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001053			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Off Label Use; Osteopenia	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	(66% Reduction)		Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S				Not Reported
	Adalimumab			S				Not Reported
	Adalimumab			C				Not Reported
	Adalimumab			C				Not Reported
	Adalimumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188267	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1036650		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16188274	EXPEDITED (15-DAY)		OT	FR-ROCHE-2301132		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown	2.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	120 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Immunoglobulin Iv			S	Intravenous (not otherwise specified)			Not Reported
	Whole Blood			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16190845	NON-EXPEDITED			US-PFIZER INC-2019157476		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S	Oral	50 Mg, 1x/Day (1 Capsule Orally At Bedtime)		Pfizer
	Lyrica			S	Oral	25 Mg, 2x/Day (1 Capsule Orally Bid(Twice A Day))		Pfizer
	Atorvastatin Calcium			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Gemfibrozil			S		Unk		Pfizer
	Crestor			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Dyazide			S		Unk		Not Reported
	Keflex [Cefalexin]			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Norco			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported
	Cefdinir			S		Unk		Not Reported
	Chlorthalidone			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16191919	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1034208		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Delirium; Hallucination, Auditory	Piperacillin/Tazobactam Mylan			S	Intravenous drip			Mylan
	Primperan			S	Oral	Si Besoin		Mylan

	Orozamudol	S	Oral	Si Besoin		Mylan
	Fluconazole Arrow	S	Oral			Mylan
	Plaquenil /00072603/	S	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2019	16192833	EXPEDITED (15-DAY)		OT	FR-ROCHE-2302893		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclosporin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Blood Transfusion			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16192880	EXPEDITED (15-DAY)		OT	FR-ROCHE-2302917		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

	Prednisone			S	Unknown					Not Reported
	Blood Transfusion			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16192926	EXPEDITED (15-DAY)		OT	ES-ABBVIE-18K-144-2445218-00		41 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Angioedema; Drug Intolerance; Exposure During Pregnancy; Hypersensitivity; Off Label Use; Therapeutic Product Effect Incomplete	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16193457	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036699		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Asa			C	Unknown					Not Reported
	Clonazepam			C	Oral					Not Reported
	Desipramine			C	Unknown					Not Reported
	Gabapentin			C	Oral					Not Reported
	Nitroglycerin			C	Unknown					Not Reported
	Rosuvastatin Calcium			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16193465	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037188			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16193469	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037321		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Oral			Barr
	Methotrexate Sodium			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Leflunomide	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine	S	Subcutaneous			Not Reported
	Neoral	S	Unknown			Not Reported
	Neoral	S	Subcutaneous			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16193521	EXPEDITED (15-DAY)		HO	SE-TEVA-2019-SE-1036562		58 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Mania	Prednisolone			S	Unknown			Actavis
	Plaquenil			S	Oral	209 Milligram Daily;		Not Reported
	Omeprazole			C				Not Reported
	Pulmicort			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2019	16193600	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown			Barr
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown			Not Reported
	Bacitracin	S	Unknown			Not Reported
	Etanercept	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Neomycin Sulfate	S	Unknown			Not Reported
	Polymyxin B Sulfate	S	Unknown			Not Reported
	Prednisone	C	Intramuscular			Not Reported
	Prednisone	C	Intramuscular			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2019	12490512	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016078471		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Daily		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2019	16194700	EXPEDITED (15-DAY)		OT	PHHY2019ES082040		35 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiocentric Lymphoma; Erythema; Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Methylprednisolone Aceponate			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	10069680	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014024889		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use	Enbrel			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclosporin A			C	Unknown	Unk		Not Reported
	Azathioprine			C		Unk		Not Reported
	Mtx			C	Unknown	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Acetazolamide			C	Unknown	Unk		Not Reported
	Alendronate			C	Unknown	Unk		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Cyclosporine			C		Unk		Not Reported

	Hydroxychloroquine	C	Unk	Not Reported
	Iron	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	11871904	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2015323580		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dyspnoea Exertional; Fibromyalgia; Kidney Infection; Musculoskeletal Stiffness; Pain In Extremity	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	12321555	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016054806		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported

	Desoximetasone			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	12430958	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016069625		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qwk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	12607949	EXPEDITED (15-DAY)		DS, HO, OT	CA-AMGEN-CANSP2016097203		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Simponi		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	17.5 Mg, Qwk		Not Reported
	Methotrexate Sodium		S	Unknown	17.5 Mg, Qwk		Not Reported
	Folic Acid		C		Unk		Not Reported
	Percocet		C		Unk Unk, As Necessary		Not Reported
	Acetaminophen		C	Unknown	Unk Unk, As Necessary		Not Reported
	Hydrochloride		C	Unknown	Unk		Not Reported
	Oxycodone Terephthalate		C	Unknown	Unk		Not Reported
	Acetaminophen W/Oxycodone		C	Unknown	Unk		Not Reported
	Acetaminophen;Oxycodone Hydrochloride		C		Unk		Not Reported
	Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol		C		Unk		Not Reported
	Thiamine Hydrochloride		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	13048407	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-105259		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Skin Neoplasm Excision	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Methotrexate			S	Unknown	17.5 Mg, Qwk		Not Reported
	Quensyl			S	Unknown	1 Df, Qd		Not Reported
	Chloroquine			S	Unknown	1 Df, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Phenprocoumon			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	14156463	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017163488		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	14224310	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175548		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	14852410	NON-EXPEDITED			US-PFIZER INC-2018184302			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Cefdinir			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15461124	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018359226		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Adalimumab			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Not Reported
	Abatacept			S		Unk Unk, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			S		Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Lyophylized Powder		Not Reported
	Dolquine			S		Unk		Not Reported
	Lornoxicam			C		Unk		Not Reported
	Enbrel			C	Unknown	50 Mg, Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15598357	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018156086			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Diarrhoea; Drug Ineffective; Fungal Infection; Hepatotoxicity; Herpes Zoster; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Apixaban			C	Unknown	5 Mg, Bid		Not Reported
	Apixaban			C	Unknown	Unk		Not Reported

	Atorvastatin	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Switched From 40 Mg Dose But Now Taking 10 Mg, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk Unk, Qd	Not Reported
	Amitriptyline	C	Unknown	25 Mg, Q Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	40 Mg, Qd	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
	Novo-Pranol	C	Unknown	40 Mg, Unk	Not Reported
	Novo-Pranol	C	Unknown	Unk	Not Reported
	Warfarin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15619213	NON-EXPEDITED			US-SA-2018SA312877			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15629126	EXPEDITED (15-DAY)		OT	CA-009507513-1811CAN005711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15641896	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018165017			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Leukopenia; Retinopathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil			S	Unknown	200 Milligram		Not Reported
	Gold			S	Intramuscular	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram, Qwk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15688400	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2018142043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			C	Subcutaneous	162 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Arava			C		20 Mg, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported
	Hydroxychloroquine			C		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15728417	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018177847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

					Hydroxychloroquine		S	Unknown	Unk		Not Reported
					Methotrexate		S	Subcutaneous	25 Milligram, Qwk		Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Unk		Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15730578	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018177973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	5 Milligram, 10 Miligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15812223	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS		48 YR	Male	JPN

INC.-GSH201901-000082

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Skin Eruption	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately;		Concordia
	Plaquenil 200 Mg Tablet			S				Concordia
	Predonine			C				Not Reported
	Prograf			C				Not Reported
	Bayaspirin			C				Not Reported
	Lansoprazole			C				Not Reported
	Lansoprazole			C				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	15896508	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019045707			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Benzylpenicillin Potassium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Entocort			S	Unknown	Unk		Not Reported
	Gentamycin			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfanilamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16082355	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000649		58 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Gnathoschisis; Herpes Zoster; White Blood Cell Count Decreased	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Valganciclovir Hydrochloride			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Predonine			C				Not Reported
	Bayaspirin			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Rabeprazole Sodium			C				Not Reported
	Halizon			C				Not Reported
	Pitavastatin Calcium			C				Not Reported
	Pitavastatin Calcium			C				Not Reported
	Alendronate			C				Not Reported
	Alendronate			C				Not Reported
	Daiphen			C				Not Reported
	Daiphen			C				Not Reported
	Nitrazepam			C				Not Reported
	Evoxac			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Equa			C				Not Reported
	Januvia			C				Not Reported
	Humulin R			C				Not Reported
	Aiphagan			C				Not Reported
	Lumigan			C				Not Reported
	Timoleate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16136314	EXPEDITED (15-DAY)		LT, OT	NO-PFIZER INC-2019133949		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent; Gastrointestinal Disorder	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16183614	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA095550		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; Fall; Inflammatory Pain; Lumbar Vertebral Fracture; Pruritus; Rheumatoid Arthritis	Plaquenil			S		Unk, Qd		Sanofi
	Leflunomide			S		10 Unk		Sanofi
	Methotrexate			C	Oral	20 Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Entocort			C				Not Reported
	Naproxen			C		Unk		Not Reported
	Depo Medrol			C		40 Mg		Not Reported
	Alendronate			C		Unk Unk, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16195257	EXPEDITED (15-DAY)		HO, LT, OT	AU-ACCORD-121355		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bone Abscess; Cachexia; Calcinosis; Delirium; Dermal Sinus; Disseminated Mycobacterium Avium	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S		Low Dose		Not Reported
	Rivaroxaban			C				Not Reported

Complex Infection; Enterobacter Infection; Peptostreptococcus Infection; Sepsis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16195280	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16195823	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rash	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16195826	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037506			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Rash;	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr

Treatment Failure	Adalimumab		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Subcutaneous	125dosage Forms, 1every 1weeks	Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16195837	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Leflunomide			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16195854	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1037760		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Arava			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16196806	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1034462			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Hypertension; Leukopenia; Off Label Use; Osteonecrosis; Osteopenia	Prednisone			S	Unknown	15 Milligram, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Mylan
	Infliximab			S	Unknown			Mylan
	Leflunomide			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16197345	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190402230		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Celgene
	Arava			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Celgene
	Enbrel			S	Unknown			Celgene
	Humira			S	Subcutaneous			Celgene
	Minocycline Hydrochloride			S	Unknown			Celgene
	Myochrysine			S	Intramuscular			Celgene
	Plaquenil			S	Unknown			Celgene
	Rituxan			S	Intravenous drip			Celgene
	Salazopyrin			S	Unknown			Celgene

	Simponi	S	Subcutaneous			Celgene
	Sirukumab	S	Unknown			Celgene
	Sulfasalazine	S	Unknown			Celgene
	Ustekinumab	S	Unknown			Celgene
	Xeljanz	S	Oral	5 Milligram		Celgene
	Methotrexate	C	Unknown			Celgene
	Orencia	C	Unknown			Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16197463	NON-EXPEDITED			US-NEOPHARMA INC-000095			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Augmentin			S				Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16197482	NON-EXPEDITED			US-NEOPHARMA INC-000098			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Augmentin			S				Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Vicodin			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Azulfidine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16198141	EXPEDITED (15-DAY)			US-ELI_LILLY_AND_COMPANY-US201904003048		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Dermatitis; Dermatophytosis	Emgality 120mg	S	Unknown	240 Mg, Single		Eli Lilly And Co
	Emgality 120mg	S	Unknown	Unk, Unknown		Eli Lilly And Co
	Plaquenil [Hydroxychloroquine Phosphate]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16198913	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038711		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Surgery	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Indometacin			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16199049	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2019153038		68 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Salmonella Sepsis; Splenic Infarction	No Subject Drug			S				Not Reported
	Lantarel			S		22.5 Mg, Weekly		Pfizer
	Quensyl			S		400 Mg, Daily		Not Reported
	Aspirine			C				Not Reported
	Corvaton			C				Not Reported
	Folsan			C				Not Reported
	Beloc Zok			C				Not Reported
	Antra [Omeprazole]			C		"Antra Mups"		Not Reported
	Delix [Ramipril]			C				Not Reported
	Simvabeta			C				Not Reported
	Allo Ct			C				Not Reported
	Decortin			C				Not Reported
	Gabagamma			C				Not Reported
	Nitrolingual			C		"Nitrolingual Spray"		Not Reported
	Novalgine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16199276	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1035023			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Chills; Condition Aggravated; Cushingoid; Drug Ineffective; Haematuria; Headache; Hypertransaminasaemia; Intentional Product Misuse; Lupus Nephritis; Meningitis Cryptococcal; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria; Pyrexia	Prednisone			S	Oral	1 Mg/Kg, Qd		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg 3 Pulse Therapies		Mylan
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg 3 Pulse Therapies For Ln		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg, 1x Pulse		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy		Mylan
	Cyclophosphamide			S	Intravenous (not otherwise specified)	300 Mg, 1x Pulse		Mylan
	Hydroxychloroquine			S	Oral	Unk		Mylan
	Mycophenolate Mofetil			S		1 G, Qd		Mylan
	Rituximab			S		375 Mg/M2 Infusion		Mylan
	Cyclophosphamide			S	Oral	1 Milligram/Kilogram, Qd		Mylan
	Cyclophosphamide			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16199869	EXPEDITED (15-DAY)		OT	PHHY2019FR086234		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Prednisone			S	Unknown	70 Mg, Qd		Novartis
	Prednisone			S	Unknown	50 Mg, Qd		Novartis
	Rituximab			S	Unknown			Not Reported
	Erythropoietin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Blood, Whole			S	Unknown			Not Reported

	Mycophenolate Mofetil			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16199877	EXPEDITED (15-DAY)		OT	FR-ROCHE-2302818		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Blood, Whole			S	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16200103	NON-EXPEDITED			US-SA-2019SA103807			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2019	16336565	DIRECT	Y				48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urticaria	Hydroxychlor Tab 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	12583928	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015117639		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Cortisone			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	12678745	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016109206		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	Unk		Amgen
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

						otherwise specified)				
		Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
		Hydroxychloroquine			C	Unknown	Unk			Not Reported
		Hydroxychloroquine			C		Unk			Not Reported
		Methotrexate			C	Unknown	Unk			Not Reported
		Methotrexate			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	12846006	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016137814		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Nodule; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	13229533	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000974		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Drug Ineffective; Musculoskeletal Pain; Vulvovaginal Rash	Plaquenil Tablet	S	Unknown			Concordia
	Enbrel	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	13238452	EXPEDITED (15-DAY)		HO, LT, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001124		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis;	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Immune Globulin Iv			S	Intravenous (not otherwise specified)			Not Reported
	Immune Globulin Iv			S	Intravenous (not otherwise specified)			Not Reported
	Immune Globulin Iv			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	(Every 2 Weel);	Not Reported
	Isoniazid;Rifampicin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	13245169	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008027		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unknown		Not Reported

Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia	S	Unknown	Unknown		Not Reported
	Rituxan	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unknown		Not Reported
	Gold	S	Unknown	Unknown		Not Reported
	Humira	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	13250490	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001016			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Methotrexate Sodium			S	Unknown	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Arava			S	Oral	Not Reported
	Arava			S	Oral	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Cortisone			C		Not Reported
	Desoximetasone			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	13709571	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0111		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain In Extremity; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	14036828	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017147366		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Full Blood Count Decreased; Gastrointestinal Disorder; Intentional Product Misuse; Malaise; Sjogren'S Syndrome;	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported

Weight Decreased; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	14624224	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Domperidone			C	Oral	10 Milligram, Qd		Not Reported
	Prednisone Acetate			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	14626534	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031841		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Unk		Not Reported

	Plaquenil			S	Oral	200 Milligram, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15483451	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA022998			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	616 Mg One Every Four Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	680 Mg, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	624 Mg, 1 Every 4 Weeks		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, On Day 1 And 15		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg Day 1 And 15		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Ferrous Gluconate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lasix [Furosemide]			C		Unk		Not Reported
	Methylprednisolone			C				Not Reported
	Naprosyn [Naproxen]			C		Unk		Not Reported

	Oxycontin			C		Unk				Not Reported
	Oxyneo			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15608670	NON-EXPEDITED			US-SA-2018SA310522			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Meloxicam			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15661522	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017003713		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Crohn'S Disease; Drug Ineffective; Elbow Operation; Inappropriate Schedule Of Product Administration; Neck Pain; Pain In Extremity; Product Dose Omission; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported

		Apo-Hydroxyquine			S	Unknown				Not Reported
		Methotrexate			C	Subcutaneous	10 Mg, Qwk			Not Reported
		Naproxen			C	Unknown	Unk, Unk, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15679558	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018170453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15703197	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15711545	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174330		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15728180	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018177979		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Apo-Leflunomide			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Prednisone			C		50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15730213	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018177854		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	20 Milligram		Not Reported
	Celebrex			S	Oral	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	8 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15810868	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000069		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Syndrome; Condition Aggravated; Condition Aggravated; Lupus Nephritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Prednisolone			C				Not Reported
	Cellcept			C				Not Reported
	Cellcept			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Amlodipine			C				Not Reported
	Enalapril Maleate			C				Not Reported
	Nexium			C				Not Reported
	Warfarin			C				Not Reported
	Ferrous Citrate Na			C				Not Reported
	Berasus			C				Not Reported
	Fexofenadine Hydrochloride			C				Not Reported
	Teprenone			C				Not Reported
	Tracleer			C				Not Reported
	Recalbon [Minodronic Acid]			C				Not Reported
	Juvela N			C				Not Reported
	Loxoprofen Sodium			C				Not Reported

	Tramcet	C		Not Reported
	Cosentyx	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	15948492	NON-EXPEDITED			US-SA-2019SA037758			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16080988	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022814		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Alendronate Sodium			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported

	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Hydroxychloroquine /00072603/	S	Oral			Not Reported
	Hydroxychloroquine /00072603/	S	Oral			Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16167083	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-000997		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Plaquenil Tablet			S	Unknown	Unknown		Concordia
	Actemra			S	Unknown	Unknown		Not Reported
	Dilaudid			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Acetaminophen			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16200279	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001127			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Leukopenia; Off Label Use;	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S				Concordia

Osteonecrosis; Osteopenia; Pulmonary Sarcoidosis; Rebound Effect	Hydroxychloroquine	S				Concordia
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown	Tapered Dose;Attempts To Taper Prednisone Below 15 Mg/Day (5 Mg Daily (Tapered Slowly)		Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Methotrexate	S				Not Reported
	Methotrexate	S				Not Reported
	Minocycline Hydrochloride	S	Unknown	Unknown		Not Reported
	Minocycline Hydrochloride	S				Not Reported
	Minocycline Hydrochloride	S				Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil	S				Not Reported
	Mycophenolate Mofetil	S				Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Leflunomide	S				Not Reported
	Leflunomide	S				Not Reported
	Adalimumab	C				Not Reported
	Adalimumab	C				Not Reported
	Adalimumab	C				Not Reported
	Azathioprine	C				Not Reported
	Azathioprine	C				Not Reported
	Azathioprine	C				Not Reported
	Infliximab	C				Not Reported
	Infliximab	C				Not Reported
	Infliximab	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16200280	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004155		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation;	Plaquenil 200 Mg Tablet			S	Oral			Concordia

Erythema Multiforme; Lymphadenopathy; Pain; Pyrexia	Predonine	C	Increased To 30mg	Not Reported
	Predonine	C	Increased To 50mg	Not Reported
	Predonine	C	Dose Of Prednisolone Was Tapered After The Administration Of 50 Mg	Not Reported
	Marzulene Combination	C		Not Reported
	Marzulene Combination	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16200290	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0777		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			C	Subcutaneous			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16200431	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3853		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Prednisone			S	Unknown	For 2 Weeks And Will Go Down To 10 Mg		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Rabeprazole			S	Unknown	Tapering Every 2 Weeks		Not Reported
	Cortisone			S	Unknown	Tapering		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16201033	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Cimzia			S	Unknown	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Alendronate Sodium			C	Oral			Not Reported
	Atenolol			C	Unknown			Not Reported
	Certolizumab Pegol			C	Subcutaneous			Not Reported
	Chlordiazepoxide;Clidinium Bromide			C	Oral			Not Reported

	Esomeprazole Magnesium Trihydrate	C	Oral			Not Reported
	Hydrochlorothiazide	C	Oral	25 Milligram Daily;		Not Reported
	Lorazepam	C	Oral	1 Milligram Daily;		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Sulfasalazine	C	Oral			Not Reported
	Trimebutine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16201040	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038038			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16201052	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1038064		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16201169	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038772		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Unknown	Powder For Suspension Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16201189	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038749			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

Arthritis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16202325	NON-EXPEDITED			US-SA-2019SA104244			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S				Sanofi
	Methotrexate			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Humira			S		Unk		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16202530	NON-EXPEDITED			US-SA-2019SA105357			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16202698	NON-EXPEDITED			US-PFIZER INC-2019156796		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin G Increased; Drug Hypersensitivity	Advil			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16202896	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2019M1036147		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acid Fast Bacilli Infection; Bone Abscess; Cachexia; Disseminated Mycobacterium Avium Complex Infection; Enterobacter Infection; Peptostreptococcus Infection; Sepsis; Skin Infection; Weight Decreased	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Prednisolone			S	Unknown	8 Milligram, Qd		Mylan
	Rivaroxaban			C	Unknown			Mylan
	Immunoglobulin /00025201/			C	Other			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16203300	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2018AMN00221			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azathioprine			S	Unknown	Unk		Amneal
	Xeljanz Xr			C	Oral	11 Mg, 1x/Day		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16203368	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP011832		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerulonephritis	Mycophenolate Mofetil			S	Unknown	Unk		Apotex

Rapidly Progressive; Histoplasmosis Disseminated	Mycophenolate Mofetil		S					Apotex
	Hydroxychloroquine		S	Unknown	Unk			Not Reported
	Hydroxychloroquine		S					Not Reported
	Prednisone		S	Unknown	Unk			Not Reported
	Prednisone		S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16203845	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019057990		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16204362	EXPEDITED (15-DAY)		LT	PHHY2019TW087387			Unknown	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16205171	EXPEDITED (15-DAY)		OT	PHHY2019CA086631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sandoz		S	Unknown	Unk		Novartis
	Methotrexate		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16205266	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001157		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; Fall; Inflammatory Pain; Lumbar Vertebral Fracture; Pruritus; Rheumatoid Arthritis	Plaquenil			S	Unknown	Unk, Qd		Concordia
	Leflunomide			S	Unknown	Daily Dose: 10 Unknown		Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Entocort			C				Not Reported
	Naproxen			C				Not Reported
	Depo Medrol			C				Not Reported
	Alendronate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16205267	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001139		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Disorder; Headache	Hydroxychloroquine 200 Mg Tablet			S	Oral	200mg Tablet Taken By Mouth Twice Daily		Concordia
	Prednisone			S		3 Tablets		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Prednisone			S		12.5-15mg		Not Reported
	Prednisone			S		15mg-20mg		Not Reported
	Relpax			S		Taken By Mouth As Needed,She Generally Only Needs To Take The		Not Reported

Relpax At Most 3 Times Monthly. Thera

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2019	16337514	DIRECT		OT			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Barrett'S Oesophagus; Nausea; Vomiting	Hydroxychloroquine			S	Oral	Quantity:1 Df Dosage Form;	2 MTH	Zydus Pharm
	Gabapentin			C				Not Reported
	Zanaflex			C				Not Reported
	Chantix			C				Not Reported
	Levothyroxine			C				Not Reported
	Zofran			C				Not Reported
	Compazine			C				Not Reported
	Folic Acid			C				Not Reported
	Celexa			C				Not Reported
	Vitamin D			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	10908207	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015017082		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain; Abdominal Pain Upper; Adrenal Insufficiency; Anxiety; Constipation; Diarrhoea; Dizziness; Duodenitis; Fatigue; Gastrointestinal Disorder; Headache; Nausea; Nervousness; Pruritus; Renal Failure; Rheumatoid Arthritis; Stress	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Arthrotec			S	Oral	75 Mg, 2x/Day		Pfizer
	Plaquenil			S	Oral	400 Mg, Daily		Not Reported
	Zostavax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	13004246	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016155213		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, (Q 14 Days)		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd At Night		Not Reported
	Folic Acid			C	Oral	2.5 Mg, Qd		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, 1 Tablet Once Daily		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

	Tenofovir Disoproxil			C	Unknown	Unk				Not Reported
	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	13367354	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0876		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dizziness; Drug Ineffective; Ear Infection; Fatigue; Headache; Lower Respiratory Tract Infection; Migraine; Nasopharyngitis; Nausea; Pneumonia; Sinusitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	13911034	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017128351		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure; Vomiting	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Plaquenil Sulfate			S	Unknown	300 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Subcutaneous	15 Milligram, Qwk		Not Reported

	Methotrexate Sodium	C	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Folic Acid	C	Oral	1 Milligram, Qd	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd	Not Reported
	Maxeran	C	Oral	10 Milligram, Q6h	Not Reported
	Salazopyrin	C	Oral	500 Milligram (Three Or Two Tablets Bid)	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	C	Oral	15 Mg, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	Unk	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
	Metoclopramide Hydrochloride	C	Oral	10 Milligram, Qid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15405187	EXPEDITED (15-DAY)		OT	AU-ROCHE-2187205			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Intentional Product Use Issue; Intentional Product Use Issue; Off Label Use	Cellcept			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Prednisolone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15468971	EXPEDITED (15-DAY)		OT	ES-AMGEN-ESPSP2018138541		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Lyophylized Powder		Not Reported
	Dolquine			S	Unknown	Unk		Not Reported
	Lornoxicam			C		Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15690084	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016305286		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Apo-Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported

Rheumatoid Factor Positive; Synovitis; Treatment Failure	Remicade			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15720109	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018512927		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	200 Mg, Bid		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15739406	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017428488		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Full Blood Count Decreased; Gastrointestinal Disorder; Intentional Product Misuse; Malaise; Sjogren'S Syndrome; Weight Decreased; White Blood Cell Count Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Enbrel			S	Unknown	50 Mg, Q2wk		Unknown
	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Qwk		Pfizer
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported

		Prednisone			S	Unknown	Unk			Not Reported
		Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15740202	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018519911		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	5 Mg, Unk		Pfizer
	Apo-Leflunomide			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15906482	NON-EXPEDITED		OT	US-SA-2019SA025812			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Toxicity To Various Agents	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	15967168	NON-EXPEDITED			US-SA-2019SA039999			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Imuran [Azathioprine Sodium]			S		Unk Unk, Unk		Not Reported
	Enbrel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16115148	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018520364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Unk		Pfizer
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

	Prednisone			C	Oral	5 Milligram, Unk				Not Reported
	Prednisone			C	Oral	10 Miligram, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16116370	EXPEDITED (15-DAY)		DE, OT	BE-ACTELION-A-CH2019-188088		30 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cardiac Arrest; Fall; Loss Of Consciousness	Uptravi			S	Oral	Unk		Actelion
	Uptravi			S	Oral	1000 Mcg, Bid		Actelion
	Volibris			S	Oral	10 Mg, Qd		Not Reported
	Adcirca			S	Oral	20 Mg, Bid		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Methylprednisolone			C	Oral	6 Mg, Qd		Not Reported
	Nifedipine			C	Oral	60 Mg, Qd		Not Reported
	Cozaar			C	Oral	100 Mg, Qd		Not Reported
	Temesta			C	Oral	2.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16186645	EXPEDITED (15-DAY)		DE, OT	US-GLAXOSMITHKLINE-US2019GSK063599			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperkalaemia; Systemic Lupus Erythematosus	Benlysta			S	Subcutaneous	200 Mg, Weekly		Glaxosmithkline
	Celebrex			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16205733	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib Capsules	S	Oral	200 Milligram, 2 Every 1 Day (S)		Aurobindo
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16205927	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-019707			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16206013	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019059600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Unknown	Unk		Amgen
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16206584	EXPEDITED (15-DAY)		OT	PHHY2019FR082862		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Ciclosporin			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	120 Mg, Qd		Not Reported
	Prednisone			S	Unknown	2.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	120 Mg, Qd		Not Reported
	Erythropoietin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Blood			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16206639	EXPEDITED (15-DAY)		OT	PHHY2019FR086219		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	7 Mg, Qd		Novartis
	Prednisone			S	Unknown	1 Mg/Kg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16206646	EXPEDITED (15-DAY)		OT	PHHY2019FR086793		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	1 Mg/Kg, Qd		Novartis
	Mycophenolate Mofetil			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16206668	EXPEDITED (15-DAY)		OT	PHHY2019FR086221		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	80 Mg, Qd		Novartis
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16209124	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167764		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2019	16209412	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2019M1036539		80 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Amoxicillin			S		12 G, Daily		Not Reported
	Amoxicillin			S		6 Gram, Qd		Not Reported
	Doxycycline			S		Unk		Not Reported
	Doxycycline			S				Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Hydroxychloroquine			S				Mylan
	Gentamycin /00047101/			S		Unk		Mylan
	Gentamycin /00047101/			S		1.5 Milligram/Kilogram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	12588027	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015378045		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Cortisone			S		Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Remicade			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	13074395	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2791		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown	On High Doses For Several Years		Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	13251344	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cystitis; Drug Ineffective; Drug Intolerance; Dysuria; Guillain-Barre Syndrome; Pain; Synovitis; Urinary Tract Disorder; Urinary Tract Infection	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	13251346	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001206		26 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Enteritis; Meningitis	Plaquenil 200 Mg Tablet			S	Oral	Daily Dose: 300 (Units Not Provided)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	14567043	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016281698		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	640 Mg, Cyclic(Every 4 Weeks)		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Sulfasalazine		C	Unknown	Unk		Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day (2 Every 1 Day(S))		Not Reported
	Xeljanz		C	Oral	5 Mg, 1x/Day		Not Reported
	Hydroxychloroquine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	14615992	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0495		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	14823769	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018055212			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Arava	S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	14845086	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1353			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15178125	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-AUROBINDO-AUR-APL-2018-036863			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus	Ramipril			S	Transplacental	20 Milligram (Exposure Duration: 0-13+6 Weeks)		Aurobindo
	Simvastatin			S	Transplacental	Unk		Aurobindo
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported

Persistent; Ventricular Septal Defect	Pantoprazole	S	Transplacental	Unk	Aurobindo
	Ezetimibe	S	Transplacental	Unk	Aurobindo
	Rivaroxaban	S	Transplacental	Unk	Not Reported
	Aliskiren	S	Transplacental	Unk	Not Reported
	Nicotine	S	Transplacental	Unk	Not Reported
	Metamizole	S	Transplacental	Unk	Not Reported
	Prednisolone	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	Unk	Not Reported
	Salbutamol	S	Transplacental	Unk	Not Reported
	Torasemide	S	Transplacental	Unk	Not Reported
	Dalteparin Sodium	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Tacrolimus	S	Transplacental	Unk	Not Reported
	Enoxaparin	C	Transplacental	Exposure Duration: 0-14 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15258820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2403		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

		Humira			S	Subcutaneous				Not Reported
		Orencia			S	Unknown				Not Reported
		Remicade			S	Unknown				Not Reported
		Apo-Hydroxyquine			S	Unknown				Not Reported
		Apo-Leflunomide			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Sodium Aurothiomalate			S	Unknown				Not Reported
		Meloxicam			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15427742	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2496411-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Joint Warmth; Localised Infection; Osteomyelitis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15549651	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003797		44 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Viraemia	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Mycophenolate Mofetil			S	Oral			Not Reported

Prograf	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Methylprednisolone	S	Oral	Not Reported
Esomeprazole Magnesium	C		Not Reported
Daiphen	C		Not Reported
Alendronate Sodium	C		Not Reported
Cellcept	C		Not Reported
Prograf	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15555435	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016241426		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1week(S)		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg,1 Every 1day(S)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone	S	Unknown	Unk		Not Reported
	Desoximetasone	S	Oral	Unk		Not Reported
	Desoximetasone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15596817	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg 2 Tablet		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15622596	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2016360750		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Muscle Spasms; Off Label Use	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qwk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Percocet			C		Unk, As Needed		Not Reported
	Acetaminophen			C		Unk Unk, As Necessary		Not Reported
	Hydrochloride B1			C	Unknown	Unk		Not Reported
	Oxycodone Terephthalate			C	Unknown	Unk		Not Reported
	Acetaminophen W/Oxycodone			C	Unknown	Unk		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C		Unk		Not Reported
	Oxycodone Hydrochloride/Oxycodone Terephthalate/Paracetamol			C		Unk		Not Reported
	Thiamine Hydrochloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15629164	EXPEDITED (15-DAY)		OT	CA-009507513-1811CAN005668			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported

Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Ukn		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15654784	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018167536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Abatacept	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	25 Milligram		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Simponi	C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Simponi	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz	C		5 Milligram		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15727096	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3760		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15735757	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018108131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Fear Of	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Methotrexate Sodium	S	Oral	25 Milligram, Qwk		Pfizer
	Celebrex	S	Unknown	Unk		Pfizer
	Humira	S	Subcutaneous	Unk		Not Reported
	Prednisone	S	Oral	5 Mg, Qd		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Domperidone	C	Oral	10 Mg, Qd		Not Reported
	Prednisone Acetate	C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15748419	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15760994	NON-EXPEDITED			US-PFIZER INC-2018522386		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Minocycline			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	15760996	NON-EXPEDITED			US-PFIZER INC-2018522384		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S		Unk		Pfizer
	Adalimumab			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16024967	NON-EXPEDITED			US-SA-2019SA054234			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16081181	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013819			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased;	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo

Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Liver Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Lung	Arava	S	Unknown	20 Milligram, Once A Day	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Once A Day	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram, 2 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, 1 Every 2 Weeks	Not Reported
	Methotrexate	S	Oral	20 Milligram, 1 Every 1 Week	Not Reported
	Naproxen	S	Oral	1000 Milligram, Once A Day	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Palafer Cf	S	Unknown	Unk, Once A Day	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Celebrex	C	Oral	200 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16210459	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020148			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Wrist Surgery	Meloxicam			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16211377	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-020286			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Arava			S	Unknown	20 Milligram, Once A Day		Not Reported
	Co Atenolol			S	Unknown	25 Milligram, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, 2 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 1 Every Week		Not Reported
	Methotrexate			S	Oral	25 Milligram, 2 Every 1 Week		Not Reported
	Naprosyn			S	Oral	1000 Milligram, Once A Day		Not Reported
	Orencia			S	Unknown	Unk Unk, Once A Day		Not Reported
	Palafer Cf			S	Unknown	Unk Unk, Once A Day		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16211385	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020289			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Pantoprazole	S	Unknown	40 Milligram, Once A Day	Aurobindo
	Abatacept	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown	20 Milligram, Once A Day	Not Reported
	Ascorbic Acid	S	Unknown	Unk	Not Reported
	Atenolol	S	Unknown	25 Milligram, Once A Day	Not Reported
	Co Atenolol	S	Unknown	20 Milligram	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Ferrous Fumarate	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram,Two Times A Day	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once A Day	Not Reported
	Naprosyn	S	Unknown	1000 Milligram, Once A Day	Not Reported
	Naproxen	S	Oral	100 Milligram, Once A Day	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Palafer	S	Unknown	Unk	Not Reported
	Pantoloc	S	Unknown	40 Milligram, Once A Day	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Celecoxib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16212668	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016514082		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Treatment Failure; Tremor	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 14 Days		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Zopiclone			C		7.5 Mg, Qd At Night		Not Reported
	Folic Acid			C	Oral	2.5 Mg, 1x/Day		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, 1x/Day		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16213013	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16213447	EXPEDITED (15-DAY)		HO, OT	IT-CELLTRION INC.-2019IT020181			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cytomegalovirus Hepatitis; Cytomegalovirus Infection Reactivation; Hypergammaglobulinaemia; Hyponatraemia; Infusion Related Reaction; Jaundice; Leukopenia; Malaise; Product Use In Unapproved Indication; Pyrexia	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported

					Cyclophosphamide	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Cyclophosphamide	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Cyclophosphamide	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Cyclophosphamide	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Mycophenolate Mofetil	S		Unk	Not Reported
					Hydroxychloroquine	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16213706	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018410356		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16213880	NON-EXPEDITED			US-SEBELA IRELAND LIMITED-2018SEB00158			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Imuran	S		Unk		Sebela
	Humira	S	Subcutaneous			Not Reported
	Xeljanz	S		Unk		Not Reported
	Enbrel	S		Unk		Not Reported
	Methotrexate	S	Oral			Not Reported
	Plaquenil	S		Unk		Not Reported
	Prednisolone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16213924	NON-EXPEDITED			US-SEBELA IRELAND LIMITED-2019SEB00080			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Imuran			S		Unk		Sebela
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16213958	NON-EXPEDITED			US-SEBELA IRELAND LIMITED-2019SEB00056			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Imuran			S		Unk		Sebela
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

		Azulfidine			S		Unk			Not Reported
		Methotrexate			C		Unk			Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16214216	NON-EXPEDITED			US-SA-2019SA105970			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Anakinra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2019	16214366	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1182		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	10756158	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014345426		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Bone Disorder; Condition Aggravated; Fall; Lower Limb Fracture; Osteoarthritis; Osteoporosis; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete; Tibia Fracture; Wrist Fracture	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	Wean Dose		Unknown
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	14383371	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	14838782	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018181641			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility	Enbrel			S	Unknown	Unk		Pfizer

Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Unknown	20 Milligram, Qwk		Pfizer
	Plaquenil	S	Unknown	200 Milligram, Bid		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Arava	S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	15568780	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1077		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	15838145	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019021334		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	2 Df, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	1 Mg, Qd		Pfizer
	Sulfasalazine			S	Rectal	1 G, Bid		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	20 G, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg, Unk		Not Reported
	Methotrexate Sodium			C	Unknown	25 Mg, Unk		Not Reported
	Methotrexate Sodium			C	Unknown	1 Mg, Qwk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16215610	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2019-CA-1039548		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular	Azathioprine			S	Unknown	100 Milligram Daily;		Not Reported
	Prednisone			S	Unknown	50 Milligram Daily;		Actavis
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Cellcept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox	S	Intravenous (not otherwise specified)			Not Reported
	Procytox	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	C	Unknown	100 Milligram Daily;		Not Reported
	Diphenhydramine	C	Oral			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Sodium Succinate	C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16215623	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-205616		35 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown			Sun
	Methylprednisolone Aceponate			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216180	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2747836-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Drug Ineffective; Empyema; Foot Deformity; Hand Deformity; Joint Effusion; Joint Stiffness; Limb	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Operation; Musculoskeletal Stiffness; Nodule; Pneumonia; Rheumatoid Arthritis; Scar; Toe Operation	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Ibuprofen	S	Unknown	Twice A Day		Not Reported
	Hydroxychloroquine	S	Urethral			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Vitamin D2	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216221	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-01		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Wrist Surgery	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216326	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-021112			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Benadryl			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira	S	Unknown	Unk		Not Reported
	Imuran	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Procytox	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5.0 Milligram, Two Times A Day		Not Reported
	Ezetrol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216335	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-021145			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Benadryl			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Procytox			S	Unknown	2000 Milligram		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported

	Ezetrol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216568	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019168322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16216633	EXPEDITED (15-DAY)		OT	PHHY2019FR086790		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Ciclosporin			S	Unknown	Unk		Novartis
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	1 Mg/Kg, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Erythropoietin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2019	16219008	EXPEDITED (15-DAY)		DE	NL-BAUSCH-BL-2019-011280		67 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Musculoskeletal Pain; Neoplasm Malignant; Product Use In Unapproved Indication	Prednisolone			S	Unknown				Bausch And Lomb
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16155209	NON-EXPEDITED			US-JNJFOC-20190316971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Injection Site Reaction	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16219800	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021111			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	2.5 Mg, Qd		Aurobindo
	Prednisone Tablet			S	Unknown	120 Mg, Qd		Aurobindo
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Erythropoietin			S	Unknown	Unk		Not Reported
	Tn			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16220395	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019059984		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Unk	Amgen
	Methotrexate		S	Unknown	25 Milligram, Qwk	Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram, Bid	Not Reported
	Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	15128531	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002344		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthritis Infective; Arthropathy; Asthenia; Bone Pain; Bronchitis; Burns Third Degree; Chest Pain; Choking; Cough; Croup Infectious; Drug Hypersensitivity; Drug Ineffective; Feeling Abnormal; Gait Disturbance; Malaise; Nasopharyngitis; Pain In Extremity; Pain In Extremity; Pain In Extremity; Secretion Discharge; Sinusitis; Upper Respiratory Tract Infection; Viral Infection; White Blood Cell Count Decreased	Plaquenil			S	Unknown	Unknown		Concordia
	Sarilumab			S	Subcutaneous			Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sarilumab			S	Unknown	Autoinjector		Not Reported
	Ambien			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	16187491	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine Gf			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	11701527	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015261409		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Infective; Diabetes Mellitus; Ear Infection; Infection; Localised Infection; Pain; Sepsis; Therapeutic Product Effect Incomplete	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Oxycontin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	13879099	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017357261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthritis; Back Pain; Bone Pain; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive;	Enbrel			S	Unknown	500 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Amitriptyline			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk(Solution)		Not Reported

Immunodeficiency; Joint Swelling; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Sacroiliitis; Somnolence; Spinal Osteoarthritis; Spondyloarthropathy; Therapeutic Product Effect Incomplete	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Apo Meloxicam		S	Unknown	Unk		Not Reported
	Mobicox		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Meloxicam		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S		Unk		Not Reported
	Folic Acid		C		Unk		Not Reported
	Methotrexate		C		Unk		Not Reported
	Naproxen		C		Unk		Not Reported
	Pantoprazole		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	15440981	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180928108		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Headache; Lower Respiratory Tract Infection; Pituitary Tumour; Visual Impairment	Simponi I. V.			S	Intravenous (not otherwise specified)			Not Reported
	Simponi I. V.			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	15670358	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018487476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown	50 Milligrams		Pfizer
	Doxycycline Hyclate			S	Unknown	50 Milligrams		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Milligrams	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C		5 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	15691437	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324261AA			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity;	Triamcinolone Acetonide			S				Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen			S				Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Immune Globulin Nos			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported

Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel		S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel		S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw		Not Reported
	Infliximab		S		5 Mg		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	15691818	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018498912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16141773	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016288735		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	4 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	300 Milligram, Qd	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg,Bid	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qwk	Not Reported
Methotrexate	C	Unknown	0.8 Ml, Unk	Not Reported
Methotrexate	C		Unk Unk, Qwk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16145228	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-017191			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Lymphopenia; Rash; Rash Erythematous; Skin Plaque; Subacute Cutaneous Lupus Erythematosus	Simvastatin Film-Coated Tablet	S	Oral	Unk		Aurobindo
	Pravastatin	S	Unknown	Unk		Aurobindo
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Acetylsalicylic Acid	C	Unknown	Unk		Not Reported
	Lansoprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16221477	EXPEDITED (15-DAY)		OT	US-SA-2019SA102265			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S				Not Reported
	Benzylpenicillin			S				Not Reported
	Budesonide			S				Not Reported
	Gentamicin Sulfate			S				Not Reported
	Orencia			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfanilamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16221842	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001192		68 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choroidal Neovascularisation	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Myslee			C				Not Reported
	Mizoribine			C				Not Reported

	Predonine			C						Not Reported
	Bayaspirin			C						Not Reported
	Bayaspirin			C						Not Reported
	Bonoteo			C						Not Reported
	Bonoteo			C						Not Reported
	Bactramin			C						Not Reported
	Bactramin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16221843	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001229		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Mania; Off Label Use; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Methylprednisolone			S	Intravenous (not otherwise specified)	High Dose		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Immune Globulin Iv			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Psoralen			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16221938	NON-EXPEDITED			PHEH2019US017135			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16222924	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-076435		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Aleve			S	Oral	Unk		Bayer
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Amitriptyline			S				Not Reported
	Celecoxib			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Misoprostol			S				Not Reported
	Prednisone			S				Not Reported
	Pregabalin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16223639	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016468901		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Nodule; Weight Decreased	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Oral	17.5 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Plaquenil			S	Unknown	200 Mg, 2x/Day		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Humira			S	Unknown	40 Mg, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Rituxan			S		Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16225026	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017336269		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure; Vomiting	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	30 Mg, 1x/Day		Not Reported
	Metoject			C	Subcutaneous	1.5 Ml, Weekly		Not Reported
	Folic Acid			C	Oral	1 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, 1x/Day		Not Reported
	Maxeran			C	Buccal	10 Milligram, As Needed (4 Times A Day When Necessary)		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Metoclopramide Hydrochloride			C	Oral	10 Mg, 4x/Day		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Weekly		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Weekly		Not Reported

Methotrexate	C	Subcutaneous	25 Mg, Weekly		Not Reported
Salazopyrin	C	Oral	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16225780	NON-EXPEDITED			PHEH2019US016577			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16366654	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Skin Discolouration	Plaquenil Tab 200mg			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	11311182	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015058278		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Disorder; Back Pain; Blister; Decreased Appetite; Dyspepsia; Herpes Virus Infection; Infection; Joint Swelling; Localised Infection; Pain; Pelvic Pain; Renal Failure; Sepsis; Skin Fissures; Vaginal Infection; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid)		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Indomethacin			S		Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Prednisone			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	12842907	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-083791		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Condition Aggravated; Diarrhoea; Drug Ineffective; Muscle Atrophy	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	13602530	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-089238			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Headache; Impaired Work Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Qmo		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20.0 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, 1 Every 1 Month		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, 1 Every 1 Week		Not Reported

	Methotrexate Sodium		S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/		S	Oral	400 Mg, Qd	Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	14400801	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000187			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Plaquenil Tablet			S	Oral	Unknown		Concordia
	Hydroxychloroquine Tablet			S	Unknown	Unknown		Concordia
	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Actemra			C				Not Reported
	Ketoprofen			C				Not Reported
	Naproxen			C				Not Reported
	Crestor			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Omeprazole			C				Not Reported
	Xeljanz			C				Not Reported

	Prednisone			C						Not Reported
	Methotrexate			C						Not Reported
	Rosuvastatin Calcium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	14404886	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-000991		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pancreatitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Hydromorph Contin			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	14871903	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018188219		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea Haemorrhagic; Dyspepsia; Pre-Existing Condition Improved; Therapeutic Response Unexpected	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Pantoprazole			S	Oral	20 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	150 Mg, 1x/Day		Not Reported
	Allegra			C		Unk, 1x/Day		Not Reported
	Aromasin			C		Unk Unk, 1x/Day		Not Reported
	Calcium + Vit D			C		Unk Unk, 2x/Day		Not Reported
	Meloxicam			C		Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	15642888	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	15708015	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3650		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	15719679	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018507000			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Haematoma Infection	No Subject Drug			S		No Dose Given		Not Reported

	Sulfasalazine	S	Unknown	2000 Mg, 1x/Day	Pfizer
	Tocilizumab	S	Intravenous (not otherwise specified)	800 Mg, Every 4 Weeks (Last Recent Dose Given Prior To The Events Was Given On 03may2018)	Not Reported
	Hydroxychloroquine	S		400 Mg, 1x/Day	Not Reported
	Clexane	C		Unk	Not Reported
	Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
	Allopurinol	C	Unknown	Unk	Not Reported
	Lodotra	C		Unk	Not Reported
	Torem [Torasemide]	C		Unk	Not Reported
	Lyrica	C		Unk	Not Reported
	Wobenzym N [Bromelains;Chymotrypsin;Pancreatin;Papain;Rutoside;Trypsin	C		Unk	Not Reported
	Spiro Comp	C		Unk	Not Reported
	Bisoprolol	C		Unk	Not Reported
	Eliquis	C		Unk	Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]	C		Unk	Not Reported
	Ibuprofen	C		Unk	Not Reported
	Xipamid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	15982552	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Failure	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qwk		Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Bid		Not Reported
	Methotrexate	S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/	S	Oral	200 Milligram, Bid		Not Reported
	Prednisone	C	Oral	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Folic Acid	C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16162034	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000920		27 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pericarditis	Plaquenil 200 Mg Tablet			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia
	Prograf			C				Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16200281	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Po Die		Concordia
	Methotrexate			S	Oral	Unknown		Not Reported

	Methotrexate	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16210242	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000966			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Mycobacterium Tuberculosis Complex Test Positive; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226437	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001137		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergic Oedema; Arthralgia; Drug Hypersensitivity; Drug Level Decreased; Pruritus; Rash; Rheumatoid Arthritis; Swelling	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous	40 Mg/0.8ml		Not Reported
	Prozac			C				Not Reported
	Buspiron [Hyoscine Butylbromide;Metamizole Sodium Monohydrate]			C				Not Reported
	Equetr			C				Not Reported
	Premarin			C				Not Reported

	Vitamin Bl2	C		Not Reported
	Folic Acid	C		Not Reported
	Vitamin C	C		Not Reported
	Omega 3	C		Not Reported
	Vitamin E	C		Not Reported
	Turmeric	C		Not Reported
	Fioricet	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226439	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001058			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226440	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001176			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Neutropenia	Hydroxychloroquine			S				Concordia
	Xeljanz			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226442	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001226			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endocarditis	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226443	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001200			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226444	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001217			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226445	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001225			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Hypoaesthesia; Joint Swelling; Pneumonia	Plaquenil			S				Concordia
	Xeljanz Tablet			S	Unknown	Increased To 5 Mg Twice Daily		Not Reported
	Xeljanz Tablet			S	Unknown	Increased To 5 Mg Twice Daily		Not Reported
	Enbrel			S				Not Reported
	Mtx			S	Unknown	15 Mg Per Week As Of Nov/2016		Not Reported
	Mtx			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226488	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110509		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Infection; Product Use Issue; Rheumatoid Arthritis	Hydroxychloroquine			S		400 Mg		Sanofi
	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		17.5 Mg		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Ergocalciferol			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin B12 [Cyanocobalamin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226489	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110489		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine			S		400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226738	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001122			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Erythema; Hallucination; Pain In Extremity; Psoriasis	Plaquenil			S	Subcutaneous			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16226844	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16227479	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019AMR072249		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Neutropenia; Rash; White Blood Cell Count Decreased	Benlysta			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16228133	NON-EXPEDITED			US-PURDUE-USA-2019-0146622			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain	Oxycodone Hydrochloride (Similar To Nda 22-272)			S	Oral			Purdue
	Flector /00372302/			S	Transdermal			Not Reported
	Oxymorphone			S	Oral			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Pennsaid			S	Unknown			Not Reported
	Voltaren /00372301/			S	Unknown			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16230363	EXPEDITED (15-DAY)		DE, OT	BE-ELI_LILLY_AND_COMPANY-BE201904010997		30 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Cardiac Arrest; Fall; Loss Of Consciousness	Adcirca 20mg			S	Oral	20 Mg, Bid		Not Reported
	Uptravi			S	Oral	1000 Mcg, Bid		Not Reported
	Uptravi			S	Oral	Unk, Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Qd		Not Reported
	Volibris			S	Oral	10 Mg, Qd		Not Reported
	Nifedipine			C	Oral	60 Mg, Qd		Not Reported

Cozaar	C	Oral	100 Mg, Qd		Not Reported
Temesta [Astemizole]	C	Oral	2.5 Mg, Qd		Not Reported
Methylprednisolone	C	Oral	6 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16231063	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001218			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Asthma; Bronchitis; Chronic Obstructive Pulmonary Disease; Laryngitis; Peripheral Swelling; Pneumonia; Sinusitis; Visual Impairment	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16231064	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001182			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Therapeutic Response Shortened	Plaquenil			S	Unknown	Decreases From 2 To 1		Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2019	16231065	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001235			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Infection; Infection; Influenza Like Illness;	Hydroxychloroquine			S				Concordia
	Methotrexate Sodium			S				Not Reported

Pneumonia; Upper Respiratory Tract Infection; Urinary Tract Infection	Infliximab (Remicade)	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	15219684	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002653			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastrointestinal Disorder; Liver Function Test Abnormal; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Mtx			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	15615931	EXPEDITED (15-DAY)		HO, OT	DE-ACCORD-092123		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer; Deep Vein Thrombosis; Foot Fracture; Fracture; Hypogammaglobulinaemia; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Radiculopathy; Rotator Cuff Syndrome; Secondary Immunodeficiency; Spinal Osteoarthritis; Stenosis;	Methotrexate			S	Unknown			Accord
	Cyanocobalamin/Folic Acid			S	Unknown			Not Reported
	Quensyl			S	Unknown	Given 2017,2018		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Most Recent Dose: /Jan/2015		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Anastrozole			C				Not Reported
	Celecoxib			C				Not Reported

Stomatitis; Vitamin D Deficiency	Folinic Acid	C			Not Reported
	Colecalciferol	C			Not Reported
	Pantozol	C			Not Reported
	Cotrimoxazole	C			Not Reported
	Tapentadol	C			Not Reported
	Prednisolone	C			Not Reported
	Mabthera	S	Intravenous (not otherwise specified)		Not Reported
	Mabthera	S	Intravenous (not otherwise specified)		Not Reported
	Mabthera	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	15856193	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-005593		86 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Product Use In Unapproved Indication; Pruritus; Rash	Opdivo			S	Unknown	Unk, Q2wk		Bristol Myers Squibb
	Opdivo			S	Intravenous (not otherwise specified)	480 Mg, Q4wk		Bristol Myers Squibb
	Opdivo			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Prednisone			C	Unknown	20 Milligram		Not Reported
	Prednisone			C	Unknown	5 Milligram		Not Reported
	Prednisone			C	Unknown	60 Unk		Not Reported
	Triamcinolone /00031902/			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	50 Milligram		Not Reported
	Advil /00044201/			C	Unknown	200 Milligram		Not Reported
	Amlodipine			C	Unknown	5 Milligram		Not Reported

			Aspirin /00002701/		C	Unknown	81 Milligram		Not Reported
			Claritin /00413701/		C	Unknown	10 Milligram		Not Reported
			Desoximetasone		C	Unknown	Unk		Not Reported
			Enalapril Maleate		C	Unknown	10 Milligram		Not Reported
			Hydroxyzine Hydrochloride		C	Unknown	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	15916824	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000198			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Ineffective; Myocardial Infarction	Plaquenil			S	Unknown			Concordia
	Adalimumab			S	Unknown	Unknown		Not Reported
	Methotrexate			C				Not Reported
	Reactine (Cetirizine Hydrochloride)			C				Not Reported
	Xeljanz			C				Not Reported
	Celebrex			C				Not Reported
	Advil			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	15967384	NON-EXPEDITED			US-SA-2019SA041886			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Peripheral Swelling	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Xeljanz Xr			C	Oral	11 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16155747	EXPEDITED (15-DAY)		LT, OT	NO-CELLTRION INC.-2019NO020033			Unknown	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent; Gastrointestinal Disorder	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Used Low-Dose Methotrexate Over Long Periods (Not Further Stated), But Eventually Withdrawn (Da		Not Reported
	Prednisolon			S	Oral	Unk		Not Reported
	Prednisolon			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16216710	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019065957		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Pain; Contusion; Fatigue; Feeling Abnormal; Heart Rate Increased; Injection Site Pain; Insomnia; Irritability; Speech Disorder	Benlysta Solution For Injection In Pre-Filled Pen			S	Subcutaneous	Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16221049	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001194			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased;	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

Meningitis; Migraine; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Benzylpenicillin			S	Unknown	Not Reported
	Budesonide			S	Unknown	Not Reported
	Sulfanilamide			S	Unknown	Not Reported
	Gentamycin			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16226438	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001156			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Joint Warmth; Localised Infection; Osteomyelitis; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231251	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021719			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	Unk, 10 Mg/Day		Aurobindo
	Prednisone Tablet			S	Unknown	1 Milligram/Kilogram, Once A Day		Aurobindo
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

			Hydroxychloroquine		S	Unknown	Unk			Not Reported
			Hydroxychloroquine		S	Unknown	Unk			Not Reported
			Erythropoietin		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231252	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021717			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Prednisone Tablet			S	Unknown	70 Milligram, Once A Day,70 Mg, Qd		Aurobindo
	Prednisone Tablet			S	Unknown	50 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Erythropoietin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231258	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021716			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	2mg/Kg/D		Aurobindo
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231284	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021708			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone Tablet			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Prednisone Tablet			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231286	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021710			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Prednisone Tablet			S	Unknown	1 Milligram (1 Mg/Kd/Day)		Aurobindo
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Erythropoietin			S	Unknown	Unk		Not Reported
	Erythropoietin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Immunglobulin			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231380	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2622		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Pulmonary Mass; Rheumatoid Nodule; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231607	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021718			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone Tablet			S	Unknown	15 Mg/D		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Erythropoietin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231616	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021711			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	7 Mg/D		Aurobindo
	Prednisone Tablet			S	Unknown	1 Milligram/Kilogram,1mg/Kg/D		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231620	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021707			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	50 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	1 Gram, (1g/3d)		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16231622	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-021706			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	80mg/D		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16233928	NON-EXPEDITED			US-SA-2019SA037757			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16234310	EXPEDITED (15-DAY)		OT	PHHY2019FR064695		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nephropathy Toxic; Skin Hypopigmentation; Systemic Lupus Erythematosus	Pemetrexed Disodium	S	Unknown	Unk		Not Reported
	Betamethasone	S	Topical	Unk		Novartis
	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported
	Prednisone	S	Oral	1 Mg/Kg, Qd		Not Reported
	Cisplatin	S	Unknown	Unk		Not Reported
	Nivolumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2019	16235252	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2019M1037501			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Salbutamol			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental	Unk		Not Reported
	Ramipril			S	Transplacental	20 Milligram		Not Reported
	Torasemide			S	Transplacental	Unk		Not Reported
	Rivaroxaban			S	Transplacental	Unk		Mylan
	Metamizole			S	Transplacental	Unk		Mylan
	Prednisolone			S	Transplacental	Unk		Mylan
	Nicotine			S	Transplacental	Unk		Mylan
	Enoxaparin			S	Transplacental	Unk		Mylan
	Aliskiren			S	Transplacental	Unk		Mylan
	Tacrolimus			S	Transplacental	Unk		Mylan
	Acetylsalicylic Acid			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	11666370	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015357741		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Haematemesis; Hepatitis; Hepatotoxicity; Jaundice; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S		3 Mg/Kg, Unk		Not Reported
	Rituxan			S		1000 Mg, Unk		Not Reported
	Actemra			S		8 Mg/Kg, Unk		Not Reported
	Vitamin C			C		Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	11927011	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015452389		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cataract; Dizziness; Drug Ineffective; Fatigue; Headache; Nausea; Osteoarthritis; Peripheral Swelling; Therapeutic Response Unexpected; Viral Infection; White Blood Cell Count Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	12225946	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015285061		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Bone Pain;	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Burning Sensation; Condition Aggravated; Diarrhoea; Fatigue; Limb Mass; Malaise; Peripheral Embolism; Peripheral Swelling; Sciatica; Urinary Tract Infection; Wound	Arava	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
	Methotrexate	C	On Hold	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	12237886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015239390		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Foot Fracture; Malaise; Nausea; Skin Depigmentation; Therapeutic Product Effect Incomplete; Treatment Failure	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Plaquenil			S		400 Mg, Unk		Not Reported
	Cortisone			C		2.5 Mg, Alternate Day		Not Reported
	Desoximetasone			C		2.5 Mg, Unk [1 Every 2 Day(S)]		Not Reported
	Desoximetasone			C		5 Mg, 1x/Day		Not Reported
	Desoximetasone			C		2.5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	12560702	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016091059		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Unk		Not Reported

Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	14766954	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1092		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	14859814	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1029231		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use	Prednisone		S	Unknown	10 Mg, Qd		Not Reported
	Prednisone		S		10 Mg, Unk		Not Reported
	Acetylsalicylic Acid		S		100 Mg, Qd		Not Reported
	Acetylsalicylic Acid		S	Unknown	75 Mg, Qd		Not Reported
	Acetylsalicylic Acid		S		100 Mg, Unk		Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine		S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	15523278	EXPEDITED (15-DAY)		OT	SA-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-188032		26 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Tuberculosis	Hydroxychloroquine			S	Unknown			Sun
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Prednisolone			S	Unknown	10-15 Mg Daily		Taro
	Rituximab			S	Unknown	1000 Mg Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	15631058	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1194		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Loss Of Personal Independence In Daily Activities; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Percocet	C	Unknown	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown	Not Reported
	Hydrochloride B1	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Oxycodone Hydrochl W/Oxycodone Tereph/Paracet	C	Unknown	Not Reported
	Thiamine Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16224322	EXPEDITED (15-DAY)			CA-SA-2019SA102666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Therapeutic Response Decreased; Vomiting	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16236502	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-022138			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone Tablet			S	Unknown	Unk, 1 Mg/Kg/D		Aurobindo
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16238068	NON-EXPEDITED			US-PFIZER INC-2019173935			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16238887	NON-EXPEDITED		OT	US-SA-2019SA111251			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Liver Function Test Increased; Meningitis; Migraine; Therapeutic Product Effect Decreased	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Budesonide			S				Not Reported
	Leflunomide			S				Sanofi
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Enbrel			S				Not Reported
	Penicillin [Penicillin Nos]			S				Not Reported
	Sulfanilamide			S				Not Reported
	Gentamycin [Gentamicin]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16238947	NON-EXPEDITED			US-SA-2019SA111875			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16239626	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1033920			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Disorder; Condition Aggravated; Headache	Prednisone Tablets Usp			S	Oral	3 Dosage Form, Qd		Mylan
	Prednisone Tablets Usp			S		25 Milligram		Mylan

	Prednisone Tablets Usp	S		20 Milligram		Mylan
	Prednisone Tablets Usp	S		15 Milligram		Mylan
	Prednisone Tablets Usp	S		12.5 Milligram		Mylan
	Relpax	S	Oral	40 Milligram, Prn		Mylan
	Hydroxychloroquine	S	Oral	200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16240333	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2019-0009986		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Dilaudid			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2019	16242888	DIRECT						Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective	Plaquenil			S				Not Reported
	Naprosyn			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	12358050	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016059330		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia;	Enbrel			S	Unknown	Unk		Amgen

Depression; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Pain; Osteoarthritis; Pain In Extremity; Peripheral Swelling; Psoriasis; Rash; Rash; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	13167858	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Reactine /00884302/	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Reactine /00884302/	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	14741313	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018074269		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Dry Mouth; Fatigue; Fear Of Injection; Groin Abscess; Headache; Heart Rate Increased; Hot Flush; Intentional Product Use Issue; Palpitations; Skin Ulcer; Sleep Apnoea Syndrome; Uterine Disorder; Weight Increased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Naproxen			C		Unk		Not Reported
	Plaquenil /00072602/			C		Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	15610084	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3233		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Musculoskeletal Disorder; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	15685747	EXPEDITED (15-DAY)		HO	CA-SAKK-2018SA324358AA			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Acetonide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
	Immune Globulin Nos			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	12.5 Unk, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported

	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw			Not Reported
	Infliximab			S	Unknown	5 Mg			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16002885	NON-EXPEDITED			US-SA-2019SA050776			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16234885	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016347636		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis;	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Swelling; Therapy Non-Responder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16235856	EXPEDITED (15-DAY)			CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Therapeutic Response Decreased; Vomiting	Plaquenil			S				Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16241909	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001259		43 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Plaquenil			S	Unknown			Concordia
	Erythromycin			S	Unknown			Concordia
	Cefalexin			S	Unknown			Not Reported
	Arava			C				Not Reported
	Simponi			C				Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2019	16242891	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Product Dose Omission	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown	Everyday Besides Sunday		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Prednisone			S	Oral	Alternate Day (Every Second For Next 2 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2019	15480596	NON-EXPEDITED		OT	US-AMGEN-USASP2018140304		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Adverse Reaction; Goitre; Lymphadenopathy; Malaise; Pain In Extremity; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2019	15491303	EXPEDITED (15-DAY)		OT	US-UCBSA-2018044550			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fear Of Injection; Mycobacterium Tuberculosis Complex Test Positive; Rheumatoid Arthritis; Treatment Failure	Cimzia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		17.5 Mg, Weekly (Qw)		Not Reported
	Tofacitinib Citrate			C		Unk		Not Reported
	Inh			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	11496388	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015181505		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Kidney Infection; Nephrolithiasis; Urinary Tract Infection	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	200 Mg, 2x/Day		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg Weekly		Unknown
	Plaquenil /00072602/			S		200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	12265974	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015219232		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dizziness; Ear Infection; Fatigue; Headache; Joint Effusion; Joint Swelling; Lower Respiratory Tract	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Infection; Malaise; Migraine; Nasopharyngitis; Nausea; Pneumonia; Sinusitis	Methotrexate Sodium	S	Oral	15 Mg, Weekly		Pfizer
	Celebrex	S	Oral	Unk		Pfizer
	Arava	S	Oral	10 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	13507425	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002637		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Exposure During Pregnancy; Pustular Psoriasis	Plaquenil 200 Mg Tablet			S	Oral	200 Mg Qd And 400 Mg Qd, Alternatively		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg Qd And 400 Mg Qd, Alternatively		Concordia
	Predonine			C	Oral			Not Reported
	Predonine			C				Not Reported
	Predonine			C				Not Reported
	Predonine			C		Stared To Be Tapered		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	14002006	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-084193			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	7.5 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	14067000	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201710-005643		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral			Concordia
	Amitriptyline			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Misoprostol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	15489168	NON-EXPEDITED			US-PFIZER INC-2018352847		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Product Use Issue; Retinal Disorder; Visual Impairment	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	15664683	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Episcleritis; Herpes Zoster; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	With Single Dose Prefilled Syringe		Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	15728553	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-108871		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	366.0 Absent		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	150 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	1000 Milligram		Not Reported

			otherwise specified)		
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Unknown	365 Absent	Not Reported
	Sulfasalazine	C	Unknown	1000 Milligram, Bid	Not Reported
	Tylenol /00020001/	C	Unknown	3000 Milligram	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Nexium /01479302/	C	Unknown	40 Milligram, Qd	Not Reported
	Wellbutrin	C	Unknown	300 Milligram, Qd	Not Reported
	Trazodone	C	Unknown	200 Milligram, Qd	Not Reported
	Suphedrine /00005601/	C	Unknown	10 Milligram, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Qd	Not Reported
	Lumigan Rc	C	Ophthalmic	Unk, Qd	Not Reported
	Tylenol Extra Strength	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16213981	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1181		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Disorder; Back Pain; Blister; Decreased Appetite; Dyspepsia; Herpes Virus Infection; Infection; Joint Swelling; Localised Infection; Pain; Pelvic Pain; Renal Failure; Sepsis; Skin Fissures; Vaginal Infection; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Fluconazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248356	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001251			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Optic Atrophy	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248357	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001110			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Sepsis; Headache; Infusion Related Reaction; Pneumonia; Urticaria	Plaquenil			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248358	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001128		33 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Deafness Neurosensory; Headache; Retinal Disorder; Uveitis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Meloxicam			C				Not Reported

		Metformin			C						Not Reported
		Omeprazole			C						Not Reported
		Vitamin D2			C						Not Reported
		Potassium			C						Not Reported
		Vitamin B			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248359	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001238		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Memory Impairment; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade (Infliximab)			S	Unknown			Not Reported
	Actemra (Tocilizumab)			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Unknown			Not Reported
	Orencia (Abatacept)			S	Unknown			Not Reported
	Enbrel (Etanercept)			S	Unknown			Not Reported
	Sulfasalazine (Sulfasalazine))			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16248360	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001213			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; Dysstasia; Gait Inability; Pain	Plaquenil			S				Concordia
	Plaquenil			S				Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Cimzia			S				Not Reported
	Cimzia			S				Not Reported
	Otezla			S				Not Reported

	Otezla	S		Not Reported
	Lyrica	S		Not Reported
	Lyrica	S		Not Reported
	Stelara	S		Not Reported
	Stelara	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16249302	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1270		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Swelling; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16251042	NON-EXPEDITED			US-PFIZER INC-2019180964		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2019	16252998	NON-EXPEDITED		OT	US-SA-2018SA133300			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Rheumatoid Arthritis	Arava			S	Oral	10 Mg,Bid		Sanofi
	Plaquenil			S	Oral	Unk Unk,Bid		Sanofi
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			C		Unk Unk, Unk		Not Reported
	Xeljanz Xr			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	13121821	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016586695		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intervertebral Disc Protrusion; Treatment Failure	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		200 Mg, Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	13520000	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038141		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, Qd		Not Reported

Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Leflunomide	S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown	10 Mg, Qd		Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Plaquenil /00072602/	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	14566246	NON-EXPEDITED		HO	US-PFIZER INC-2018074823		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk Unk, Weekly (8 Tabs 1xwk)		Pfizer
	Hydroxychloroquine			S		1 Df, 1x/Day		Not Reported
	Metoprolol			C		50 Mg, 2x/Day		Not Reported
	Glimepiride			C		2 Mg, 1x/Day		Not Reported
	Pravastatin			C		40 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	14751941	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-019988			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Missed Labour	Prednisone			S	Unknown	15 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15113399	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002193		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Injection Site Reaction; Paralysis; Therapeutic Product Effect Decreased; Transaminases Increased	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15457873	EXPEDITED (15-DAY)			JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003427		53 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Medrol Acne			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Alfacalcidol			C				Not Reported
	Alendronate Sodium			C				Not Reported
	Imidapril Hydrochloride			C				Not Reported
	Atorvastatin			C				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported
	Xalatan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15631235	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0706		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Haematemesis; Jaundice; Nausea; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Vitamin C			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15778803	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004217		29 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Exposure During Pregnancy; Gestational Diabetes	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prograf			C				Not Reported
	Edirol			C				Not Reported
	Olopatadine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15958882	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endocarditis	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15978234	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	15978320	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	400 Mg, Qd		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Caffeine W/Codeine Phosphate/Meprobamate/Para	C	Unknown			Not Reported
	Dorzolamide And Timolol	C	Ophthalmic			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Levothyroxine	C	Unknown			Not Reported
	Prednisone	C	Unknown	7 Mg, Qd		Not Reported
	Ramipril	C	Unknown	1 Df, Unk		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qwk		Not Reported
	Timolol Maleate	C	Unknown	2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16126123	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-028078			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

	Doxycycline	S	Unknown	50 Milligram		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Simponi	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16136516	NON-EXPEDITED			PHEH2019US012629			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperhidrosis; Vertigo; Vomiting	Hydroxychloroquine Sulphate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253468	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001243		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	Weaned From 60 To 20 Mg/D		Not Reported
	Prednisone			S	Unknown	Waned From 60 To 20 Mg/D		Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Tmp-Smx(Bactrim)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253469	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001260			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Petechiae; Platelet Count Decreased; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253824	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001287		40 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16253937	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039666			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Sulfasalazine	S	Unknown	Unk		Not Reported
	Varicella Zoster H	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone	C	Oral	Unk		Not Reported
	Diclofenac	C	Unknown	100 Milligram		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid= 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16254595	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001272			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypersensitivity Pneumonitis; Interstitial Lung Disease	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			C				Not Reported
	Doxycycline			C				Not Reported
	Xeljanz			C				Not Reported
	Celebrex			C				Not Reported
	Tylenol			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16254745	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1298		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Osteoarthritis; Osteoporosis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported
	Hydroxychloroquine Phosphate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16255951	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016247250		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Psoriasis; Rash	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2019	16258094	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019179990		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, Unk		Not Reported
	Arava			C		20 Mg, Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	11927006	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016026743		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Condition Aggravated; Hypoacusis; Rheumatoid Arthritis	Celebrex			S		Unk		Pfizer
	Caltrate Plus			S		Unk		Unknown
	Centrum			S		Unk		Pfizer
	Folic Acid			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Actonel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	13278888	EXPEDITED (15-DAY)		HO	CA-AMGEN-CANSP2017029881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Oral	10 Mg, Unk, For Two Months		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Viread			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	14699775	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1018868			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Maculopathy; Off Label Use; Retinal Toxicity; Visual Acuity Reduced; Visual Field	Hydroxychloroquine			S	Unknown	Qd,>1500 G On Varying Doses		Not Reported

Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	15633824	NON-EXPEDITED		OT	US-SA-2018SA317174			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Episcleritis; Herpes Zoster; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Kevzara			S		200 Mg		Sanofi
	Prednisone			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Actemra			S		162 Mg, Qw		Not Reported
	Celebrex			S				Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	15808456	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019011051		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	No Subject Drug			S		No Dose Given		Not Reported
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qwk		Pfizer
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Not Reported
	Chloroquine			S	Unknown	1 Df/400mg, Qd		Not Reported
	Quensyl			S	Unknown	400 Mg, 1x/Day (1 Df, Qd, 1df = 400mg)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Phenprocoumon			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	15968120	NON-EXPEDITED			US-SA-2019SA042854		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nervous System Disorder; Peripheral Swelling; Therapeutic Product Effect Incomplete	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Oral	2 Df, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16009766	NON-EXPEDITED			US-SA-2019SA050851			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Abnormal	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Remicade			C		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16259354	EXPEDITED (15-DAY)		LT	NO-ACCORD-125478		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent	Methotrexate			S		But Eventually Withdrawn (Date Not Stated) Due To Gastrointestinal Side-Effects.		Accord
	Infliximab			S				Not Reported
	Rituximab			S		Also Used In 2012		Not Reported
	Prednisolone			S	Oral	Also Received From 2018 For 1 Year		Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16260133	NON-EXPEDITED			US-PFIZER INC-2019179691		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Eye Disorder; Inflammation	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16260833	EXPEDITED (15-DAY)		HO	CA-SA-2019SA110750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Malaise; Therapeutic Product Effect Decreased	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Humira			S				Not Reported
	Enbrel			S				Not Reported
	Prednisone			C				Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16260837	EXPEDITED (15-DAY)		HO	CA-SA-2019SA110494		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Leflunomide			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Actemra			S		Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Humira			S		Unk Unk, Unk		Not Reported

Atenolol	C		50 Mg, Qd		Not Reported
Hydrochlorothiazide	C	Oral	25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16261220	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown	Unk Mg		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Sanofi
	Minocycline Hydrochloride			S		Unk Unk, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16261221	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110396		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Drug Ineffective; Erythema; Joint Swelling; Lower Respiratory Tract Infection; Pain In Extremity; Peripheral Swelling; Pyrexia	Arava			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16261404	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110776		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Ineffective; Therapeutic Product Effect Incomplete	Arava			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2019	16261679	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2019-0010016		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	15615464	EXPEDITED (15-DAY)			US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003918			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

	Leflunomide			C						Not Reported
	Actemra			C						Not Reported
	Humira			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16183343	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1093		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Pain In Extremity; Parkinson'S Disease; Peripheral Swelling; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Risedronate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16232050	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001247		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Ejection Fraction Decreased	Hydroxychloroquine			S	Unknown	Unknown For 30 Years		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16235766	EXPEDITED (15-DAY)		OT	PHHY2019IN089614		22 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Vaginal Discharge	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Acetylsalicylic Acid			S	Unknown	75 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262723	NON-EXPEDITED		OT	KR-LUPIN PHARMACEUTICALS INC.-2019-00220		55 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262724	NON-EXPEDITED		OT	KR-LUPIN PHARMACEUTICALS INC.-2019-00219		44 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262725	NON-EXPEDITED			GR-LUPIN PHARMACEUTICALS INC.-2019-00096		53 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Gingival Hyperpigmentation	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Lupin
	Prednisone	S	Unknown	Unk		Not Reported
	Nebivolol Hydrochloride	C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262730	NON-EXPEDITED		OT	KR-LUPIN PHARMACEUTICALS INC.-2019-00179		58 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262731	NON-EXPEDITED			NL-LUPIN PHARMACEUTICALS INC.-2019-00670		46 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Alopecia	Hydroxychloroquine			S	Unknown	200 Milligram		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	20 Milligram, Qd (Temporarily Increased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262732	NON-EXPEDITED			FR-LUPIN PHARMACEUTICALS INC.-2019-00445		73 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Levothyroxine			S	Unknown	Unk		Lupin
	Haloperidol			S	Unknown	Unk		Not Reported
	Molsidomine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262733	NON-EXPEDITED		OT	KR-LUPIN PHARMACEUTICALS INC.-2019-01592		55 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262734	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01645		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262740	NON-EXPEDITED		OT	KR-LUPIN PHARMACEUTICALS INC.-2019-00221		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262741	NON-EXPEDITED		OT	IN-LUPIN PHARMACEUTICALS INC.-2019-00802		55 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262742	NON-EXPEDITED		OT	KR-LUPIN PHARMACEUTICALS INC.-2019-01596		52 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Retinopathy	Hydroxychloroquine	S	Unknown	300 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16262977	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1670		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16264172	EXPEDITED (15-DAY)		HO, OT	CA-IGSA-SR10008248			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Incorrect Route Of Product Administration;	Gamastan S/D			S	Intravenous (not otherwise specified)	70 G, Unk		Grifols
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q.2wk.		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Q.Wk.		Not Reported

Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S		5 Mg, Unk		Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Q.Wk.		Not Reported
	Naproxen	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q.M.T.		Not Reported
	Prednisone	S	Oral	5 Mg, Unk		Not Reported
	Prednisone	S	Oral	3 Mg, Unk		Not Reported
	Sulfasalazine	S	Oral	250 Mg, Unk		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported
	Triamcinolone	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16266051	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK077638		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Belimumab			S		528 Mg, Unk		Glaxosmithkline
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2019	16266250	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2765267-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	13132082	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2017VAL000089			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Drug Reaction; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual	Lasix			S	Unknown	Unk		Validus
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xanax			S	Oral	0.5 Mg, Tid		Not Reported
	Isordil			S	Unknown	Unk		Not Reported
	Actifed /00005601/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ampicillin			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	100 Mg, Qd (At Bedtime)		Not Reported
	Zyrtec /00884302/			S	Unknown	10 Mg, Qd (As Needed)		Not Reported
	Geodon /01487002/			S	Unknown	Unk		Not Reported
	Antivert /00007101/			S	Oral	12.5 Mg, Tid (As Needed)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Compazine /00013302/			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Diamox /00016901/			S	Unknown	Unk		Not Reported
	Dilaudid			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Dyazide			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

Impairment; Vomiting; Weight Decreased; Wheezing	Hepatitis B Vaccine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Iron	S	Unknown	Unk	Not Reported
	Keflex /00145501/	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Potassium	S	Unknown	Unk	Not Reported
	Sudafed /00076302/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Trileptal	S	Unknown	Unk	Not Reported
	Ultram /00599202/	S	Unknown	Unk	Not Reported
	Lialda	S	Unknown	Unk	Not Reported
	Bactrim	S	Unknown	Unk	Not Reported
	Abreva	S	Unknown	Unk	Not Reported
	Zenpep	S	Unknown	Unk	Not Reported
	Celexa /00582602/	S	Unknown	Unk	Not Reported
	Flagyl /00012501/	S	Unknown	Unk	Not Reported
	Vitamin D2	C		Unk	Not Reported
	Mupirocin	C		Unk	Not Reported
	Tamiflu	C		Unk	Not Reported
	Tylenol /00020001/	C		Unk	Not Reported
	Singulair	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Zoloft	C		Unk	Not Reported
	Vitamins Nos	C		Unk	Not Reported
	Restasis	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Nasocort	C		Unk	Not Reported
	Advair	C		Unk	Not Reported

Prevacid	C	Unk	Not Reported
Flexeril /00428402/	C	Unk	Not Reported
Vicodin	C	Unk	Not Reported
Refresh /00007001/	C	Unk	Not Reported
Fosamax	C	Unk	Not Reported
Phenergan /00033001/	C	Unk	Not Reported
Tazact /01173601/	C	Unk	Not Reported
Vitamin D /00107901/	C	Unk	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unk	Not Reported
Isopto Alkaline	C	Unk	Not Reported
Mobic	C	Unk	Not Reported
Lamictal	C	Unk	Not Reported
Diamode	C	Unk	Not Reported
Nexium /01479302/	C	Unk	Not Reported
Calcium Carbonate	C	Unk	Not Reported
Zanaflex	C	Unk	Not Reported
Retin A	C	Unk	Not Reported
Flu Vaccine Vii	C	Unk	Not Reported
Pneumococcal Vaccine	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Norco	C	Unk	Not Reported
Hydrocortisone	C	Unk	Not Reported
Zinc	C	Unk	Not Reported
Zaditor /00495201/	C	Unk	Not Reported
Rubramin	C	Unk	Not Reported
Zantac	C	Unk	Not Reported
Deltasone /00016001/	S	Unk	Not Reported
Vitamin B12 /00056201/	C	Unk	Not Reported
Protopic	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	13165410	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005006			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	14556782	NON-EXPEDITED			US-PFIZER INC-2018071460		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Decreased Appetite; Diarrhoea; Drug Ineffective; Drug Intolerance; Dysgeusia; Fatigue	Methotrexate Sodium			S		Unk, Weekly(Once A Week)		Unknown
	Prednisone			C		9 Mg, (1x)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, (2x)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16244079	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2019176093		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy	Methylprednisolone Acetate			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16267473	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001279		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain; Altered State Of Consciousness; Altered State Of Consciousness; Facial Bones Fracture	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Famciclovir			S	Unknown			Not Reported
	Carbocisteine			C				Not Reported
	Montelukast			C				Not Reported
	Protopic			C				Not Reported
	Antebate			C				Not Reported
	Hirudoid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16267826	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001290		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Exfoliative Generalised; Eosinophil Count Increased; Erythema; Pigmentation Disorder; Pruritus; Urticaria	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16267827	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16267885	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0938		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Intolerance; Liver Function Test Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2019	16267938	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1341		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2019	13118570	EXPEDITED (15-DAY)		HO, OT	PHEH2017US000753		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait	Trileptal			S	Unknown			Novartis
	Ciclosporin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Ampicillin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Xanax			S	Oral	0.5 Mg, Tid (1 Tablet As		Not Reported

Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Hypotension; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Stridor; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing				Needed)	
	Isordil	S	Unknown		Not Reported
	Actifed [Codeine Phosphate\Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride]	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Lyrica	S	Oral	100 Mg, Qd (Bedtime)	Not Reported
	Zyrtec	S	Unknown	10 Mg, Qd (As Needed)	Not Reported
	Geodon	S	Unknown		Not Reported
	Antivert	S	Unknown	12.5 Mg, Tid	Not Reported
	Actemra	S	Oral	12.5 Mg, Tid (As Necessary)	Not Reported
	Rituxan	S	Unknown		Not Reported
	Colchicine	S	Unknown		Not Reported
	Compazine	S	Unknown		Not Reported
	Diamox	S	Unknown		Not Reported
	Dilaudid	S	Unknown		Not Reported
	Dyazide	S	Unknown		Not Reported
	Hepatitis B Vaccin	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Iron	S	Unknown		Not Reported
	Keflex	S	Unknown		Not Reported
	Lasix	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Potassium	S	Unknown		Not Reported
	Sudafed	S	Unknown		Not Reported
	Ultram	S	Unknown		Not Reported
	Zenpep	S	Unknown		Not Reported
	Lialda	S	Unknown		Not Reported
	Bactrim	S	Unknown		Not Reported

Abreva	S	Unknown	Not Reported
Celexa	S	Unknown	Not Reported
Flagyl	S	Unknown	Not Reported
Vitamin D2	C	Unknown	Not Reported
Bactroban	C	Unknown	Not Reported
Tamiflu	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Zoloft	C	Unknown	Not Reported
Mvi	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Nasocort	C	Unknown	Not Reported
Advair	C	Unknown	Not Reported
Prevacid	C	Unknown	Not Reported
Flexeril	C	Unknown	Not Reported
Vicodin	C	Unknown	Not Reported
Refresh	C	Unknown	Not Reported
Fosamax	C	Unknown	Not Reported
Phenergan	C	Unknown	Not Reported
Tazact	C	Unknown	Not Reported
Vitamin D2	C	Unknown	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unknown	Not Reported
Isopto Tears	C	Unknown	Not Reported
Mobic	C	Unknown	Not Reported
Lamictal	C	Unknown	Not Reported
Diamode	C	Unknown	Not Reported
Nexium	C	Unknown	Not Reported

	Calcium Carbonate	C	Unknown			Not Reported
	Zanaflex	C	Unknown			Not Reported
	Retin A	C	Unknown			Not Reported
	Flu Vaccine Vii	C	Unknown	Unk		Not Reported
	Pneumococcal Vaccine	C		Unk		Not Reported
	Vitamin D3	C	Unknown			Not Reported
	Vitamin B12	C	Unknown			Not Reported
	Norco	C	Unknown	Unk		Not Reported
	Hydrocortisone	C	Unknown			Not Reported
	Zinc	C	Unknown			Not Reported
	Zaditor	C	Unknown			Not Reported
	Rubramin	C	Unknown			Not Reported
	Zantac	C	Unknown			Not Reported
	Deltasone	C	Unknown			Not Reported
	Protopic	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2019	15114145	EXPEDITED (15-DAY)		HO	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002266		51 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Malaise; Mobility Decreased; Nausea; Pain; Pustular Psoriasis; Pustule; Pyrexia; Rash	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400mg/Day, Alternately (10 Doses Each)		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400mg/Day, Alternately (10 Doses Each)		Concordia
	Cefaclor			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Prednisolone			C		Increased From 7.5 Mg To 30 Mg		Not Reported

	Prednisolone	C				Not Reported
	Prednisolone	C	Oral			Not Reported
	Prednisolone	C		Decreased By 5 Mg In 3 To 5 Days		Not Reported
	Prednisolone	C				Not Reported
	Famotidine Dci	C				Not Reported
	Edirol	C				Not Reported
	Posterisan Akut	C				Not Reported
	Lecicarbon A	C				Not Reported
	Adoair	C				Not Reported
	Cor Tyzine	C				Not Reported
	Ceftriaxone Sodium Hydrate	C				Not Reported
	Meptin Air	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2019	16271431	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001300		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Urticaria	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-May-2019	16276368	EXPEDITED (15-DAY)		OT	PHHY2019FR101259		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rebound Effect; Still'S Disease	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Prednisone			S	Unknown	1 Mg/Kg, Qd		Novartis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	13111117	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1700925US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Event; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing; Wound	Zenpep 3,000ul Delayed-Release Capsules			S				Allergan
	Enbrel			S	Unknown			Not Reported
	Simponi			S				Not Reported
	Xanax			S	Oral	0.5 Mg, Tid, (1 Tablet As Needed)		Not Reported
	Isordil			S				Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S				Not Reported
	Arava			S				Not Reported
	Ampicillin			S				Not Reported
	Lyrica			S	Oral	100 Mg, Qhs		Not Reported
	Zyrtec			S		10 Mg, Qd, As Needed		Not Reported
	Geodon			S				Not Reported
	Antivert			S	Oral	12.5 Mg, Tid, As Necessary		Not Reported
	Actemra			S				Not Reported
	Rituxan			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Colchicine			S				Not Reported
	Compazine			S				Not Reported
	Cyclosporine			S				Not Reported
	Diamox			S				Not Reported
	Dilaudid			S				Not Reported
	Doxycycline			S				Not Reported
	Dyazide			S				Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Hepatitis B Vaccine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Iron			S				Not Reported
	Keflex			S				Not Reported
	Lasix			S				Not Reported

Abreva	S		Not Reported
Liada	S		Not Reported
Bactrim	S		Not Reported
Methotrexate	S		Not Reported
Plaquenil	S		Not Reported
Potassium	S		Not Reported
Sudafed	S		Not Reported
Sulfasalazine	S		Not Reported
Trileptal	S		Not Reported
Ultram	S		Not Reported
Celexa	S	Unknown	Not Reported
Tamiflu	C		Not Reported
Tylenol	C	Unknown	Not Reported
Singular	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Zoloft	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Nasocort	C	Unknown	Not Reported
Advair	C		Not Reported
Prevacid	C	Unknown	Not Reported
Flexeril	C		Not Reported
Vicodin	C	Unknown	Not Reported
Refresh	C	Unknown	Not Reported
Fosamax	C	Unknown	Not Reported
Phenergan	C		Not Reported
Tazact	C	Unknown	Not Reported
Vitamin D2	C	Unknown	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unknown	Not Reported
Isopto Tears	C	Unknown	Not Reported
Mobic	C	Unknown	Not Reported
Lamictal	C	Unknown	Not Reported
Diamode	C	Unknown	Not Reported

				Nexium	C	Unknown			Not Reported
				Calcium Carbonate	C	Unknown			Not Reported
				Zanaflex	C	Unknown			Not Reported
				Retin A	C	Unknown			Not Reported
				Influenza Vaccine	C		Unk		Not Reported
				Pneumococcal Vaccine	C	Unknown			Not Reported
				Vitamin D3	C	Unknown			Not Reported
				Norco	C		Unk		Not Reported
				Hydrocortisone	C				Not Reported
				Zinc	C				Not Reported
				Zaditor	C	Unknown			Not Reported
				Rubramin	C	Unknown			Not Reported
				Zantac	C	Unknown			Not Reported
				Deltasone	C	Unknown			Not Reported
				Vitamin B12	C	Unknown			Not Reported
				Protopic	C	Unknown			Not Reported
				Vitamins Nos	C				Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
06-May-2019	14485212	NON-EXPEDITED			US-PFIZER INC-2018048253		41 YR	Female	USA
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Varenicline Tartrate			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Hydroxychloroquine			S		Unk		Not Reported	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	15647786	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-191707		23 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection; Pancytopenia	Methylprednisolone			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Sun
	Prednisone			S	Unknown	Unknown		Mutual
	Cyclophosphamide			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	15989653	NON-EXPEDITED			US-PFIZER INC-2019071658			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16271739	EXPEDITED (15-DAY)		HO	HK-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-206924		24 YR	Male	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumomediastinum	Prednisolone			S	Oral	1 Mg/Kg/Day		Taro
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisolone			S	Oral	Unk		Taro
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Sun
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16271961	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000915		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Erythroblast Count Decreased	Plaquenil 200 Mg Tablet			S	Oral	1 Tablet Qd And 2 Tablets Qd, Alternately		Concordia
	Belimumab			S				Not Reported
	Predonine			C				Not Reported
	Predonine			C				Not Reported
	Tacrolimus Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16272296	NON-EXPEDITED			US-AMGEN-USASP2019069142		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain In Extremity; Throat Clearing; Vision Blurred; Weight Increased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16273623	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Retinal Depigmentation; Visual Field Defect	Hydroxychloroquine			S	Unknown	A Dose Of 400 Mg Daily For 14 Years		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16275796	NON-EXPEDITED		OT	US-SA-2019SA118676			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Sepsis; Headache; Infusion Related Reaction; Pneumonia; Urticaria	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Enbrel			S		Unk, Till 2012		Not Reported
	Rituxan			S		Unk		Not Reported
	Remicade			S				Not Reported
	Actemra			S		Unk, Till Jul-2016		Not Reported
	Orencia			S		Unk, Dec-2016		Not Reported
	Acthar [Corticotropin]			S		Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2019	16278274	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087991		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Naproxen Sodium (<= 220 Mg)			S				Bayer
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Enbrel			S				Not Reported
	Folic Acid			C				Not Reported

	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg		Not Reported
	Leflunomide	S				Not Reported
	Methotrexate	C				Not Reported
	Orencia	S				Not Reported
	Prednisone	S				Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	13136262	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-17P-163-1835558-00		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Reaction; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain;	Humira			S	Subcutaneous			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Xanax			S	Oral	0.5 Mg, Tid		Not Reported
	Isordil			S	Unknown			Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ampicillin			S	Unknown			Not Reported
	Lyrica			S	Oral	Dose Qd (At Bedtime)		Not Reported
	Zyrtec			S	Unknown	Dose Qd		Not Reported
	Geodon			S	Unknown			Not Reported
	Antivert			S	Oral	Tid		Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Compazine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported

Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing; Wound	Diamox	S	Unknown	Not Reported
	Dilaudid	S	Intravenous (not otherwise specified)	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Dyazide	S	Unknown	Not Reported
	Erythromycin	S	Unknown	Not Reported
	Hepatitis B Vaccine	S	Unknown	Not Reported
	Iron	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Lasix	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Potassium	S	Unknown	Not Reported
	Sudafed	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Trileptal	S	Unknown	Not Reported
	Ultram	S	Unknown	Not Reported
	Zenpep	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Lialda	S	Unknown	Not Reported
	Bactrim	S	Unknown	Not Reported
	Abreva	S	Unknown	Not Reported
	Celexa	S	Unknown	Not Reported
	Suboxone	S	Unknown	Not Reported
	Vimpat	S	Unknown	Not Reported
	Vitamin D2	C		Not Reported
	Bactroban	C		Not Reported
	Tamiflu	C		Not Reported
	Tylenol	C		Not Reported
	Singulair	C		Not Reported
	Synthroid	C		Not Reported
	Zoloft	C		Not Reported

	Restasis	C	Not Reported
	Folic Acid	C	Not Reported
	Nasocort	C	Not Reported
	Advair	C	Not Reported
	Prevacid	C	Not Reported
	Flexeril	C	Not Reported
	Vicodin	C	Not Reported
	Refresh	C	Not Reported
	Fosamax	C	Not Reported
	Phenergan	C	Not Reported
	Tazact	C	Not Reported
	Vitamin D2	C	Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Not Reported
	Isopto Tears	C	Not Reported
	Mobic	C	Not Reported
	Lamictal	C	Not Reported
	Diamode	C	Not Reported
	Nexium	C	Not Reported
	Calcium Carbonate	C	Not Reported
	Zanaflex	C	Not Reported
	Retin A	C	Not Reported
	Flu Vaccine Vii	C	Not Reported
	Pneumococcal Vaccine	C	Not Reported
	Vitamin D3	C	Not Reported
	Norco	C	Not Reported
	Hydrocortisone	C	Not Reported
	Zinc	C	Not Reported
	Zaditor	C	Not Reported
	Rubramin	C	Not Reported
	Zantac	C	Not Reported
	Deltasone	C	Not Reported
	Protopic	C	Not Reported
	Vitamin B12	C	Not Reported
	Flagyl	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	13520474	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038267		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Orencia	S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz	S	Unknown	12.5 Milligram, Bid		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	15228030	EXPEDITED (15-DAY)		OT	US-SA-2018SA177210		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Injection Site Reaction; Paralysis; Therapeutic Product Effect Decreased; Transaminases Increased	Plaquenil			S				Sanofi
	Kevzara			S	Subcutaneous			Sanofi
	Enbrel			S				Not Reported
	Rituxan			S				Not Reported
	Humira			S				Not Reported
	Cimzia			S				Not Reported
	Orencia			S				Not Reported
	Imuran [Azathioprine Sodium]			S				Not Reported
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported

	Methotrexate			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	15740635	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK228507		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Drug Reaction; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness;	Dyazide			S		Unk		Glaxosmithkline
	Abreva			S		Unk		Glaxosmithkline
	Lamictal			S				Glaxosmithkline
	Bactroban (Mupirocin)			S				Glaxosmithkline
	Antivert			S	Oral	12.5 Mg, Prn		Glaxosmithkline
	Calcium Carbonate			S				Glaxosmithkline
	Zantac			S				Glaxosmithkline
	Isordil			S		Unk		Glaxosmithkline
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S		Unk		Glaxosmithkline
	Ampicilline (Ampicillin Trihydrate)			S		Unk		Glaxosmithkline
	Ciprofloxacin			S		Unk		Glaxosmithkline
	Cyclosporin			S		Unk		Not Reported
	Keflex			S				Glaxosmithkline
	Colchicine			S		Unk		Not Reported
	Bactrim			S		Unk		Glaxosmithkline
	Sudafed			S		Unk		Glaxosmithkline
	Zyrtec			S		10 Mg, Qd		Glaxosmithkline
	Erythromycin			S		Unk		Glaxosmithkline
	Enbrel			S				Not Reported
	Celexa			S		Unk		Not Reported
	Xanax			S		0.5 Mg, Prn		Not Reported
	Geodon			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing; Wound	Rituxan	S		Unk	Not Reported
	Arava	S		Unk	Not Reported
	Compazine	S		Unk	Not Reported
	Lialda	S		Unk	Not Reported
	Dilaudid	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Lyrica	S		100 Mg, Qd	Not Reported
	Doxycycline	S		Unk	Not Reported
	Ery Max	S			Glaxosmithkline
	Humira	S			Not Reported
	Iron	S		Unk	Not Reported
	Lasix	S			Not Reported
	Methotrexate	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Trileptal	S		Unk	Not Reported
	Simponi	S		Unk	Not Reported
	Ultram	S			Not Reported
	Zenpep	S		Unk	Not Reported
	Diamox	S		Unk	Not Reported
	Flagyl	S		Unk	Not Reported
	Potassium	S		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Nexium	C			Not Reported
	Cholecalciferol	C			Not Reported
	Mobic	C			Not Reported
	Isopto Tears	C			Not Reported
	Retin A	C			Not Reported
	Zanaflex	C			Not Reported
	Norco	C			Not Reported
	Zinc	C			Not Reported
	Loperamide Hydrochloride	C			Not Reported
	Hydrocortisone	C			Not Reported
	Deltasone	C			Not Reported

	Rubramin	C	Not Reported
	Protopic	C	Not Reported
	Tylenol	C	Not Reported
	Synthroid	C	Not Reported
	Zaditor	C	Not Reported
	Restasis	C	Not Reported
	Folic Acid	C	Not Reported
	Refresh	C	Not Reported
	Vitamin B 12	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	15742114	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018520329		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Celebrex			S	Oral	200 Milligram, Qd		Pfizer
	Arava			S	Unknown	20 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Prednisone			C	Unknown	8 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16215299	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001168		61 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Tinea Cruris; Urethral Haemorrhage	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia

	Plaquenil 200 Mg Tablet	S	Oral	200 Mg/Day And 400 Mg/Day, Alternately	Concordia
	Prednisolone	S	Oral		Concordia
	Predonine	C			Not Reported
	Cellcept	C			Not Reported
	Nu-Lotan	C			Not Reported
	Nexium	C			Not Reported
	Nexium	C			Not Reported
	Bonalon	C			Not Reported
	Bonalon	C			Not Reported
	Daiphen	C			Not Reported
	Daiphen	C			Not Reported
	Tenelia	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16234398	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-037179		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Clavulin /00756801/			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16279461	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001307			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Oral			Not Reported
	Humira			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16280373	NON-EXPEDITED			US-AMGEN-USASP2019068439			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Methotrexate			S	Subcutaneous	10 Milligram/0.2ml		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16281578	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-042077		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Infection	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported

	Xeljanz			C	Oral	5.0 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16281913	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1039831		17 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypomania	Prednisolone			S	Oral	40 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16282301	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2771703-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Shoulder Operation; Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Tramadol			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16282308	EXPEDITED (15-DAY)		OT	PHHY2019FR103511		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Ciclosporin			S	Unknown			Novartis
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Rituximab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown			Not Reported
	Methylprednisolone		S	Unknown	1 G, Bid		Not Reported
	Mycophenolate Mofetil		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16283002	EXPEDITED (15-DAY)		OT	PHHY2019BD102899			Male	BGD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Prednisolone			S	Transplacental	Maternal Dose: 55 Mg Daily And 15 Mg/Day		Novartis
	Hydroxychloroquine Sulphate			S	Transplacental	Maternal Dose: 300 Mg Daily , 400 Mg Daily		Not Reported
	Aspirin			S	Transplacental	Maternal Dose: 75 Mg Qd		Not Reported
	Heparin			S	Transplacental	Maternal Dose: 10000 Iu, 2 Ml Bid		Not Reported
	Enoxaparin			S	Transplacental	Maternal Dose: 60 Mg Qd And 40 Mg Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16283046	EXPEDITED (15-DAY)		OT	PHHY2019BD102900		34 YR	Female	BGD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication; Thrombocytopenia	Prednisolone			S	Unknown	55 Mg, Qd		Novartis
	Prednisolone			S	Unknown	15 Mg Qd		Novartis
	Hydroxychloroquine Sulphate			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, Qd		Not Reported
	Aspirin			S	Unknown	75 Mg, Qd		Not Reported
	Aspirin			S	Unknown	75 Mg Qd		Not Reported
	Aspirin			S	Unknown	75 Mg Qd		Not Reported
	Heparin			S	Unknown	10000 Iu, 2 Ml Bid		Not Reported
	Enoxaparin			S	Unknown	60 Mg, Qd		Not Reported

	Enoxaparin			S	Unknown	40 Mg, Qd				Not Reported
	Enoxaparin			S	Unknown	60 Mg Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2019	16283483	NON-EXPEDITED		OT	US-SA-2019SA118207			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Leukopenia	Arava			S		Unk Unk, Unk		Sanofi
	Sulfasalazine			S		Unk Unk, Unk		Not Reported
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	12335905	EXPEDITED (15-DAY)		OT	CA-AMGEN-KDL444284		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract Operation; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Lyrica			S	Oral	Unk		Not Reported

	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	12856154	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016137890		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	12894351	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016154529		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Grip Strength Decreased; Nausea	Enbrel			S		Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Once Weekly		Pfizer
	Methotrexate Sodium			S	Oral	2.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Once Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Leflunomide			S	Oral	25 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leucovorin /00566701/			C	Oral	5 Mg, Unk		Not Reported
	Quinapril			C		40 Mg, 1x/Day		Not Reported
	Rosuvastatin			C		20 Mg, 1x/Day		Not Reported

		Hydrochlorothiazide			C		5 Mg, 1x/Day			Not Reported
		Oxycodone			C	Oral	3.25-5 Mg (6-8 Pills A Day) As Needed			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	12894906	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016035211		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Cholesterol Increased; Diarrhoea; Drug Ineffective; Dyspepsia; Gastrointestinal Disorder; Grip Strength Decreased; Headache; Hypertension; Joint Swelling; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate Sodium			S	Oral	2.5 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Oral	25 Mg, Qd		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Leucovorin			C	Oral	5 Mg, Unk		Not Reported
	Quinapril			C		40 Mg, Qd		Not Reported
	Rosuvastatin			C		20 Mg, Qd		Not Reported
	Rosuvastatin			C		20 Mg, Qd		Not Reported
	Hydrochlorothiazide			C		5 Mg, Qd		Not Reported
	Oxycodone			C		3.25mg-5mg, Take 6-8 Pills A Day		Not Reported
	Orencia			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	13118835	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2016-003864		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Event; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing; Wound	Isordil			S	Unknown			Not Reported
	Doxycyline Hyclate			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Bausch And Lomb
	Ciprofloxacin			S	Unknown			Not Reported
	Ultram			S	Unknown			Not Reported
	Iron			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi Aria			S	Unknown	Received Three Treatment In September And October Of 2014		Not Reported
	Xanax			S	Oral	1 Tablet As Needed		Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ampicillin			S	Unknown			Not Reported
	Lyrica			S	Oral	At Bedtime		Not Reported
	Zyrtec			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported
	Antivert			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Compazine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Diamox			S	Unknown			Not Reported
	Dilaudid			S	Intravenous (not otherwise specified)			Not Reported
	Dyazide			S	Unknown			Not Reported
	Hepatitis B Vaccin			S	Unknown			Not Reported

Humira	S	Subcutaneous		Not Reported
Keflex	S	Unknown		Not Reported
Lasix	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Potassium	S	Unknown		Not Reported
Sudafed	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Trileptal	S	Unknown		Not Reported
Zenpep	S	Unknown		Not Reported
Lialda	S	Unknown		Not Reported
Bactrim	S	Unknown		Not Reported
Abreva	S	Unknown		Not Reported
Celexa	S	Unknown		Not Reported
Flagyl	S	Unknown		Not Reported
Vitamin D2	C			Not Reported
Bactroban	C			Not Reported
Tamiflu	C			Not Reported
Tylenol	C	Oral	2 Tablets Every Evening As Needed Maximum Of 4000 Mg Of Acetaminophen	Not Reported
Singulair	C			Not Reported
Synthroid	C			Not Reported
Zoloft	C			Not Reported
Mvi	C			Not Reported
Restasis	C			Not Reported
Folic Acid	C			Not Reported
Nasocort	C			Not Reported
Advair	C			Not Reported
Prevacid	C			Not Reported
Flexeril	C			Not Reported
Vicodin	C			Not Reported
Refresh	C			Not Reported
Fosamax	C			Not Reported

		Phenergan			C					Not Reported
		Tazact			C					Not Reported
		Vitamin D Nos			C					Not Reported
		Systane (Polyethylene Glycol 400\Propylene Glycol)			C					Not Reported
		Isopto Tears			C					Not Reported
		Mobic			C					Not Reported
		Lamictal			C					Not Reported
		Diamode			C					Not Reported
		Nexium			C					Not Reported
		Calcium Carbonate			C					Not Reported
		Zanaflex			C					Not Reported
		Retin A			C					Not Reported
		Flu Vaccine Vii			C					Not Reported
		Pneumococcal Vaccine			C					Not Reported
		Vitamin D3			C					Not Reported
		Norco			C					Not Reported
		Hydrocortisone			C					Not Reported
		Zinc			C					Not Reported
		Zaditor			C					Not Reported
		Rubramin			C					Not Reported
		Zantac			C					Not Reported
		Deltasone			C					Not Reported
		Vitamin B12			C					Not Reported
		Protopic			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	14658489	NON-EXPEDITED			US-PFIZER INC-2018112338		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Chantix			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Zyprexa			S		Unk		Not Reported
	Quinine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	15720817	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20181205753		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Reaction; Drug Intolerance; Intestinal Obstruction; Sjogren'S Syndrome; Weight Decreased	Zyrtec		Y	S	Unknown			Not Reported
	Zyrtec			S	Unknown			Not Reported
	Sudafed		Y	S	Unknown			Not Reported
	Sudafed			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Diamox			S	Unknown			Not Reported
	Dilaudid			S	Intravenous (not otherwise specified)			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Dyazide			S	Unknown			Not Reported
	Iron			S	Unknown			Not Reported
	Keflex			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium			S	Unknown			Not Reported
	Xanax			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Trileptal			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lialda			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Isordil			S	Unknown	At Bedtime		Not Reported
	Arava			S	Unknown	At Bedtime		Not Reported
	Ampicillin			S	Unknown	At Bedtime		Not Reported
	Geodon			S	Unknown	12.5mg, As Required		Not Reported
	Antivert			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Rituxan	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Colchicine	S	Unknown	Not Reported
Lyrica	S	Oral	Not Reported
Erythromycin	S	Unknown	Not Reported
Hepatitis B Vaccine	S	Unknown	Not Reported
Zenpep	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Compazine	S	Unknown	Not Reported
Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)	S	Unknown	Not Reported
Abreva	S	Unknown	Not Reported
Celexa	S	Unknown	Not Reported
Flagyl	S	Unknown	Not Reported
Vitamin D2 (Ergocalciferol)	C	Unknown	Not Reported
Multi Vitamin	C	Unknown	Not Reported
Bactroban	C	Unknown	Not Reported
Tamiflu	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Zoloft	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Hydrocortisone	C	Unknown	Not Reported
Zinc	C	Unknown	Not Reported
Zaditor	C	Unknown	Not Reported
Rubramin	C	Unknown	Not Reported
Zantac	C	Unknown	Not Reported

Deltasone /00016001/	C	Unknown	Not Reported
Protopic	C	Unknown	Not Reported
Cyanocobalamine	C	Unknown	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C	Unknown	Not Reported
Isopto Tears	C	Unknown	Not Reported
Mobic	C	Unknown	Not Reported
Lamictal	C	Unknown	Not Reported
Diamode	C	Unknown	Not Reported
Nexium	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Zanaflex	C	Unknown	Not Reported
Retin A	C	Unknown	Not Reported
Influenza Vaccine	C	Unknown	Not Reported
Pneumococcal Vaccine	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Nasocort	C	Unknown	Not Reported
Advair	C	Unknown	Not Reported
Prevacid	C	Unknown	Not Reported
Flexeril	C	Unknown	Not Reported
Norco	C	Unknown	Not Reported
Refresh	C	Unknown	Not Reported
Fosamax	C	Unknown	Not Reported
Phenergan	C	Unknown	Not Reported
Pip/Tazo	C	Unknown	Not Reported
Vitamin D2 (Ergocalciferol)	C	Unknown	Not Reported
Vitamin D2	C	Unknown	Not Reported
Vicodin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	15759967	EXPEDITED (15-DAY)		CA, OT	NL-UCBSA-2018055742			Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Premature Baby; Strabismus Congenital	Certolizumab Pegol			S	Transplacental	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Sulfasalazine			S	Transplacental	1000 Mg, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Mg, Once Daily (Qd)		Not Reported
	Novorapid			C	Transplacental			Not Reported
	Omeprazol			C	Transplacental	20 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16284676	EXPEDITED (15-DAY)		OT	CA-SA-2019SA124470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Topicort			S				Sanofi
	Prednisone			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Arava			S				Sanofi
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Sulfasalazine			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Actemra			S	Topical			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16286356	EXPEDITED (15-DAY)		OT	FR-ROCHE-2310609			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hyperkalaemia; Hypokalaemia; Nephropathy Toxic; Ototoxicity; Sedation	Mycophenolate Mofetil			S	Unknown			Not Reported
	Fluconazole			S	Unknown			Not Reported
	Nicardipine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Roxithromycine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Ursodesoxycholic Acid			S	Unknown			Not Reported
	Voriconazole			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Posaconazole			S	Unknown			Not Reported
	Piperacilline [Piperacillin]			S	Unknown			Not Reported
	Esomeprazole			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Vincristine			S	Unknown			Not Reported
	Trimetoprim			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2019	16286719	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019016959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported

	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Naprosyn	S			Not Reported
	Penicillin G Sodium	S			Not Reported
	Plaquenil	S			Not Reported
	Silver	S	Oral		Not Reported
	Sulfadiazine	S			Not Reported
	Desoximetasone	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Tofacitinib Citrate	C			Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	11287273	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015069964		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Gallbladder Disorder; Headache; Infection; Latent Tuberculosis; Liver Function Test Abnormal; Liver Function Test Increased; Lower Respiratory Tract Infection; Lung Disorder; Nausea; Pneumonia; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Ulcer	Enbrel			S	Subcutaneous	25 Mg, Qwk		Amgen
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Qwk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Celebrex			C	Oral	200 Mg, Bid (If Needed)		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	11515767	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015288282		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea;	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Unknown	20 Mg, 1x/Day		Pfizer

Pain; Product Use Issue; Rheumatoid Arthritis; Swelling; Weight Decreased	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine	S		1 G, 2x/Day		Pfizer
	Sulfasalazine	S	Unknown	500 Mg, 2x/Day		Pfizer
	Plaquenil	S	Unknown	250 Mg, 1x/Day		Not Reported
	Arava	S	Oral	20 Mg, 1x/Day		Not Reported
	Chloroquine	S	Unknown	250 Mg, 1x/Day		Not Reported
	Leflunomide	S		20 Mg, Once Daily		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	12211260	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015452611		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diarrhoea; Drug Intolerance; Influenza; Musculoskeletal Pain; Rash Macular; Treatment Failure; Vomiting	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	1 Ml (25 Mg), Weekly (Injection)		Unknown
	Leflunomide			S		20 Mg, Alternate Day		Not Reported
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Tylenol /00020001/			C		As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	12340586	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015089393		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea;	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Leflunomide			S	Unknown	20 Mg, Once Daily		Not Reported

Pain; Product Use Issue; Rheumatoid Arthritis; Swelling; Weight Decreased	Arava		S	Oral	20 Milligram, Qd	Not Reported
	Chloroquine		S	Unknown	250 Milligram, Qd	Not Reported
	Methotrexate Sodium		S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil		S	Unknown	250 Mg, Qd	Not Reported
	Sulfasalazine		S	Unknown	1 G, Twice Daily	Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	12657642	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015207566		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Arthralgia; Condition Aggravated; Constipation; Depressed Mood; Drug Ineffective; Fall; Fatigue; Gait Disturbance; Gait Disturbance; Inflammation; Musculoskeletal Stiffness; Nasopharyngitis; Pain; Pain In Extremity; Peripheral Swelling; Poor Quality Sleep; Product Dose Omission; Rheumatoid Arthritis; Stress; Synovitis; Upper Respiratory Tract Infection; Weight Bearing Difficulty; Wound Infection; Wrist Fracture	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, As Needed		Pfizer
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, 1x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, 1x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Celebrex			S	Oral	200 Mg, 1x/Day		Pfizer
	Plaquenil			S		200 Mg, Daily		Not Reported
	Prednisone			S		2.5 Mg, Daily		Not Reported

	Prednisone			S			2.5 Mg, Alternate Day (Every 2 Days)			Not Reported
	Advil			C	Oral		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	13045053	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016177893		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Feeling Abnormal; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Pneumonia; Rash; Sinusitis; Somnolence	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	13057802	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016069550		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Drug Ineffective; Gait Disturbance; Gait Inability; Hypoaesthesia; Joint Swelling; Musculoskeletal Pain; Neck Pain; Peripheral Swelling; Pharyngeal Oedema; Rash; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported

	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C		8 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	15764822	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3829		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	15890143	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2359730-00		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Famotidine			S	Unknown			Not Reported

	Effexor	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Trandolapril	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Flomax	S	Unknown	Not Reported
	Furosemide	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Reglan	S	Unknown	Not Reported
	Victoza	S	Unknown	Not Reported
	Trazodone	S	Unknown	Not Reported
	Loperamide Hcl	S	Unknown	Not Reported
	Ambien	S	Unknown	Not Reported
	Gabapentin	S	Unknown	Not Reported
	Nexium	S	Unknown	Not Reported
	Imdur	S	Unknown	Not Reported
	Plavix	S	Unknown	Not Reported
	Crestor	S	Unknown	Not Reported
	Potassium Acetate	S	Unknown	Not Reported
	Nitroglycerin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	15928812	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16268281	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001212		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting;	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Slmponl Arla			S	Unknown			Not Reported
	Xanax			S	Oral	1 Tablet As Needed		Not Reported
	Isordil			S	Unknown			Not Reported
	Actifed (Pseudoephedrine Hydrochloride\Triprolidine Hydrochloride)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ampicillin			S	Unknown			Not Reported
	Lyrica			S	Oral	At Bedtime		Not Reported
	Zyrtec			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported
	Antivert			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Colchlclne			S	Unknown			Not Reported
	Compazine			S	Unknown			Not Reported
	Cyclosporlne			S	Unknown			Not Reported
	Diamox			S	Unknown			Not Reported
	Dilaudid			S	Intravenous (not otherwise specified)			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Dyazide			S	Unknown			Not Reported

Weight Decreased; Wheezing; Wound	Erythromycin	S	Unknown	Not Reported
	Hepatitis B Vaccin	S	Unknown	Not Reported
	Humlra	S	Subcutaneous	Not Reported
	Lron	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Laslx	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Potassium	S	Unknown	Not Reported
	Sudafed	S	Unknown	Not Reported
	Sulfasalazlne	S	Unknown	Not Reported
	Trileptal	S	Unknown	Not Reported
	Ultram	S	Unknown	Not Reported
	Llalda	S	Unknown	Not Reported
	Bactrim	S	Unknown	Not Reported
	Abreva	S	Unknown	Not Reported
	Zenpep	S	Unknown	Not Reported
	Celexa	S	Unknown	Not Reported
	Flagyl	S	Unknown	Not Reported
	Lamictal	C		Not Reported
	Vitamin D2	C		Not Reported
	Bactroban	C		Not Reported
	Tamiflu	C		Not Reported
	Tylenol	C		Not Reported
	Singular	C		Not Reported
	Synthroid	C		Not Reported
	Zoloft	C		Not Reported
	Mvi	C		Not Reported
	Restasis	C		Not Reported
	Folic Acid	C		Not Reported
	Nasocort	C		Not Reported
	Advair	C		Not Reported
	Prevacid	C		Not Reported
	Flexeril	C		Not Reported
	Vicodin	C		Not Reported

		Refresh			C				Not Reported
		Fosamax			C				Not Reported
		Phenergan			C				Not Reported
		Tazact			C				Not Reported
		Vitamin D Nos			C				Not Reported
		Systane (Polyethylene Glycol 400\Propylene Glycol)			C				Not Reported
		Isopto Tears			C				Not Reported
		Mobic			C				Not Reported
		Diamode			C				Not Reported
		Nexium			C				Not Reported
		Calcium Carbonate			C				Not Reported
		Zanaflex			C				Not Reported
		Retin A			C				Not Reported
		Flu Vaccine Vii			C				Not Reported
		Pneumococcal Vaccine			C				Not Reported
		Vitamin D3			C				Not Reported
		Norco			C				Not Reported
		Hydrocortisone			C				Not Reported
		Zinc			C				Not Reported
		Zaditor			C				Not Reported
		Rubramin			C				Not Reported
		Zantac			C				Not Reported
		Deltasone			C				Not Reported
		Vitamin B12			C				Not Reported
		Protopic			C				Not Reported
		Celexa			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16288399	EXPEDITED (15-DAY)		OT	FR-CELLTRION INC.-2019FR020873			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Paraesthesia; Product Use In Unapproved Indication	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1 Df		Not Reported
	Plaquenil			S	Oral	1 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16288425	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL		26 YR	Female	USA

						INDUSTRIES LTD-2018US-188922			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Screen False Positive; Electrocardiogram Qrs Complex Prolonged; Hypokalaemia; Hypoxia; Mental Status Changes; Overdose; Pulmonary Alveolar Haemorrhage; Somnolence; Systemic Lupus Erythematosus; Toxicity To Various Agents; Ventricular Extrasystoles	Hydroxychloroquine			S	Oral	20 Tablets (200 Mg) With Ethanol		Sun
	Ethanol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16288466	EXPEDITED (15-DAY)		OT	PHHY2019EC102622		14 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Tonic-Clonic Seizure; Posterior Reversible Encephalopathy Syndrome	Prednisone			S	Unknown	30 Mg, Unk		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Furosemide			C	Unknown	40 Mg, Unk		Not Reported
	Atorvastatin			C	Unknown	10 Mg, Unk		Not Reported
	Enalapril			C	Unknown	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16288627	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001313			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hypersensitivity; Leukopenia	Plaquenil	S	Unknown	Concordia
	Arava	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16289669	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2019-US-1046754		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16289677	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1046762		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16289993	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087579		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qod		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

		Xeljanz			S	Oral	5.0 Mg, Bid			Not Reported
		Xeljanz			S	Oral	5.0 Mg, Bid			Not Reported
		Folic Acid			C	Unknown				Not Reported
		Hydroxychloroquine			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290046	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1046758		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290115	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-087624		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290192	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087649		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290193	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087627			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Ow		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290298	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-087652		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		400 Mg		Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S				Not Reported
	Prednisone			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290392	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087680			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Arava			S	Oral			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Ow		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Ow		Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290393	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087669		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Aleve			S	Unknown	Unk		Bayer
	Acetaminophen			C	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	624 Mg, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	680 Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Lasix [Furosemide]			C	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported
	Oxycontin			C	Unknown	Unk		Not Reported
	Oxyneo			C		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	624 Mg, Q4wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	1000.0 Mg			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	680.0 Mg, Q4wk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000.0 Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16290450	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Aleve			S	Unknown	500 Mg, Qid		Bayer
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	50 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	50 Mg, Tid		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Ow		Not Reported
	Methotrexate			S	Oral	15 Mg, Ow		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16291844	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-087642		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired	Aleve			S		Unk		Bayer
	Actemra			S		Unk		Not Reported

Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide			S		Unk	Not Reported
	Apo-Prednisone			S		Unk	Not Reported
	Enbrel			S		Unk	Not Reported
	Folic Acid			C		Unk	Not Reported
	Humira			S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine			S		Unk	Not Reported
	Hydroxychloroquine Sulfate			C		Unk	Not Reported
	Methotrexate			S		Unk	Not Reported
	Naproxen Sodium			S		Unk	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine			C		Unk	Not Reported
	Xeljanz			S	Oral	2 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16291876	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-087659		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16291879	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-087651		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Weight Decreased	Aleve			S		500.0 Mg		Bayer
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25.0 Mg, Ow		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16291963	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087665			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Naproxen Sodium (<= 220 Mg)			S	Oral	500 Mg, Bid		Bayer
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, Biw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C	Unknown	10 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16292266	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087664			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Acetylsalicylic Acid (Cardio)			C	Unknown	81.0 Mg		Bayer

Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Df, Q1mon	Not Reported
	Arava	S	Oral	10 Mg, Qd	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Ow	Not Reported
	Enbrel	S		20 Mg, Ow	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg	Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Not Reported
	Lantus	C	Unknown		Not Reported
	Leflunomide	S	Oral	10.0 Mg, Qd	Not Reported
	Lozide [Gliclazide]	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Methotrexate	S		25.0 Mg	Not Reported
	Methotrexate	S	Oral	25.0 Mg	Not Reported
	Naproxen Sodium (<= 220 Mg)	C	Unknown	Unk	Bayer
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Q1mon	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported
	Vitamin D [Vitamin D Nos]	C	Unknown		Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C		5.0 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16292395	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Aleve	S	Unknown	500 Mg, Bid	Bayer
	Diclofenac Sodium	S	Unknown	75.0 Mg, Bid	Not Reported
	Methotrexate	S	Unknown	25.0 Mg, Ow	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Hydroxychloroquine	C	Unknown	400.0 Mg, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Piroxicam	C	Unknown	20 Mg, Qd	Not Reported
	Prednisone	C	Unknown	20.0 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16292809	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1046792		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Left Ventricular Dysfunction	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16293522	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Barrett'S Oesophagus; Drug Ineffective; Dysstasia; Nausea; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Prednisone			S		Unk Unk, Unk		Not Reported
	Actemra			S				Not Reported
	Rituxan			S		Unk Unk, Unk		Not Reported
	Simponi			S				Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2019	16293677	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2019M1042970		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Biaxin			S	Unknown	Unk		Mylan
	Arava			S	Unknown	Unk		Mylan
	Celebrex			S	Unknown	Unk		Mylan
	Ciprofloxacin			S	Unknown	Unk		Mylan
	Clindamycin			S		Unk		Mylan
	Codeine			S	Unknown	Unk		Mylan
	Enalapril			S	Unknown	Unk		Mylan
	Enbrel			S	Unknown	Unk		Mylan
	Fosamax			S	Unknown	Unk		Mylan
	Hctz			S	Unknown	Unk		Mylan
	Hydralazine Hydrochloride			S	Unknown	Unk		Mylan
	Keflex /00145501/			S	Unknown	Unk		Mylan
	Levaquin			S	Unknown	Unk		Mylan
	Losartan			S	Unknown	Unk		Mylan
	Methotrexate			S	Subcutaneous	10.0 Milligram, Qw (1 Every 1 Week)		Mylan
	Metoprolol Tartrate			S	Unknown	Unk		Mylan
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Mylan
	Pantoprazole Magnesium			S	Unknown	Unk		Mylan
	Pariet			S	Unknown	Unk		Mylan
	Penicillin G /00000901/			S		Unk		Mylan
	Plaquenil /00072602/			S	Unknown	Unk		Mylan
	Esomeprazole			C	Unknown	Unk		Mylan
	Gold			C	Unknown	Unk		Mylan
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Mylan

	Iron Sucrose			C	Unknown	Unk		Mylan
	Cipro /00697201/			C	Unknown	Unk		Mylan
	Prednisone			C	Unknown	8.5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	12424903	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016281613		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Celebrex			S	Oral	200 Mg, Daily		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, 2x/Day		Not Reported
	Arava			S	Unknown	20 Mg, Daily		Not Reported
	Prednisone			C		8 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	12909719	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016131565		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cataract; Drug Hypersensitivity; Drug Ineffective; Fatigue; Grip Strength Decreased; Heart Rate Increased; Impaired Self-Care; Joint Effusion; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Leflunomide			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Arava			C		Unk		Not Reported

Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pre-Existing Condition Improved; Swelling; Synovitis; Therapeutic Response Unexpected; Urinary Incontinence	Telmisartan	C	Oral	50 Milligram		Not Reported
	Telmisartan	C	Oral	80 Milligram		Not Reported
	Depomedrol	C		Unk		Not Reported
	Meloxicam	C		Unk		Not Reported
	Vitamin D (Ergocalciferol)	C		1000 Iu, Weekly		Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)	C		Unk		Not Reported
	Tylenol Arthritis Pain	C		Unk, As Necessary		Not Reported
	Macrogol 400 W/Propylene Glycol	C		Unk		Not Reported
	Macrogol 400 W/Propylene Glycol	C		Unk		Not Reported
	Ergocalciferol	C		1000 Iu, Qwk		Not Reported
	Ergocalciferol	C		1000 Iu, Qwk		Not Reported
	Methylprednisolone Acetate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	13049973	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016178859		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Chronic Sinusitis; Drug Ineffective; Drug Resistance; Dry Eye; Fibromyalgia; Impaired Work Ability; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Sjogren'S Syndrome; Spinal Pain; Therapeutic Product Effect Incomplete; Upper-Airway	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 10 Days		Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	50 Milligram, 1 Every 1 Minute		Not Reported
	Imuran			C		Unk Unk, Qd		Not Reported
	Leflunomide			C		20 Mg, 1 Every 1 Day		Not Reported

Cough Syndrome; Weight Increased	Prednisone		C	4 Mg, 1 Every 1 Day	Not Reported
	Sulfasalazine		C	500 Mg, 4 Every 1 Day	Not Reported
	Venlafaxine		C	225 Mg, Qd (1 Every 1 Day)	Not Reported
	Alendronate Sodium		C	Unk	Not Reported
	Amitriptyline		C	Unk	Not Reported
	Atorvastatin		C		Not Reported
	Azathioprine		C		Not Reported
	Venlafaxine Hydrochloride		C	225 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	15849724	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1004984		38 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Dyspnoea; Oedema Peripheral; Pulmonary Oedema	Warfarin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16296647	EXPEDITED (15-DAY)		OT	AR-IPCA LABORATORIES LIMITED-IPC-2019-AR-000536			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
American Trypanosomiasis	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16297276	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1044332		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Blindness; Retinopathy; Visual Field	Hydroxychloroquine			S	Unknown	Receiving From 12 Years		Not Reported

Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16297918	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR080384			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Myalgia; Neck Pain; Pain In Extremity	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Paroxetine			C		Unk		Glaxosmithkline
	Canasa			C		Unk		Not Reported
	Tizanidine			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported
	Amoxicillin-Pot Clavulanate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16298285	EXPEDITED (15-DAY)		OT	AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2019-03884			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Intussusception	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Oxycodone Hydrochloride			S	Unknown	Unk		Alkem
	Aspirin			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Xylocaine			S	Unknown	Unk		Not Reported
	Slow-K			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Intragam 10			S	Unknown	Unk		Not Reported
	Mylanta			S	Unknown	Unk		Not Reported

	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Movicol			S	Unknown	Unk		Not Reported
	Panadeine [Codeine Phosphate;Paracetamol]			S	Unknown	Unk		Not Reported
	Buscopan			S	Unknown	Unk		Not Reported
	Microlax (Sodium Citrate\Sodium Lauryl Sulfoacetate\Sorbitol)			S	Unknown	Unk		Not Reported
	Novorapid			S	Unknown	Unk		Not Reported
	Enoxaparin			S	Unknown	Unk		Not Reported
	Ondansetron			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16298591	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-025166			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rebound Effect; Still'S Disease	Prednisone			S	Unknown	20 Mg, Qd		Aurobindo
	Prednisone			S	Unknown	1 Mg/Kg, Qd		Aurobindo
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16300875	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087772			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Enbrel			S	Subcutaneous	12.5 Mg, Ow		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Not Reported

Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab		S	Unknown	5 Mg	Not Reported
	Methotrexate		S	Subcutaneous	15 Mg/M2, Ow	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Mg, Q1mon	Not Reported
	Prednisone		S	Oral	3 Mg, Bid	Not Reported
	Sulfasalazine		S	Oral	250 Mg, Qd	Not Reported
	Tocilizumab		S		280 Mg, Q2wk	Not Reported
	Triamcinolone		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-May-2019	16301240	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-087849			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium (<= 220 Mg)			S	Oral			Bayer
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate			C						Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	12901768	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2152		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	13063081	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2727		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Chronic Sinusitis; Drug Ineffective; Drug Resistance; Dry Eye; Fibromyalgia; Impaired Work Ability; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Peripheral Swelling; Poor Quality Sleep; Rheumatoid	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

Arthritis; Sjogren'S Syndrome; Spinal Pain; Therapeutic Product Effect Incomplete; Upper-Airway Cough Syndrome; Weight Increased	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Venlafaxine	C	Unknown		Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Alendronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	14254200	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017517689		81 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dementia With Lewy Bodies; Fall; Hip Fracture; Movement Disorder; Parkinson'S Disease	Xeljanz			S	Oral	5 Mg, Once Daily		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	14995459	NON-EXPEDITED			US-SA-2018SA146367			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Arava			S		Unk Unk, Unk		Sanofi
	Humira			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk, Unk		Not Reported
	Methotrexate			S		Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	15271033	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2446766-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac			S				Not Reported
	Diclofenac			S				Not Reported
	Diclofenac			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported
	Voltaren			S	Unknown			Not Reported
	Voltaren			S				Not Reported
	Voltaren			S				Not Reported
	Voltaren			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	15866137	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0206			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16224859	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-074414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug	Moxifloxacin Oral			S	Unknown	Unk		Bayer
	Ciprofloxacin			S	Unknown			Bayer
	Arava			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported

Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Celebrex	S	Unknown		Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown		Not Reported
	Enalapril Maleate	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Isoniazid	S	Unknown		Not Reported
	Keflex [Cefalexin Monohydrate]	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Lopresor [Metoprolol Tartrate]	S	Unknown		Not Reported
	Losartan Potassium	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10 Mg/L, Qd	Not Reported
	Pantoprazole Magnesium	S	Unknown		Not Reported
	Pariet	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Cipro [Ciprofloxacin]	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Iron Sucrose	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16241908	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001246		57 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Meningitis Aseptic	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Micardis			C				Not Reported

	Thyradin S	C	Not Reported
	Baktar	C	Not Reported
	Baktar	C	Not Reported
	Takepron	C	Not Reported
	Takepron	C	Not Reported
	Onealfa	C	Not Reported
	Onealfa	C	Not Reported
	Bonalon	C	Not Reported
	Bonalon	C	Not Reported
	Persantin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16263526	EXPEDITED (15-DAY)		HO, LT, OT	AU-LUPIN PHARMACEUTICALS INC.-2019-02688		16 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Depressed Mood; Drug Withdrawal Syndrome; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Hypotension; Intentional Overdose; Lupus-Like Syndrome; Suicide Attempt	Hydroxychloroquine Sulfate Tablets			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Oral	100 Dosage Form		Lupin
	Sertraline			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16302500	NON-EXPEDITED			US-SA-2019SA123654			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Decreased Appetite; Diarrhoea; Hypersensitivity; Taste Disorder	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S		200 Mg, 2x		Sanofi
	Prednisone			S		9 Mg, 1x		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16302687	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-043370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16303224	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-126823		39 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Citrobacter Infection; Haemolytic Anaemia; Meningitis Bacterial; Off Label Use; Pneumonia Klebsiella; Thrombocytopenia; Urinary Retention	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16303276	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16305153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA124971			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Unknown	5 Mg, Prn		Not Reported
	Celecoxib			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

Orencia	S	Unknown	Unk Unk, Unk		Not Reported
Xeljanz	S	Oral	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2019	16463328	DIRECT	Y				68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Pain In Extremity	Humira 40 Mg			S	Subcutaneous	Other Frequency:Every 2 Weeks As D;		Abbvie
	Hydroxychloroquine 200 Mg			S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	12918589	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016451421		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cataract; Drug Hypersensitivity; Drug Ineffective; Fatigue; Grip Strength Decreased; Heart Rate Increased; Impaired Self-Care; Joint Effusion; Joint Swelling; Pre-Existing Condition Improved; Synovitis; Therapeutic Response Unexpected	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Mg (Multiple-Use Vial), Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Vitamin D			C		1000 Iu, Weekly		Not Reported
	Telmisartan			C	Oral	80 Mg, Die		Not Reported
	Telmisartan			C	Oral	50 Mg, Die		Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)			C		Unk		Not Reported
	Tylenol Arthritis			C		Unk, As Necessary		Not Reported
	Depo-Medrol			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Arava			C		Unk		Not Reported

	Macrogol 400 W/Propylene Glycol	C	Unk	Not Reported
	Macrogol 400 W/Propylene Glycol	C	Unk	Not Reported
	Ergocalciferol	C	1000 Iu, Qwk	Not Reported
	Ergocalciferol	C	1000 Iu, Qwk	Not Reported
	Methylprednisolone Acetate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	13145218	EXPEDITED (15-DAY)		OT	US-ROCHE-1878352		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Xanax			S	Oral			Not Reported
	Isordil			S	Unknown			Not Reported
	Actifed [Pseudoephedrine Hydrochloride;Triprolidine Hydrochloride]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ampicillin			S	Unknown			Not Reported
	Lyrica			S	Oral	Qd At Bedtime		Not Reported
	Zyrtec [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Ziprasidone Hydrochloride			S	Unknown			Not Reported
	Antivert [Meclozine Hydrochloride]			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Prochlorperazine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported

Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased; Wheezing	Diamox [Acetazolamide]	S	Unknown	Not Reported
	Dilaudid	S	Intravenous (not otherwise specified)	Not Reported
	Dyazide	S	Unknown	Not Reported
	Erythromycin	S	Unknown	Not Reported
	Hepatitis B Vaccine	S	Unknown	Not Reported
	Keflex [Cefalexin]	S	Unknown	Not Reported
	Lasix [Furosemide]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sudafed [Pseudoephedrine Hydrochloride]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Trileptal	S	Unknown	Not Reported
	Ultram [Tramadol Hydrochloride]	S	Unknown	Not Reported
	Zenpep	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Lialda	S	Unknown	Not Reported
	Bactrim	S	Unknown	Not Reported
	Vitamin D2	C	Unknown	Not Reported
	Bactroban [Mupirocin]	C	Unknown	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Not Reported
	Tramadol	C		Not Reported
	Celexa [Citalopram Hydrobromide]	C		Not Reported
	Tamiflu	C		Not Reported
	Singulair	C		Not Reported
	Synthroid	C		Not Reported
	Zoloft	C		Not Reported
	Restasis	C		Not Reported

	Folic Acid	C		Not Reported
	Nasocort	C		Not Reported
	Advair	C		Not Reported
	Prevacid	C		Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]	C		Not Reported
	Vicodin	C		Not Reported
	Other Ophthalmologicals	C		Not Reported
	Fosamax	C		Not Reported
	Phenergan [Promethazine]	C		Not Reported
	Systane (Polyethylene Glycol 400\Propylene Glycol)	C		Not Reported
	Mobic	C		Not Reported
	Lamictal	C		Not Reported
	Esomeprazole	C		Not Reported
	Calcium Carbonate	C		Not Reported
	Zanaflex	C		Not Reported
	Retin A	C		Not Reported
	Influenza Vaccine	C	Unknown	Not Reported
	Pneumococcal Vaccine	C	Unknown	Not Reported
	Vitamin D3	C		Not Reported
	Norco	C		Not Reported
	Hydrocortisone	C		Not Reported
	Zaditor [Ketotifen]	C		Not Reported
	Rubramin Pc	C		Not Reported
	Zantac	C		Not Reported
	Deltasone [Prednisone]	C		Not Reported
	Protopic	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	14436122	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018006328		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Rituximab			S	Unknown	1000 Milligram, Q6mo		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

	Adalimumab	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 2 Times/Wk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Methotrexate Sodium	C	Oral	25 Mg, Qwk	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	14952620	NON-EXPEDITED			US-PFIZER INC-2018220737		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		0.8 Ml, Weekly (0.8ml Injection Once A Week)		Unknown
	Methotrexate Sodium			S		0.6 Ug, Unk		Unknown
	Methotrexate Sodium			S		0.8 Ug, Unk		Unknown
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	15096339	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2018265098		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Knuckle Pads; Loss Of Personal Independence In Daily Activities; Pain; Pain In Extremity	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg-400mg, Altrenate Day		Not Reported
	Methotrexate			S	Oral	2.5 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	2.5 Mg, Weekly (10 Pills Week 5 Am 2.5 Mg 5 Pm)		Not Reported
	Plaquenil			S		200mg-400mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	15939188	NON-EXPEDITED			US-PFIZER INC-2019051181			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Toviaz			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Darvon [Betahistine Mesilate]			S		Unk		Not Reported
	Brimonidine			S		Unk		Not Reported
	Cevimeline			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Duradrin			S		Unk		Not Reported
	Midrin [Dichloralphenazone;Isomethepteme Mucate;Paracetamol]			S		Unk		Not Reported

Valium	S	Unk	Not Reported
Darvocet	S	Unk	Not Reported
Lodine	S	Unk	Not Reported
Famotidine	S	Unk	Not Reported
Proair [Fluticasone Propionate]	S	Unk	Not Reported
Advair	S	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
Iodine	S	Unk	Not Reported
Meloxicam	S	Unk	Not Reported
Metolazone	S	Unk	Not Reported
Nubain	S	Unk	Not Reported
Oxycodone	S	Unk	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	S	Unk	Not Reported
Paracetamol Accord Healthcare	S	Unk	Not Reported
Pilocarpine Hcl	S	Unk	Not Reported
Simvastatin	S	Unk	Not Reported
Temazepam	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16027296	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-018359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatic Steatosis; Squamous Cell Carcinoma; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

	Actemra			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16199878	EXPEDITED (15-DAY)		OT	FR-ROCHE-2303126		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Rituximab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Erythropoietin			S	Intravenous (not otherwise specified)			Not Reported
	Erythropoietin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16307637	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-025360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lipodystrophy Acquired; Oedema	Prednisone	S	Unknown	Unk		Aurobindo
	Prednisone	S	Unknown	Taper		Aurobindo
	Potassium Chloride	S	Unknown	180 Milliequivalent, Per Day		Aurobindo
	Hydroxychloroquine	S	Unknown	300 Milligram, Per Day		Not Reported
	Azathioprine	S	Unknown	50-100 Mg/Day		Not Reported
	Sodium Bicarbonate	S	Unknown	1960 Milligram, Per Day		Not Reported
	Amiloride	C	Unknown	10 Milligram, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16308087	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1422		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Inability	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16308875	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-026287			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disseminated Tuberculosis; Peripheral Swelling; Pneumonia; Pyomyositis; Tuberculosis	Prednisone	S	Unknown	30 Milligram, Daily		Aurobindo
	Prednisone	S	Unknown	10 Milligram, Tapered Dose		Aurobindo
	Hydroxychloroquine	S	Unknown	200 Milligram, Daily		Not Reported
	Cotrimoxazol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16308881	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-027002			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Erythema; Hypotension; Hypoxia; Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia; Pustule; Pyrexia; Respiratory Distress	Prednisone			S	Unknown	60 Milligram Per Day		Aurobindo
	Prednisone			S	Unknown	20 Milligram Per Day		Aurobindo
	Prednisone			S	Unknown	Dose Increased		Aurobindo
	Prednisone			S	Unknown	Unk		Aurobindo
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16308884	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-025638			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Disease Progression; Type 1 Diabetes Mellitus	Prednisone			S	Oral	Unk		Aurobindo
	Apremilast			S	Oral	30 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Mycophenolate Mofetil	C	Unknown	Unk		Not Reported
	Azathioprine	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Acitretin	C	Unknown	Unk		Not Reported
	Immunoglobulin Iv	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus	C	Unknown	Unk		Not Reported
	Chlorambucil	C	Unknown	Unk		Not Reported
	Infliximab	C	Unknown	Unk		Not Reported
	Rituximab	C	Unknown	Unk		Not Reported
	Insulin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16309796	EXPEDITED (15-DAY)		OT	AU-SA-2019SA128949		71 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Weight Decreased	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16310182	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019199013			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain; Peripheral Swelling; Stevens-Johnson Syndrome	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Apo-Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	8646975	EXPEDITED (15-DAY)		HO, OT	FR-SANOFI-AVENTIS-2012SA045077		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brief Psychotic Disorder With Marked Stressors; Suicidal Ideation	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Cortancyl			S	Oral	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	13054731	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016593285		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Chronic Sinusitis; Disease Recurrence; Drug Ineffective; Drug Resistance; Dry Eye; Fibromyalgia; Impaired Work Ability; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Sjogren'S Syndrome; Spinal Pain; Therapeutic Product Effect Incomplete; Upper-Airway Cough Syndrome; Weight Increased	Enbrel			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk (1 Every 1 Minute(S))		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic (1 Every 10 Day(S))		Not Reported
	Imuran			C		Unk Unk, Qd		Not Reported
	Leflunomide			C		20 Mg, 1 Every 1 Day		Not Reported
	Prednisone			C		4 Mg, 1 Every 1 Day		Not Reported
	Sulfasalazine			C		500 Mg, 4 Every 1 Day		Not Reported
	Venlafaxine			C		225 Mg, Qd (1 Every 1 Day)		Not Reported
	Alendronate Sodium			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Azathioprine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	13055587	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016591013		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Fatigue; Feeling Abnormal; Musculoskeletal Stiffness; Nausea; Pain; Pneumonia; Rash; Sinusitis; Somnolence	Enbrel			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	14530647	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018008929		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Chest Discomfort; Chest Pain; Fatigue; Paraesthesia Oral; Product Use Issue; Skin Burning Sensation; Therapeutic Product Effect Incomplete	Xeljanz			S	Oral	5 Mg, Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		1.5 G, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Atorvastatin			C		81 Mg, 1x/Day		Not Reported
	Ezetimibe			C		10 Mg, 1x/Day		Not Reported
	Coversyl /00790702/			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported
	Tecta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	15727090	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Levofloxacin	S	Unknown		Not Reported
	Demerol	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Benadryl	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Imuran	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Procytox	S	Intravenous (not otherwise specified)	Strength: 2000 Mg	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Ezetrol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	15742925	EXPEDITED (15-DAY)		DE, HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-193870		31 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Interleukin Level Increased; Interleukin Level	Hydroxychloroquine			S	Unknown	Unk		Sun
	Sulfasalazine			S	Unknown	Unk		Sun

Increased; Lymphocytosis; Shock; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16087060	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000663		46 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Exudates	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternate Administration		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternate Administration		Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16228049	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019164148		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Methylprednisolone			S	Unknown	1 G, Unk, 3 Days		Pfizer
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	50 Mg, 1x/Day		Not Reported
	Cyclosporine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16287471	NON-EXPEDITED		HO, OT	US-SHIRE-US201914404		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Event; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Arthritis Infective; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Intolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhagic Diathesis; Hallucination; Headache; Hypoaesthesia; Interstitial Lung Disease; Intestinal Obstruction; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Sneezing; Tenderness; Thinking Abnormal; Visual Impairment; Vomiting; Weight Decreased;	Lialda			S	Unknown			Shire
	Enbrel			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported
	Xanax			S	Unknown	0.5 Milligram, 3x/Day:Tid		Not Reported
	Isordil			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ampicillin			S		Unk		Not Reported
	Lyrica			S	Oral	100 Milligram, 1x/Day:Qd		Not Reported
	Zyrtec			S	Unknown	10 Milligram, 1x/Day:Qd		Not Reported
	Geodon			S	Unknown			Not Reported
	Antivert [Meclozine Hydrochloride]			S	Unknown	12.5 Milligram, 3x/Day:Tid		Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Compazine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Diamox			S	Unknown			Not Reported
	Dilaudid			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Dyazide			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Wheezing; Wound	Iron	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Lasix	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Potassium	S	Unknown	Not Reported
	Sudafed	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Trileptal	S	Unknown	Not Reported
	Ultram	S	Unknown	Not Reported
	Bactrim	S	Unknown	Not Reported
	Abreva	S	Unknown	Not Reported
	Zenpep	S	Unknown	Not Reported
	Celexa	S	Unknown	Not Reported
	Flagyl	S	Unknown	Not Reported
	Bactroban	C		Not Reported
	Vitamin D2	C		Not Reported
	Actifed Allergie	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16311995	EXPEDITED (15-DAY)		OT	AR-IPCA LABORATORIES LIMITED-IPC-2019-AR-000568			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Second Degree; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16312516	EXPEDITED (15-DAY)		OT	BD-SUN PHARMACEUTICAL INDUSTRIES LTD-		34 YR	Female	BGD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Premature Delivery	Aspirin			S	Unknown	75 Milligram, Daily, From 6th Week		Sun
	Aspirin			S	Unknown	From 10th Week		Sun
	Hydroxychloroquine			S	Unknown	300 Milligram, Daily		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily, From 19th Week		Sun
	Enoxaparin Sodium			S	Unknown	60 Milligram, From 11th Weeks		Not Reported
	Enoxaparin Sodium			S	Unknown	40 Milligram, Daily		Not Reported
	Enoxaparin Sodium			S		60 Milligram, Daily, From 21st Week		Not Reported
	Prednisolone			S	Unknown	55 Milligram, Daily		Not Reported
	Heparin			S	Unknown	10000 International Unit 2 Ml, Bid, From 6th Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16313762	NON-EXPEDITED			US-PFIZER INC-2019204686		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Herpes Virus Infection	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16314061	NON-EXPEDITED			US-PFIZER INC-2019204667		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance	Nitroglycerin	S	Unk	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2019	16314799	EXPEDITED (15-DAY)		DS, HO	NL-TEVA-2019-NL-1048836		39 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Matter Lesion	Hydroxychloroquine			S		200mg, 1x/D		Teva
	Foliumzuur			C		10mg, 1x/W		Not Reported
	Methotrexaat			C		25mg, 1x/W		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	12859483	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-CA-WYE-H18058010		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Enbrel			S	Subcutaneous	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk, Injection		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	14713137	NON-EXPEDITED			US-PFIZER INC-2017496026		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Celebrex			C		200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	14949897	EXPEDITED (15-DAY)		OT	GB-CONCORDIA PHARMACEUTICALS INC.-E2B_00011958		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Prednisolone			S	Unknown	7.5 Mg, Qd		Concordia
	Itraconazole			S	Oral	100 Mg, Qd		Concordia
	Levothyroxine			S	Unknown	75 Microg, Qd		Concordia
	Domperidone			S	Unknown	10 Mg,3x 1 10 Mg, Tid		Not Reported
	Domperidone			S	Unknown	10 Mg, Tid		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Uniphyllin			S	Unknown	200 Mg, 2x Per Day 200 Mg, Bid		Not Reported
	Uniphyllin			S	Unknown	200 Mg, Bid		Not Reported
	Carbocisteine			S	Unknown	750 Mg, Bid		Not Reported
	Risedronate Sodium			S	Unknown	35 Mg, Unk		Not Reported
	Amylase, Lipase, Protease			S	Unknown	10 Mg, 3x 1 10 Mg, Tid		Not Reported
	Amylase, Lipase, Protease			S	Unknown	10 Mg, Tid		Not Reported
	Creon			S		10 Mg, Tid		Not Reported

	Creon	S	Unknown	10 Mg, Tid		Not Reported
	Ivig	S				Not Reported
	Propanolol	C				Not Reported
	Hydroxychloroquine	C		200 Mg, Qd		Not Reported
	Lansoprazole	C		30 Mg, Qd		Not Reported
	Creon	C		10 Mg, Tid		Not Reported
	Carbocisteine	C		750mg 2 Tds		Not Reported
	Uniphyllin	C		200 Mg, Bid		Not Reported
	Risedronate	C		35 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	15747014	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-MYLANLABS-2018M1092371			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg, Unk (From Gestational Week 0-113+6)		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported

	Xarelto	S	Transplacental	From Gestational Week 0-5	Mylan
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Mylan
	Metamizole	S	Transplacental	From Gestational Week 0-14	Mylan
	Aliskiren	S	Transplacental	Unk	Mylan
	Enoxaparin Sodium	S	Transplacental	From Gestational Week 0-14	Mylan
	Dalteparin Sodium	S		Unk	Mylan
	Rituximab	S		Unk	Mylan
	Heparin Lmw	S	Transplacental	Unk	Mylan
	Clexane	S		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	15981837	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1007439		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Pantoprazole			S	Unknown	Gestational Week 0-14		Not Reported
	Tacrolimus			S	Unknown	Gestational Week 0-14		Not Reported
	Salbutamol			S	Unknown	Gestational Week 0-14		Not Reported
	Ezetimibe			S	Unknown	Gestational Week 0-14		Not Reported
	Simvastatin			S	Unknown	Gestational Week 0-14		Not Reported
	Torasemide			S	Unknown	Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Unknown	Gestational Week 0-14		Not Reported
	Prednisolone			S		Gestational Week 0-14		Not Reported
	Ramipril			S		20 Milligram (Gestational Week 0-13+6)		Not Reported
	Acetylsalicylic Acid			S		Gestational Week 0-14		Not Reported

Nicotine	S	Unknown	Gestational Week 0-14		Mylan
Dipyrone	S		Unk		Mylan
Rivaroxaban	S	Unknown	Gestational Week 0-5		Mylan
Aliskiren	S	Unknown	Gestational Week 0-5		Mylan
Metamizole	C	Unknown	Gestational Week 0-14		Mylan
Enoxaparin /01708202/	C	Unknown	14 Weeks, Gestational Week 0-14		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16271427	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001301		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colour Vision Tests Abnormal; Retinal Degeneration; Retinal Toxicity; Visual Field Defect	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16317559	EXPEDITED (15-DAY)		OT	NL-ROCHE-2318581		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone Acetate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16317994	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001387			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16318010	EXPEDITED (15-DAY)		HO	EC-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-207974		14 YR	Female	ECU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Reversible Encephalopathy Syndrome	Atorvastatin			S	Unknown	10 Milligram		Sun
	Atorvastatin			S				Sun
	Enalapril			S	Unknown	5 Milligram		Ranbaxy
	Enalapril			S				Ranbaxy
	Furosemide			S	Unknown	40 Milligram		Sun
	Furosemide			S				Sun
	Hydroxychloroquine			S	Unknown	200 Milligram		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			S	Unknown	30 Milligram		Mutual
	Prednisone			S				Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16318617	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000783			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16318723	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000787			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16319237	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000788			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16319806	EXPEDITED (15-DAY)		OT	PHHY2019NL108699		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16322314	EXPEDITED (15-DAY)		HO, OT	MX-GLAXOSMITHKLINE-MX2019GSK085670		21 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Affect Lability;	Lamotrigine			S				Glaxosmithkline
Altered State Of	Lamotrigine			S				Glaxosmithkline

Consciousness; Anhedonia; Asthenia; Behaviour Disorder; Cerebral Atrophy; Cognitive Disorder; Depressed Mood; Depression; Dizziness; Drug Ineffective; Drug Interaction; Hyperreflexia; Impulsive Behaviour; Insomnia; Intellectual Disability; Irritability; Nausea; Psychotic Disorder; Psychotic Symptom; Sleep Disorder; Status Epilepticus; Suicidal Ideation; Suicide Attempt	Levetiracetam	S	Unk		Glaxosmithkline
	Warfarin	S	Unk		Glaxosmithkline
	Warfarin	S			Glaxosmithkline
	Phenobarbital	S			Not Reported
	Valproate Magnesium	S			Not Reported
	Topiramate	S			Not Reported
	Topiramate	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Azathioprine	C			Glaxosmithkline
	Azathioprine	C			Glaxosmithkline
	Calcium	C			Glaxosmithkline
	Vitamin D	C			Glaxosmithkline
	Vitamin D	C			Glaxosmithkline
	Vitamin D	C			Glaxosmithkline
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported
	Citalopram	C	Unk		Not Reported
	Citalopram	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16474808	DIRECT	Y				66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bone Pain	Methotrexate			S				Unknown
	Plaquenil		Y	S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	12528936	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015097304		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Folic Acid			S		Weekly		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil			S		200 Mg, 1x/Day (Everyday		Not Reported

Omission				Besides Sundays)	
	Plaquenil	S		200 Mg, 2x/Day	Not Reported
	Cimzia	S		200 Mg, Every 2 Weeks	Not Reported
	Humira	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	281 Mg, Every 4 Weeks	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Weekly	Not Reported
	Prednisone	S	Oral	2 Df, Alternate Day (Every Second Day For The Next 2 Weeks)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	12748863	EXPEDITED (15-DAY)		HO	NL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-071206		62 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Diarrhoea; Headache; Laryngitis; Myalgia; Nausea; Oral Candidiasis; Upper Respiratory Tract Infection; Upper Respiratory Tract Inflammation; Vomiting	Abatacept			S	Subcutaneous	125 Mg/Ml, Qwk		Bristol Myers Squibb
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Salazopyrine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	12824564	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016464814		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise;	Xeljanz			S	Oral	10 Mg, 1x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Tecta			S	Oral	Unk		Pfizer

Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Pantoprazole	S	Oral	Unk	Pfizer
	Sulfasalazine	S	Oral	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Sulfasalazine	S	Oral	500 Mg, 1x/Day	Pfizer
	Lisinopril	S	Unknown	Unk	Not Reported
	Prinivil	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, 1x/Day	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Voltaren [Diclofenac]	S	Oral	75 Mg, 2x/Day	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Diclofenac Potassium	S	Oral	75 Mg, As Needed	Not Reported
	Diclofenac Potassium	S	Oral	75 Mg, 2x/Day	Not Reported
	Pantoprazole Sodium	S		Unk	Not Reported
	Pantoprazole Magnesium	S	Oral	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Diclofenac	S	Oral	75 Mg, 2x/Day	Not Reported
	Apo-Folic Acid	S		Unk	Not Reported
	Apo-Diclofenac	S	Oral	75 Mg, 2x/Day	Not Reported
	Apo-Lisinopril	S		Unk	Not Reported
	Voltaren Sr	S	Oral	75 Mg, 2x/Day	Not Reported
	Lisinopril Dihydrate	S	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	14256850	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017295802		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly		Pfizer
	Sulfasalazine	S		Unk		Pfizer
	Leflunomide	S		Unk		Not Reported
	Gold	S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Remicade	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	14556169	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022466		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	14676512	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hypersensitivity	Hydroxychloroquine			S						Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	15683595	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018170987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Nausea; Retinal Toxicity; Therapeutic Product Effect Decreased; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	6 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	15707926	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018175026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported
	Benadryl			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322959	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001583			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322960	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001713			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Headache; Liver Function Test Abnormal; Malaise; Nausea; Palmoplantar Pustulosis	Plaquenil			S	Unknown			Concordia
	Humira(Solution For Injection)			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322961	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001761			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Percocet			S				Not Reported
	Tylenol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322962	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001765			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322963	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001770		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Ultram			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322964	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001777			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia
	Levaquin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322965	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001778			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322966	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001783			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322967	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001791			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Plaquenil			S				Concordia
	Asa			S				Not Reported
	Cefdinir			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Cimzia			S				Not Reported
	Codeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322968	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001793			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16322969	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-			Female	USA

001807

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ultram			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Sulfa (Sulfadiazine)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16323531	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000808			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324993	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000507			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Rash	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324994	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000508			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324995	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000510			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Plaquenil			S				Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324996	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000512			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16324997	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000516			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2019	16485146	DIRECT	N	HO			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocardial Infarction	Hydroxychloroquine S 200mg Mylan Pharmaceuticals Inc			S	Oral			Actavis

	Mycophenolate 500mgt Tab	S	Oral			Genentech
	Aspirin	C				Not Reported
	Atorvastatin	C				Not Reported
	Brilnta	C				Not Reported
	Carvedilol	C				Not Reported
	Coumadin	C				Not Reported
	Eliquis	C				Not Reported
	Lisinopril	C				Not Reported
	Plaquenil	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	14751081	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001113			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	15368607	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003201		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Plaquenil			S	Unknown			Concordia
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	15470572	EXPEDITED (15-DAY)		OT	PHHY2016CA163833		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Blood Glucose Abnormal; Cataract; Dizziness; Ear Discomfort; Erythema;	Sandostatin			S	Subcutaneous	50 Ug, Once/Single (Test Dose)		Not Reported
	Sandostatin			S				Not Reported
	Sandostatin Lar			S	Intramuscular	20 Mg, Qw4 (Every 4		Not Reported

Fatigue; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Muscle Spasms; Nausea; Rheumatoid Arthritis; Vomiting					Weeks)	
	Sandostatin Lar	S	Intramuscular	30 Mg, Qmo		Not Reported
	Sandostatin Lar	S	Intramuscular	30 Mg, Qmo		Not Reported
	Atorvastatin	S	Unknown	10 Mg, Qd		Novartis
	Bisoprolol	S	Unknown	2.5 Mg, Bid		Not Reported
	Plaquenil	S	Unknown	200 Mg, 2 Tablets Once A Day		Not Reported
	Forxiga	C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328167	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000951		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Methotrexate			S				Not Reported
	Xeljanz Xr			C				Not Reported
	Arava			C				Not Reported
	Arava			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328176	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001032			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328180	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002636			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia	Plaquenil			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			C				Not Reported
	Mtx			C				Not Reported
	Humira			C				Not Reported
	Remicade			C				Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328182	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003064		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328232	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003753			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Venous Disease	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328233	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003756			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328234	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003784			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Vomiting	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328235	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003790			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328236	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003798			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Respiratory Disorder	Plaquenil			S				Concordia
	Gold			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Tetanus Antitoxin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328237	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003802			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328238	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003803			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328239	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003816			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328240	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003919			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328241	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004007			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammatory Marker Increased	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Leflunomide				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328266	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003194			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Exfoliative Rash; Pain	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328267	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003200			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328268	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Treatment Failure	Plaquenil			S				Concordia
	Methotrexate			S				Not Reported
	Goldshots (Gold Sodium Thiomalate)			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328269	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003221			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort	Hydroxychloroquine 200 Mg	S		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328270	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003224			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations; Palpitations	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328271	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003275			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Plaquenil			S				Concordia
	Celebrex			S				Not Reported
	Sulfacetamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328272	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003290			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S	Unknown			Concordia
	Lipitor			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Toviaz			S	Unknown			Not Reported
	Requip			S	Unknown			Not Reported
	Vytorin			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported

	Omeprazole				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328273	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003345			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia
	Humira			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328274	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003626			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Infection	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328302	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201811-004010			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder; Visual Impairment	Plaquenil			S	Unknown	Over 5 Years		Concordia
	Xeijanz			S	Oral			Not Reported
	Xeijanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328303	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004063		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dyspepsia	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Clinoril			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Follc Acid			C				Not Reported
	Prolia			C				Not Reported
	Centrum			C				Not Reported
	Baclofen			C				Not Reported
	Vlt D3			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328304	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004064			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Disorder	Plaquenil			S				Concordia
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328305	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004087			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328306	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004196		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328307	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000004			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328308	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000089			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lactose Intolerance; Pain; Product Formulation Issue	Plaquenil 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328309	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000209			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Urticaria	Plaquenil			S				Concordia
	Penicillins			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328310	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000214			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Allergic Reaction To Excipient; Dermatitis Contact; Hypersensitivity	Plaquenil				S					Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16328315	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000288			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2019	16330264	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001222			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	15707115	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2018174142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram, Q4wk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Indometacin			S	Oral	50 Milligram, Tid		Not Reported
	Indometacin			S	Oral	50 Milligram (4 Every 1 Day)		Not Reported
	Indometacin			S	Oral	50 Milligram, Q6h		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

	Plaquenil		S	Oral	200 Milligram, Bid		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q8wk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram, Two Every One Day		Not Reported
	Indomethacin		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16323777	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000794			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Vomiting	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16323899	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000800			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16324129	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000822			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Treatment Failure	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328716	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000532			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Leukopenia; Off Label Use	Plaquenil			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328717	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000539			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328718	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000543			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328719	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000551			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Disturbance	Plaquenil			S						Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328720	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000553			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Leukopenia; Paraesthesia	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328721	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000569			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328722	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000573			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328723	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000574			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure; Visual	Plaquenil			S				Concordia

Field Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328724	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000578			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Synovitis	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328725	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000579			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328726	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000580			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328727	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000585			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapy Non-Responder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328728	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000620			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328729	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000636			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328730	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000637			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328731	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000639			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance;	Plaquenil			S				Concordia
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328732	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Unknown	USA

							INC.-GSH201903-000643			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Swelling	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328733	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000653			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328734	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000677			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective	Plaquenil Plaquenil			S S				Concordia Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328776	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000780			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328777	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Unknown	USA

						INC.-GSH201903-000782			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapeutic Product Effect Decreased	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328778	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000812			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S		200 Bid		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328779	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000816			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328780	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000817			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328781	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000823			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328782	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000824			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328795	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001203			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Toxicity To Various Agents	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328796	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001206			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Injection Site Pruritus; Liver Function Test Increased	Plaquenil		S	Unknown	Treatment Length 3 Years	Concordia
	Humira		S	Subcutaneous	Treatment Length 2 Years	Not Reported
	Methotrexate		S	Unknown	Treatment Length 4 Years	Not Reported
	Actemra		S	Unknown	Treatment Length 3 Years	Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328797	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001208			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Swelling; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328798	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001215			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Diarrhoea; Drug Hypersensitivity; Hepatic Function Abnormal; Psoriasis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Glimepiride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328799	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001223			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328800	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001234			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328801	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001245			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328803	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000872			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Injection Site Swelling	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328804	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000873			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Plaquenil			S				Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328805	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000828			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328806	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000830			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328807	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000832			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Muscle Spasms	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328808	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000833			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328826	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000886			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Hydroxychloroquine 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328827	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000906			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Nausea	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328828	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000908			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328829	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000912			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Serum Sickness	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328830	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000913			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328831	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000922			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S	Unknown			Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328832	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000926			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Infection	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Methotrexate				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328833	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000927			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328834	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000929			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Headache; Pain; Paranasal Sinus Discomfort; Pyrexia	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328835	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000938			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise	Plaquenil 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328836	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000857			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328837	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000860			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Therapy Non-Responder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328838	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000861			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328839	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000864			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328840	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000869			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328841	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000872			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Rash	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328842	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000877			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328843	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000878			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328844	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000879			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328845	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000880			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dry Skin; Swelling Of Eyelid	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328848	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000681			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Stomatitis	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328849	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000682			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328850	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort	Plaquenil				S					Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328851	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000712			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328852	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000715			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Treatment Failure	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328854	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000722			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328855	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000726			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Treatment Failure	Plaquenil			S				Concordia
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported
	Arava			S				Not Reported

	Prednisone				S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328856	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000737			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328857	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000738			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Treatment Failure	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328858	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000743			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328876	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000744			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328877	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000745			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Treatment Failure	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328878	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000767			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328879	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000769			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328880	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000772			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328989	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003042			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Rlfampin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328990	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328991	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003105		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328992	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003107		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported

	Azulfidine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328993	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003131			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Solar Lentigo	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328994	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003143			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328997	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002788		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oropharyngeal Pain	Plaquenil			S				Concordia
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328998	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002864			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea;	Plaquenil			S				Concordia
Hypersensitivity	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16328999	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002913			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Panic Attack	Hydroxychloroquine			S		(Took 1 Tablet) On Friday,		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329000	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002999			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Discolouration	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329001	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003033			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective	Plaquenil			S				Concordia
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329002	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003039			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Hydroxychloroquine			S				Concordia
	Actemra			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329092	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003173			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329093	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003179			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Nausea	Plaquenil			S				Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329094	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000835			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329095	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000837			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329096	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Unknown	USA

INC.-GSH201903-000843

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329097	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000845			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329098	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000848			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329099	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000851			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2019	16329100	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000856			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	9241094	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2013008286		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Apo Prednison			S	Unknown	5 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	11457075	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015090326		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; C-Reactive Protein Abnormal;	Enbrel			S	Subcutaneous	Unk		Amgen
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

Cataract; Cerebrovascular Accident; Crying; Depressed Mood; Depression; Disability; Disease Progression; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Fine Motor Skill Dysfunction; Foot Deformity; Gait Disturbance; Hand Deformity; Hepatic Enzyme Increased; Hepatitis C; Hypokinesia; Impaired Healing; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Muscle Spasms; Musculoskeletal Disorder; Musculoskeletal Pain; Myalgia; Nodule; Pain In Extremity; Papule; Peripheral Swelling; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Shoulder Deformity; Sleep Disorder Due To A General Medical Condition; Surgical Failure; Swelling; Weight Decreased; Wrist Deformity	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	One Tablet Orally, Qd	Not Reported
	Senokot	C		Unk	Not Reported
	Coversyl	C		Unk	Not Reported
	Percocet	C		Unk	Not Reported
	Ativan	C	Sublingual	Unk, Every Night At Bedtime	Not Reported
	Lovastatin	C		Unk	Not Reported
	Flexeril	C	Sublingual	Unk, Qd	Not Reported
	Cyclobenzaprine Hydrochloride	C	Sublingual	Unk	Not Reported
	Cyclobenzaprine Hydrochloride	C		Unk	Not Reported
	Cyclobenzaprine Hydrochloride	C	Subcutaneous	Unk Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	11729658	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015117867		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel	S	Subcutaneous	Unk	Amgen
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	12147335	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016026213		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Hypertension; Insomnia; Pain; Rash; Seronegative Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Visual Impairment	Enbrel	S	Subcutaneous	50 Mg, Qwk		Amgen
	Leflunomide	S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride	S	Oral	150 Milligram, Qd		Not Reported
	Plaquenil	S	Unknown	300 Milligram, Qd		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Venlafaxine	S	Unknown	150 Milligram, Qd		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Reactine (Cetirizine Hydrochloride)	C	Unknown	10 Milligram, Qd		Not Reported
	Effexor	C	Oral	150 Milligram, Qd		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Cetirizine	C		10 Milligram, Qd		Not Reported
	Ultram	C	Unknown	Unk, Q4h		Not Reported
	Zopiclone	C	Unknown	7.5 Milligram, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	12893999	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016505237		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	13916066	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017127993			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tenofovir Disoproxil			C		Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C		Unk		Not Reported
	Tenofovir Disoproxil Fumarate			C		300 Milligram		Not Reported
	Xeljanz			C		Unk		Not Reported
	Zopiclone			C		Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Milligram, Qd		Not Reported
	Folic Acid			C	Oral	2.5 Milligram, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported
	Methotrexate			C	Oral	15 Milligram, Qwk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	14606725	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000890			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Laboratory Test Abnormal; Treatment Failure; Urticaria	Plaquenil		S			Concordia
	Methotrexate		S			Not Reported
	Arava		S			Not Reported
	Meloxicam		S	Unknown		Not Reported
	Remicade		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	14667549	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000993			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Night Sweats	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	15009513	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2018079449			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Infliximab			S	Unknown	5 Milligram/Kilogram, Q8wk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Qd (More Than Or Equal To 2 Grams Daily For 3 Months)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	15826954	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2019004229		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	2 Df, Qd		Not Reported
	Leflunomide			S	Oral	20 G, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	1 Mg, Qd		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg, Unk		Not Reported
	Sulfasalazine			S	Rectal	1 G, Bid		Not Reported
	Methotrexate Sodium			C	Unknown	25 Mg, Unk		Not Reported
	Methotrexate Sodium			C	Unknown	1 Mg, Qwk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	15841468	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019007348			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Prednisone			C				Not Reported
	Folic Acid			C	Unknown	1 Df, Qwk		Not Reported
	Simponi			C	Subcutaneous			Not Reported

	Xeljanz			C	Oral	5 Mg, Bid				Not Reported
	Xeljanz			C	Oral	5 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	15994383	NON-EXPEDITED			US-PFIZER INC-2019076166		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Inderal			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Dextran			S		Unk		Unknown
	Fentanyl Citrate			S		Unk		Unknown
	Gabapentin			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Pfizer
	Zaleplon			S		Unk		Unknown
	Viaspan (Adenosine\Allopurinol\Glutathione\Magnesium Sulfate\Potassium Phosphate, Monobasic)			S		Unk		Not Reported
	Benzoin			S		Unk		Not Reported
	Cardizem			S		Unk		Not Reported
	Welchol			S		Unk		Not Reported
	Zetia			S		Unk		Not Reported
	Proscar			S		Unk		Not Reported
	Norco			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Palladone			S		Unk		Not Reported
	Imdur			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Methadone			S		Unk		Not Reported
	Kadian			S		Unk		Not Reported

Nabumetone	S	Unk	Not Reported
Oxycodone	S	Unk	Not Reported
Paroxetine	S	Unk	Not Reported
Compazine	S	Unk	Not Reported
Aciphex	S	Unk	Not Reported
Crestor	S	Unk	Not Reported
Simvastatin	S	Unk	Not Reported
Tizanidine	S	Unk	Not Reported
Azmacort	S	Unk	Not Reported
Paxil Cr	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16092843	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000755		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oedema Peripheral; Pericardial Effusion; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous	1 In 2 - 2		Not Reported
	Lotensin			C				Not Reported
	Benazepril			C				Not Reported
	Pantoprazole			C				Not Reported
	Xalantan			C				Not Reported
	Timolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16116661	EXPEDITED (15-DAY)		OT	SE-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000775		72 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Tachycardia	Plaquenil 200 Mg Tablet			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16117272	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-028277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergic Oedema; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Cefazolin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Milligram 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Mg, Bid		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16169032	EXPEDITED (15-DAY)		OT	NL-ROCHE-2297004		26 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Use Issue; Meningitis Aseptic; Off Label Use	Rituximab	S	Unknown			Not Reported
	Rituximab	S				Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Mycophenolate Mofetil	S				Not Reported
	Azathioprine	S	Unknown			Not Reported
	Azathioprine	S				Not Reported
	Cyclophosphamide	S	Unknown			Not Reported
	Cyclophosphamide	S				Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S				Not Reported
	Prednisolone	S	Unknown			Not Reported
	Prednisolone	S				Not Reported
	Belimumab	C	Unknown			Not Reported
	Belimumab	C				Not Reported
	Fresh Frozen Plasma	C	Unknown	Initially Up To 4 Units		Not Reported
	Fresh Frozen Plasma	C	Unknown	2 Units		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16226441	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001022			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Toxicity To Various Agents	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16231066	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001232		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 M/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400		Concordia

							M/Day, Alternately			
		Prednisolone			S	Oral				Concordia
		Prograf			C					Not Reported
		Edirol			C					Not Reported
		Edirol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16324935	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001597			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea	Plaquenil			S				Concordia
	Methotrexate			C	Oral			Not Reported
	Methotrexate Injection Usp			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329142	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000806			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindication To Medical Treatment; Drug Intolerance; Treatment Failure	Hydroxychloroquine			S				Concordia
	Arava			S				Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329143	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000821			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329144	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000827			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vertigo	Hydroxychloroquine			S				Concordia
	Methotrexate			C				Not Reported
	Remicade			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329160	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000434		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fatigue; Joint Stiffness; Nausea	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329161	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000799			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Pain	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329162	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000804			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance	Plaquenil			S						Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329168	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000401			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fear Of Injection; Headache; Rash	Plaquenil			S				Concordia
	Arava			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329281	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000297			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329282	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000300			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertension	Plaquenil			S				Concordia
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329283	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000305			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329284	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000307			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329285	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000309			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329309	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000317			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection	Plaquenil			S				Concordia
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329310	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000320			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329311	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Unknown	USA

						INC.-GSH201902-000323				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329312	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000328			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329313	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000334			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329346	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-025996			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Changed	Prednisone			S	Unknown	Unk		Aurobindo
	Xeljanz			S	Oral	6 Milligram, Two Times A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329357	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001012			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia
	Methotrexate			C				Not Reported
	Arava			C				Not Reported
	Orencia			C				Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329358	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001077			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inflammation; Treatment Failure	Plaquenil			S				Concordia
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329359	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-001081			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329360	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001157			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Plaquenil			S				Concordia

Intolerance; Gastrointestinal Disorder	Methotrexate Sodium	S	Unknown		Not Reported
	Arava	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329361	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001166			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastrointestinal Disorder; Nausea	Plaquenil			S				Concordia
	Methotrexate Sodium			S	Unknown	Daily Dose: 50mg/2ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329362	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001169			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal	Plaquenil			S				Concordia
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329363	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001179			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329364	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Female	USA

						INC.-GSH201804-001186			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Transaminases Increased; Vision Blurred	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329365	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001194			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329366	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001199			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stress; Treatment Noncompliance	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329375	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA132527		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Famotidine			S		Unk		Not Reported
	Venlafaxine Hydrochloride			S		Unk		Not Reported
	Doxycycline Hyclate			S		Unk		Not Reported
	Trandolapril			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Plavix			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Furosemide			S		Unk		Sanofi
	Nifedipine			S		Unk		Not Reported
	Glyceryl Trinitrate			S		Unk		Sanofi
	Rosuvastatin Calcium			S		Unk		Not Reported
	Metoclopramide Hydrochloride			S				Not Reported
	Trazodone Hydrochloride			S				Not Reported
	Loperamide Hydrochloride			S				Not Reported
	Ambien			S				Sanofi
	Gabapentin			S		Unk		Not Reported
	Esomeprazole Magnesium			S				Not Reported
	Flomax [Morniflumate]			S	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Potassium Acetate			S		Unk		Not Reported
	Victoza			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329401	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000335			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Plaquenil 200 Mg			S				Concordia

Hydroxychloroquine				S					Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329402	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000356			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Nausea; Vomiting	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329403	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000366			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329404	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000371			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329405	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000376			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329407	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001114			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329431	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Psoriasis	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329432	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000384			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ophthalmological Examination Abnormal	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329433	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Ocular Toxicity; Rash; Therapeutic Product Effect Decreased	Plaquenil			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Simponi Aria	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Xeljanz Xr	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329434	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000395			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329435	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000407			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Ocular Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329474	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001205			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329475	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001216			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspepsia	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329476	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001229			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Drug Ineffective; Nausea; Pruritus; Vomiting	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329477	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001269			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Therapeutic Product Effect Incomplete	Plaquenil			S				Concordia
	Humira			S				Not Reported
	Acetmra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329478	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001294			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ulcer	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329479	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001324			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Plaquenil			S	Unknown			Concordia

Intolerance; Drug Intolerance; Drug Intolerance; Injection Site Reaction; Therapeutic Product Effect Decreased; Urticaria; Urticaria; Urticaria	Plaquenil	S			Concordia
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Otezia	S	Unknown		Not Reported
	Otezia	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329480	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001334			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Mouth Ulceration	Plaquenil			S	Unknown	More Than 3 Months.		Concordia
	Humira(Solution For Injection)			S	Subcutaneous	More Than 3 Months.		Not Reported
	Arava			S	Unknown	More Than 3 Months.		Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329481	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001337			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder	Plaquenil 200 Mg			S		Before 2010		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329482	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001355			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Product Substitution Issue	Plaquenil Tablet			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329483	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001360			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329533	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000408			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329534	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000439			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329535	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Unknown	USA

						INC.-GSH201902-000451				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil Tablet			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329536	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201902-000462			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329537	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000484			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329555	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000489			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Muscle Fatigue; Muscular Weakness; Peripheral Swelling	Plaquenil			S				Concordia
	Methotrexate			S				Not Reported
	Qrava			S				Not Reported
	Sulfazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329556	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000505		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329557	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000648			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329558	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000655			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Plaquenil			S				Concordia
Leukopenia	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329559	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000659			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329694	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS			Unknown	USA

INC.-GSH201903-000840

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329695	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000954			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain; Swelling	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329696	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000958			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329697	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000970			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329698	NON-EXPEDITED		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000975			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Rash Pruritic; Urticaria	Plaquenil Tablet			S	Oral	9 Doses		Concordia
	Plaquenil Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329731	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000979			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329732	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000983			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Somnolence	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329733	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000997			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Palpitations	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329734	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001000			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329735	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001005			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329745	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001395			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Plaquenil			S				Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329746	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001398			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Nausea; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Humira (Solution For Injection)			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Injection			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329747	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001484			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia
	Methotrexate			S	Oral			Not Reported
	Imuran			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329758	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001488			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329759	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001507			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Imuran			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329760	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001521			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329761	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001522			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Plaquenil			S				Concordia
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329762	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001529			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Plaquenil			S				Concordia
	Arava			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329763	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001531			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia
	Tamoxifen			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329764	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001532			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329799	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001011			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Pain	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329800	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001014			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329801	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001018			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329802	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001029			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329851	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001535			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Inflammatory Marker Increased; Mouth Ulceration; Rash	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329852	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001541			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Aspirin			S				Not Reported
	Minocycline			S				Not Reported
	Sulfamethoxazole			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329853	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001544			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329854	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-			Female	USA

001549

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Plaquenil			S				Concordia
	Methotrexate			S				Not Reported
	Azulfidine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329855	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001553			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329856	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001575			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective	Plaquenil			S	Unknown			Concordia
	Humira (Solution For Injection)			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329857	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001577			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329858	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001608			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Fatigue	Plaquenil			S				Concordia
	Codeine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16329859	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001632			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Remicad			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330299	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001076			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia	Hydroxychloroquine 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330300	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001077			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Plaquenil			S					Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330301	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001088			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Eye Swelling	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330302	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001091			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330303	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001096			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rash	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330310	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001098			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330311	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001101			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea;	Plaquenil			S				Concordia
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330312	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001121			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330313	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001126			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Hydroxychloroquine			S				Concordia
Gastrointestinal Disorder;	Plaquenil			S				Concordia
Headache								

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330314	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001131			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330421	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001154			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Respiration Abnormal	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330422	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001155			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330431	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001209			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330432	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001210			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Skin Disorder; Visual Impairment	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330434	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001211			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330435	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001227			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330444	NON-EXPEDITED		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001170			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Cardiac Disorder; Heart Rate Irregular; Palpitations; Visual Impairment	Plaquenil			S				Concordia
	Kevzara			S		200 Mg/1-14ml Pfs (2/Box)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330447	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001197			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330449	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001202			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330498	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000494			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration	Plaquenil 200 Mg			S				Concordia
	Fexofenadine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330499	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000498			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330537	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000109			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning	Hydroxychloroquine 200 Mg			S				Concordia

Sensation; Hepatic Pain; Overdose	Tablet Hydroxychloroquine 200 Mg Tablet	S	Started To Take Only Half The Days	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330565	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-046096			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330603	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002029			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Synovitis; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown			Concordia
	Humira (Solution For Injection)			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330604	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Female	USA

INC.-GSH201806-002165

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S				Concordia
	Adalimumab			S				Not Reported
	Etanercept			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330605	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Rash Macular; Skin Swelling; Vomiting	Plaquenil			S	Unknown			Concordia
	Humira (Solution For Injection)			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330606	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002207			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea	Hydroxychloroquine			S				Concordia
	Enbrel			S				Not Reported
	Reglan			S				Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			C				Not Reported
	Diclofenac			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16330607	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002211			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Nausea; Vomiting	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16332524	NON-EXPEDITED			US-PFIZER INC-2019207605		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16332922	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1047243		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Left Atrial Dilatation	Methotrexate			S	Unknown	Later Dose Reduced To 7.5mg Every 10 Days		Not Reported
	Methotrexate			S	Unknown	7.5 Milligram		Not Reported
	Certolizumab Pegol			S	Unknown	Dose Administered Every Other Week; Later Dosing Frequency Changed To One Injection Every 21 Days		Mylan
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16333118	EXPEDITED (15-DAY)		DS, OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2019DEP000475		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac Potassium			S	Oral	75 Mg, Bid		Assertio Therapeutics
	Diclofenac Potassium			S	Oral	1 Df, Unk		Assertio Therapeutics
	Diclofenac Potassium			S	Oral	2 Df, Qd		Assertio Therapeutics
	Diclofenac Potassium			S	Oral	Unk		Assertio Therapeutics
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	1 Df, Qd		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Weekly		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16335054	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001422		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Discharge; Drug Ineffective; Excessive Granulation Tissue; Off Label Use; Pyoderma	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Prednisone			S		Doses Were Reduced		Not Reported

Gangrenosum; Rebound Effect; Skin Ulcer	Prednisone		S	Unknown	Increased Dose		Not Reported
	Mycophenolate Mofetil		S		4months Ago		Not Reported
	Mycophenolate Mofetil		S		B6 4months Ago		Not Reported
	Mycophenolate Mofetil		S		B12 4months Ago		Not Reported
	Mycophenolate Mofetil		S	Unknown	Dose Increased To 3g Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16335057	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001415			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia Alzheimer'S Type	Plaquenil			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16335058	EXPEDITED (15-DAY)		OT	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001423			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Haematochezia; Stress	Hydroxychloroquine 200 Mg Tablet			S	Unknown	Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16335059	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001396		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Goitre; Lymphadenopathy;	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Subcutaneous	Single Dose Prefilled		Not Reported

Malaise; Pain In Extremity; Treatment Failure					Autoinjector	
	Enbrel	S			Single Dose Prefilled Autoinjector	Not Reported
	Methotrexate	S	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2019	16335090	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001942			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective	Plaquenil			S				Concordia
	Aspirin			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	11529881	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015293041		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Tecta			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Plaquenil			S	Oral	200 Mg, (2 Tablets) 1x/Day		Not Reported
	Voltaren Sr			S	Oral	75 Mg, Twice Daily And As Needed		Not Reported
	Synthroid			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported

	Depo-Medrol			C	Intramuscular	Unk			Not Reported
	Depo-Medrol			C	Intramuscular	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	12146307	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016128043		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Drug Ineffective; Gastrooesophageal Reflux Disease; Joint Swelling; Urinary Tract Infection; Weight Decreased	Tecta			S	Unknown	Unk		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	700 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Cyclobenzaprine Hydrochloride			C	Unknown	Unk		Not Reported
	Diphenhydramine			C	Oral	50 Mg, Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Nabilone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	20 Mg, 1x/Day		Not Reported
	Prevacid			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Zomig			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	13053442	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016180166		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haemorrhage; Drug	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen

Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Haemorrhage; Infection; Influenza Like Illness; Malaise; Nausea; Rheumatoid Arthritis; Urinary Tract Infection	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, Q6wk Cyclical	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil	C	Oral	2 Tablets, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	13892859	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015098022		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Ml, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Milliliter, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

	Arava	S	Unknown	20 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	20 Ml, Weekly		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	14701426	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018101252		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gait Disturbance; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Arava			S		20 Mg, Daily		Not Reported
	Cortef			S	Oral	30 Mg, Daily		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Prednisone			C		10 Mg, Daily		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	14987130	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001934		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased	Hydroxychloroquine			S	Unknown			Concordia
	Xeljanz			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	14993896	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001971			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Plaquenil 200 Mg Tablet			S	Oral	Unknown		Concordia
	Cortisone			S	Unknown	Unknown (Twice)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15041864	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine 200 Mg Tablet			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Arava			C				Not Reported
	Sulfasalazine			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15206299	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018101252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15353995	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018121475		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Tramacet			C		Unk		Not Reported
	Tramadol			C		100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15395344	NON-EXPEDITED			US-PFIZER INC-2018375181		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15715581	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018511504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Levofloxacin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Demerol			S	Unknown	Unk		Pfizer
	Azithromycin			S	Unknown	250 Mg, Qd		Pfizer
	Azithromycin			S	Unknown	250 Milligram, Qd		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Benadryl			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Procytox			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Ezetrol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15843387	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019007301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15849142	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019026667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Minocycline Hcl			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg, Bid (2 Every 1 Day(S))		Pfizer
	Arava			S	Unknown	Unk		Not Reported

				Azathioprine	S	Unknown	100 Mg, Unk	Not Reported
				Humira	S	Subcutaneous	Unk	Not Reported
				Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
				Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
				Leflunomide	C	Unknown	Unk	Not Reported
				Hydroxychloroquine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	15853002	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019007864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Diphenhydramine			C	Oral	50 Mg, Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16210004	EXPEDITED (15-DAY)		HO, OT	PHHY2019GB088178		74 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin G Decreased; Bronchiectasis; Condition Aggravated; Infection; Pneumococcal Infection; Respiratory Tract Infection; Upper Respiratory Tract Infection	Methotrexate			S	Unknown	25 Mg, Qw		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Pneumococcal Vaccine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16257921	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039626		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Unknown	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335144	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002215			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Rash	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Cimzia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335145	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002221			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Hydroxychloroquine 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335146	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002232			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Hydroxychloroquine			S				Concordia
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335147	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002304			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335148	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002308		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance	Plaquenil			S	Unknown			Concordia
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335149	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002352		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pharyngeal Swelling; Pruritus; Rash	Plaquenil 200 Mg Tablet			S				Concordia
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Vitamin Supplements			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335150	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002376			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Therapy Non-Responder	Hydroxychloroquine			S				Concordia
	Methotrexate			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335151	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Female	USA

						INC.-GSH201807-002388				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia
	Orencia			S				Not Reported
	Enbrel			S				Not Reported
	Metoprolol			S				Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335152	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002403			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Plaquenil			S				Concordia
	Methotrexate			S				Not Reported
	Arava			S				Not Reported
	Mobic			S				Not Reported
	Levaquin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335153	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002404			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydroxychloroquine			S				Concordia
Alopecia; Drug	Sulfa			S				Not Reported
Hypersensitivity; Drug	Remicade			S				Not Reported
Ineffective; Urticaria	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335154	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS			Female	USA

						INC.-GSH201807-002407				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Ph Decreased; Weight Decreased	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335155	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002567			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling	Plaquenil			S				Concordia
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335420	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001843			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335489	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001850			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335519	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-			Female	USA

001891

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Plaquenil			S				Concordia
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335589	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002595		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Pain; Lacrimation Increased; Ocular Hyperaemia	Hydroxychloroquine			S		Last 20 Years		Concordia
	Kevzara			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335590	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002633		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335591	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002634			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335592	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002678			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Plaquenil			S				Concordia
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16335708	EXPEDITED (15-DAY)		OT	CA-SA-2019SA098642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Arava			S		Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S				Not Reported
	Cimzia			S		Unk		Not Reported
	Myfortic			S		Unk Unk, Bid		Not Reported
	Remicade			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336048	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002737			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Treatment Failure	Plaquenil			S				Concordia
	Arava			S				Not Reported
	Predniosone			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336049	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002740			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S				Concordia
	Sulfa			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336050	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002774		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lip Swelling; Rash Vesicular	Hydroxychloroquine 200 Mg			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336069	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002695			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336094	NON-EXPEDITED			US-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002721			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Dizziness	Hydroxychloroquine			S				Concordia
	Flomax			C				Not Reported
	Gabapentin			C				Not Reported
	2 Baby Aspirin			C				Not Reported

	Lipitor			C					Not Reported
	Propafenone Hcl			C					Not Reported
	Meclizine			C		As Needed			Not Reported
	Advil			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16336131	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2788286-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Disability; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2019	16339164	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-045877			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	14937952	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001712		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Plaquenil Tablet			S	Oral			Concordia
	Erythromycin			S	Unknown			Concordia
	Erythromycin			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported

	Norfloxacin	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cefaclor	S	Unknown		Not Reported
	Celecoxib	S	Oral		Not Reported
	Meperidine Hydrochloride	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	15209009	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018101792		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	15714011	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018510705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Q4wk (1 Every 4)		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Indometacin			S	Oral	50 Milligram, Tid		Not Reported
	Indometacin			S	Oral	50 Milligram (4 Every 1 Day)		Not Reported

	Indometacin	S	Oral	50 Milligram, Q6h	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Q8wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Two Every One Day	Not Reported
	Indomethacin [Indometacin]	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16340855	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001420		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Lipodystrophy Acquired; Oedema; Off Label Use; Therapeutic Response Decreased; Treatment Noncompliance	Hydroxychloroquine 200 Mg Tablet			S	Unknown	From Day 1		Concordia
	Prednisone			S	Unknown	From Day 1		Not Reported
	Prednisone			S	Unknown	From Day 30		Not Reported
	Prednisone			S	Unknown	From Day 60		Not Reported
	Prednisone			S	Unknown	From Day 90		Not Reported
	Azathioprine			S	Unknown	Starting From Day 30		Not Reported
	Azathioprine			S	Unknown	Starting From Day 60		Not Reported
	Sodium Bicarbonate			C				Not Reported
	Amllorlde			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sumatriptan			C				Not Reported
	Citalopram			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16341215	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019078780		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Enbrel		S	Unknown	Unk		Amgen
	Actemra		S	Unknown	Unk		Not Reported
	Arava		S	Oral	Unk		Not Reported
	Cimzia		S	Subcutaneous	Unk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram, Bid		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi		S	Subcutaneous	Unk		Not Reported
	Gold		C		Unk		Not Reported
	Methotrexate		C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone		C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16341891	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000245			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline Hyclate			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plavix			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported

	Glyceryl Trinitrate			S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk	Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk	Not Reported
	Trazodone Hydrochloride			S	Unknown	Unk	Not Reported
	Loperamide Hydrochloride			S	Unknown	Unk	Not Reported
	Ambien			S	Unknown	Unk	Not Reported
	Gabapentin			S	Unknown	Unk	Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk	Not Reported
	Flomax /00889901/			S	Unknown	Unk	Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk	Not Reported
	Potassium Acetate			S	Unknown	Unk	Not Reported
	Victoza			S	Unknown	Unk	Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16342056	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028116			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye;	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, One Every Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Myochrysine			S	Intramuscular	60 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported
	Orencia			S	Intravenous (not	750 Milligram, Once Every		Not Reported

Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)	Month	
	Orencia	S	Subcutaneous	Unk Unk, Every Week	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nexium	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Lomotil	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16342626	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018021652		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Adalimumab			S	Subcutaneous	40 Mg, 1x/Day (40 Mg, Cyclic (1 Every 2 Week(S)))		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (Every 2 Weeks)		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	Unk		Not Reported
	Rituximab	S		1000 Milligram, Q6mo		Not Reported
	Prednisone	C	Oral	10 Mg, Daily		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
	Folic Acid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344364	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019210121		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Diovan			C		Unk		Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid			C		Unk		Not Reported
	Sertraline			C		Unk		Not Reported
	Valtrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344779	EXPEDITED (15-DAY)		OT	PHHY2019NL112319		67 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ecthyma; Necrosis; Product Use In Unapproved Indication;	Prednisone			S	Unknown			Novartis
	Prednisone			S				Novartis

Pseudomonas Infection; Rash Macular; Skin Lesion; Vasculitis	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Adrenalin	S	Unknown		Not Reported
	Adrenalin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2019	16344842	EXPEDITED (15-DAY)		HO	DE-BAXTER-2019BAX009797		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Exposure During Pregnancy; Live Birth; Premature Rupture Of Membranes; Pyrexia; Tachycardia; Twin Pregnancy	Endoxan 1g			S	Unknown			Baxter
	Endoxan 1g			S	Unknown	Unk		Baxter
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S	Unknown			Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hcq			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	11107644	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015138590		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion;	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	1 Mg, Weekly		Pfizer
	Celebrex			S		Unk, 2x/Day		Pfizer

Nasopharyngitis; Paraesthesia; Product Dose Omission; Rheumatoid Arthritis; Rhinorrhoea	Celebrex	S		2 Df, 1x/Day	Pfizer
	Sulfasalazine	S	Rectal	1 G, 2x/Day	Pfizer
	Arava	S		Unk	Not Reported
	Leflunomide	S	Oral	20 G, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	30 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	11147510	EXPEDITED (15-DAY)		DE, OT	CA-AMGEN-CANSP2015051198		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Qid		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Q6h		Not Reported
	Hydroxychloroquine			S	Unknown	Unk (200mg/400mg Daily)		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Q12h		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15119199	EXPEDITED (15-DAY)		HO, OT	US-ASTRAZENECA-2018SE86626		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Nexium			S	Oral			Astrazeneca
	Imdur			S	Oral			Not Reported
	Crestor			S	Oral			Not Reported
	Potassium			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml, 40 Mg One In 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml, 40 Mg One In 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml, 40 Mg One In 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Mg/0.8 Ml, 40 Mg One In 2 Week		Not Reported
	Famotidine			S	Unknown			Not Reported
	Famotidine			S	Unknown			Not Reported
	Victoza			S	Unknown			Not Reported
	Trazodone			S	Unknown			Not Reported
	Loperamide			S	Unknown			Not Reported
	Ambien			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Plavix			S	Unknown			Not Reported
	Nitroglycerin			S	Unknown			Not Reported
	Trandolapril			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Flomax	S	Unknown	Not Reported
	Furosemide	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Reglan	S	Unknown	Not Reported
	Effexor	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15173335	EXPEDITED (15-DAY)		HO	PHHY2018DE049425		79 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Dysuria; General Physical Health Deterioration; Headache; Pyrexia; Vomiting	Prednisolone			S	Oral	5 Mg, Qd		Novartis
	Quensyl			S	Oral	200 Mg, Qd		Not Reported
	L Thyroxin			C	Oral	50 Ug, Qd		Not Reported
	Furosemid			C	Oral	125 Mg, Bid		Not Reported
	Apidra			C	Subcutaneous	Unk		Not Reported
	Toujeo			C	Subcutaneous	Unk		Not Reported
	Novalgin (Metamizole Sodium)			C	Oral	500 Mg, Qid		Not Reported
	Fentanyl			C	Transdermal	37.5 Ug, Unk		Not Reported
	Lyrica			C	Oral	25 Mg, Bid		Not Reported
	Allopurinol			C	Oral	100 Mg, Qd		Not Reported
	Simvastatin			C	Oral	20 Mg, Qd		Not Reported
	Perenterol Forte			C	Oral	250 Mg, Unk		Not Reported
	Nebivolol			C	Oral	5 Mg, Qd		Not Reported
	Movicol			C	Oral	13.125|0.35|0.18|0.05 G, Bedarf, Beutel		Not Reported
	Ramipril			C	Oral	2.5 Mg, Qd		Not Reported
	Pantozol			C	Oral	40 Mg, Bid		Not Reported
	Ecural			C	Transdermal	Unk, Bid		Not Reported
	Pipamperone			C	Oral	Unk		Not Reported
	Dekristol			C	Oral	20000 Ie / Woche, 1-0-0-0,		Not Reported

					Kapseln	
	Vomex A	C	Oral	Unk		Not Reported
	Hydrochlorothiazid	C	Oral	25 Mg, Qd		Not Reported
	Ass	C	Oral	100 Mg, Qd		Not Reported
	Magnetrans Forte	C	Oral	Unk		Not Reported
	Iberogast	C	Oral	Unk		Not Reported
	Pantoprazole	C	Oral	40 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15195381	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-031227			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Carbocisteine			S	Unknown	750 Milligram, Once A Day,(750mg 2 Tds)		Not Reported
	Carbocisteine			S	Unknown	750 Milligram, Two Times A Day (750 Mg, Bid)		Not Reported
	Risedronate			S	Unknown	35 Milligram		Aurobindo
	Domperidone			S	Unknown	30 Milligram, Once A Day,(10 Mg, Tid)		Not Reported
	Domperidone			S	Unknown	10 Milligram, 3 Times A Day		Not Reported
	Domperidone			S	Unknown	10 Milligram, Once A Day		Not Reported
	Levothyroxine			S	Unknown	75 Milligram, Once A Day		Not Reported
	Levothyroxine			S	Unknown	75 Microgram, Daily (75 Ug, Qd)		Not Reported
	Amylase/Lipase/Protease			S	Unknown	30 Milligram, Once A Day, 10 Mg, Tid		Not Reported
	Amylase/Lipase/Protease			S	Unknown	10 Milligram, 3 Times A Day		Not Reported
	Amylase/Lipase/Protease			S	Unknown	10 Milligram, Once A Day		Not Reported
	Iviglob-Ex			S	Unknown	Unk		Not Reported

	Itraconazol			S	Oral	100 Milligram, Once A Day	Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Once A Day	Not Reported
	Lansoprazole			S	Unknown	30 Milligram, Once A Day	Not Reported
	Uniphyllin			S	Unknown	400 Milligram, Once A Day,(200 Mg, Bid)	Not Reported
	Uniphyllin			S	Unknown	200 Milligram, Two Times A Day, 200 Mg, Bid	Not Reported
	Uniphyllin			S	Unknown	200 Milligram, Once A Day	Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Once A Day, 200 Mg, Qd	Not Reported
	Creon			S	Unknown	10 Milligram, Once A Day (10 Mg, Tid)	Not Reported
	Creon			S	Unknown	30 Milligram, Once A Day (10 Mg, Tid)	Not Reported
	Propanolol			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15214443	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018304754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15605751	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3229		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Cyclic		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15807100	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375923			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Mg, Weekly (1 Every 1 Week)		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Adalimumab	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Tenofovir Disoproxil	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C		300 Mg, Unk	Not Reported
Xeljanz	C		Unk	Not Reported
Zopiclone	C		Unk	Not Reported
Zopiclone	C	Unknown	7.5 Mg, 1x/Day	Not Reported
Folic Acid	C	Oral	2.5 Mg, 1x/Day	Not Reported
Methotrexate	C	Oral	15 Mg, Weekly (1 Every 1 Week(S))	Not Reported
Methotrexate	C	Oral	10 Mg, Weekly (1 Every 1 Week(S))	Not Reported
Pantoprazole	C		Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15841281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Enbrel		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Twice Weekly	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Monthly	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15853608	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019027167			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15860969	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019030919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Enbrel	S	Unknown	Unk		Pfizer
	Xeljanz Xr	S	Unknown	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Arava	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk		Not Reported
	Diphenhydramine	C	Oral	50 Mg, Unk		Not Reported
	Hydroxychloroquine	C		Unk		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	15948305	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014211			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16059894	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020843		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16133268	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0894		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

	Celebrex	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346097	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346222	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027626			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Azithromycin			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5.0 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346229	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-028619			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Risedronate Tablet			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Oral	22.5 Milligram, Every Week		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Marijuana			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346814	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027619			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Daily		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Benadryl			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Demerol	S	Unknown	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Imuran	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Procytox	S	Unknown	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day		Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day		Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day		Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day		Not Reported
Ezetrol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16346955	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027447			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Venlafaxine			S	Oral	150.0 Milligram, Daily		Aurobindo
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	300.0 Milligram, Daily		Not Reported
	Cetrizine			C	Unknown	10.0 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16347143	EXPEDITED (15-DAY)		HO, LT, OT	MX-TORRENT-00000149		19 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Asthenia; Dizziness; Drug Interaction; Impulsive Behaviour; Intentional Overdose; Irritability; Major Depression; Nausea; Suicidal Ideation; Suicide Attempt	Calcium			C		Unknown		Unknown
	Vitamin D			C		Unknown		Unknown
	Levetiracetam			S		Unknown		Unknown
	Valproate Magnesium			S		Unknown		Unknown
	Warfarin			S		Unknown		Unknown
	Lamotrigine			S		Unknown		Unknown
	Azathioprine			C		Unknown		Unknown
	Prednisone			S		Unknown		Unknown
	Phenobarbital			S		Unknown		Unknown
	Hydroxychloroquine			S		Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16347535	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-027959			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Red Blood Cell Sedimentation Rate	Tramadol+Paracetamol			S	Oral	Unk		Aurobindo
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2.0 Gram, Once A Day		Not Reported

Abnormal; Sleep Disorder; Spinal Operation; Spinal Stenosis	Actonel		C	Unknown	Unk		Not Reported
	Calcium		C	Unknown	Unk		Not Reported
	Lorazepam		C	Unknown	Unk		Not Reported
	Lyrica		C	Unknown	Unk		Not Reported
	Metformin		C	Unknown	Unk		Not Reported
	Methylprednisolone		C	Unknown	Unk		Not Reported
	Nortriptyline		C	Unknown	Unk		Not Reported
	Premarin		C	Unknown	Unk		Not Reported
	Tylenol		C	Unknown	Unk		Not Reported
	Vagifem		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16348439	EXPEDITED (15-DAY)		OT	AR-TEVA-2019-AR-1052942		57 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
American Trypanosomiasis; Infection Reactivation	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16348587	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2793228-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Penicillin G	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Actemra	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Prednisone	C		Not Reported
Hydroxychloroquine	C		Not Reported
Tylenol	C		Not Reported
Calcium	C		Not Reported
Vitamin D	C		Not Reported
Plaquenil	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16349128	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20190522141			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Shock; Dermatitis Psoriasiform; Epstein-Barr Virus Infection; Infection; Leukopenia; Meningitis Enteroviral; Off Label Use; Paradoxical Drug Reaction; Product Use In Unapproved Indication; Sepsis; Syncope; Systemic Lupus Erythematosus; Varicella Zoster Virus Infection	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Golimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16349185	NON-EXPEDITED		OT	US-TEVA-2019-US-1052753		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Night Blindness;	Hydroxychloroquine			S	Unknown	6 Mg/Kg Daily; Receiving		Teva

Retinopathy; Visual Field Defect

From 12 Years

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2019	16350071	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2792891-00		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability; Herpes Zoster; Hiatus Hernia; Insomnia; Muscle Spasms; Sarcoidosis; Skin Cancer	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	12712380	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016130276		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Effexor Xr			S	Oral	150 Mg, 1x/Day		Pfizer
	Venlafaxine Hcl			S	Unknown	150 Mg, 1x/Day		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Mg, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			C	Unknown	10 Mg, 1x/Day		Not Reported
	Cetirizine			C		10 Milligram, Qd		Not Reported
	Ultram			C	Unknown	Unk, Q4h		Not Reported
	Zopiclone			C	Unknown	7.5 Milligram, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	13373784	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017043340		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Renal Failure; Thrombocytopenia	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	17.5 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	13929674	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2699		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Statex			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

	Morphine Sulfate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	15216767	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018305503		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	15227516	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018308304		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Qwk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Cyclic		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	15721383	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION			Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Indomethacin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	15950856	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014302			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Vectra /00141802/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16049080	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2019-0009756		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Oxycodone Hydrochloride			S	Unknown	10 Mg, Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ilaris			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	7 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16352111	EXPEDITED (15-DAY)		HO, LT, OT	MX-AUROBINDO-AUR-APL-2019-029143			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Asthenia; Dizziness; Drug Interaction; Impulsive Behaviour; Intentional Overdose; Irritability; Major Depression; Nausea; Suicidal Ideation; Suicide Attempt	Levetiracetam			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Lamotrigine			S				Not Reported
	Phenobarbital			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Valproate Magnesium			S	Unknown	Unk		Not Reported
	Valproate Magnesium			S				Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Vitamin D			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16353814	EXPEDITED (15-DAY)		HO	PHHY2019AU116105		16 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrolyte Imbalance; Hypotension; Intentional Overdose	Hydroxychloroquine			S	Oral	100 Df, Unk		Novartis
	Prednisolone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2019	16353921	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-033		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Lipodystrophy Acquired	Prednisone			S	Unknown			Westward
	Prednisone			S	Unknown			Westward

	Prednisone	S	Unknown			Westward
	Prednisone	S	Unknown			Westward
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S				Not Reported
	Azathioprine	S	Unknown	50-100 Mg/Day		Not Reported
	Azathioprine	S				Not Reported
	Potassium Chloride	S	Unknown	Meq/Day		Not Reported
	Potassium Chloride	S	Unknown			Not Reported
	Potassium Chloride	S	Unknown			Not Reported
	Potassium Chloride	S	Unknown			Not Reported
	Sodium Bicarbonate	S	Unknown			Not Reported
	Sodium Bicarbonate	S				Not Reported
	Amiloride	S	Unknown			Not Reported
	Amiloride	S				Not Reported
	Sumatriptan	C	Unknown			Not Reported
	Citalopram	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2019	16355403	EXPEDITED (15-DAY)		OT	MX-ZYDUS-037198			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Behaviour Disorder; Depressed Mood; Drug Interaction; Hyperreflexia; Impulsive Behaviour; Insomnia; Irritability; Major Depression; Suicidal Ideation	Levetiracetam			S	Unknown			Zydus Pharm
	Topiramate			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Calcium Gluconate			S	Unknown			Not Reported
	Colecalciferol			S	Unknown			Not Reported
	Lamotrigine			S	Oral			Not Reported
	Magnesium Valporate			S	Unknown			Not Reported

	Phenobarbital		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2019	16355605	EXPEDITED (15-DAY)		HO, OT	PHHY2019FR112266		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Hypergammaglobulinaemia Benign Monoclonal; Plasma Cell Myeloma; Rheumatoid Arthritis	Methotrexate			S	Unknown	15 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2019	16317691	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014004069		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram		Amgen
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	15 Milligram		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	11542413	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015288389		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cataract; Cerebrovascular Accident; Depressed Mood; Depression; Disease	Enbrel			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Humira			S		Unk		Not Reported

Progression; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Foot Deformity; Gait Disturbance; Hepatic Enzyme Increased; Insomnia; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Musculoskeletal Disorder; Nodule; Pain In Extremity; Papule; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Surgical Failure; Weight Decreased; Wrist Deformity	Humira	S	Subcutaneous	Unk	Not Reported
	Simponi	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	1 Tablet, 1x/Day	Not Reported
	Sennokott	C		Unk	Not Reported
	Senna Alexandrina	C			Not Reported
	Coversyl	C		Unk	Not Reported
	Percocet	C		Unk	Not Reported
	Ativan	C	Sublingual	Unk, 1x/Day At Bedtime	Not Reported
	Lovastatin	C		Unk	Not Reported
	Flexeril	C	Oral	Unk Unk, Daily	Not Reported
	Flexeril	C	Oral	Unk, Daily	Not Reported
	Cyclobenzaprine Hydrochloride	C		Unk	Not Reported
	Cyclobenzaprine Hydrochloride	C	Subcutaneous	Unk, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	14813158	EXPEDITED (15-DAY)		DE, HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001364		77 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Avium Complex Infection	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Baktar			C				Not Reported
	Baktar			C				Not Reported
	Nexium			C				Not Reported
	Nexium			C				Not Reported
	Bonalon			C				Not Reported
	Bonalon			C				Not Reported
	Rozerem			C				Not Reported
	Maintate			C				Not Reported
	Nu-Lotan			C				Not Reported

		Vesicare			C					Not Reported
		Carnaculin			C					Not Reported
		Erythrocin			C					Not Reported
		Kary Uni			C					Not Reported
		Imuran			C					Not Reported
		Adona			C					Not Reported
		Warfarin			C					Not Reported
		Prednisolone			C					Not Reported
		Januvia			C					Not Reported
		Halizon			C					Not Reported
		Pirespa			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	14950652	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001826		49 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Tacrolimus Monohydrate			S	Oral			Not Reported
	Prednisolone			C				Not Reported
	Onealfa			C				Not Reported
	Onealfa			C				Not Reported
	Aspartate Comps			C				Not Reported
	Aspartate Comps			C				Not Reported
	Takepron			C				Not Reported
	Bayaspirin			C				Not Reported
	Warfarin			C				Not Reported
	Avapro			C				Not Reported
	Metgluco			C				Not Reported
	Myslee			C				Not Reported
	Hyalein Eye Drops			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	15847419	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION		52 YR	Female	CAN

PHARMA-TREX2019-0102

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Fatigue; Headache; Inflammation; Insomnia; Migraine; Nasal Congestion; Nasopharyngitis; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Rectal			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	15946152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011272			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility	Orencia			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Tofacitinib	S	Unknown	Unk		Not Reported
	Gabapentin	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	15956801	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-015030			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Tolerance Decreased; Stomatitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16055232	EXPEDITED (15-DAY)		OT	AU-ROCHE-2278269			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Chronic Spontaneous Urticaria; Intentional Product Use Issue; Off Label Use; Osteoporosis; Rash Vesicular	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous	Unk (Off Label Supply)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

				Montelukast	C	Unknown			Not Reported
				Montelukast	C				Not Reported
				Prednisolone	C	Unknown			Not Reported
				Prednisolone	C				Not Reported
				Cyclosporine	C	Unknown			Not Reported
				Cyclosporine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16060352	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000558		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Asthma; Benign Ovarian Tumour; Chest Discomfort; Chest Discomfort; Chills; Cough; Crying; Dyspnoea; Emotional Disorder; Gastrointestinal Disorder; Hot Flush; Hypoxia; Impaired Work Ability; Malaise; Nasopharyngitis; Oxygen Therapy; Pulmonary Embolism; Pulmonary Embolism; Urinary Tract Infection	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz Xr			S	Oral			Not Reported
	Minocycline			C				Not Reported
	Ranitidine			C				Not Reported
	Choline Salicylate W/Magnesium Salicylate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16142599	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027743		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown	125 Milligram, Qd		Bristol Myers Squibb

Decreased	Actemra	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	200 Milligram 2every 1 Day	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown	1 Gram, 2 Every 1 Day	Not Reported
	Arava	C	Unknown		Not Reported
	Humira	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16231800	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-037213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	3 Milligram, Qd		Not Reported
	Prednisone	S	Unknown	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356744	EXPEDITED (15-DAY)		HO, LT, OT	MX-ACCORD-129110		19 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Asthenia; Dizziness; Drug Interaction; Impulsive Behaviour; Intentional Overdose; Irritability; Major Depression; Nausea; Suicidal Ideation; Suicide Attempt	Levetiracetam			S				Accord
	Valproic Acid			S				Not Reported
	Warfarin			S				Not Reported
	Phenobarbital			S				Not Reported
	Lamotrigine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Calcium Carbonate			C				Not Reported
	Vitamin D			C				Not Reported
	Azathioprine			C				Not Reported
	Valproate Magnesium			S				Not Reported
	Lamotrigine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356905	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Methotrexate			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Cimzia			S	Unknown				Not Reported
	Myfortic			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356906	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001456			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S		Second Day		Concordia
	Plaquenil			S				Concordia
	Plaquenil			S		Second Day		Concordia
	Xeljanz Xr			S				Not Reported
	Methotrexate			S		10 Pills A Week 5 Am 5 Pm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16356979	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1563		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Plaquenil (Hydroxychloroquine Sulphate)	S	Unknown			Not Reported
	Diovan	C	Unknown			Not Reported
	Docosah	C	Unknown			Not Reported
	Sertraline	C	Unknown			Not Reported
	Valtrex	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16358472	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019224222		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Avelumab			S		Unk		Pfizer
	Gemcitabine Hydrochloride			S		Unk		Unknown
	Abraxane			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16358650	EXPEDITED (15-DAY)		OT	CA-SA-2019SA051722			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Brenzys			C		Unk		Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16358766	EXPEDITED (15-DAY)		DE, HO	PHJP2019JP005752		70 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchopulmonary Aspergillosis; C-Reactive Protein Increased; Hypopharyngeal Cancer; Klebsiella Bacteraemia; Pericardial Effusion; Pleural Effusion; Product Use In Unapproved Indication	Neoral Cap	S	Oral	100 Mg, Qd		Novartis
	Neoral Cap	S				Novartis
	Prednisolone	S	Oral	40 Mg, Qd		Not Reported
	Prednisolone	S				Not Reported
	Cellcept	S	Oral	1000 Mg, Qd		Not Reported
	Cellcept	S				Not Reported
	Plaquenil	S	Oral	200 Mg, Qd		Not Reported
	Plaquenil	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2019	16358844	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2742875-00		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Healing; Incision Site Discharge; Meniscus Injury	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Protonix			C				Not Reported
	Amlodipine			C				Not Reported
	Mobic			C				Not Reported
	Lexapro			C				Not Reported
	Lipitor			C				Not Reported
	Pepcid			C				Not Reported
	Xanax			C				Not Reported
	Valsartan			C				Not Reported
	Calcium Plus D3			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	12298116	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016049365		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Blood Pressure Increased; Dependence; Drug	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Gold			S	Unknown	Unk		Not Reported

Ineffective; Fibromyalgia; Foot Operation; Gait Disturbance; Hip Arthroplasty; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To A General Medical Condition; Temperature Intolerance; Therapeutic Product Effect Incomplete; Treatment Failure	Humira	S	Unknown	40 Mg, Cyclical		Not Reported
	Lyrica	S	Oral	Unk		Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Xeljanz	C	Oral	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	14623072	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018CA037117		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Flutter; Atrioventricular Block First Degree; Blood Creatine Phosphokinase Increased; Cardiac Failure; Cardiomyopathy; Dilatation Atrial; Dyspnoea Exertional; Left Ventricular Hypertrophy; Oedema Peripheral; Pulmonary Haemorrhage; Right Ventricular Hypertrophy; Septic Shock; Skin Hyperpigmentation	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Nifedipine			C	Unknown	30 Mg, Qd		Not Reported
	Irbesartan			C	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	15377544	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Spiriva			S	Unknown			Boehringer Ingelheim
	Zenhale			S	Unknown	Dosage Form: Aerosol, Metered Dose		Not Reported
	Zenhale			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Lipitor			S	Unknown	Form- Not Specified		Not Reported
	Methotrexate			S	Unknown	Form-Not Specified		Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	15734611	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2018226626		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Adverse Reaction; Anaphylactic Reaction; Appetite Disorder; Arthralgia; Asthenia; Asthenia; Back Pain; Blister; Chills; Constipation; Contusion; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Tolerance; Dry Skin; Dysphagia; Dysphoria; Dyspnoea; Ear Pain; Erythema; Fatigue; Gait Disturbance; Haemorrhage;	Zyrtec			S	Unknown	10 Milligram		Glaxosmithkline
	Sudafed			S	Unknown	Unk		Glaxosmithkline
	Metronidazole			S	Unknown	Unk		Glaxosmithkline
	Cyclosporin			S		Dosage Form: Unspecified		Glaxosmithkline
	Hydrochlorothiazide + Triamterene			S	Unknown	Unk		Glaxosmithkline
	Iron Sulphate			S	Unknown	Unk		Glaxosmithkline
	Potassium Chloride			S				Glaxosmithkline
	Abreva			S	Unknown	Unk		Glaxosmithkline
	Keflex			S		Unk		Glaxosmithkline
	Isordil			S		At Bedtime		Glaxosmithkline
	Bactrim			S		Unk		Glaxosmithkline

Hallucination; Headache; Hypoaesthesia; Infection; Interstitial Lung Disease; Interstitial Lung Disease; Intestinal Obstruction; Joint Injury; Joint Swelling; Loss Of Consciousness; Musculoskeletal Stiffness; Myalgia; Nausea; Neck Pain; Oedema; Oral Pain; Osteoarthritis; Pain; Photophobia; Pruritus; Pruritus; Rash; Rheumatoid Arthritis; Rhinorrhoea; Sjogren'S Syndrome; Skin Disorder; Skin Warm; Sneezing; Tenderness; Thinking Abnormal; Unevaluable Event; Visual Impairment; Vomiting; Weight Decreased; Wheezing	Ampicillin	S		At Bedtime	Glaxosmithkline
	Antivert	S	Oral	12.5 Mg, Unk	Glaxosmithkline
	Ciprofloxacin	S		Dosage Form: Unspecified	Glaxosmithkline
	Colchicine	S		Dosage Form: Unspecified	Glaxosmithkline
	Colchicine	S			Glaxosmithkline
	Erythromycin	S		Dosage Form: Unspecified	Glaxosmithkline
	Diamox	S		Unk	Not Reported
	Dilaudid	S		Unk	Not Reported
	Citalopram Hydrobromide	S		Unk	Not Reported
	Doxycycline	S		Unk	Not Reported
	Lasix	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Xanax	S	Oral	0.5 Mg, Tid	Not Reported
	Xanax	S	Oral	.5 Milligram	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Trileptal	S		Unk	Not Reported
	Trileptal	S			Not Reported
	Enbrel	S		Unk	Not Reported
	Lialda	S		Unk	Not Reported
	Arava	S			Not Reported
	Geodon	S		12.5mg, As Required	Not Reported
	Actemra	S		Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Lyrica	S	Oral	Dosage Form: Unspecified	Not Reported
	Lyrica	S	Oral	Dosage Form: Unspecified	Not Reported
	Zenpep	S		Dosage Form: Unspecified	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Compazine	S		Dosage Form: Unspecified	Not Reported

Pseudoephedrine + Triprolidine Hcl	S			Not Reported
Hepatitis B Vaccine	S	Unknown	Dosage Form: Unspecified	Not Reported
Etanercept	S		Dosage Form: Unspecified	Not Reported
Vitamin D2	C			Glaxosmithkline
Mupirocin	C			Glaxosmithkline
Singulair	C		Dosage Form: Unspecified	Glaxosmithkline
Hydrocortisone	C			Glaxosmithkline
Zinc Sulfate	C		Dosage Form: Unspecified	Glaxosmithkline
Zantac	C		Dosage Form: Unspecified	Glaxosmithkline
Hypromellose	C			Glaxosmithkline
Lamotrigine	C			Glaxosmithkline
Budesonide	C			Glaxosmithkline
Lansoprazole	C			Glaxosmithkline
Tamiflu	C		Dosage Form: Unspecified	Not Reported
Synthroid	C		Dosage Form: Unspecified	Not Reported
Zoloft	C		Dosage Form: Unspecified	Not Reported
Restasis	C		Dosage Form: Unspecified	Not Reported
Restasis	C			Not Reported
Tylenol	C	Oral	Dosage Form: Unspecified	Not Reported
Celexa	C		Dosage Form: Unspecified	Not Reported
Zaditor	C		Dosage Form: Unspecified	Not Reported
Rubramin	C		Dosage Form: Unspecified	Not Reported
Deltasone	C			Not Reported
Protopic	C		Dosage Form: Unspecified	Not Reported
Protopic	C			Not Reported
Cyanocobalamine	C		Dosage Form: Unspecified	Not Reported
Systane (Polyethylene Glycol 400\Propylene Glycol)	C			Not Reported
Meloxicam	C			Not Reported
Loperamide Hydrochloride	C			Not Reported
Calcium Carbonate	C			Not Reported
Tretinoin	C			Not Reported
Tizanidine Hydrochloride	C			Not Reported
Influenza	C			Not Reported
Pneumococcal Vaccine	C			Not Reported

	Colecalciferol	C			Not Reported
	Colecalciferol	C			Not Reported
	Folic Acid	C			Not Reported
	Folic Acid	C			Not Reported
	Seretide	C			Not Reported
	Cyclobenzaprine Hydrochloride	C			Not Reported
	Vicodin	C			Not Reported
	Tears Plus	C			Not Reported
	Alendronate Sodium	C			Not Reported
	Hydromorphone Hydrochloride	S		Unk	Not Reported
	Promethazine	C			Not Reported
	Promethazine	C			Not Reported
	Tazact	C			Not Reported
	Morphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16072868	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2019075094		68 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Haemophilus Infection; Lung Consolidation; Pneumococcal Infection; Staphylococcal Infection; Swelling Face	Salazopirina En			S	Oral	500 Mg, 2x/Day (1 Tablet At Breakfast And Another At Dinner)		Pfizer
	Plaquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Prednisolone			S	Oral	5 Mg, 1x/Day		Not Reported
	Prednisolone			S	Oral	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16184304	NON-EXPEDITED			US-PFIZER INC-2019151814			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Expired Product Administered	Sulfasalazine			S		500 Mg, Twice A Day		Pfizer
	Plaquenil Sulfate			S		200 Mg, 2x/Day		Not Reported
	Plaquenil Sulfate			S		200 Mg, Alternate Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16359788	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03160		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Losartan			C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16359972	EXPEDITED (15-DAY)		DE, HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03155		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Flutter; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Pulmonary Haemorrhage; Septic Shock; Skin Hyperpigmentation	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (4 Mg/Kg)		Lupin
	Nifedipine			C	Unknown	30 Milligram, Qd		Not Reported
	Irbesartan			C	Unknown	150 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360130	EXPEDITED (15-DAY)		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03156		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (6.6 Mg/Kg)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360236	EXPEDITED (15-DAY)		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03157		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrioventricular Block Complete; Bundle Branch Block Right; Cardiomyopathy; Retinal Toxicity	Hydroxychloroquine	S	Unknown	400 Milligram, Qd (7.9 Mg/Kg)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360281	EXPEDITED (15-DAY)		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2016-04173		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrioventricular Block First Degree; Bundle Branch Block Left; Bundle Branch Block Right; Cardiac Failure Congestive; Cardiomyopathy	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	342 Milligram, Qd (6.5 Mg/Kg)		Lupin
	Prednisone			C	Unknown	5 Milligram		Not Reported
	Warfarin			C	Unknown	4 Milligram		Not Reported
	Ramipril			C	Unknown	10 Milligram		Not Reported
	Amlodipine			C	Unknown	5 Milligram		Not Reported
	Atenolol			C	Unknown	75 Milligram		Not Reported
	Levothyroxine			C	Unknown	100 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360458	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000655			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glycogen Storage Disease Type Ii; Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Ipca
	Losartan			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16360571	EXPEDITED (15-DAY)		OT	CA-SA-2019SA142796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Unevaluable Event; White Blood Cell Count Decreased	Hydroxychloroquine	S	400 Mg	Sanofi
	Methotrexate	S	20 Mg	Not Reported
	Leflunomide	S	Unk	Sanofi
	Sulfasalazine	S	1 G, Bid	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Unk	Not Reported
	Tofacitinib	C	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16361025	EXPEDITED (15-DAY)		DE, HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001477		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acute Kidney Injury; Candida Infection; Chills; Diarrhoea; Fatigue; Haemodynamic Instability; Headache; Herpes Simplex; Histoplasmosis Disseminated; Hypotension; Jaundice; Nausea; Ocular Icterus; Pyrexia; Respiratory Distress; Retroperitoneal Haemorrhage; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Etodolac			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown	Adalimumab Therapy Was Interrupted For Several Months In Late 2006		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16361211	EXPEDITED (15-DAY)		OT	PHHY2019US122235		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Loss Of Weight; Glycogen Storage Disease Type Ii; Hypoaesthesia; Muscular Weakness; Myopathy Toxic; Paraesthesia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis
	Losartan			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16362939	EXPEDITED (15-DAY)		OT	PHHY2019US117730		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Mg, Qd For 2 Years 10 Months (Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G)		Novartis
	Docetaxel			C	Unknown	21-Day Cycles		Not Reported
	Cyclophosphamide			C	Unknown	21-Day Cycles		Not Reported
	Anastrozole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16362952	EXPEDITED (15-DAY)		OT	PHHY2018CA037119		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Left Ventricular Hypertrophy; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16363223	EXPEDITED (15-DAY)		OT	NL-BAUSCH-BL-2019-015341		26 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intentional Product Use Issue; Meningitis Aseptic; Off Label Use	Prednisolone	S	Unknown			Not Reported
	Prednisolone	S				Not Reported
	Cyclophosphamide	S	Unknown			Not Reported
	Cyclophosphamide	S				Not Reported
	Rituximab	S	Unknown			Not Reported
	Rituximab	S				Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Mycophenolate Mofetil	S				Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S				Not Reported
	Azathioprine	S	Unknown			Not Reported
	Azathioprine	S				Not Reported
	Belimumab	C				Not Reported
	Belimumab	C				Not Reported
	Fresh Frozen Plasma	C	Unknown	Initially Up To 4 Units		Not Reported
	Fresh Frozen Plasma	C	Unknown	2 Units		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2019	16363871	EXPEDITED (15-DAY)		OT	PHHY2019US119187		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Hypokalaemia; Lipodystrophy Acquired; Metabolic Acidosis; Oedema	Azathioprine			S	Unknown	50–100 Mg/Day		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis
	Prednisone			S	Unknown			Not Reported
	Sodium Bicarbonate			S	Unknown	1960 Mg, Qd		Not Reported
	Potassium Chloride			S	Unknown	180 Meq, Qd		Not Reported
	Amiloride			C	Unknown	10 Mg, Qd		Not Reported
	Sumatriptan			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	14181390	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS		54 YR	Female	CAN

INC.-GSH201711-006334

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Hypertrophy; Cardiomyopathy; Left Ventricular Hypertrophy; Ocular Toxicity	Hydroxychloroquine			S	Unknown	(Dose 6.6 Mg/Kg).		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	14181391	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006341		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Blood Creatine Phosphokinase Increased; Brain Natriuretic Peptide Abnormal; Bundle Branch Block Right; Cardiac Septal Hypertrophy; Cardiomyopathy; Diastolic Dysfunction; Left Ventricular Hypertrophy; Retinal Toxicity; Troponin I Increased	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	14181392	EXPEDITED (15-DAY)		DE, HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006346		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Flutter; Atrioventricular	Hydroxychloroquine			S	Unknown	(4 Mg/Kg)		Concordia
	Nifedipine			C				Not Reported

Block; Blood Creatine Phosphokinase Increased; Brain Natriuretic Peptide Abnormal; Cardiac Failure; Cardiac Septal Hypertrophy; Cardiomyopathy; Diastolic Dysfunction; Dyspnoea Exertional; Left Atrial Dilatation; Left Ventricular Hypertrophy; Myocardial Necrosis Marker Increased; Oedema Peripheral; Right Atrial Dilatation; Right Ventricular Hypertrophy; Skin Hyperpigmentation	Irbesartan	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	14181393	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006347		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Brain Natriuretic Peptide Abnormal; Cardiac Septal Hypertrophy; Cardiomyopathy; Diastolic Dysfunction; Hypertension; Left Atrial Dilatation; Left Ventricular Hypertrophy; Myocardial Necrosis Marker Increased	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	14186392	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Natriuretic Peptide Abnormal; Cardiac Septal Hypertrophy; Cardiomyopathy; Left Atrial Dilatation; Left Ventricular Hypertrophy; Right Atrial Dilatation; Troponin I Increased	Hydroxychloroquine			S	Unknown	(4.1 Mg/Kg)		Concordia
	Prednisone			C				Not Reported
	Mycophenolic Acid			C				Not Reported
	Cyclosporine			C				Not Reported
	Atorvastatin			C				Not Reported
	Amlodipine			C				Not Reported
	Metoprolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	14870985	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2018GMK034958			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, (1 Every 1 Month)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Apo Celecoxib			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw (1 Every 1 Week)		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Apo Gabapentin			S	Oral	100 Mg, Bid		Not Reported
	Fentanyl Matrix			S	Unknown	Unk		Not Reported
	Apo Fentanyl Matrix			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Mg, Qd		Not Reported

Methotrexate	S	Subcutaneous	Unk, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
Diphenoxylate Hcl	C	Unknown	2.5 Mg, Qd	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Actonel	C	Unknown	36 Mg, Qw (1 Every 1 Week)	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Esomeprazole	C	Unknown	400 Mg, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Pantoprazole	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Trazodone	C	Oral	50 Mg, Qd	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Unknown	50 Mg, Qd	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	15620409	EXPEDITED (15-DAY)		HO, LT, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201811-003930		73 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Atrial Fibrillation; Epilepsy; Hypoxic-Ischaemic Encephalopathy; Pneumonia Aspiration; Pyelonephritis; Sepsis; Steroid Diabetes	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral	Transiently Discontinued		Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Imuran			C				Not Reported
	Thyradin			C				Not Reported
	Anplag			C				Not Reported
	Pariet			C				Not Reported
	Carbocisteine			C				Not Reported
	Saligren			C				Not Reported
	Actonel			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Daiphen			C				Not Reported

	Amphotericin B			C						Not Reported
	Forteo			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	15622617	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555903-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	15854172	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2019GMK039373			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis;	Gabapentin			S	Oral	100 Mg, (1 Every 2 Weeks)		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month		Not Reported
	Sulfasalazine			S	Oral	2.5 G, Od		Not Reported

Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Celebrex	S	Oral	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Od	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month	Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1 Df Every 2 Weeks	Not Reported
	Nasonex	C	Unknown	2 Df, Od (Spray Metered Dose)	Not Reported
	Prednisone	C	Unknown	5 Mg, Od	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Zoledronic Acid	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16038527	EXPEDITED (15-DAY)		OT	US-SA-2019SA060001		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Asthma; Benign Ovarian Tumour; Chest Discomfort; Chest Discomfort; Chills; Cough; Crying; Dyspnoea; Emotional Disorder; Gastrointestinal Disorder; Hot Flush; Hypoxia; Impaired Work Ability; Malaise; Nasopharyngitis; Oxygen Therapy; Pulmonary Embolism;	Arava			S		100 Mg, Qw		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported
	Minocycline			C		Unk		Not Reported
	Ranitidine			C		Unk		Not Reported
	Choline Salicylate W/Magnesium Salicylate			C		Unk		Not Reported

Pulmonary Embolism;
Urinary Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16279459	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001306		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Chorioretinal Atrophy	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Pl			C				Not Reported
	Warfarin			C				Not Reported
	Pravastatin Na			C				Not Reported
	Epadel			C				Not Reported
	Nexium			C				Not Reported
	Nexium			C				Not Reported
	Arotinolol Hydrochloride			C				Not Reported
	Atelec			C				Not Reported
	Micardis			C				Not Reported
	Bonalon			C				Not Reported
	Bonalon			C				Not Reported
	Ferrostec			C				Not Reported
	Myslee			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16327214	NON-EXPEDITED			US-SA-2019SA136135			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16364632	EXPEDITED (15-DAY)		OT	CA-IPCA LABORATORIES LIMITED-IPC-2019-CA-000662			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Treatment Failure	Hydroxychloroquine			S	Oral	200 Mg, Bid		Ipca
	Hydroxychloroquine			S				Ipca
	Prednisone			S	Oral	50 Mg, Opd		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16365035	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2799877-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16365584	EXPEDITED (15-DAY)		OT	IT-ACCORD-129865		68 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection Bacterial	Methotrexate			S	Subcutaneous			Accord
	Plaquenil			S	Oral			Not Reported
	Salazopyrin En			S	Oral			Not Reported
	Duloxetine			C				Not Reported
	Dibase			C				Not Reported
	Cardirene			C				Not Reported
	Domperidone			C				Not Reported
	Folina [Folic Acid]			C				Not Reported
	Omeprazole			C				Not Reported
	Prednisone			C				Not Reported

	Lyrica			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16366288	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2799054-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Pain; Drug Intolerance; Eye Disorder; Impaired Healing; Localised Infection; Mobility Decreased; Musculoskeletal Disorder; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hepatitis B Vaccine Hbsag			C	Unknown			Not Reported
	Hepatitis A Vaccine Inact W/Hepatitis B Vacci			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16366482	EXPEDITED (15-DAY)		OT	AR-TEVA-2019-AR-1055542		78 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypoglycaemia	Hydroxychloroquine			S	Unknown			Teva
	Glibenclamide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16367253	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1050443		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Retinal Toxicity; Toxicity To Various Agents; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown	Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G		Not Reported
	Docetaxel			S	Unknown	4 Cycles Of 21 Days Each		Not Reported

	Anastrozole	S	Unknown		Not Reported
	Cyclophosphamide	S	Unknown	4 Cycles Of 21 Days Each	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16367278	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2799901-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Humira			S	Subcutaneous			Not Reported
	Percocet			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydromorphone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16367775	EXPEDITED (15-DAY)		OT	PHHY2019CA117840		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Dermatitis Exfoliative Generalised; Limb Discomfort; Mechanic'S Hand; Product Use In Unapproved Indication; Treatment Failure	Prednisone			S	Oral	50 Mg, Qd		Novartis
	Prednisone			S	Oral	20 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2019	16368602	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2799057-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	8647044	EXPEDITED (15-DAY)		HO, OT	FR-SANOFI-AVENTIS-2012SA045402		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bradycardia	Plaquenil			S	Oral	1 Df,Qd		Sanofi
	Plaquenil			S	Oral	1 Df,Qd		Sanofi
	Hexaquine			S	Oral	1 Df,Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	11093298	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015149483		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Pain In Extremity; Parkinson'S Disease; Peripheral Swelling; Therapeutic Product Effect Incomplete	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	2.5 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Pregabalin			S	Oral	2 Df, Daily		Pfizer
	Pregabalin			S	Oral	5 Mg, Daily		Pfizer
	Pregabalin			S	Oral	2 Df, 2x/Day		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Plaquenil			S	Oral	400 Mg, 2x/Day		Not Reported
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Risedronate			S	Oral	1 Df (Pill), 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	11624805	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478295-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	For 94 Weeks		Not Reported

Lung Disease; Treatment Failure	Hydroxychloroquine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	13074088	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007954		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrioventricular Block First Degree; Bundle Branch Block Left; Bundle Branch Block Right; Cardiac Septal Hypertrophy; Cardiomegaly; Chest Discomfort; Chest Pain; Diastolic Dysfunction; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Endocardial Fibrosis; Hypertrophic Cardiomyopathy; Left Atrial Dilatation; Left Ventricular Dysfunction; Left Ventricular Dysfunction; Left Ventricular Hypertrophy; Mitral Valve Incompetence; Myocardial Fibrosis; Oedema Peripheral; Right Atrial Dilatation; Right Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	400 Mg/D For 6 D/Wk Since 2002		Concordia
	Hydroxychloroquine			S	Unknown	6.5 Mg/Kg		Concordia
	Prednisone			C				Not Reported
	Warfarin			C				Not Reported
	Ramipril			C				Not Reported
	Amlodipine			C				Not Reported
	Atenolol			C				Not Reported
	Levothyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	13423404	EXPEDITED (15-DAY)		OT	IT-TEVA-755327ACC		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	7.5 Milligram Daily;		Barr
	Certolizumab Pegol			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	15280441	EXPEDITED (15-DAY)			CA-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002963		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata	Hydroxychloroquine			S				Concordia
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16046937	NON-EXPEDITED			US-PFIZER INC-2019094143			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Azulfidine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Flexeril [Cefixime]			S		Unk		Not Reported
	Prednisone			S		20 Mg, Unk		Not Reported
	Prednisone			S		2.5 Mg, Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16369548	EXPEDITED (15-DAY)		HO, LT, OT	MX-LUPIN PHARMACEUTICALS INC.-2019-03314		19 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Asthenia; Dizziness; Drug Interaction; Impulsive Behaviour; Intentional Overdose; Irritability; Major Depression; Nausea; Suicidal Ideation; Suicide Attempt	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Lamotrigine			S	Unknown	Unk,		Lupin
	Lamotrigine			S	Unknown	Unk, Overdose For Suicide		Lupin
	Levetiracetam			S	Unknown	Unk		Lupin
	Warfarin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Valproate Magnesium			S	Unknown	Unk, Overdose		Not Reported
	Valproate Magnesium			S				Not Reported
	Phenobarbital			S	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16370614	EXPEDITED (15-DAY)		OT	SG-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-209316			Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Mycophenolate			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16371843	EXPEDITED (15-DAY)		HO, OT	MX-TEVA-2019-MX-1055827			Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Asthenia; Dizziness; Drug Interaction; Impulsive Behaviour; Irritability; Major Depression; Nausea; Suicide Attempt	Levetiracetam			S	Unknown			Teva
	Phenobarbital			S	Unknown			Not Reported
	Magnesium Valproate			S	Oral			Not Reported
	Magnesium Valproate			S				Not Reported
	Warfarin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2019	16372586	EXPEDITED (15-DAY)		HO	CA-ROCHE-2326114			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	11158512	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015183008		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Dizziness; Drug	Methotrexate Sodium			S		20 Mg, Weekly		Unknown

Hypersensitivity; Drug Intolerance; Hypoaesthesia; Infection; International Normalised Ratio Fluctuation; Iron Deficiency; Lyme Disease; Malaise; Pain In Extremity; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Demerol	S		Unk	Pfizer
	Lyrica	S		Unk	Pfizer
	Sulfasalazine	S		Unk	Pfizer
	Arthrotec	S		Unk	Pfizer
	Celebrex	S	Oral	200 Mg, 1x/Day	Pfizer
	Erythromycin	S		Unk	Pfizer
	Bisoprolol Fumarate	S		Unk	Not Reported
	Flagyl	S		Unk	Pfizer
	Levofloxacin	S		Unk	Unknown
	Plaquenil	S	Oral	400 Mg, 1x/Day	Not Reported
	Arava	S	Oral	400 Mg, 1x/Day	Not Reported
	Prednisone	S		Unk	Not Reported
	Ceclor	S		Unk	Not Reported
	Norfloxacin	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	400 Mg For About 3 Months	Not Reported
	Misoprostol	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	12036740	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015139707		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Emphysema; Hand Deformity; Joint Swelling; Nausea; No Adverse Event; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Unknown	1000 Mg, Bid		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Apo-Naproxen	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Zostavax	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	12775415	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016215956		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Actemra			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tylenol			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	14473048	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2018006616		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Arthropathy; Bone Erosion; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fall; Foot Deformity; Hand Deformity; Impaired Work Ability; Infection; Joint Dislocation; Joint Prosthesis User; Limb Discomfort; Loss Of Personal Independence In	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk Unk, Qd		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

Daily Activities; Musculoskeletal Disorder; Pneumonia; Post Procedural Infection; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rheumatoid Nodule; Sensitivity To Weather Change; Surgery; Synovitis; Treatment Failure	Celebrex	C	Unknown	Unk Unk, As Necessary		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	14570802	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0539			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Tofacitinib Citrate			S				Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	15449708	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-959126		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Erythromycin			S	Unknown			Not Reported
	Bisoprolol Fumarate			S				Duramed
	Norfloxacin			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Actavis
	Levofloxacin Hemihydrate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram Daily;		Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ceclor			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16377418	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1049949		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Reactivation; Visceral Leishmaniasis	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Lansoprazole			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16378736	EXPEDITED (15-DAY)		HO, LT, OT	MX-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-051041		21 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Labelled Drug-Drug Interaction Medication Error; Major Depression; Status Epilepticus; Suicide Attempt	Warfarin Sodium			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Vitamin D [Colecalciferol]			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Lamotrigine			S	Unknown			Not Reported
	Magnesium Valproate			S	Unknown			Not Reported
	Phenobarbital			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2019	16379770	EXPEDITED (15-DAY)		OT	PHHY2019GB121127			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Product Use In Unapproved Indication	Amoxicillin + Clavulanate Potassium			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Mg, Unk		Not Reported
	Azathioprine			S	Transplacental	100 Mg, Qd		Not Reported
	Prednisolone			S	Transplacental	Unk		Novartis
	Aspirin			S	Transplacental			Not Reported
	Gentamicin			S	Transplacental			Not Reported
	Tazocin			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2019	16380533	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1055962			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Malaise; Nausea	Sulfasalazine			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	12913935	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093087		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bronchitis; C-Reactive Protein Abnormal; Chronic Sinusitis; Contraindicated Product Administered; Drug Intolerance; Infection; Monocytosis; Nausea; Neutropenia; Pruritus; Psoriasis; Red Blood Cell Sedimentation Rate Abnormal; Sinusitis; Synovitis; Urinary Tract Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	13618127	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-042682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Abatacept			S	Unknown	250 Mg, Unk		Bristol Myers Squibb
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

			Plaquenil /00072602/		S	Unknown	200 Mg, Unk	Not Reported
			Naproxen		C	Oral	500 Mg, Prn	Not Reported
			Methotrexate		C	Oral	25 Mg, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	14217444	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175100		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Xeljanz			C	Oral	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	14654551	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2016M1042333		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrioventricular Block First Degree; Bundle Branch Block Bilateral; Cardiac Failure Congestive; Cardiomyopathy	Hydroxychloroquine			S	Unknown	342 Mg, 400 Mg/D For 6 D/Wk		Not Reported
	Prednisone			C	Unknown	5 Mg		Mylan
	Warfarin			C	Unknown	4mg		Mylan
	Ramipril			C	Unknown	10mg		Mylan
	Amlodipine			C	Unknown	5mg		Mylan

	Atenolol		C	Unknown	75mg			Mylan
	Levothyroxine Sodium		C	Unknown	100 Mg, Qd			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	14972514	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001903		65 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Fluid Retention; Hepatic Enzyme Increased; Herpes Zoster; Purulence; Spondylitis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

	Prednisolone	S	Oral	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Danazol	S	Oral	Not Reported
	Danazol	S	Oral	Not Reported
	Danazol	S	Oral	Not Reported
	Danazol	S	Oral	Not Reported
	Danazol	S	Oral	Not Reported
	Danazol	S	Oral	Not Reported
	Glycyron (Ammonium Glycyrrhizate\Glycine\Racemethionine)	S	Oral	Not Reported
	Samtirel	C		Not Reported
	Samtirel	C		Not Reported
	Slow K	C		Not Reported
	Slow K	C		Not Reported
	Nifedipine	C		Not Reported
	Halizon	C		Not Reported
	Furosemide	C		Not Reported
	Magmitt	C		Not Reported
	Magmitt	C		Not Reported
	Januvia	C		Not Reported
	Januvia	C		Not Reported
	Adona	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	15627672	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015472845		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20-25 Mg, Dosage 3/2 To 1/7		Pfizer

Intolerance; Emphysema; Hand Deformity; Joint Swelling; Nausea; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine	S	Unknown	1000 Mg, 2x/Day (Bid)		Pfizer
	Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day		Not Reported
	Apo-Naproxen	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide	S		20 Mg, Daily		Not Reported
	Naproxen	S		Unk		Not Reported
	Zostavax	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	15928263	EXPEDITED (15-DAY)		DE, HO, OT	CA-MYLANLABS-2018M1016062		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Atrial Flutter; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Pulmonary Haemorrhage; Septic Shock; Skin Hyperpigmentation	Hydroxychloroquine			S	Unknown	400mg/Day (4mg/Kg)		Not Reported
	Nifedipine			C	Unknown	30 Milligram		Mylan
	Irbesartan			C	Unknown	150 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16046574	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057903		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Exostosis; Osteoarthritis; Pain In Extremity; Pulmonary Thrombosis; Thrombosis	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Bid		Sanofi

		Pantoprazole			C	Unknown	40 Mg, Qd			Not Reported
		Pravastatin			C	Unknown	40 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16344935	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001438		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Hydroxychloroquine			S	Unknown	Daily Dose: Unknown		Concordia
	Famotidine			S	Unknown	Daily Dose: Unknown		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Daily Dose: Unknown		Not Reported
	Doxycycline Hyclate			S	Unknown	Daily Dose: Unknown		Not Reported
	Trandolapril			S	Unknown	Daily Dose: Unknown		Not Reported
	Prednisone			S	Unknown	Daily Dose: Unknown		Not Reported
	Plavix			S	Unknown	Daily Dose Unknown		Not Reported
	Furosemide			S	Unknown	Daily Dose: Unknown		Not Reported
	Nifedipine			S	Unknown	Daily Dose: Unknown		Not Reported
	Glyceryl Trinitrate			S	Unknown	Daily Dose: Unknown		Not Reported
	Rosuvastatin Calcium			S	Unknown	Daily Dose: Unknown		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Daily Dose: Unknown		Not Reported
	Trazodone Hydrochloride			S	Unknown	Daily Dose: Unknown		Not Reported
	Loperamide Hydrochloride			S	Unknown	Daily Dose: Unknown		Not Reported
	Ambien			S	Unknown	Daily Dose: Unknown		Not Reported
	Gabapentin			S	Unknown	Daily Dose: Unknown		Not Reported
	Esomeprazole Magnesium			S	Unknown	Daily Dose: Unknown		Not Reported
	Flomax			S	Unknown	Daily Dose: Unknown		Not Reported
	Isosorbide Mononitrate			S	Unknown	Daily Dose: Unknown		Not Reported
	Potassium Acetate			S	Unknown	Daily Dose Unknown		Not Reported
	Victoza			S	Unknown	Daily Dose: Unknown		Not Reported

	Humira			S	Subcutaneous	1 Dosage Form				Not Reported
	Humira			S	Subcutaneous	1 Dosage Form				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16378177	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019224946			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16381234	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2804589-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Symbicort			C		Turbuhaler		Not Reported
	Gabapentin			C	Unknown			Not Reported
	Atorvastatin Calcium			C				Not Reported
	Lansoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16381331	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001486			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Unevaluable Event; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16381379	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-209375		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Anastrozole			S	Unknown	Unk		Sun
	Docetaxel			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily (7.1 Mg/Kg Real Body Weight)		Sun
	Cyclophosphamide			S	Unknown	Unk (21-Day Cycle, 4 Cycles)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16382145	EXPEDITED (15-DAY)		HO	SG-TEVA-2019-SG-1058512		47 YR	Female	SGP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Kidney Infection	Mycophenolate Mofetil			S	Unknown	2 Gram Daily;		Teva

	Prednisolone			S	Oral	5 Milligram Daily;				Actavis
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16383373	EXPEDITED (15-DAY)		HO	PHHY2019FR124758		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Paracetamol			S	Unknown	3 G, Qd		Not Reported
	Lyrica			S	Oral	150 Mg, Unk		Not Reported
	Naftidrofuryl			S	Oral	20 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Hydrocortisone Roussel			C	Oral	20 Mg, Qd		Not Reported
	Forlax			C	Oral	3 Df, Qd		Not Reported
	Levothyrox			C	Oral	100 Ug, Qd		Not Reported
	Diltiazem			C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16383686	NON-EXPEDITED			US-SA-2019SA147674			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Liver Function Test Increased; Nausea; Weight Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16385174	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1059343		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome;	Mycophenolate Mofetil			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis

Ulcer; Vasculitis	Belimumab		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16385502	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019230632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	12287016	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016215635		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dependence; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Lyrica			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S		40 Mg, Every 2 Weeks		Not Reported
	Gold			S		Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	13059185	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016178872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Muscle Spasms; Pyelonephritis	Enbrel			S	Unknown	Unk		Amgen
	Lyrica			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	14157919	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165202		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Apo-Amitriptyline			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Diacerein			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	14367878	EXPEDITED (15-DAY)		CA, HO	PHHY2018PT001790		23 DAY	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; C-Reactive Protein Increased; Cardiomegaly; Foetal Exposure During Pregnancy; Heart Block Congenital; Hypoxia; Leukopenia; Lung Infiltration; Lupus Pneumonitis; Patent Ductus Arteriosus; Premature Baby; Pulmonary Embolism; Rash Erythematous; Respiratory Failure; Sepsis; Staphylococcal Infection; Tachypnoea; Thrombocytopenia	Salbutamol			S	Transplacental	Maternal Dose: 32mg/D On Week 26		Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental			Novartis
	Dexamethasone			S	Transplacental	Maternal Dose: 8 Mg/D On Week 26		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	14546367	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022138		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Elavil [Amitriptyline Hydrochloride]			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Apo-Diclofenac			S	Topical	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

	Naprosyn	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Amitriptyline	S	Unknown	Unk		Not Reported
	Diclofenac Sodium	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	15376670	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083714		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Methotrexate			S	Oral	22.5 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	15400658	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083665		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Abatacept			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Align			C	Unknown			Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	3 Every 1 Days (S)		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	15478193	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018023983		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Erosion; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fall; Foot Deformity; Hand Deformity; Impaired Work	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Ability; Infection; Joint Dislocation; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Pneumonia; Post Procedural Infection; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rheumatoid Nodule; Sensitivity To Weather Change; Synovitis; Treatment Failure; Treatment Failure	Gold	S		Unk		Not Reported
	Methotrexate	C	Oral	20 Mg, Weekly		Not Reported
	Celebrex	C		Unk		Not Reported
	Xeljanz	C		Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk, 1x/Day		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	15630999	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	15759957	EXPEDITED (15-DAY)		HO, OT	NL-UCBSA-2018053932		31 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Pre-Eclampsia; Premature	Certolizumab Pegol			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day (Bid)		Not Reported

Delivery	Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Once Daily (Qd)	Not Reported
	Novorapid	C	Subcutaneous	Unk	Not Reported
	Omeprazol	C	Oral	20 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	15953668	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011560			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Naprosyn			S	Oral	500 Mg, Bid		Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown	10 Milligram		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16381352	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001479		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Phospholipidosis	Hydroxychloroquine			S		Concordia
	Azathioprine			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16386658	EXPEDITED (15-DAY)		HO, OT	IT-DEXPHARM-20190378		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Reactivation	Lansoprazole			S				Not Reported
	Diclofenac			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16386659	EXPEDITED (15-DAY)		HO, OT	MX-DEXPHARM-20190376		21 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abulia; Anhedonia; Antiphospholipid Syndrome; Behaviour Disorder; Deep Vein Thrombosis; Depressed Mood; Drug Ineffective; Dyke-Davidoff-Masson Syndrome; Gastrointestinal Haemorrhage; Impulsive Behaviour; Insomnia; Irritability; Suicidal Ideation; Suicide Attempt	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Warfarin			S				Not Reported
	Calcium			S				Not Reported
	Vitamin D			S				Not Reported
	Levetiracetam			S				Not Reported
	Lamotrigine			S				Not Reported
	Magnesium Valproate			S				Not Reported
	Phenobarbital			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387073	EXPEDITED (15-DAY)		OT	PT-ALKEM LABORATORIES LIMITED-PT-ALKEM-2019-02713			Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Colchicine			S	Unknown	0.6 Mg, Qd		Alkem
	Colchicine			S				Alkem

	Mycophenolate Mofetil	S	Unknown	1.5-2 G, Qd		Alkem
	Mycophenolate Mofetil	S				Alkem
	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387092	EXPEDITED (15-DAY)			CN-SA-2019SA151835		39 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Tid		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387119	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030072			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	2.68 Milligram, 1 Every 4 Week		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Week		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Oral	10 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	760 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Myochrysine	S	Parenteral	50 Milligram, 1 Every 1 Month	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Oral	25 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 4 Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Week	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 4 Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 4 Week	Not Reported

Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram, 1 Every 4 Week	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, 1 Every 1 Week	Not Reported
Apo-Leflunomide	S	Oral	380 Milligram	Not Reported

	Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	Unk Unk, Once A Day	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387258	EXPEDITED (15-DAY)		HO	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209399		16 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrolyte Imbalance; Hypotension; Intentional Overdose; Lupus-Like Syndrome; Suicidal Ideation	Hydroxychloroquine			S	Oral	One Hundred 200 Mg Tablets At Once		Sun
	Sertraline			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387275	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP015455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Vomiting; Weight Decreased	Ibuprofen			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Tramadol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387672	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP015496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Ibuprofen			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Plaquenil /00072602/			S	Unknown	Unk				Not Reported
	Tramadol			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387749	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2018M1016061		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Stress Cardiomyopathy	Hydroxychloroquine			S	Unknown	200mg/Day (4.1 Mg/Kg)		Not Reported
	Prednisone			C	Unknown	5 Milligram		Mylan
	Mycophenolic Acid			C	Unknown	720 Milligram		Mylan
	Cyclosporine			C	Unknown	250 Milligram		Mylan
	Atorvastatin			C	Unknown			Mylan
	Amlodipine			C	Unknown	5 Milligram		Mylan
	Metoprolol			C	Unknown	25 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387885	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019022634		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	200 Milligram		Ucb
	Enbrel			S		50 Milligram		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387975	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030109			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Alendronic Acid			S	Unknown	Unk		Aurobindo

Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Actemra	S	Unknown	360 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	680 Milligram, 1 Every 4 Weeks	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	760 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
	Rituxan	S	Intravenous (not	Unk	Not Reported

						otherwise specified)				
		Sulfasalazine			S	Unknown	Unk			Not Reported
		Ciclosporin			C	Unknown	Unk			Not Reported
		Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16387989	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029731			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Daily		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Daily		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk, Two Times A Day		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388014	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029885			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness;	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Celecoxib			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported

Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Arava	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Milligram, Two Times A Day	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388022	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029850			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Confusional State; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	75 Milligram, As Necessary		Not Reported
	Diclofenac			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

Sulfasalazine	S	Oral	2 Gram, Once A Day	Not Reported
Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
Synthroid	S	Unknown	Unk	Not Reported
Tecta	S	Oral	Unk	Not Reported
Xeljanz	S	Oral	10 Milligram, Once A Day	Not Reported
Voltaren	S	Oral	75 Milligram, Two Times A Day	Not Reported
Voltaren	S	Oral	Unk	Not Reported
Apo-Folic Acid	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Oral	75 Milligram, Two Times A Day	Not Reported
Apo-Diclofenac	S	Oral	75 Milligram	Not Reported
Apo-Lisinopril	S	Unknown	Unk	Not Reported
Depo-Medrol	C	Intramuscular	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388023	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030040			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Methotrexate		S	Oral	10 Milligram, Every Week	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Unknown	1000 Milligram	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	10 Milligram, Once A Day	Not Reported
	Ciclosporin		C	Unknown	150 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388040	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029819			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; No Adverse Event; Respiratory Arrest; Visual Impairment	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Daily		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclical		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388050	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Alendronic Acid	S	Unknown	Unk	Aurobindo
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	500 Milligram	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Unk	Not Reported
	Tocilizumab	S	Unknown	360 Unk, 1 Every Month	Not Reported

	Alendronate Sodium	C	Unknown	700 Milligram, Every Week	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388099	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1058534		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Reactivation; Visceral Leishmaniasis	Diclofenac			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388530	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029884			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril			S	Unknown	Unk		Aurobindo
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Voltaren			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388548	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Gabapentin			S	Oral	100.0 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488.0 Milligram, Once A Day		Not Reported
	Apo Gabapentin			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20.0 Milligram, Once A Day		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50.0 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Weeks		Not Reported
	Nortriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Unk, 1 Every 1 Month		Not Reported
	Orencia			S	Subcutaneous	1 Dosage Form, 1 Every1 Week		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram, Once A Day		Not Reported

Acetaminophen	C	Unknown	Unk	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Fentanyl	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Fish Oil	C	Unknown	Unk	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Nasonex	C	Unknown	Unk	Not Reported
Nexium	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Omega 3	C	Unknown	Unk	Not Reported
Omega 3 6 9	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hcl	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

	Tylenol	C	Unknown	Unk		Not Reported
	Vitamin A	C	Unknown	Unk		Not Reported
	Vitamin B3	C	Unknown	Unk		Not Reported
	Vitamin B12	C	Unknown	Unk		Not Reported
	Vitamin D	C	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported
	Vitamin E	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388588	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029890			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388741	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019235728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Lyrica			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Baclofen			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388803	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Contraindicated Product Administered; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

					Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Simponi	S	Subcutaneous	Unk	Not Reported
					Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16388905	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019231785			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Lyrica			S	Unknown	Unk		Pfizer
	Atorvastatin Calcium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Trichlormethiazide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16389860	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019022635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Weekly (Qw)		Not Reported
	Arava			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported

	Humira	S	Subcutaneous	40 Milligram, Weekly (Qw)		Not Reported
	Hydroxychloroquine Sulfate	S		Unk		Not Reported
	Imuran	S		Unk		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)		Not Reported
	Methotrexate	S		Unk		Not Reported
	Sulfasalazine	S		Unk		Not Reported
	Tocilizumab	S		640 Milligram, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16389901	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-017758		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Orencia			S	Intravenous (not otherwise specified)	200 Mg, Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	300 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072602/			C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16389965	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019079832		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Low Density Lipoprotein Decreased	Methotrexate Sodium			S		10 Mg, Weekly		Pfizer
	Salazopyrin			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16390212	EXPEDITED (15-DAY)			CN-SA-2019SA151815		30 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Tid		Sanofi
	Prednisone			S		10 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	12787787	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0929		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Tyelenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	14164901	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017477176		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk		Pfizer
	Lyrica	S		Unk		Pfizer
	Methotrexate Sodium	S		Unk		Pfizer
	Arthrotec	S		Unk		Pfizer
	Diclofenac Potassium	S		Unk		Not Reported
	Celecoxib	S		Unk		Not Reported
	Apo-Amitriptyline	S		Unk		Not Reported
	Hydroxychloroquine Sulfate	S		Unk		Not Reported
	Naprosyn	S		Unk		Not Reported
	Prednisone	S		Unk		Not Reported
	Apo-Hydroxyquine	S		Unk		Not Reported
	Apo-Prednisone	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Diacerein	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	14251906	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021818			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Acetaminophen Tablets Usp 325 Mg			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.I.W		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

						otherwise specified)			
		Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
		Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
		Meloxicam			C	Unknown	Unk		Not Reported
		Synthroid			C	Unknown	Unk		Not Reported
		Methotrexate			C	Unknown	25 Df, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	14557672	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018071967		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Arthrotec			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Amitriptyline [Amitriptyline Hydrochloride]			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Diclofenac			S	Topical	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Elavil (Amitriptyline Hydrochloride)			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	14760416	EXPEDITED (15-DAY)		DE, LT, OT	JP-CONCORDIA PHARMACEUTICALS		59 YR	Female	JPN

						INC.-GSH201804-001244			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Cerebellar Haemorrhage	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			C				Not Reported
	Mizoribine			C				Not Reported
	Pariet			C				Not Reported
	Pariet			C				Not Reported
	Crestor			C				Not Reported
	Alositol			C				Not Reported
	Sennoside A+B			C				Not Reported
	Iodine			C	Unknown			Not Reported
	Iodine			C				Not Reported
	Mohrus			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	15235443	NON-EXPEDITED			US-PFIZER INC-2018313489			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	15274674	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Methotrexate (Trade Name			S	Oral	4 Times/Week Strength:		Not Reported

Drug Hypersensitivity; Drug Ineffective	Unknown)			2.5mg		
	Methotrexate (Trade Name Unknown)	S	Oral	4 Every 5 Weeks Strength: 2.5mg		Not Reported
	Apo-Hydroxyquine	S	Oral			Not Reported
	Apo-Hydroxyquine	S	Oral			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Leflunomide	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	15423322	EXPEDITED (15-DAY)		OT	IT-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003368		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Plaquenil			S	Oral			Concordia
	Diltiazem			S	Oral			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Lisinopril			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	15683671	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3520			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Spinal Compression Fracture	Methotrexate (Trade Name Unknown)		S	Oral	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16226644	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP012193		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastroenteritis Viral; Limb Injury	Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16368393	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019226047			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Avelumab			S	Intravenous (not otherwise specified)	Unk, Infusion		Pfizer
	Gemcitabine Hydrochloride			S	Intravenous (not otherwise specified)	Unk, Infusion		Unknown
	Abraxane			S	Intravenous (not otherwise specified)	Unk, Infusion		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Gabapentin			C	Oral	800 Mg, Unk		Not Reported

	Tresiba Flextouch			C	Subcutaneous	10 Units, Unk			Not Reported
	Metformin			C	Oral	850 Mg, Unk			Not Reported
	Miralax			C	Oral	17 G, Unk			Not Reported
	Oxycodone			C	Oral	5-10 Mg			Not Reported
	Oxycodone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16391502	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000685			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Azathioprine			C	Unknown	Unk		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16392595	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumonia	Plaquenil			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Leflunomide			C				Not Reported
	Humira			C		The Patient Was On It For 10 Years, Wash Out Two Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16392596	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001507			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Drug Hypersensitivity; Skin Exfoliation; Stevens-Johnson Syndrome	Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16392749	EXPEDITED (15-DAY)		HO, OT	FR-ALKEM LABORATORIES LIMITED-FR-ALKEM-2019-03541			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Exposure During Pregnancy	Aspirin			S	Unknown	100 Milligram, Qd		Not Reported
	Aspirin			S	Unknown	75 Milligram, Qd		Not Reported
	Aspirin			S	Unknown	160 Milligram, Qd		Not Reported
	Colchicine			S	Unknown	1 Milligram, Qd		Alkem
	Ibuprofen			S	Unknown	1.8 Gram, Qd		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Hydroxochloroquine			S	Unknown	Unk		Not Reported
	Atorvastatine			C	Unknown	80 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16392915	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2019-GB-000691			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16393146	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2019M1053326		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Diabetes Mellitus; Disease Recurrence; Fall	Hydroxychloroquine			S		Unk		Not Reported
	Avelumab			S		Unk		Mylan
	Gemcitabine Hydrochloride			S		Unk		Mylan
	Abraxane			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16393551	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2019-FR-000689			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Glomerulonephritis Membranous; Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Ipca
	Ramipril			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16395397	EXPEDITED (15-DAY)		DE	US-CELGENEUS-USA-20190511152		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Abraxane			S	Intravenous drip			Not Reported
	Abraxane			S	Intravenous drip			Not Reported
	Gemcitabine			S	Unknown			Not Reported
	Gemcitabine			S	Unknown			Not Reported
	Avelumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydrochlorothiazide W/Losartan			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16395864	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1053399		6 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Immunoglobulin /00025201/			S	Intravenous (not otherwise specified)			Mylan
	Rituximab			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jun-2019	16592382	DIRECT	Y				68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Therapy Interrupted	Hydroxychloroquine 200 Mg Tab,			S	Oral			Unknown
	Methotrexate 2.5 Mg Tablet,			S	Oral	Other Frequency:7tabsoncewkly ;		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	14566761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0503		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

	Lyrica	S	Unknown	Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Elavil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	15411603	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-046465			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Lisinopril			S	Oral	1 Dosage Form, In Total		Aurobindo
	Plaquenil			S	Oral	1 Dosage Form, In Total		Not Reported
	Diltiazem			S	Oral	1 Dosage Form, In Total		Not Reported
	Hydrochlorothiazide			S	Oral	1 Dosage Form, In Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	15754963	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201812-004162		48 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Cataract; Cataract; Dermatitis; Diarrhoea; Gastroenteritis; Inflammation; Oedema; Oliguria; Pyrexia; Shock;	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

Steroid Diabetes; Vomiting	Prednisolone			S	Oral				Not Reported
	Prednisolone			S	Oral				Not Reported
	Prednisolone			S	Oral				Not Reported
	Prednisolone			S	Oral				Not Reported
	Prednisolone			S	Oral				Not Reported
	Amitriptyline Hydrochloride			S	Oral				Not Reported
	Prograf			C					Not Reported
	Prednisolone			C					Not Reported
	Amitiza			C					Not Reported
	Alfacalcidol			C					Not Reported
	Samtirel			C					Not Reported
	Nexium			C	Oral				Not Reported
	Menatetrenone			C					Not Reported
	Magmitt			C					Not Reported
	Atorvastatin			C					Not Reported
	Daikenchuto			C					Not Reported
	Odomel			C					Not Reported
	Mucosta			C					Not Reported
	Calonal			C					Not Reported
	Gatiflo			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	15979879	EXPEDITED (15-DAY)		OT	GB-ACCORD-093129		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Cushing'S Syndrome; Drug Interaction; Myopathy; Orthostatic Hypotension	Risedronic Acid			S	Unknown			Not Reported
	Prednisolone			S	Unknown	7.5 Milligram Daily;		Not Reported
	Carbocisteine			S	Unknown	750 Mg,		Not Reported
	Itraconazole			S	Oral	100 Milligram Daily		Not Reported
	Lansoprazole			S	Unknown	30 Milligram Daily;		Not Reported
	Domperidone			S	Unknown	10 Milligram Three Times Daily;		Not Reported
	Levothyroxine			S	Unknown	75 Microgram Daily;		Not Reported
	Uniphyllin			S	Unknown	200 Milligram Bid;		Not Reported

	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Amylase/Lipase/Protease	S	Unknown	10 Milligram Three Times Daily;		Not Reported
	Creon	S	Unknown	10 Milligram Three Times Daily;		Not Reported
	Ivig	S				Not Reported
	Propranolol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16138975	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0925		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Auditory Disorder; Blood Pressure Increased; Dependence; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Winpred			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16269815	NON-EXPEDITED			US-PFIZER INC-2019184528		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder	Inderal	S	Unk		Pfizer
	Clinoril	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16371472	EXPEDITED (15-DAY)		DE	US-EMD SERONO-E2B_90068200			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Avelumab			S	Intravenous (not otherwise specified)	Unk, Infusion		Not Reported
	Gemcitabine Hydrochloride			S	Intravenous (not otherwise specified)	Unk, Infusion		Not Reported
	Abraxane			S	Intravenous (not otherwise specified)	Unk, Infusion		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Gabapentin			C	Oral	800 Mg, Unk		Not Reported
	Tresiba Flextouch			C	Subcutaneous	10 Units, Unk		Not Reported
	Metformin			C	Oral	850 Mg, Unk		Not Reported
	Miralax			C	Oral	17 G, Unk		Not Reported
	Oxycodone/Oxycodone Hydrochloride Hydrate			C	Oral	5-10 Mg		Not Reported
	Oxycodone/Oxycodone Hydrochloride Hydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16391574	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg		Not Reported
Lyrica	S	Oral			Not Reported
Actemra	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16396670	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-192656		58 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Optic Atrophy; Overdose; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Daily (7.3 Mg/Kg Actual Bodyweight)		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Daily (3.7 Mg/Kg Actual Bodyweight, Cumulative Dose Greater Than 1160 G)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16396673	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-192792		69 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Macular Degeneration; Overdose; Retinal Injury; Retinal Toxicity; Vision Blurred; Visual Field Defect	Hydroxychloroquine			S	Unknown	500 Milligram, Daily (11.4 Mg/Kg Actual Body Weight Cumulative Dose Greater Than 440 G)		Sun
	Hydroxychloroquine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16396798	EXPEDITED (15-DAY)		HO, LT	AU-APPCO PHARMA LLC-2067846		16 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Electrolyte Imbalance; Hypotension; Intentional Overdose; Suicide Attempt	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16396962	EXPEDITED (15-DAY)		OT	CA-SA-2019SA152983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Sarilumab			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Adalimumab			S		40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G (Solution)		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S				Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Qd		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16397400	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1057622		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Minocycline Hydrochloride			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Orencia			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16397482	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-209694		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Premature Delivery	Co-Amoxiclav			S	Unknown	Unk		Ranbaxy
	Aspirin			S	Unknown	75 Milligram, Unk		Sun
	Gentamicin			S	Unknown	Unk		Taro

	Prednisolone		S	Unknown	40 Milligram, Unk	Taro
	Prednisolone		S	Unknown	Unk	Taro
	Hydroxychloroquine		S	Unknown	200 Milligram, Unk	Sun
	Tazocin		S	Unknown	Unk	Not Reported
	Azathioprine		S	Unknown	100 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16397646	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0582		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Low Density Lipoprotein Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Reported As 200 5/7 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16399555	EXPEDITED (15-DAY)		OT	NL-AMNEAL PHARMACEUTICALS COMPANY GMBH-2019AGH0004		35 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine Sulfate			S	Unknown			Amneal
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16400562	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1059227		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Retinal Toxicity; Toxicity To Various Agents; Visual	Hydroxychloroquine			S	Unknown	400 Milligram Daily; 7.01 Mg/Kg Daily Dose (2.01 Mg/Kg Greater Than		Teva

Acuity Reduced					Current Recommendations)	
	Docetaxel		S	Unknown	4 Cycles Of 21 Days Each	Actavis
	Anastrozole		S	Unknown		Teva
	Cyclophosphamide		S	Unknown	4 Cycles Of 21 Days Each	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	12287934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-011187		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Abatacept			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Indocin /00003801/			C	Unknown			Not Reported
	Indometacin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	13065626	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016597755			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Muscle Spasms; Pyelonephritis	Enbrel			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Remeron			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	14173706	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3471		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Diacerein			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	14227433	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506136		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Auditory Disorder; Blood Pressure Increased; Dependence; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, Bid		Pfizer
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Winpred			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	14483179	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005771			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	14987671	NON-EXPEDITED			US-ALLERGAN-1825190US			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity	Dicyclomine Hcl - Bp			S	Unknown	Unk		Allergan
	Plaquenil			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	15630661	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105244		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Joint Swelling; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			C	Oral	500 Mg, Bid		Not Reported

		Apo-Leflunomide			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Leflunomide			S	Unknown				Not Reported
		Naproxen			C	Unknown	500 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	15743394	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-194339			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Live Birth; Maternal Distress During Labour; Premature Baby	Hydroxychloroquine			S	Unknown	Unknown		Sun
	Prednisone			S	Unknown	Unknown		Mutual
	Tacrolimus			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	15743522	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-194365			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphopenia; Premature Baby	Hydroxychloroquine			S	Transplacental	Unknown		Sun
	Prednisone			S	Transplacental	Unknown		Mutual
	Tacrolimus			S	Transplacental	Unknown		Not Reported
	Azathioprine			S	Transplacental	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	15953854	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011836			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Orencia	S	Unknown	Unk		Bristol Myers Squibb
	Anakinra	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Arava	S	Oral	10.0 Mg, Qd		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naprosyn /00256201/	S	Oral	500.0 Mg, Qd		Not Reported
	Rituximab	S	Unknown			Not Reported
	Vioxx	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	10.0 Mg, Unk		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16286005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-044948		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	9 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported

Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Enbrel	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Plaquenil S	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	9 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Cortisone	C	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16288628	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Brenzys			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16401983	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16402022	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2806410-00		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toe Amputation	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rub A535			C				Not Reported
	Asa			C				Not Reported
	Folic Acid			C				Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16402048	EXPEDITED (15-DAY)		OT	PHHY2019GB126888		36 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dermatitis Bullous; Skin Plaque	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	30 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16402965	EXPEDITED (15-DAY)		OT	US-ZYDUS-037468		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Overdose; Retinal Toxicity; Toxicity To Various Agents; Visual Field Defect	Anastrozole			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown	400 Mg Of Hcq Daily Hcq Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G		Zydus Pharm
	Docetaxel			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403295	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1701			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg		Not Reported
	Lyrica			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

	Tylenol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403323	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1719			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Trichlormethiazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403341	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2019-1711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

	Meloxicam			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16403450	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001472		64 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Dizziness Postural	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Macitentan			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Imuran			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Ursodeoxycholic Acid			C				Not Reported
	Thyradin S			C				Not Reported
	Rabeprazole Na			C				Not Reported
	Daiphen			C				Not Reported
	Pralia			C				Not Reported
	Tracleer			C				Not Reported
	Azilva			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16404167	EXPEDITED (15-DAY)		OT	CA-SA-2019SA155269		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia;	Sarilumab			S				Sanofi
	Hydroxychloroquine			S		400 Mg		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Sulfasalazine			S		2 Every 1 Day (1 Gram)		Not Reported
	Enbrel			S		Unk		Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C		2 Every 1 Day (5 Mg)		Not Reported

Nausea; Pruritus;
Synovitis; Unevaluable
Event

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16406460	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1052937			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromatopsia	Methotrexate			S	Unknown	17.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16406462	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1052939			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Ischaemia	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Mylan
	Sulfasalazine	S	Unknown	1500 Mg, Unk	Mylan
	Sulfasalazine	S	Unknown	1500 Mg, Unk	Mylan
	Sulfasalazine	S	Unknown	1500 Mg, Unk	Mylan
	Sulfasalazine	S	Unknown	1500 Mg, Unk	Mylan
	Sulfasalazine	S	Unknown	1500 Mg, Unk	Mylan

	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2019	16406465	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1052935			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Pulmonary Embolism; Renal Failure	Azathioprine			S	Unknown	25 Milligram		Not Reported
	Azathioprine			S	Unknown	25 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Leflunomide			S	Unknown	10 Milligram		Mylan
	Leflunomide			S	Unknown	10 Milligram		Mylan
	Leflunomide			S	Unknown	15 Milligram		Mylan
	Leflunomide			S	Unknown	20 Mg, Unk		Mylan
	Quensyl			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14018106	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2954		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonitis; Pulmonary Toxicity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14495798	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007121		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50.0 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14505012	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007258		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	25 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Milligram, Qd	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Reactine /00884302/	S	Unknown	10 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Oral	5 Milligram	Not Reported
Golimumab	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported
Atasol /00020001/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14731421	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201804-		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Compression Fracture	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14813779	NON-EXPEDITED			US-PFIZER INC-2018165730		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Vancomycin Hcl			S		Unk		Pfizer
	Atenolol			S		Unk		Not Reported
	Ancef [Cefazolin Sodium]			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Darvon			S		Unk		Not Reported
	Glimepiride			S		Unk		Not Reported
	Losartan			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Spirolactone			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Vitamin D			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14917099	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567 Milligram, Q4wk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	14929605	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLABS-2018M1033296		51 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Drug Interaction; Serotonin Syndrome; Vomiting	Fluoxetine			S	Oral	20 Mg, Daily		Not Reported
	Fluoxetine			S	Oral	40 Mg, Daily,Verhoging Van 1 X 1 Tablnaar 1 X 2 Tab		Not Reported
	Fluoxetine			S	Oral	40 Mg, Qd		Not Reported
	Fluoxetine			S	Oral	40 Mg, Qd		Not Reported

	Plaquenil /00072603/	S	Oral	200 Mg, Bid		Mylan
	Plaquenil /00072603/	S	Oral	400 Milligram, Qd (2 Dd 200mg)		Mylan
	Zopiclon	C	Oral	7.5 Mg, Prn		Mylan
	Celecoxib	C	Unknown	200 Mg, Bid		Mylan
	Celecoxib	C	Oral	100 Mg,Bid		Mylan
	Ethinylestradiol/Desogestrel	C	Oral	1 Df, Daily		Mylan
	Nasacort	C	Nasal	1 Df, Daily		Mylan
	Esomeprazol /01479301/	C	Oral	20 Mg, Bid		Mylan
	Oxazepam	C	Oral	10 Mg, Prn		Mylan
	Hydroxychloroquine	C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16164825	EXPEDITED (15-DAY)		OT	CA-SA-2019SA093060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Sarilumab			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Sulfasalazine			C		3 G, Qd		Not Reported
	Leflunomide			C		20 Mg		Not Reported
	Meloxicam			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16274465	EXPEDITED (15-DAY)		HO, OT	NL-CELLTRION INC.-2019NL020568			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angioedema; Disease Progression; Drug Specific Antibody Present; Intentional Product Use Issue; Meningitis Aseptic; Off Label Use; Petechiae; Systemic Lupus Erythematosus; Urticaria	Rituximab (Unknown)	S	Unknown	Unk	Not Reported
	Rituximab (Unknown)	S			Not Reported
	Prednisolone	S	Unknown	10 Mg, Daily	Not Reported
	Prednisolone	S		Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	1000 Mg, Daily	Not Reported
	Mycophenolate Mofetil	S		Unk	Not Reported
	Cyclophosphamide	S	Unknown		Not Reported
	Cyclophosphamide	S		Unk	Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S		Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Daily	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Belimumab	C	Unknown	Unk	Not Reported
	Belimumab	C		Unk	Not Reported
	Fresh Frozen Plasma	C	Unknown	Initially Up To 4 Units	Not Reported
	Fresh Frozen Plasma	C	Unknown	2 Units	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16335056	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001410		54 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Steroid Diabetes	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

	Prednisolone			S	Oral				Not Reported
	Prednisolone			S	Oral				Not Reported
	Prednisolone			S	Oral				Not Reported
	Losartan Potassium			C					Not Reported
	Persantin-L			C					Not Reported
	Ursodeoxycholic Acid			C					Not Reported
	Omeprazole			C					Not Reported
	Omeprazole			C					Not Reported
	Alfacalcidol			C					Not Reported
	Zetia			C					Not Reported
	Bezafibrate			C					Not Reported
	Azosemide			C					Not Reported
	Spironolactone			C					Not Reported
	Predonine			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16408542	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001504		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Healing; Incision Site Discharge; Meniscus Injury	Plaquenil 200 Mg			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Folic Acid			C		Must Take Concurrently With Methotrexate		Not Reported
	Protonix			C				Not Reported
	Amlodipine			C				Not Reported
	Mobic			C				Not Reported
	Lexapro			C				Not Reported
	Lipitor			C				Not Reported
	Pepcid (Lucol)			C				Not Reported
	Xanax			C		At Bedtime To Help With Sleep		Not Reported
	Valsartan			C				Not Reported
	Calcium Plus D3			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16408576	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001510		39 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Musculoskeletal Pain; Nausea; Rheumatoid Arthritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prograf			C				Not Reported
	Unkeito			C				Not Reported
	Loxonin			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16409259	EXPEDITED (15-DAY)		OT	CA-SA-2019SA155321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Sarilumab			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Acetaminophen			C				Not Reported
	Aluminium Acetate			C				Not Reported
	Atacand			C				Not Reported
	Benzethonium Chloride			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Tylenol [Paracetamol]			C		650 Mg, Bid		Not Reported
	Neurontin			C		600 Mg, Tid		Not Reported
	Premarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16409261	EXPEDITED (15-DAY)		OT	CA-SA-2019SA155341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Sarilumab			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Xeljanz			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Acetaminophen			C		650 Mg, Bid		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Aluminium Acetate;Benzethonium Chloride			C		Unk		Not Reported
	Atacand			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Neurontin			C		600 Mg, Tid		Not Reported
	Premarin			C		Unk		Not Reported
	Hydrodiuril			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16409754	EXPEDITED (15-DAY)		OT	US-NEOPHARMA INC-000135		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Anastrozole			S				Not Reported
	Hydroxychloroquine			S		7.01 Mg/Kg Daily Dose And Total Cumulative Dose 402 G For A Total		Not Reported

							Duration Of 2 Years And 10 Months			
		Docetaxel			S					Not Reported
		Cyclophosphamide/Cyclophosphamide Monohydrate			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16411066	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1053603			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Contusion; Renal Impairment	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Leflunomide			S	Unknown	20 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16411285	NON-EXPEDITED			US-TEVA-2019-US-1055735		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Depigmentation; Retinal Disorder; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16411426	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1060445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoloc [Pantoprazole]			C	Oral			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Synthroid			C	Oral			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2019	16411525	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-016279		17 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cholecystitis; Cryoglobulinaemia; Disease Progression; Fatigue; Haematochezia; Malaise; Mood Swings;	Prednisolone			S	Unknown			Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

Nephrocalcinosis; Neuropathy Peripheral; Neutropenia; Palindromic Rheumatism; Paraproteinaemia; Polyarthritis; Purpura; Recrudescent Typhus; Sjogren'S Syndrome; Stomatitis; Tenosynovitis; Tubulointerstitial Nephritis; Vasculitis	Cyclophosphamide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	14045466	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Visual Impairment	Hydroxychloroquine			S	Oral			Concordia
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Sulfasalazine			C				Not Reported
	Orencia			C				Not Reported
	Cimzia			C				Not Reported
	Simponi			C				Not Reported
	Inflectra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16158038	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1030735		17 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Off Label Use; Pancytopenia; Product Administered To Patient Of Inappropriate Age; Pulmonary Arterial Hypertension	Sildenafil			S	Unknown	Unk		Not Reported
	Iloprost			S	Unknown	Unk		Mylan
	Ambrisentan			S	Unknown	Unk		Mylan
	Ventavis			S	Unknown	Unk		Mylan
	Ruxolitinib			S	Unknown	7.5 Mg, Bid (Maintained)		Mylan

	Ruxolitinib	S	Unknown	10 Mg, Bid		Mylan
	Ruxolitinib	S	Unknown	High Doses		Mylan
	Abatacept	S	Unknown	Unk		Mylan
	Hydroxychloroquine /00072603/	S	Unknown	Unk		Mylan
	Mepacrine /00221302/	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16186346	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019043816		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mycobacterium Test Positive; Mycobacterium Tuberculosis Complex Test Positive	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			C	Oral	200 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16259484	EXPEDITED (15-DAY)		OT	JP-ASTELLAS-2019JP007814		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Exposure During Pregnancy; Hypocomplementaemia; Infectious Pleural Effusion; Off Label Use; Platelet Count Decreased; Premature Delivery	Prograf			S	Unknown			Astellas
	Plaquenil /00072602/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisolone			C	Unknown	10 Mg/Day, Unknown Freq.		Not Reported
	Prednisolone			C	Unknown	30 Mg/Day, Unknown Freq.		Not Reported
	Prednisolone			C	Unknown	Tapered		Not Reported
	Infliximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16411506	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016400783		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413110	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001535			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Neuropathy Peripheral	Plaquenil 200 Mg Tablet			S	Oral	Daily Dose: Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413197	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-032358			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis;	Paracetamol			S	Unknown	3 Gram, Daily		Aurobindo

Hepatocellular Injury	Lyrica		S	Oral	150 Milligram, Daily		Not Reported
	Naftidrofuryl		S	Oral	20 Milligram, Daily		Not Reported
	Plaquenil		S	Oral	200 Milligram, Daily		Not Reported
	Hydrocortisone Roussel		C	Oral	20 Milligram, Daily		Not Reported
	Forlax		C	Oral	3 Dosage Form, Daily		Not Reported
	Levothyrox		C	Oral	100 Microgram, Daily		Not Reported
	Diltiazem Hydrochloride		C	Oral	200 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16413579	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1061339		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Interstitial Lung Disease	Prednisone			S	Unknown			Actavis
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16414386	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1055032		11 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Posterior Reversible Encephalopathy Syndrome; Reversible Cerebral Vasoconstriction Syndrome; Seizure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S				Mylan
	Rituximab			S	Unknown			Mylan
	Rituximab			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16414395	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1055038		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Reversible Cerebral Vasoconstriction Syndrome	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16414858	NON-EXPEDITED			US-PFIZER INC-2019243585		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Prednisone			S		10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16416071	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS COMPANY GMBH-2019AGH0001			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16416842	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1061172		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Neoplasm	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16417279	NON-EXPEDITED			PHEH2019US023966			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Weight Increased	Hydroxychloroquine Sulphate			S	Unknown	Unk Unk, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16417334	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1053931		76 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown	17.5 Mg, Qwk		Not Reported
	Quensyl			S	Unknown	1 Df, Qd		Mylan
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Mylan
	Chloroquine			S	Unknown	1 Df, Qd		Mylan
	Folic Acid			C	Unknown	Unk		Mylan
	Phenprocoumon			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2019	16417361	EXPEDITED (15-DAY)		OT	IT-BAUSCH-BL-2019-016317		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Leishmaniasis	Diclofenac	S	Unknown			Bausch And Lomb
	Diclofenac	S		Unk		Bausch And Lomb
	Hydroxychloroquine	S	Unknown			Not Reported
	Lansoprazole	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	14415482	EXPEDITED (15-DAY)		DS, HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000272		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bladder Catheterisation; Blood Calcium Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Iron Decreased; Blood Pressure Increased; Calcinosis; Cardiac Disorder; Cd4 Lymphocytes Decreased; Chest Pain; Condition Aggravated; Connective Tissue Inflammation; Diabetes Mellitus; Diarrhoea; Drug Monitoring Procedure Not Performed; Erythema; Fall; Fatigue; Gait Disturbance; Haemoglobin Decreased; Hand Fracture; Heart Rate Increased; Hyperparathyroidism Primary; Immunodeficiency; Joint Injury; Limb Injury; Loss Of Consciousness; Nephrolithiasis; Night Sweats; Optic Nerve	Plaquenil			S	Unknown			Concordia
	Alemtuzumab			S	Intravenous drip			Not Reported
	Alemtuzumab			S		Second Cycle		Not Reported

Injury; Peripheral Swelling; Platelet Count Increased; Precancerous Cells Present; Pyrexia; Pyrexia; Renal Failure; Sinusitis; Urinary Tract Infection; Visual Impairment; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	15630207	EXPEDITED (15-DAY)		DS, OT	CA-ICU MEDICAL, INC.-ICU2018CA00036		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Meperidine Hydrochloride Injection Usp 300 Mg/30ml (10 Mg/Ml) (30ml)			S	Unknown	Unk		Icu Medical
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram 1 Every 24 Hour(S)		Not Reported
	Demerol			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Humira			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram (1 Every 1 Week)		Not Reported

	Metronidazole	S	Unknown	5 Milligram		Not Reported
	Norfloxacin	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Oral	400 Milligram 1 Every 24 Hours		Not Reported
	Prednisone	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	15889064	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017466567		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Hair Texture Abnormal; Neuropathy Peripheral; Pain In Extremity; Pain Of Skin; Rash Macular; Skin Discolouration; Skin Disorder; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16076562	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022598		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil Hydrochloride			S	Unknown			Teva
	Piroxicam			S	Unknown			Teva
	Prednisone			S	Unknown	1 Dosage Forms Daily;		Actavis
	Pregabalin			S	Oral			Not Reported

Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine/00072603/	S	Unknown	Not Reported
	Hydroxychloroquine/00072603/	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16081572	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023152		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Arava		S	Unknown	Not Reported
	Celebrex		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16228179	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP012029			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Acetaminophen			S	Unknown	Unk		Apotex
	Apo Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Ramipril			S	Unknown	Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk, Bid		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk, Bid		Not Reported
	Methotrexaat /00113801/			S	Unknown	25 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16418829	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-031765			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive;	Pantoprazole			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo

Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Losartan	S	Unknown	Unk	Aurobindo
	Moxifloxacin	S	Unknown	Unk	Aurobindo
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every Week	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16418876	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16418883	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1062204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Diarrhoea; Disability; Drug Ineffective; Hypoaesthesia; Rheumatoid Arthritis; Rheumatoid Nodule; Weight Decreased	Prednisone			S	Unknown			Actavis
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Actemra			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Myochrysine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Ergocalciferol	C	Unknown	2000 Iu (International Unit) Daily;		Not Reported
	Enbrel	C	Unknown			Not Reported
	Actonel	C	Unknown			Not Reported
	Orencia	C	Intravenous (not otherwise specified)			Not Reported
	Cimzia	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16419203	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001542			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Variable	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16421037	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019247475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Celebrex			S		Unk		Pfizer
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported
	Toradol			S		Unk		Not Reported
	Methotrexate			C		25 Mg, Weekly		Not Reported
	Sulfasalazine			C		2 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16421754	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019246250		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Lyrica			S	Oral	150 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Paracetamol			S		3 G, 1x/Day		Not Reported
	Naftidrofuryl			S	Oral	20 Mg, 1x/Day		Not Reported
	Forlax			C	Oral	3 Df, 1x/Day		Not Reported
	Hydrocortisone Acetate			C	Oral	20 Mg, 1x/Day		Not Reported
	Levothyrox			C	Oral	100 Ug, 1x/Day		Not Reported
	Diltiazem			C	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16422388	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1054016			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Chronic Obstructive Pulmonary Disease; Rheumatoid Arthritis; Transaminases Increased	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	500 Mg, Unk		Mylan
	Leflunomide			S	Unknown	10 Mg, Unk		Mylan
	Leflunomide			S	Unknown	10 Mg, Unk		Mylan
	Leflunomide			S	Unknown	10 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Roactemra			S	Unknown	162 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jun-2019	16422401	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1054022			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Liver Disorder; Syncope	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Leflunomide			S	Unknown	20 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	12153562	EXPEDITED (15-DAY)		OT	CA-ROCHE-1566340		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Arthralgia; Blood Pressure Increased; Burning Sensation; Chills; Cough; Eye Disorder; Feeling Cold; Joint Swelling; Limb Mass; Malaise; Nausea; Nerve Compression; Osteoporosis; Pain; Peripheral Coldness; Respiratory Rate Increased; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	(First Pir Received) Date Of Most Recent Rituximab Infusion: 23/Mar/2016, 27/Dec/2016		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral	Most Recent Dose: 27/Dec/2016		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Premarin			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported
	Imovane			C				Not Reported
	Prednisone			C				Not Reported
	Gravol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15530220	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018420382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not	8 Mg/Kg, 1 Every 4 Week		Not Reported

						otherwise specified)	(S)		
		Certolizumab Pegol		S	Unknown	400 Mg, 1 Every 2 Week (S)			Not Reported
		Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
		Leflunomide		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15538613	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1078843		4 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Dyspnoea; Haemoptysis; Product Use In Unapproved Indication; Product Use Issue; Pulmonary Haemosiderosis	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15569803	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018433561		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nephrolithiasis	Enbrel			S		Unk, Weekly		Unknown
	Azulfidine			S		Unk (6 Per Day-3 Am And 3 Pm)		Pfizer
	Azulfidine			S				Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15577960	NON-EXPEDITED			US-PFIZER INC-2018449919			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Enbrel	S	Unk	Pfizer
	Methotrexate Sodium	S	Unk	Pfizer
	Remicade	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	200 Mg, 2x/Day	Not Reported
	Actemra	S	Unk	Not Reported
	Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15594889	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2018154608		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Unevaluable Event; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	10 Milligram, Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Q2wk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Amlodipine	C		Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	50 Unk	Not Reported
	Naproxen	C		500 Milligram	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Viread	C	Unknown	Unk	Not Reported
	Viread	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15601456	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018156309		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	15821613	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019013254			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Neutropenia	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	200 Mg, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16165932	EXPEDITED (15-DAY)		HO, OT	GB-ACCORD-117803		74 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Infection; Pneumococcal Infection; Respiratory Tract Infection	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16423685	EXPEDITED (15-DAY)		HO	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001544			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pneumonitis	Hydroxychloroquine			S				Concordia
	Leflunomide			S				Not Reported
	Codeine			S				Not Reported
	Tramadol			S				Not Reported
	Levofloxacin			S				Not Reported
	Lipitor			S				Not Reported
	Augmentin			S				Not Reported
	Infliximab			S				Not Reported

	Amoxicillin			S						Not Reported
	Atorvastatin			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16424149	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1062108		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Codeine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Actavis
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Ramipril			S	Unknown	1 Dosage Forms Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown	7 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Acetaminophen	C			Not Reported
	Acetaminophen W/Caffeine	C			Not Reported
	Acetaminophen W/Caffeine/Dihydrocodeine	C			Not Reported
	Acetaminophen/Caffeine/Codeine Phosphate	C			Not Reported
	Acetaminophen/Codeine Phosphate	C			Not Reported
	Diphenhydramine	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methylprednisolone	C			Not Reported
	Plaquenil	C		400 Milligram Daily;	Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16424272	EXPEDITED (15-DAY)		OT	PHHY2019CA131846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Aclasta			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Psyllium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Qw		Not Reported
	Lipitor			C	Unknown	10 Mg, Qd (Od)		Not Reported
	Tums			C	Unknown	Unk		Not Reported
	Marijuana			C	Unknown	1.8 Ot, Q24h		Not Reported
	Folic Acid			C	Unknown	5 Mg, Q3w		Not Reported

	Vitamin D			C	Unknown	2000 Iu, Qd		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16424318	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1062208		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anorectal Discomfort; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Dyspepsia; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Skin Hyperpigmentation; Treatment Failure	Prednisone			S	Unknown			Actavis
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16425210	NON-EXPEDITED		OT	US-APOTEX-2019AP011180			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia	Mycophenolate			S	Unknown	Unk		Apotex
	Mycophenolate			S				Apotex
	Mycophenolate			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Leflunomide			S				Apotex
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

	Methotrexate	S				Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Azathioprine	S				Not Reported
	Azathioprine	S				Not Reported
	Minocycline	S	Unknown	Unk		Not Reported
	Minocycline	S				Not Reported
	Minocycline	S				Not Reported
	Adalimumab	S	Unknown	Unk		Not Reported
	Adalimumab	S				Not Reported
	Adalimumab	S				Not Reported
	Infliximab	S	Unknown	Unk		Not Reported
	Infliximab	S				Not Reported
	Infliximab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16425615	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1061416		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Teva
	Losartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16426340	EXPEDITED (15-DAY)		OT	PHHY2019KR130476		24 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Generalised Oedema; Glomerulonephritis Minimal Lesion; Proteinuria	Prednisolone			S	Unknown	5 Mg, Qd		Novartis
	Prednisolone			S	Unknown	60 Mg, Qd		Novartis
	Prednisolone			S	Unknown	10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16426638	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1061357		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown			Teva
	Coumadin			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16427108	EXPEDITED (15-DAY)		HO	JP-AMNEAL PHARMACEUTICALS COMPANY GMBH-2019AGH0004		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilic Pneumonia Acute	Hydroxychloroquine Sulfate			S	Unknown	200 Mg Per Day		Amneal
	Betamethasone			S	Oral	.5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16427746	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1061880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Bismuth Subsalicylate			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16428163	EXPEDITED (15-DAY)		OT	PHHY2019US133097		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Flushing; Malaise; Mast	Hydroxychloroquine			S	Unknown			Novartis

Cell Activation Syndrome; Product Use In Unapproved Indication; Urticaria	Heparin	C	Unknown	Not Reported
	Warfarin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16631531	DIRECT	Y				78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Knee Arthroplasty; Pain	Plaquenil		Y	S				Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	13519995	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Once Every 24 Hours		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Once Every 24 Hours		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Cimzia			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	14971865	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-001893		19 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Predonine			C				Not Reported
	Predonine			C				Not Reported
	Neoral			C				Not Reported
	Cellcept			C				Not Reported
	Pariet			C				Not Reported
	Pariet			C				Not Reported
	Micardis			C				Not Reported
	Edirol			C				Not Reported
	Edirol			C				Not Reported
	Baktar			C				Not Reported
	Baktar			C				Not Reported
	Ferrous Sodium Citrate			C				Not Reported
	Ferrous Sodium Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	15603166	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018457593			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Twice Daily		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, Every Month		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Plaquenil			S	Unknown	400 Mg, Once Daily		Not Reported

Remicade	S	Intravenous (not otherwise specified)	5 Ug/Kg, Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Every 15 Days		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Days		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	15665379	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018485712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16077917	NON-EXPEDITED			US-PFIZER INC-2019106172		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Infection; Pain; Pain In Extremity; Synovitis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16376922	EXPEDITED (15-DAY)		HO	PHHY2019GB121126		28 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Lactate Dehydrogenase Decreased; Cholestasis; Drug Ineffective; Maternal Exposure During Pregnancy; Normal Newborn; Platelet Count Decreased; Premature Delivery; Product Use In Unapproved Indication; Pruritus; Total Bile Acids Increased	Amoxicillin + Clavulanate Potassium			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown			Novartis
	Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Tazocin			S	Unknown	Unk		Not Reported
	Gentamicin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	75 Mg, Unk		Not Reported
	Gammaglobulin			S	Intravenous (not otherwise specified)	1 G/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16419099	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001539		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Alopecia; Bedridden; Vertigo	Hydroxychloroquine 200 Mg			S		200 Mg In The Am And 200 Mg In The Pm		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429193	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-		29 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Warfarin Sodium			S	Oral	Unk		Bristol Myers Squibb
	Low Molecular Weight Heparin			S	Unknown	1 Dosage Form, Bid		Not Reported
	Aspirin [Acetylsalicylic Acid]			S	Unknown	100 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16429200	EXPEDITED (15-DAY)		OT	NL-TEVA-2019-NL-1060870			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diabetes Insipidus; Drug Interaction; Therapeutic Product Effect Decreased	Desmopressine			S	Unknown			Teva
	Hydroxycloroquine			S		2x A Tablet Of 200 Mg Twice A Day		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430174	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-032563			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lethargy; Pruritus; Rash; Skin Exfoliation	Clopidogrel			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Imuran			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430483	EXPEDITED (15-DAY)		OT	IN-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-057798			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Premature Baby	Warfarin Sodium		S	Transplacental	Unk	Bristol Myers Squibb
	Prednisolone		S	Transplacental	Unk	Not Reported
	Azathioprine		S	Transplacental	Unk	Not Reported
	Hydroxychloroquine		S	Transplacental	Unk	Not Reported
	Labetalol		S	Transplacental	Unk	Not Reported
	Hydralazine		S	Transplacental	Unk	Not Reported
	Nifedipine		S	Transplacental	Unk	Not Reported
	Prazosin		S	Transplacental	Unk	Not Reported
	Low Molecular Weight Heparin		S	Transplacental	Unk	Not Reported
	Metoclopramide		S	Transplacental	Unk	Not Reported
	Ranitidine		S	Transplacental	Unk	Not Reported
	Hydrocortisone		S	Transplacental	Unk	Not Reported
	Atropine		S	Transplacental	Unk	Not Reported
	Bupivacaine		S	Transplacental	1.6 Milliliter	Not Reported
	Fentanyl		S	Transplacental	20 Microgram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430484	EXPEDITED (15-DAY)		OT	IN-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-057799			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby	Warfarin Sodium			S	Transplacental	Unk		Bristol Myers Squibb
	Prednisolone			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Labetalol			S	Transplacental	Unk		Not Reported
	Hydralazine			S	Transplacental	Unk		Not Reported
	Nifedipine			S	Transplacental	Unk		Not Reported
	Prazosin			S	Transplacental	Unk		Not Reported
	Low Molecular Weight Heparin			S	Transplacental	Unk		Not Reported

	Metoclopramide			S	Transplacental	Unk	Not Reported
	Ranitidine			S	Transplacental	Unk	Not Reported
	Hydrocortisone			S	Transplacental	Unk	Not Reported
	Atropine			S	Transplacental	Unk	Not Reported
	Bupivacaine			S	Transplacental	1.6 Milliliter	Not Reported
	Fentanyl			S	Transplacental	20 Microgram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16430486	EXPEDITED (15-DAY)		OT	IN-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-053892		29 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage In Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Premature Separation Of Placenta; Twin Pregnancy	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Labetalol			S	Unknown	Unk		Not Reported
	Hydralazine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Prazosin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ranitidine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydrocortisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Atropine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bupivacaine			S	Unknown	1.6 Milliliter		Not Reported
	Fentanyl			S	Unknown	20 Microgram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16433694	EXPEDITED (15-DAY)		HO	US-SA-2019SA162655			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pneumonitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Codeine			S				Not Reported
	Tramadol Hydrochloride			S				Not Reported
	Amoxicillin			S				Not Reported
	Levofloxacin			S				Not Reported
	Atorvastatin			S				Not Reported
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S				Not Reported
	Infliximab			S				Not Reported
	Lipitor			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16434245	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15150		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Parenteral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported

	Tofacitinib			C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jun-2019	16637805	DIRECT	Y				49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphasia; Balance Disorder; Nervous System Disorder	Plaquenil Tab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2019	16437261	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-032658			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Clopidogrel Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported

	Plaquenil	S	Oral	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Sodium Aurothiomalate	S	Oral	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sulfamethoxazole	S	Unknown	Unk		Not Reported
	Sulfamethoxazole;Trimethoprim	S	Unknown	Unk		Not Reported
	Trimethoprim	S	Unknown	Unk		Not Reported
	Vitamin C	S	Unknown	Unk		Not Reported
	Voltaren	S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2019	16437421	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-210728		87 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Hepatocellular Injury	Paracetamol		Y	S	Unknown	3 Gram, Daily		Ohm Lab
	Naftidrofuryl			S	Oral	20 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	200 Milligram, Daily		Not Reported
	Lyrica			S	Oral	150 Milligram, Daily		Not Reported
	Hydrocortisone Roussel			C	Oral	20 Milligram, Daily		Not Reported
	Forlax			C	Oral	3 Dosage Form, Daily		Not Reported
	Levothyrox			C	Oral	100 Microgram, Daily		Not Reported
	Diltiazem (Chlorhydrate De)			C	Oral	200 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2019	16437535	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2019-15135		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Etanercept	S	Unknown			Not Reported
	Etanercept	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Alendronate	S	Unknown			Not Reported
	Codeine	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
	Leflunomide	S	Oral	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Myochrysine	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Remicade	S	Unknown	Unknown		Not Reported
	Rituximab Gp2013	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jun-2019	16437609	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

	Rituximab Gp2013			S	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported
	Simponi			C	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2019	16437841	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2819905-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Pantoprazole			C				Not Reported
	Loperamide			C				Not Reported
	Celebrex			C				Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Actemra			C				Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2019	16437858	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2820169-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	275		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	11173487	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015055265		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	9 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Increased; Rheumatoid Arthritis; Synovitis	Xeljanz	S	Unknown	1 Dosage Form, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Cyclical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Die	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	200 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	9 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Desoximetasone	C		Unk	Not Reported
	Acetaminophen	C		500 Mg, Unk	Not Reported
	Gabapentin	C		600 Mg, Tid	Not Reported
	Reactine [Cetirizine Hydrochloride]	C		10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	11319755	EXPEDITED (15-DAY)		DS, HO, OT	CA-AMGEN-CANSP2015075405		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil S	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	11348854	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015078411		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic	Enbrel			S	Unknown	Unk, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	1 Df, Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported

Product Effect Incomplete; Treatment Failure	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Advil	S	Unknown	400 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Mefenamic Acid	S	Unknown	400 Milligram, Bid	Not Reported
	Mefenamic Acid	S	Unknown	400 Milligram, Bid	Not Reported
	Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	11398119	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2014106314		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Methotrexate		S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate		S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate		S	Unknown	20 Milligram, 4 Times/Wk	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Apo-Hydroxyquine		S	Unknown	400 Milligram	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	11443387	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015088203		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Etanercept			S	Unknown	50 Milligram, Qwk		Amgen
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Gram, Q6mo		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Sulfasalazin			S	Unknown	500 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported

	Arava			S	Unknown	Unk				Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk				Not Reported
	Prednisone			C		20 Milligram, Qd				Not Reported
	Methotrexate			C	Subcutaneous	20 To 25 Milligram, Qwk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	11977863	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016008627		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Enbrel			S	Unknown	Unk		Amgen
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	1 Df, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	12335824	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016054789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Remicade			S	Unknown	200 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	12456060	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016073585		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	More Than 20mg Every Week		Not Reported

Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment; X-Ray Abnormal	Methotrexate Sodium	S	Unknown	Unk Unk, Qwk (One Every One Week)	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	12727439	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015013046		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue;	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Not Reported

Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Sulfathalidine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram, Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	22.5 Milligram, Qwk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	10 Milligram, Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C	Oral	5 Milligram, Qd	Not Reported
	Prednisone	C	Oral	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	13111830	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017003772		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration;	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Unknown	1000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra		S	Unknown	Unk	Not Reported
	Methotrexate		S	Oral	25 Milligram, Qwk	Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Sulfasalazine		S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)	2000 Milligram, Bid	Not Reported
	Hydroxychloroquine		S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Bid	Not Reported
	Apo-Hydroxyquine		S	Oral	200 Milligram, Bid	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Prednisone		C	Oral	5 Milligram, Bid	Not Reported
	Prednisone		C	Unknown	5 Milligram, Bid	Not Reported
	Synthroid		C	Unknown	Unk	Not Reported
	Restasis		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	13853157	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Oral	400.0 Mg, Qd		Not Reported
	Arava			S	Unknown	20.0 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25.0 Mg, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Unknown					Not Reported
		Plaquenil /00072603/			S	Unknown	Unk, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	13909419	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017127785		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	14158464	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017138198		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Discomfort; Drug Ineffective; Erythema; Joint Swelling; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	14389624	EXPEDITED (15-DAY)		HO, OT	CA-DEPOMED, INC.-CA-2018DEP000081		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Hospitalisation; Joint Swelling; Pain In Extremity; Weight Decreased	Diclofenac Potassium			S	Unknown	Unk		Assertio Therapeutics
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Dexilant			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	14633096	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019934			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Off Label Use; Pain; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	1 Df, Unk		Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	1000 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qwk		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	14838374	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2018M1027473		39 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Anaphylactic Reaction; Cystitis; Fatigue; Mixed Incontinence; Nausea; Panic Attack; Parotitis; Pruritus; Rheumatoid Nodule; Vomiting; Weight Increased	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Mylan
	Olumiant			S	Unknown	Unk		Mylan
	Botox			S	Unknown	Unk		Mylan
	Cimzia			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15535217	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15563179	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1080211		82 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Therapy Partial Responder	Hydroxychloroquine			S	Unknown	Unk,		Not Reported
	Minoxidil			S		2 Percent		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15635333	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105890		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Piroxicam			C	Unknown	Unk		Not Reported

	Prednisone			C	Unknown	7.5 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15831803	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0073			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Neutropenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	15898292	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3356		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Hair Texture Abnormal; Neuropathy Peripheral; Pain In Extremity; Pain Of Skin; Rash Macular; Skin Discolouration; Skin Disorder; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16109719	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Endocervical	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methylprednisolone			S	Unknown	80 Milligram		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Milligram, Q8wk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16378230	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019214591		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Drug Ineffective; Muscular Weakness; Pain In Extremity	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S		More Than Or Equal To 2 Gm Daily For 3 Months		Pfizer

	Sulfasalazine	S	Oral	1 G, Twice Daily	Pfizer
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	300 Mg, Daily	Not Reported
	Amlodipine	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16387707	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030049			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	12 Milligram, 4 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 4 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, 4 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, 4 Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, 4 Every 1 Week		Not Reported

	Methotrexate	S	Oral	10 Milligram, 4 Every 1 Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, Daily	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Actemra	S	Unknown	360 Milligram, Every Month	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438418	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033232			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia;	Alendronic Acid			S	Unknown	70 Milligram,1 Every 1 Weeks		Aurobindo
	Actemra			S	Unknown	2.68 Milligram,1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	360 Milligram,1 Every 4 Weeks		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 2 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram,1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram,1 Every 1	Not Reported

				Weeks	
Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Weeks		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram,1 Every 1 Weeks		Not Reported
Myochrysine	S	Intramuscular	50 Milligram,1 Every 1 Weeks		Not Reported
Orencia	S	Unknown	780 Milligram,1 Every 1 Weeks		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram,1 Every 12 Hours		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Tocilizumab	S	Unknown	380 Milligram		Not Reported
Tocilizumab	S	Unknown	360 Milligram		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438425	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033252			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia;	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	360 Milligram,1 Every 1 Months		Not Reported
	Actemra			S	Unknown	680 Milligram,1 Every 4 Weeks		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram,2 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram,1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram,1 Every 2 Week(S)	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	760 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438446	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-15084		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438448	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2019-15080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S				Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438535	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001165		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Asthenia; Blister; General Physical Health Deterioration;	Plaquenil 200 Mg Tablet			S	Oral			Concordia

Insomnia; Mucosal Inflammation; Neutrophil Count Increased; Oedema Mouth; Pain; Productive Cough; Pruritus; Pustule; Pyrexia; Pyrexia; Skin Fissures

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438565	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Pneumonia	Plaquenil			S	Unknown	Daily Dose: Unknown		Concordia
	Prednisone			S	Unknown	Daily Dose: Unknown		Not Reported
	Cimzia			S	Unknown	Daily Dose: Unknown		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Crestor			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438681	EXPEDITED (15-DAY)		HO, LT, OT	CN-SA-2019SA162864		27 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Myalgia; Pneumonia; Pyrexia	Prednisolone			S	Oral	Unk		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Methylprednisolone			S		500 Mg, Qd		Not Reported
	Methylprednisolone			S		500 Mg, Qd		Not Reported

	Leflunomide		S		20 Mg, Qd		Sanofi
	Cyclosporin A		S		100 Mg, Qd		Not Reported
	Immunoglobulin I.V		S	Intravenous (not otherwise specified)	20 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16438997	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-14997		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold Injections			S	Intramuscular	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16439001	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15199		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Tolerance; Fatigue;	Etanercept			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hyperhidrosis; Inappropriate Schedule Of Product Administration; Influenza; Joint Swelling; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Prednisone	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Celebrex	C	Unknown	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unknown		Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported
	Vitamin D	C	Unknown	Unknown		Not Reported
	Methotrexate	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16439240	NON-EXPEDITED			PHEH2019US024890			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Gastrointestinal Disorder; Muscle Spasms	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Novartis
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16439514	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15152		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

			Hydroxychloroquine Sulfate		S	Unknown	Unknown		Not Reported
			Methotrexate		S	Subcutaneous			Not Reported
			Methotrexate		S	Oral			Not Reported
			Methotrexate		S	Unknown			Not Reported
			Orencia		S	Unknown	Unknown		Not Reported
			Orencia		S	Intravenous (not otherwise specified)	Unknown		Not Reported
			Plaquenil		S	Unknown	Unknown		Not Reported
			Rituxan		S	Intravenous (not otherwise specified)	Unknown		Not Reported
			Xeljanz		C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16440030	EXPEDITED (15-DAY)		DE	US-CELGENEUS-USA-20190605340			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Abraxane			S	Intravenous drip			Not Reported
	Gemcitabine			S	Intravenous drip			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Avelumab			S	Intravenous drip			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tresiba			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Macrogol			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16440221	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056335		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Abatacept	S	Unknown			Bristol Myers Squibb
	Enbrel	S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Celebrex	C	Unknown	200 Milligram, Qd		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported
	L-Thyroxine [Levothyroxine]	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16441505	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15309		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported

					Methotrexate	S	Oral	Unknown	Not Reported
					Methotrexate	S	Parenteral	Unknown	Not Reported
					Methotrexate	S	Unknown	Unknown	Not Reported
					Orencia	S	Unknown	Unknown	Not Reported
					Orencia	S	Subcutaneous		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
					Sulfasalazine	S	Unknown	Unknown	Not Reported
					Tofacitinib	C	Unknown	Unknown	Not Reported
					Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16441506	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16441509	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-15328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis	Etanercept	S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Tocilizumab	S	Unknown	Unknown		Not Reported
	Azathioprine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16441510	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15380		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Drug Intolerance; Herpes Zoster; Liver Disorder; Myocardial Infarction; Polyarthritis; Rash; Seronegative Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Salazopyrin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16442783	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201906004452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alopecia;	Cymbalta			S	Unknown	Unk Unk, Unknown		Eli Lilly And Co

Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Retinopathy; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Apo-Leflunomide	S	Unknown	Unk Unk, Unknown		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unknown		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unknown		Not Reported
	Methotrexate	S		Unk Unk, Unknown		Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unknown		Not Reported
	Prolia	S	Subcutaneous	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16442969	EXPEDITED (15-DAY)		OT	PHHY2019IL136689		55 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Renal Function Test Abnormal	Hydroxychloroquine Sulphate			S	Oral	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16442978	EXPEDITED (15-DAY)		OT	PHEH2019US025019		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jun-2019	16443133	EXPEDITED (15-DAY)		OT	IT-CELLTRION INC.-2019IT021963			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complement Factor C3	Rituximab (Unknown)			S	Transplacental			Not Reported

Decreased; Foetal Exposure During Pregnancy; Premature Baby; Thrombocytopenia; Total Complement Activity Decreased	Low Molecular Weight Heparin		S	Transplacental	Unk Unk, 100 Iu/Kg, Bid	Not Reported
	Hydroxychloroquine		S	Transplacental	300 Mg, 1d	Not Reported
	Eculizumab		S	Transplacental	600 Mg, Unk (45 Min)	Not Reported
	Antithrombin Iii		S	Transplacental	1.7 Iu/Kg, Unk	Not Reported
	Aspirin		S	Transplacental	100 Mg, 1d	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	11224671	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015212917		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	11392208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015254734		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Intolerance; Gout; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Renal Impairment	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		4 Doses		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	11636953	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Bursitis; Carpal Tunnel Syndrome; Drug Ineffective; Dry Mouth; Fall; Hand Deformity; Intervertebral Disc Disorder; Joint Range Of Motion Decreased; Muscle Tightness; Neck Deformity; Nerve Compression; Nerve Injury; Pruritus; Respiratory Disorder; Skin Wound; Staphylococcal Infection; Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day, For Over 3 Months		Not Reported
	Humira			S	Subcutaneous	10 Mg, Cyclic: Every Second Week For Over 6 Months		Not Reported
	Humira			S	Subcutaneous	40 Mg, 2x/Week		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Amitriptyline			C				Not Reported
	Gabapentin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	11695383	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015115178		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Enbrel			S	Subcutaneous	Unk		Amgen
	Celebrex			S	Oral	200 Milligram, As Necessary		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not	8 Milligram		Not Reported

							otherwise specified)			
					Leflunomide	S	Unknown	20 Milligram		Not Reported
					Orencia	S	Subcutaneous	125 Milligram, Qwk		Not Reported
					Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
					Hydroxychloroquine Sulfate	C	Unknown	200 Milligram, Bid		Not Reported
					Hydroxychloroquine	C	Unknown	200 Milligram, Bid		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
18-Jun-2019	12247551	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2016042951		59 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Enbrel			S	Unknown	Unk		Amgen		
	Actemra			S	Unknown	Unk		Not Reported		
	Prednisone			S	Unknown	20 Milligram, Qd		Not Reported		
	Warfarin			S	Unknown	Unk		Not Reported		
	Apo-Prednisone			S	Unknown	20 Milligram, Qd		Not Reported		
	Rituxan			S	Unknown	Unk		Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported		
	Apo-Warfarin			S	Unknown	Unk		Not Reported		
	Humira			S	Subcutaneous	Unk		Not Reported		
	Humira			S	Unknown	Unk		Not Reported		
	Methotrexate Sodium			S	Unknown	Unk		Not Reported		
	Arava			S	Unknown	Unk		Not Reported		
	Hydroxychloroquine			S	Unknown	Unk		Not Reported		
	Plaquenil			S	Unknown	Unk		Not Reported		
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported		
	Sulfasalazine			S	Unknown	Unk		Not Reported		
	Remicade			S	Unknown	Unk		Not Reported		
	Remicade			S	Intravenous (not	Unk		Not Reported		

				otherwise specified)		
	Warfarin Sodium		S	Unknown	Unk	Not Reported
	Warfarin Sodium		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Amitriptyline		C	Unknown	Unk (Capsule And Tablet)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12312494	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016039095		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	592 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	10 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk, Qwk		Not Reported

Arava	S	Unknown	Unk, Qwk	Not Reported
Arava	S	Intravenous (not otherwise specified)	592 Milligram, Q4wk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Oral	10 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	C		Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Infliximab	C	Unknown	300 Milligram	Not Reported
Infliximab	C	Unknown	300 Milligram, Q8wk	Not Reported
Infliximab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12335795	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015060641		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclical	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Rabeprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12470396	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016074646		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	4 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1 Gram		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 Gram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported

					Hydroxychloroquine		S	Oral	300 Milligram, Qd	Not Reported
					Hydroxychloroquine		S	Unknown	Unk	Not Reported
					Hydroxychloroquine		S	Oral	Unk	Not Reported
					Hydroxychloroquine		S	Unknown	Unk	Not Reported
					Cimzia		S	Unknown	Unk	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	200 Mg, Bid	Not Reported
					Adalimumab		S	Unknown	Unk	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Simponi		S	Subcutaneous	Unk	Not Reported
					Leflunomide		C	Unknown	20 Milligram, Qd	Not Reported
					Leflunomide		C	Unknown	20 Milligram, Qd	Not Reported
					Sulfasalazine		C	Unknown	Unk	Not Reported
					Tocilizumab		C	Unknown	Unk	Not Reported
					Methotrexate		C	Unknown	0.8 Milliliter, Qwk	Not Reported
					Methotrexate		C	Subcutaneous	20 Milligram, Qwk	Not Reported
					Methotrexate		C	Oral	Unk, Qwk	Not Reported
					Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
					Xeljanz		C	Oral	5 Milligram	Not Reported
					Celebrex		C	Unknown	Unk	Not Reported
					Diclofenac		C	Unknown	Unk	Not Reported
					Lyrica		C	Unknown	Unk	Not Reported
					Valsartan		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12607819	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016097103		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock;	Enbrel			S	Subcutaneous	Unk		Amgen

Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Cortisone	C		5 Milligram	Not Reported
	Cyclobenzaprine	C	Unknown	10 Milligram,1/2 Tablet As Necessary	Not Reported
	Cyclobenzaprine	C	Unknown	10 Milligram	Not Reported
	Tylenol	C	Unknown	Unk Unk, As Required	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	5 Milligram, Qd	Not Reported
	Desoximetasone	C	Unknown	5 Milligram	Not Reported
	Prednisone Acetate	C	Unknown	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12674300	EXPEDITED (15-DAY)		HO, LT, OT	CA-AMGEN-CANSP2016004849		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12682206	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016109003		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12730817	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016117127		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Milligram, Qd		Not Reported

Illness; Insomnia; Nasopharyngitis; Pain In Jaw; Pelvic Prolapse; Post Procedural Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Vitamin D2	C		Unk	Not Reported
	Vitamin B12	C	Oral	1 Dosage Form, Qd	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fentanyl	C	Unknown	1 Dosage Form	Not Reported
	Gabapentin	C	Oral	400 Milligram, Bid	Not Reported
	Metformin And Sitagliptin	C	Oral	Unk Unk, Bid	Not Reported
	Perindopril Erbumine	C	Oral	8 Milligram, Qd	Not Reported
	Rabeprazole	C	Oral	180 Milligram, Qd	Not Reported
	Ranitidine	C	Oral	150 Milligram, Qd	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Milligram, Bid	Not Reported
	Synthroid	C	Oral	1 Dosage Form, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Zopiclone	C	Oral	7.5 Milligram, Qd	Not Reported
	Metformin	C	Oral	Unk Unk, Bid	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Sitagliptin	C	Oral	Unk Unk, Bid	Not Reported
	Acetaminophen	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	12823599	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016136989		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Cellcept			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13070457	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016180736		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Methotrexate		S	Subcutaneous	25 Milligram, Unk	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, Unk	Not Reported
	Apo Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Amlodipine		C	Oral	5 Milligram, Qd	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13160482	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017011814		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Knee Arthroplasty; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Penicillin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Up To 20 Milligram Once Week		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Arava			C	Unknown	Unk		Not Reported

	Plaquenil			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13380121	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2017045167		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Cosopt			S	Unknown	Unk Unk, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk Unk, Qd		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

Ramipril	S	Unknown	1 Dosage Form, Qd	Not Reported
Ramipril	S	Unknown	Unk, Unk, Qd	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Prednisone	S	Unknown	Unk Unk, Qd	Not Reported
Altace	S	Unknown	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Levothyroxine Sodium	S	Unknown	Unk Unk, Qd	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Unk Unk, Bid (2 Every 1 Day)	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Unk	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Unk	Not Reported
Caffeine	C		Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Acetaminophen	C	Oral	1000 Milligram	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C	Unknown	Unk	Not Reported
Acetaminophen W/Codeine Phosphate	C		Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Meprobamate	C		Unk	Not Reported
Phosphate [Phosphoric Acid Sodium]	C		Unk	Not Reported
Timolol Maleate	C	Unknown	2 Dosage Form, Qd	Not Reported
Tylenol No.2	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13458847	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSL2017058064		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Hospitalisation; Joint Swelling; Pain In Extremity; Weight Decreased	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Diclofenac Sodium			S	Unknown			Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Dexilant			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13618076	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017084624		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Infection; Eye Inflammation; Rheumatoid Arthritis; Vulvovaginal Mycotic Infection	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk (Injection)		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported
	Diltiazem			C	Unknown	Unk		Not Reported
	Irbesartan			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported

	Omeprazole			C	Unknown	Unk				Not Reported
	Trazodone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13834570	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017076491		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			C	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13915705	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017127800		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug	Enbrel			S	Unknown	Unk		Amgen
	Abatacept			S	Intravenous (not	1000 Milligram, Q4wk		Not Reported

Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis			otherwise specified)		
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk, Q4wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Alprazolam	C	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown	5 Milligram, Qd	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Asa	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Mtx	C	Unknown	Unk	Not Reported

	Pantoprazole			C	Unknown				Not Reported
	Paroxetine			C	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported
	Risedronate			C	Unknown	Unk			Not Reported
	Simvastatin			C	Unknown	Unk			Not Reported
	Statex			C	Unknown	Unk			Not Reported
	Telmisartan			C	Unknown	Unk			Not Reported
	Xeljanz			C	Unknown	Unk			Not Reported
	Acetylsalicylic Acid			C		Unk			Not Reported
	Morphine Sulfate			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13939894	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017131173		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Nodule; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	1500 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	13943305	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017133238		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatitis	Enbrel		S	Subcutaneous	50 Milligram, Qwk	Amgen
	Methotrexate		S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram, 3/7 Days Of The Week	Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram, 2/7 Days Of The Week	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Actemra		S	Subcutaneous	162 Milligram, 2 Times/Wk	Not Reported
	Leflunomide		C		Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14185047	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017169967		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Bid		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported

	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Intravenous (not otherwise specified)	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14186403	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017169922		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk		Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Methotrexate		S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14187488	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017170129		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14187498	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017170110		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Cimzia		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Methotrexate		C	Subcutaneous	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14222286	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175431			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14224295	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017175653		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis;	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Unknown	40 Milligram		Not Reported

Rheumatoid Factor Positive; Synovitis	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	0.8 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qod	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qod	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	5 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Doxycycline	S	Unknown	50 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sulfasalazine	C		Unk Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14553025	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Enbrel		S	Unknown	Unk		Amgen
	Etanercept		S	Unknown	Unk		Amgen
	Actemra		S	Unknown	Unk		Not Reported
	Arava		S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Xeljanz		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14629084	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14741909	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018046259		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram		Not Reported
	Cimzia			S	Unknown	200 Milligram		Not Reported
	Tylenol			C	Unknown	Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14761808	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018049385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	1000 Mg, Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	14914002	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018066720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			C		5 Milligram, Qd		Not Reported
	Depo-Medrol			C	Intramuscular	120 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15464166	EXPEDITED (15-DAY)		OT	CA-ELI_LILLY_AND_COMPANY-CA201809012393		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Constipation; Dactylitis; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Psoriasis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect Incomplete	Cymbalta	S	Unknown	Unk, Unknown	Not Reported
	Enbrel	S	Unknown	50 Mg, Unknown	Not Reported
	Amitriptyline	S	Unknown	Unk, Unknown	Not Reported
	Lyrica	S	Unknown	Unk, Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk, Unknown	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown	Not Reported
	Elavil [Allopurinol]	S	Unknown	Unk, Unknown	Not Reported
	Elavil [Allopurinol]	S	Unknown	Unk, Unknown	Not Reported
	D-Alpha Tocopherol	C			Not Reported
	Clonazepam	C		1 Mg, Unknown	Not Reported
	Ergocalciferol	C		4000 International Unit, Daily	Not Reported
	Tylenol /00020001/	C			Not Reported
	Flaxseed Oil Nature Made	C	Unknown	Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15579383	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018447943		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Cefazolin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	10 Milligram, Unk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Q2wk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Amlodipine	C		Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Arava	C		Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	50 Unk	Not Reported
Naproxen	C		500 Mg, Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Viread	C	Unknown	Unk	Not Reported
Viread	C		Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15703259	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174419		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatine Phosphokinase Increased; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	50 Mg, Unk		Amgen
	Arava	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Parenteral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15772081	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014095170		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign	Etanercept			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk		Not Reported
	Mtx			C	Unknown	Unk		Not Reported
	Mtx			C				Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Leflunomide			C				Not Reported
	Leflunomide			C				Not Reported
	Cyclosporine			C		Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported
	Azathioprine			C				Not Reported
	Azathioprine			C				Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Acetazolamide			C	Unknown	Unk		Not Reported
	Acetazolamide			C				Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported

			Calcium		C	Unknown	Unk		Not Reported
			Calcium		C				Not Reported
			Calcium		C				Not Reported
			Hydroxychloroquine		C	Unknown	Unk		Not Reported
			Hydroxychloroquine		C				Not Reported
			Hydroxychloroquine		C				Not Reported
			Iron		C	Unknown	Unk		Not Reported
			Iron		C				Not Reported
			Iron		C				Not Reported
			Alendronate		C	Unknown	Unk		Not Reported
			Alendronate		C				Not Reported
			Cyclosporine A		C	Unknown	Unk		Not Reported
			Cyclosporine A		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15946613	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019019976		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis; Unevaluable Event	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C		5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	15951897	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019020117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Amgen

Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Actemra	S	Subcutaneous	162 Mg, Unk		Not Reported
	Arava	S	Unknown	20 Mg, Qd		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Qwk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16115542	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019044215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16125985	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	125 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Xanax			S	Unknown	Unk		Not Reported
	Macrobid /00024401/			S	Unknown	Unk		Not Reported
	Sulfa /00076401/			S	Unknown	Unk		Not Reported
	Meperidine Hcl			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16386739	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029986			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Celecoxib Capsules			S	Oral	200 Milligram, Once A Day		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported

Bisoprolol	S	Unknown	Unk	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Ceclor	S	Unknown	Unk	Not Reported
Cefaclor	S	Unknown	Unk	Not Reported
Celebrex	S	Oral	200 Milligram, Once A Day	Not Reported
Demerol	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	400 Milligram	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Meperidine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Metronidazole	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16413118	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001536			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Genital Haemorrhage	Plaquenil 200 Mg Tablet	S	Oral	Daily Dose: Unknown	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16443495	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-15235		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; No Adverse Event; Respiratory Arrest; Visual Impairment	Etanercept			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Celebrex			S	Oral	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Subcutaneous	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16443917	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033328			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram Every Month		Not Reported
	Actemra			S	Unknown	680 Milligram Every Month		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Every Week		Not Reported

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Humira	S	Subcutaneous	40 Milligram 1 Every Two Weeks	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every1 For 4 Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram Every 1 For 4 Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram Every 1 For 4	Not Reported

			Week	
Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	15 Milligram Every 1 For 4 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram Every 1 For 4 Week	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Myochrysine	S	Parenteral	50 Milligram Every Month	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Rituximab	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram 1 Every 4 Week	Not Reported
Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16443925	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033256			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Anti-Cyclic Citrullinated Peptide	Alendronic Acid			S	Oral	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported

Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hcl	S	Unknown	Unk	Not Reported
	Cetirizine Hcl	S	Unknown	10 Milligram, Once A Day	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Cortisone Acetate	S	Oral	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Gram, Two Times A Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444054	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-11562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Prednisone			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444383	NON-EXPEDITED			PHEH2019US025135			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Urticaria	Xolair			S	Unknown	300 Mg, (Every 4 Week)		Not Reported
	Xolair			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Novartis
	Prednisolone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444842	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033478			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Meloxicam		S	Unknown	Unk		Aurobindo
	Plaquenil		S	Unknown	Unk		Not Reported
	Prednisone		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16444972	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033540			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Mirtazapine Tablet			S	Unknown	15.0 Milligram		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16445245	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1055627			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertensive Crisis; Peripheral Swelling; Rheumatoid Arthritis; Tooth Abscess; Urine Analysis Abnormal	Methotrexate			S	Unknown	20mg, Unk		Not Reported
	Methotrexate			S	Unknown	20mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	500mg, Unk		Mylan
	Sulfasalazine			S	Unknown	500mg, Unk		Mylan
	Sulfasalazine			S	Unknown	500 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	500mg, Unk		Mylan

	Hydroxychloroquine	S	Unknown	200mg, Unk		Mylan
	Hydroxychloroquine	S	Unknown	200mg, Unk		Mylan
	Hydroxychloroquine	S	Unknown	200mg, Unk		Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16445852	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Plaquenil S			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16446296	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15326		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Treatment Failure	Etanercept	S	Subcutaneous	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Anakinra	S	Unknown			Not Reported
	Anakinra	S	Subcutaneous	Unknown		Not Reported
	Azathioprine	S	Unknown	Unknown		Not Reported
	Azathioprine	S	Oral	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Gold	S	Unknown	Unknown		Not Reported
	Leflunomide	S	Oral			Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16446346	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015143971		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chapped Lips; Condition Aggravated; Fatigue; Gallbladder Disorder;	Methotrexate Sodium			S	Subcutaneous	1 Ml, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	1 Ml, Once Every 2 Weeks		Unknown

Oropharyngeal Pain; Psoriasis; Rheumatoid Arthritis; Skin Fissures	Methotrexate Sodium	S	Subcutaneous	0.7 Ml, Once Every 2 Weeks		Unknown
	Plaquenil	S		Unk		Not Reported
	Orencia	S		Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Vitamin B Complex	C		Unk		Not Reported
	Losec	C		Unk		Not Reported
	Tylenol Extra Strength	C		As Needed		Not Reported
	Tylenol Extra Strength	C				Not Reported
	Ibuprofen	C		Regular Strength, As Needed		Not Reported
	Ibuprofen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16446531	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056484		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Unknown	15 Milligram/Sq. Meter, Qwk		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Rituximab			S	Unknown	420 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16446654	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2019	16446678	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016129553		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatitis; Liver Disorder	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	10965143	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015028493		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Fatigue; Hyperhidrosis; Intervertebral Disc	Enbrel			S	Unknown	Unk		Amgen
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; No Adverse Event; Overwork; Peripheral Swelling; Poor Quality Sleep; Temperature Intolerance; Therapeutic Product Effect Incomplete; Vomiting	Hydromorphone	S	Oral	12 Milligram, Qd		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz	S	Unknown	2 Dosage Form, Qd		Not Reported
	Percocet	S	Oral			Not Reported
	Percocet	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11020617	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015023435		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Hydromorph Contin			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11143442	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015050092		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	50 Mg, Weekly		Amgen
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical		Not Reported
	Arava	S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Arava	S	Unknown	Unk 1 Every 2 Days		Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram		Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk		Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
	Tofacitinib	C		Unk		Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11233611	EXPEDITED (15-DAY)		HO, OT	CA-AMGEN-CANSP2015064980		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	25 Milligram, Bid		Amgen
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Cellcept	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	7 Milligram, Qd	Not Reported
Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	1 Milliliter, Qwk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	1 Milliliter, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	17 Milligram, Qwk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported

	Sulfasalazine			S	Unknown	1 Gram, Bid			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11320728	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2015249673		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil S			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11444708	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015089323		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product	Enbrel			S	Subcutaneous	50 Milligram		Amgen

Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Cimzia	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Q2wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Q2wk	Not Reported
	Prednisone	S	Oral	15 Milligram, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Tofacitinib	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11444767	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015088930		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	20 Milligram, Qd	Not Reported
	Prednisone	S	Oral	50 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	S	Unknown	8 Milligram/Kilogram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Unk (7 Years)	Not Reported
	Orencia	S	Unknown	750 Milligram, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Unk (9 Months)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram, Bid (5 Months)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Bid	Not Reported
	Simponi	S	Unknown	50 Milligram, Unk (3 Years)	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk Unk, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	11449345	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2015089273		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Synovitis; Thyroid Cancer	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Avapro			C		Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Gluconorm			C		Unk		Not Reported
	Metformin Hydrochloride			C		Unk		Not Reported
	Biaxin			C		Unk		Not Reported
	Nystatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12249911	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016193745		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile	Enbrel			S	Unknown	Unk		Pfizer

Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S		500 Milligram, Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Prednisone	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Warfarin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	20 Milligram, Qd	Not Reported
	Warfarin	S	Unknown	Unk	Not Reported
	Warfarin	S	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk (Capsule And Tablet)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12255274	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016044796		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Swelling; Rheumatoid Arthritis; Wheelchair User	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Aspirin		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone		C	Unknown	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12330565	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2015075515		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Desoximetasone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12335693	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016054143		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tramadol Hcl			C	Oral	50 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12349342	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016057289			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Impaired Work Ability; Joint	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	25 Mg, Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported

Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Humira	S	Subcutaneous	Unk	Not Reported
	Apo Ibuprofen	S	Unknown	Unk	Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	200 Mg, Qd	Not Reported
	Prednisone	C		Unk	Not Reported
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12351104	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015204403		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S		400 Mg, Daily		Not Reported

Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclic (Every 4 Weeks)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic (Every 2 Weeks)		Not Reported
	Arava	S	Unknown	20 Mg, Daily		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid		Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd		Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Cortisone	C				Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown			Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Naprosyn	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Rabeprazole	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12451180	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016288416		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	More Than 20mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk, Weekly		Pfizer

Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment; X-Ray Abnormal	Methotrexate Sodium		S		Unk	Pfizer
	Methotrexate Sodium		S	Unknown	Unk, Daily	Pfizer
	Sulfasalazine		S	Oral	1 G, 2x/Day	Pfizer
	Adalimumab		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S		Unk	Not Reported
	Apo-Leflunomide		S		20 Mg, 1x/Day	Not Reported
	Apo-Leflunomide		S		20 Mg, Weekly	Not Reported
	Apo-Hydroxyquine		S		Unk	Not Reported
	Hydroxychloroquine		S		Unk	Not Reported
	Hydroxychloroquine		S		Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S		Unk	Not Reported
	Leflunomide		S		20 Mg, 1x/Day	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12570978	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015119458		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis;	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	25 Milligram, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Vomiting	Arava	S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate	S	Unknown	25 Milligram		Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
	Kineret	C		Unk		Not Reported
	Anakinra	C	Unknown	10 Milligram, Qd		Not Reported
	Anakinra	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12612693	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015128883		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12642905	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016102459		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukoplakia Oral; Pneumonia	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Orencia			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12669990	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016107257		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Nifedipine	C		Unk	Not Reported
	Palafer	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Prednisone	C			Not Reported
	Synthroid	C		Unk	Not Reported
	Toloxin	C		Unk	Not Reported
	Valsartan	C			Not Reported
	Vitamin D3	C		Unk	Not Reported
	Xarelto	C		Unk	Not Reported
	Zinc Citrate	C		Unk	Not Reported
	Atorvastatin Calcium	C		Unk	Not Reported
	Hydrochlorothiazide	C			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12689894	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016402430		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

			Apo-Hydroxyquine		S	Subcutaneous	Unk			Not Reported
			Apo-Leflunomide		S	Unknown	Unk			Not Reported
			Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
			Hydroxychloroquine		S	Unknown	Unk			Not Reported
			Leflunomide		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12945877	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016158750		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	20 Milligram Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	7.5 Milligram, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Unk	Not Reported
Methotrexate	S			Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid (For 8 Years)	Not Reported
Methotrexate Sodium	S	Unknown	7.5 Milligram Unk (For 8 Years)	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	50 Milligram, Bid	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	7.5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Arthrotec	C	Unknown	50 Milligram, Bid	Not Reported
Gold	C		Unk	Not Reported
Imuran	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Plaquenil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	12989018	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015138593		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported

	Sulfasalazine		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	13049424	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016048704		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Estradiol	C	Unknown	0.6 Percent, Tid	Not Reported
	Estradiol	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Valsartan	C	Unknown	320 Mg, Qd	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	50 Milligram, Qd	Not Reported
	Xalatan	C	Unknown	Unk	Not Reported
	Xalatan	C		50 Microgram, Qd	Not Reported
	Xalatan	C		Unk, Solution Opthalmic	Not Reported
	Dorzolamide Hcl/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
	Potassium Chloride	C		1500 Milligram, Qd	Not Reported
	Potassium Chloride	C	Unknown	Unk	Not Reported
	Zingiber Officinale	C	Unknown	500 Mg, Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Baclofen	C	Unknown	10 Mg, Bid	Not Reported
	Levaquin	C		500 Mg, Qd For 10 Days	Not Reported
	Levaquin	C		Unk	Not Reported
	Atasol (Acetaminophen)	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	500 Milligram, Qd	Not Reported
	Gravol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	13067459	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015077401		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen

Enzyme Abnormal; Rheumatoid Arthritis	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Celebrex		C	Unknown	Unk	Not Reported
	Plaquenil		C	Unknown	Unk	Not Reported
	Plaquenil		C		Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Sulfasalazine		C		Unk	Not Reported
	Humira		C		Unk Unk, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	13105545	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016064817		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

				Methotrexate		S	Unknown	Unk	Not Reported
				Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
				Arava		S	Unknown	20 Milligram, Qd	Not Reported
				Arava		S	Unknown	20 Milligram	Not Reported
				Arava		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	13110718	EXPEDITED (15-DAY)		DS, HO, OT	CA-AMGEN-CANSP2017001889		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Enbrel			S	Unknown	Unk		Amgen
	Abatacept			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actonel			C	Unknown	135 Mg, Qwk		Not Reported
	Advair			C		500 Mug, Unk		Not Reported
	Amlodipine			C		5 Mg, Qd		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Qd		Not Reported
	Aspirin			C		81 Mg, Qd		Not Reported
	Calcium			C		500 Mg, Bid		Not Reported
	Citalopram			C		30 Mg, Qd		Not Reported
	Docusate Sodium			C		Unk		Not Reported
	Ergocalciferol			C		3000 Df, Qd		Not Reported
	Ferrous Gluconate			C	Oral	300 Mg, Qd		Not Reported
	Folic Acid			C	Oral	5 Milligram, Qd		Not Reported

Hydrochlorothiazide	C		25 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	C	Oral	2 Df, Qd	Not Reported
Olmesartan Medoxomil	C		40 Mg, Qd	Not Reported
Oxybutynin	C		2.5 Mg, Qd	Not Reported
Prednisone	C		9 Mg, Qd	Not Reported
Rabeprazole	C		20 Milligram, Qd	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Bid	Not Reported
Senna Alexandrina	C	Oral	Unk	Not Reported
Spiriva	C		Unk	Not Reported
Tiotropium Bromide	C		18 Microgram, Qid	Not Reported
Tylenol	C		Unk Unk, Qid	Not Reported
Vitamin B12	C		1500 Mg, Qd	Not Reported
Zinc Gluconate	C		25 Mg, Qd	Not Reported
Zopiclone	C		7.5 Milligram, Qd	Not Reported
Manganese Sulfate	C			Not Reported
Copper Sulfate	C			Not Reported
Omega 3	C			Not Reported
Coenzyme Q10	C			Not Reported
Dha	C			Not Reported
Epa	C			Not Reported
D-Alpha Tocopherol	C			Not Reported
Fish Oil	C			Not Reported
Vitamin C	C	Oral	1000 Mg, Qd	Not Reported
Omega-3 Marine Triglycerides	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol/ Fish Oil	C		Unk	Not Reported
Fatty Acids Nos	C		Unk	Not Reported
Hydroxychloroquine	C	Oral	Unk Unk, Qd	Not Reported
Magnesium Sulfate	C		Unk	Not Reported
Oxybutin	C		2.5 Milligram, Qd	Not Reported
Vitamin C Mse Matrix	C	Oral	1000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	13160856	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017013161		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Q Weekly		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	10 Mg, Q Weekly (Prev. Injection)		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Q Weekly		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Asa			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen Sodium			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Ramipril			C		2.5 Milligram, Qd		Not Reported
	Tylenol [Paracetamol]			C	Unknown	650 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	13859345	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017119294		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

					Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Abatacept	S	Unknown		Not Reported
					Orencia	S	Unknown	Unk	Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
					Acetaminophen W/Codeine Phosphate	C		Unk	Not Reported
					Folic Acid	C		Unk	Not Reported
					Leflunomide	C	Unknown	20 Mg, Qwk	Not Reported
					Leflunomide	C	Unknown	Unk	Not Reported
					Methotrexate	C	Unknown	20 Mg, Qwk	Not Reported
					Methotrexate	C	Unknown	Unk	Not Reported
					Naproxen	C	Unknown	Unk	Not Reported
					Acetaminophen;Caffeine	C		Unk	Not Reported
					Arava	C		Unk	Not Reported
					Tylenol With Codeine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14024853	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017394570		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Drug Ineffective; Lower Respiratory Tract Infection; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14068092	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017151688			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	50 Die, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown	50, Unk, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Imuran			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14156191	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017165016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk Unk, Q2wk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported

	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk Unk, Q2wk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Abatacept	C		Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14156238	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164837		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported

General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Unk	Not Reported
	Orencia	S	Unknown	200 Milligram, Unk	Not Reported
	Prednisone	S	Unknown	20 Nanogram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Cyclical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, (Every 6 Months)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Unknown	20 Nanogram, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14191064	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491476		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14208253	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017173752			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14546342	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018022075			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14620249	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017219290		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Sarcoidosis; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Hydroxychloroquine			S	Unknown	200 Mg, Die		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Salazopyrin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14767205	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018049677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Abatacept			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Azathioprine			S	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported
	Prednisone			C		Unk			Not Reported
	Hydroxychloroquine			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14770529	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018155235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	1000 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Qwk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	14829773	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017243705		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Condition Aggravated; Drug Ineffective; Eye Inflammation; Rheumatoid Arthritis; Vulvovaginal Mycotic Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

	Omeprazole	C	Unk	Not Reported
	Irbesartan	C	Unk	Not Reported
	Diltiazem	C	Unk	Not Reported
	Trazodone	C	Unk	Not Reported
	Levothyroxine	C	Unk	Not Reported
	Bupropion	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15206458	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018100976		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milliliter, Qwk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Milliliter, Qwk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15208133	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2018100920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15504213	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015057703		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

	Prednisone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15554646	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016054122		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Gold			S	Intramuscular	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Kineret			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15556949	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015270940		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Weekly		Pfizer

Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Methotrexate Sodium	S	Unknown	20 Mg, Qweek		Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium	S	Unknown	20 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium	S	Unknown	20 Mg, Qwk		Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day		Pfizer
	Actemra	S		Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Arava	S	Unknown	20 Mg, Unk		Not Reported
	Rituxan	S		Unk		Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15562825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015053449		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	22.5 Mg, Qwk		Pfizer
	Orencia			S	Unknown	Unk		Not Reported

	Simponi			S	Subcutaneous	Unk	Not Reported
	Actemra			S	Unknown	Unk	Not Reported
	Apo-Leflunomide			S		10 Mg, Unk	Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk	Not Reported
	Hydroxychloroquine			S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine			S	Oral	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15700856	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017009448		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid (200 Mg, 2 In 1 Day)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day		Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	5 Mg, Bid (2 In 1 Day)		Not Reported

		Prednisone			C	Unknown	5 Mg, Bid (2 In 1 Day)			Not Reported
		Restasis			C	Unknown	Unk			Not Reported
		Synthroid			C	Unknown	Unk			Not Reported
		Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15705982	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018174141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Discomfort; Joint Stiffness; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	L-Thyroxine [Levothyroxine]			C	Unknown	Unk		Not Reported
	Nexium [Esomeprazole Magnesium]			C		Unk		Not Reported
	Tylenol Arthritis Pain			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15708907	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016090467		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil		S	Unknown	Unk			Not Reported
	Arava		S	Unknown	Unk			Not Reported
	Humira		S	Subcutaneous				Not Reported
	Methotrexate		S	Unknown				Not Reported
	Simponi		S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15710943	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2586275-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15711251	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018509477		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Parenteral	Unk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15802644	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616920-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cannabis			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15834550	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016246729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
	Methotrexate			S		25 Mg, Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported

					Humira		S	Subcutaneous	40 Mg, Q2wk		Not Reported
					Humira		S	Subcutaneous	40 Mg, 2x/Week		Not Reported
					Orencia		S	Intravenous (not otherwise specified)	500 Mg, Monthly (Q4wk)		Not Reported
					Orencia		S	Intravenous (not otherwise specified)	500 Mg, Monthly(Qmo)		Not Reported
					Plaquenil		S	Unknown	400 Mg, 1x/Day		Not Reported
					Remicade		S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
					Remicade		S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15852469	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019007337		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	0.8 Milligram/Kilogram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15960525	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019020220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel		S	Unknown	Unk		Amgen
	Actemra		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	25 Milligram, Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	15962071	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018392740		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Joint Swelling; Pain In Extremity; Weight Decreased	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Voltaren [Diclofenac]			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Dexilant			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16017566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019087372		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Arthritis; Condition Aggravated; Menopausal Symptoms; Musculoskeletal Stiffness;	Enbrel			S	Unknown	Unk Unk, Qwk		Unknown
	Enbrel			S		One Injection Every Two Weeks		Unknown
	Enbrel			S		1 Df, Monthly(1 Injection)		Unknown

Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	50 Mg, Weekly	Unknown
	Enbrel	S	Subcutaneous	50 Mg, Unk	Unknown
	Enbrel	S	Unknown	50 Mg, Unk	Unknown
	Enbrel	S	Unknown	Unk	Unknown
	Enbrel	S	Unknown	1 Df, Unk	Unknown
	Xeljanz	S	Oral	5 Mg, 2x/Day (2 Every 1 Day)	Pfizer
	Xeljanz	S	Unknown	Unk	Pfizer
	Xeljanz	S	Unknown	Unk, 2x/Day	Pfizer
	Xeljanz	S	Unknown	5 Mg, 2x/Day	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Advil	S	Unknown	400 Mg, 2x/Day (2 Every 1 Day)	Pfizer
	Mefenamic Acid	S	Unknown	400 Mg, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, 1x/Day (1 Every 1 Day)	Not Reported
	Leflunomide	S	Unknown	20 Mg, 1x/Day (1 Every 1 Day)	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1x/Day (1 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16344740	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2793192-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16373980	EXPEDITED (15-DAY)		OT	ES-SAMSUNG BIOEPIS-SB-2019-00498		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Neutropenia	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Dolquine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Infliximab Hospira			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Dosage Form: Lyophilized		Not Reported

						Powder			
	Paracetamol			C	Unknown	Unknown			Not Reported
	Pantoprazole			C	Unknown	Unknown			Not Reported
	Enbrel			C	Unknown				Not Reported
	Lornoxicam			C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16386391	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017164310		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil			S	Oral	600 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	1.0 Dosage Form, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16433056	NON-EXPEDITED			PHHY2019IL136683		48 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Visual Field Defect	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16439060	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2019017409			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S				Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Pamidronate			S	Unknown	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Doxycycline Hyclate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Tenoxicam			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported

	Xeljanz			S	Unknown	Unk				Not Reported
	Cyclosporine			S	Unknown	Unk				Not Reported
	Pamidronate Disodium			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16447405	EXPEDITED (15-DAY)		OT	US-ZYDUS-037802		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Azathioprine			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449497	EXPEDITED (15-DAY)			US-ROCHE-2269467			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pruritus; Liver Function Test Increased	Actemra			S	Unknown	Treatment Length 3 Years		Not Reported
	Humira			S	Subcutaneous	Treatment Length 2 Years		Not Reported
	Methotrexate			S	Unknown	Treatment Length 4 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Treatment Length 3 Years		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449538	EXPEDITED (15-DAY)			US-ROCHE-2279737			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased; Therapeutic	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Product Effect Decreased	Orencia			S	Unknown				Not Reported
	Simponi			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449549	EXPEDITED (15-DAY)			US-ROCHE-2278520			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449735	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1851			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16449922	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2019-101859			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Folic Acid			S	Unknown	Unk Unknown, Unknown		Vintage
	Plaquenil /00072602/			S	Unknown	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16450974	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822464-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Methotrexate			C				Not Reported

Toxicity To Various Agents; Visual Impairment	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16451191	EXPEDITED (15-DAY)		OT	CA-SA-2017SA120538		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Interstitial Lung Disease	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S				Sanofi
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported
	Celebrex			C		100 Mg, Bid (100mg Bid As Needed)		Not Reported
	Methotrexate			C		12.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16451824	NON-EXPEDITED			PHEH2019US025497		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastric Dilatation; Nausea	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	200 Mg, Qd		Novartis
	Prilosec			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16452077	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017115401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Lock; Pain In Extremity; Psoriatic Arthropathy; Synovitis; Therapeutic	Enbrel			S	Unknown	Unk		Amgen
	Calcium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

Product Effect Decreased; Trigger Finger	Orencia		S	Unknown	Unk	Not Reported
	Cimzia		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	400 Milligram	Not Reported
	Plaquenil		S	Unknown		Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cosentyx		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Imuran [Azathioprine]		S	Unknown	Unk	Not Reported
	Actonel		C		35 Milligram, Qwk	Not Reported
	Depo Medrol		C		40 Dosage Form	Not Reported
	Depo Medrol		C		80 Dosage Form	Not Reported
	Ergocalciferol		C		2000 Dosage Form, Qd	Not Reported
	Codeine		C	Unknown	Unk	Not Reported
	Xeljanz		C			Not Reported
	Otezla		C			Not Reported
	Prednisone		C	Oral	5 Milligram	Not Reported
	Prednisone		C	Oral	1 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16452228	EXPEDITED (15-DAY)			US-ROCHE-2263181			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Humira			C						Not Reported
	Cimzia			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16452569	EXPEDITED (15-DAY)			US-ROCHE-2159334			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nodule	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16452830	NON-EXPEDITED			US-SA-2019SA157684			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Disorder; Pneumonitis; Psoriasis; Urticaria	Atorvastatin Calcium			S		20 Mg, Qd		Not Reported
	Levofloxacin			S		Unk Unk, Unk		Not Reported
	Amoxicillin			S		Unk Unk, Unk		Not Reported
	Amoxicillin Sodium/Potassium Clavulanate			S		250 Mg, Unk		Not Reported
	Leflunomide			S		Unk Unk, Unk		Sanofi
	Codeine			S		Unk Unk, Unk		Not Reported
	Tramadol Hydrochloride			S		1 Df, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Not Reported
	Atorvastatin Calcium			S		Unk Unk, Unk		Not Reported
	Infliximab			S		250 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16453077	EXPEDITED (15-DAY)		OT	US-ROCHE-2208787			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Sepsis; Headache; Infusion Related Reaction; Pneumonia; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acthar [Corticotropin]			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16453660	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1065780		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Swelling	Naproxen			S	Unknown			Teva
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16453780	EXPEDITED (15-DAY)		OT	PHHY2019CA138629		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug	Meperidine Hcl Inj Usp			S	Intravenous (not	Unk		Not Reported

Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting			otherwise specified)		
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Novartis
	Methotrexate Sandoz	S	Oral	20 Mg, Qw	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16453855	EXPEDITED (15-DAY)			US-ROCHE-2177714			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16454258	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1057399		47 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Off Label Use; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Prednisolone			S	Unknown	Decreased Gradually, For 2 Months		Mylan
	Prednisolone			S	Unknown	For 2 Months		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2019	16455424	EXPEDITED (15-DAY)		HO	PHHY2019CA136653		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported

Symptom; Parkinsonism; Postural Tremor; Resting Tremor

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	11469398	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-HQWYE709921AUG07		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 To 25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Sulfasalazine			S		1000 Mg, Twice Daily		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2gm Every 6 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 G, Unk		Not Reported
	Arava			S	Unknown	10 Mg, Daily		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Gold			S		Injection		Not Reported
	Prednisone			S		20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12328394	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016213277		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S		50 Milligram, Qwk		Pfizer
	Enbrel			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	0.6 %, 3x/Day		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Xalatan			C	Ophthalmic	50 Mg, Qd		Not Reported

	Xalatan	C	Unknown	Unk	Not Reported
	Xalatan	C		50 Mug, Unk	Not Reported
	Dorzolamide Hcl/Timolol Maleate	C	Unknown	Unk, Bid	Not Reported
	Baclofen	C		10 Mg, 2x/Day	Not Reported
	Baclofen	C	Unknown	10 Mg, Bid	Not Reported
	Levaquin	C		500 Mg, Qd For 10 Days	Not Reported
	Levaquin	C		Unk	Not Reported
	Morphine	C		Unk	Not Reported
	Potassium Chloride	C		1500 Mg, Qd	Not Reported
	Potassium Chloride	C	Unknown	Unk	Not Reported
	Zingiber Officinale	C	Unknown	500 Mg, Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
	Estrogel	C	Unknown	0.6 %, 3x/Day	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	500 Milligram, Qd	Not Reported
	Gravol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12386958	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015297426		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Synovitis; Thyroid Cancer	Enbrel			S		50 Mg, Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported

	Leflunomide	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Lantus	C		Unk		Not Reported
	Insulin	C		Unk		Not Reported
	Humalog	C		Unk		Not Reported
	Avapro	C		Unk		Not Reported
	Aspirin	C		Unk		Not Reported
	Gluconorm	C		Unk		Not Reported
	Metformin Hydrochloride	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12488521	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016264308		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Celebrex			S	Oral	200 Mg, Bid		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, (Solution Intravenous)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported

	Arava			S	Oral	Unk	Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk	Not Reported
	Arava			C	Unknown	20 Mg, Qd	Not Reported
	Arava			C	Unknown	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12609531	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016362505		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cortisone			C		5 Milligram, 1x/Day		Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg (Half A Tablet), As Needed		Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg, Unk		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, 1x/Day		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, 1x/Day		Not Reported
	Tylenol			C	Unknown	Unk, As Needed		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

	Leflunomide			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12684966	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2016020067		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	4 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12690290	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016038279		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Intolerance; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S		Unk		Not Reported

	Simponi		S	Subcutaneous	Unk		Not Reported
	Simponi		S	Unknown	Unk		Not Reported
	Orencia		S		Unk		Not Reported
	Orencia		S		1 Df, Single		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide		S	Unknown	10 Mg, 1x/Day		Not Reported
	Prednisone		S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine		S	Unknown	400 Mg, 1x/Day		Not Reported
	Apo-Leflunomide		S	Unknown	10 Mg, 1x/Day		Not Reported
	Apo-Prednisone		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12859447	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016464718		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Cyclosporine			S		Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported

	Xeljanz			C	Oral	5 Mg, Bid				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12914291	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092038		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk , Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	12939528	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016521754		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort;	Enbrel			S	Unknown	Unk		Pfizer

Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	7.5 Milligram, Unk (For 8 Years)	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S			Unknown
	Diclofenac Sodium/Misoprostol	S	Unknown	50 Mg, Bid	Pfizer
	Diclofenac Sodium/Misoprostol	S	Unknown	7.5 Milligram, Bid	Pfizer
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid (For 8 Years)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Leflunomide	S	Unknown	20 Mg, Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		For 8 Years		Not Reported
Vitamin D	C		Unk		Not Reported
Arthrotec	C	Unknown	50 Mg, 2 Every 1 Day		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Imuran [Azathioprine]	C	Unknown	Unk		Not Reported
Gold	C		Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	13147225	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004948		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported

	Hydroxychloroquine			S	Unknown	400 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	13516210	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037961		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Penicillamine			S	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported
	Elavil /00002202/			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	13816338	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017217268		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Surgical Failure; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			C	Unknown	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	13917840	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372776		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Joint Swelling; Knee Arthroplasty; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	13922127	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017374665		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Unk		Unknown
	Abatacept			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Monthly		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, 1x/Day (400 Mg, Qd (1 Every 24 Hours))		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Actonel			C	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	5 Milligram, Qd		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported

	Folic Acid		C	Unknown	Unk	Not Reported
	Metformin		C	Unknown	Unk	Not Reported
	Mtx		C	Unknown	Unk	Not Reported
	Pantoprazole		C	Unknown	Unk	Not Reported
	Paroxetine		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Risedronate		C	Unknown	Unk	Not Reported
	Simvastatin		C	Unknown	Unk	Not Reported
	Statex		C	Unknown	Unk	Not Reported
	Telmisartan		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day	Not Reported
	Acetylsalicylic Acid		C		Unk	Not Reported
	Morphine Sulfate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	14226677	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017507919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qd		Unknown
	Methotrexate Sodium			S		15 Mg, Qd		Pfizer
	Sulfasalazine			S	Oral	1 G, Qd		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	14232038	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017510749		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Pfizer
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	0.8 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qod		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qod		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	5 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported

	Simponi		C	Subcutaneous	Unk			Not Reported
	Simponi		C	Unknown	Unk			Not Reported
	Xeljanz		C	Unknown	Unk			Not Reported
	Sulfasalazine		C		Unk Unk, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	14557673	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018071956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	14562842	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018073950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	14637077	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018106239			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	1 G, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15215888	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017373157		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nodule	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Apo Leflunomida			S	Unknown	Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Naproxen			C		1500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15481544	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003454		36 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction	Plaquenil 200 Mg Tablet			S	Oral			Concordia

	Prednisolone	C	2 Mg/Day	Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Rabeprazole Sodium	C		Not Reported
	Rabeprazole Sodium	C		Not Reported
	Cilostazol	C		Not Reported
	Edirol	C		Not Reported
	Edirol	C		Not Reported
	Risedronate Sodium	C		Not Reported
	Risedronate Sodium	C		Not Reported
	Cephadol	C		Not Reported
	Betahistine Mesilate	C		Not Reported
	Acecol	C		Not Reported
	Diltiazem Hydrochloride	C		Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Febuxostat	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15545618	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA023360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 4 Week (S)		Not Reported
	Certolizumab Pegol			S	Unknown	400 Mg, 1 Every 2 Week (S)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15555588	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015248416		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Enbrel	S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Orencia	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15563285	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016246540		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tramadol Hcl			C	Oral	50 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15567238	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015216227		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	25 Milligram, Bid		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		1 Ml, Weekly (Injectable)		Unknown
	Methotrexate Sodium			S		25 Mg, Weekly: 0.65 Ml, Weekly (Injectable), (Reduced To 0.65 Ml Since Start On Xeljanz		Unknown
	Methotrexate Sodium			S	Subcutaneous	17 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Prednisone			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	7 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15567248	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016181292		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	Dose Range From 20, 15, Than 10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S		Unk, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S		10 Mg, Unk	Unknown
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Unknown
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	50 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Oral	50 Mg, Unk	Unknown
	Remicade	S	Subcutaneous	300 Mg, Every 8 Weeks	Not Reported
	Remicade	S	Subcutaneous	300 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	592 Mg, Every 4 Weeks	Not Reported
	Actemra	S		Unk, Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Weekly	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk, Weekly	Not Reported
	Arava	S	Intravenous (not	592 Mg, Monthly (Q4wk)	Not Reported

				otherwise specified)		
	Arava		S	Oral	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Desoximetasone		C		Unk	Not Reported
	Infliximab		C	Unknown	300 Mg, Unk	Not Reported
	Infliximab		C	Unknown	300 Milligram, Q8wk	Not Reported
	Infliximab		C	Unknown	Unk	Not Reported
	Cortisone		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15569060	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3091		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15575085	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015369675		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Unknown
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer

Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Methotrexate Sodium		S	Oral	25 Mg, Qwk	Pfizer
	Celebrex		S	Oral	200 Milligram, As Necessary	Pfizer
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	8 Mg, Unk	Not Reported
	Leflunomide		S	Unknown	20 Mg, Unk	Not Reported
	Orencia		S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine		C	Unknown	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15714497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018510033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Discomfort; Joint Stiffness; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	L-Thyroxine [Levothyroxine]			C	Unknown	Unk		Not Reported
	Nexium [Esomeprazole			C		Unk		Not Reported

	Magnesium] Tylenol Arthritis Pain			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15930717	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2655663-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15957210	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019066858			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qwk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported

Cell Count Decreased	Humira	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	15958047	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019066483		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16055845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2273676		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Dizziness; Drug Interaction; Epistaxis; Feeling Abnormal; Feeling Abnormal; Gastroenteritis Viral; Headache; Ill-Defined Disorder; Joint Warmth; Lower	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported

Respiratory Tract Infection; Oropharyngeal Pain; Weight Increased	Omeprazole		C	Unknown	Not Reported
	Clindamycin		C	Unknown	Not Reported
	Methotrexate		C	Subcutaneous	Not Reported
	Moxifloxacin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16215711	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1200		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Urticaria	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16269632	NON-EXPEDITED			US-PFIZER INC-2019186222		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16388646	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029944			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

			Humira		S	Subcutaneous	Unk			Not Reported
			Hydroxychloroquine		S	Unknown	Unk			Not Reported
			Methotrexate		S	Oral	Unk			Not Reported
			Orencia		S	Unknown	Unk			Not Reported
			Remicade		S	Unknown	Unk			Not Reported
			Rituxan		S	Intravenous (not otherwise specified)	Unk			Not Reported
			Prednisone		C	Unknown	2 Milligram, Once A Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16451752	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019048692		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Interstitial Lung Disease; Treatment Failure	Enbrel			S		Unk		Pfizer
	Pamidronate Disodium			S		Unk		Unknown
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Doxycycline			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	Unk		Pfizer
	Stelara			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Tenoxicam			S	Unknown	Unk		Not Reported
	Bromocriptine			S		Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16455390	EXPEDITED (15-DAY)		OT	US-ZYDUS-038170		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Flushing; Malaise; Reaction To Excipient; Urticaria	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16456142	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016336252		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16457586	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1056610			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Deep Vein Thrombosis; Foot Fracture; Hypogammaglobulinaemia; Intervertebral Disc Protrusion; Radiculopathy; Stomatitis; Thrombosis	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported
	Methotrexate			S		25 Mg, Unk		Not Reported

	Mabthera			S	Unknown	Unk	Mylan
	Quensyl			S	Unknown	Unk	Mylan
	Leflunomide			S	Unknown	15 Mg, Unk	Mylan
	Leflunomide			S	Unknown	15 Mg, Unk	Mylan
	Leflunomide			S		Unk	Mylan
	Leflunomide			S	Unknown	15 Mg, Unk	Mylan
	Leflunomide			S	Unknown	15 Mg, Unk	Mylan
	Leflunomide			S	Unknown	15 Mg, Unk	Mylan
	Leflunomide			S	Unknown	15 Mg, Unk	Mylan
	Sulfasalazine			S	Unknown	2000 Mg, Unk	Mylan
	Sulfasalazine			S	Unknown	3000 Mg, Unk	Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Unk	Mylan
	Humira			S	Unknown	40 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16457587	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1056608			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Whipple'S Disease	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported

	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Roactemra		S	Unknown	634 Milligram	Mylan
	Roactemra		S	Unknown	620 Milligram	Mylan
	Roactemra		S	Unknown	620 Milligram	Mylan
	Roactemra		S	Unknown	574 Mg, Unk	Mylan
	Hydroxychloroquine		S	Unknown	200 Milligram	Mylan
	Hydroxychloroquine		S	Unknown	200 Milligram	Mylan
	Hydroxychloroquine		S	Unknown	200 Milligram	Mylan
	Hydroxychloroquine		S	Unknown	200 Mg, Unk	Mylan
	Hydroxychloroquine		S	Unknown	400 Milligram	Mylan
	Orencia		S	Unknown	750 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16459083	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019254673		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Infusion Related Reaction; Infusion Related Reaction; Off Label Use; Pharyngeal Swelling; Poor Venous Access; Vasculitis	Epinephrine			S	Unknown	Unk		Unknown
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not	1000 Mg, Unk		Not Reported

						otherwise specified)			
		Rituxan			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
		Fentanyl			C	Unknown	Unk		Not Reported
		Immunoglobulin Human Normal			C		Unk		Not Reported
		Losartan			C	Unknown	25 Mg, Unk		Not Reported
		Mirtazapine			C		Unk		Not Reported
		Progesterone			C		Unk		Not Reported
		Rabeprazole			C		Unk		Not Reported
		Sertraline			C	Unknown	150 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jun-2019	16460537	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2019M1057496			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Avelumab			S	Intravenous (not otherwise specified)	Unk		Mylan
	Abraxane			S	Intravenous (not otherwise specified)	Unk		Mylan
	Gemcitabine Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Mylan
	Gabapentin			C		Unk		Mylan
	Tresiba Flextouch			C		Unk		Mylan
	Metformin			C		Unk		Mylan
	Miralax			C		Unk		Mylan
	Oxycodone			C		Unk		Mylan
	Oxycodone			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	11476817	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2014-US-010624			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Carbon Monoxide Poisoning; Carpal Tunnel Syndrome; Cyst Removal; Infusion; Limb Operation; Loss Of Consciousness; Post Procedural Complication; Pruritus; Sciatica; Seizure; Suicidal Ideation	Xyrem			S	Oral	1.75 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	11585225	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015099893		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Hypersensitivity; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Vertigo	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, 1 Every 1 Week		Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk (Solution Intraarterial)		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 2 Times/Wk		Not Reported
	Avelox			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Norvasc			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	11865586	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015447286		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Treatment Failure; Vomiting	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072603/			S	Oral	400 Mg, Daily		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic (Every 2 Weeks)		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	12376354	NON-EXPEDITED		OT	US-PFIZER INC-2016260125		21 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; C-Reactive Protein Increased; Drug Ineffective; Dysstasia; Finger Deformity; Gait Disturbance; Grip Strength Decreased; Hand Deformity; Impaired Work Ability; Joint Contracture; Joint Noise; Joint Swelling; Menorrhagia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S		Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S	Oral	1000 Mg, Twice Daily (After Meals)		Pfizer
	Sulfasalazine			S		500 Mg, Twice Daily		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg (6 Tablet), Weekly		Not Reported
	Methotrexate Sodium			S				Not Reported
	Humira			S	Subcutaneous	0.8 Ml, Unk, (Once Every 2 Weeks As Directed)		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Twice Daily		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Naprosyne			C	Oral	500 Mg, Bid		Not Reported

Vitamin D2	C	Oral	1 Capsule, Weekly		Not Reported
Prednisone	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	12684109	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016108047		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Drug Ineffective; Nodule; Pain	Enbrel			S	Parenteral	50 Milligram		Amgen
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	13132140	NON-EXPEDITED			US-AMGEN-USASP2017006755		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Body Temperature Fluctuation; Chills; Chondropathy; Dizziness; Drug Hypersensitivity; Electrolyte Imbalance; Feeling Cold; Headache; Herpes Virus Infection; Hot Flush; Hyperhidrosis; Hypoaesthesia; Inflammation; Liver Disorder; Malaise; Night Sweats; Pain; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pyrexia; Renal Disorder; Sinus Congestion;	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	2.5 Milligram (Four Days A Week)		Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram (For One Day)		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Potassium			C	Unknown	80 Milliequivalent, Qd		Not Reported
	Simvastatin			C	Unknown	20 Milligram, Qd		Not Reported
	Alendronate			C	Unknown	70 Milligram, Qwk		Not Reported

Therapy Non-Responder; Visual Impairment; Weight Decreased	Fosamax		C	70 Milligram	Not Reported
	Klor-Con		C	80 Milligram	Not Reported
	Levothyroxine		C	75 Microgram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	13519975	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038393		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Gabapentin			S	Oral	100 Milligram, Q2wk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Apo Celecoxib			S	Oral	Unk		Not Reported
	Apo Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported

Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Oral		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Actonel	C	Unknown	36 Milligram, Qwk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Nasonex	C	Unknown	Unk, Bid	Not Reported
	Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Qh	Not Reported
	Omega 3 /07931301/	C	Unknown	1200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Qh	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
	Alfa-Tocoferol	C	Unknown	1200 Mg, Bid	Not Reported
	Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
	Genteal /00445101/	C	Ophthalmic	Unk	Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
	Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
	Loperamide Hydrochloride	C	Unknown	25 Mg, Unk	Not Reported
	Nicotinamide	C	Unknown		Not Reported
	Pantoprazole	C	Unknown	400 Mg, Qd	Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
	Pyridoxine Hydrochloride	C	Unknown		Not Reported
	Sodium	C	Unknown		Not Reported
	Thiamine Hydrochloride	C	Unknown		Not Reported

	Vitamin D3	C	Unknown	Unk	Not Reported
	Vitamin A /00056001/	C	Unknown		Not Reported
	Vitamin B12 /00056201/	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Vit D	C	Unknown	400 Dosage Form, Qd	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown		Not Reported
	Trazodone	C	Unknown		Not Reported
	Zoledronic Acid	C	Unknown		Not Reported
	Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	C	Unknown		Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown	2.5 Milligram, Qd	Not Reported
	Salmo Salar Oil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	13766732	EXPEDITED (15-DAY)		HO, LT	CA-PFIZER INC-2675436			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Pain; Pancytopenia; Sepsis; Tongue Coated	Methotrexate Sodium			S	Oral	2.5 Mg, 1x/Day		Pfizer
	Pro-Hydroxyquine			S	Oral	1 Df, 1x/Day		Not Reported
	Apo-Cal			C		Unk		Not Reported
	Alendronate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	13864958	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015286770		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Milligram, Bid		Pfizer
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	50 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram, Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk (7 Years)		Not Reported
	Orencia			S	Unknown	750 Milligram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Mg, Unk (9 Months)		Not Reported
	Remicade			S		500 Mg, Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Bid (5 Months)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk (3 Years)		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported

	Leflunomide		S		Unk		Not Reported
	Apo-Prednisone		S	Oral	Unk Unk, Qd		Not Reported
	Cimzia		S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	14196393	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491769		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Hypertension; Impaired Work Ability; Pain	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	14217958	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Oral	Unk		Not Reported

	Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	14406642	EXPEDITED (15-DAY)		CA, HO, OT	PT-ASPEN-GLO2018PT000341		23 DAY	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; C-Reactive Protein Increased; Cardiomegaly; Foetal Exposure During Pregnancy; Heart Block Congenital; Hypoxia; Leukopenia; Lung Infiltration; Lupus Pneumonitis; Patent Ductus Arteriosus; Premature Baby; Pulmonary Embolism; Rash Erythematous; Respiratory Failure; Sepsis; Staphylococcal Infection; Tachypnoea; Thrombocytopenia	Dexamethasone			S	Transplacental	Maternal Dose: 8 Mg/D On Week 26		Aspen
	Prednisolone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Salbutamol			S	Transplacental	Maternal Dose: 32mg/D On Week 26		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	14501694	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Every 24 Hours)		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil S			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	14921431	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044618			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased				otherwise specified)			
	Methotrexate		S	Oral	4 Dosage Form, Qwk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Methotrexate Sodium		S	Oral	Unk, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	14921972	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Apo Mycophenolate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15205520	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018100944		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Leflunomida			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomida			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	300 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Magnesium			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Mtx			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15565456	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-098135		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cutaneous T-Cell Lymphoma; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Ineffective; Gait Inability; Herpes Zoster; Hiatus Hernia; Insomnia; Muscle Spasms; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Sarcoidosis; Skin Cancer; Sleep Disorder Due To General Medical Condition, Insomnia Type	Cimzia	S	Unknown	Unk			Not Reported
	Enbrel	S	Unknown	Unk			Not Reported
	Humira	S	Unknown				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown				Not Reported
	Methotrexate	S	Unknown	Unk			Not Reported
	Leflunomide	C	Unknown				Not Reported
	Plaquenil S	C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15568769	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1700		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Product Use Issue; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15627288	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557075-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arthrotec			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Tylenol			C				Not Reported
	Mefenamic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15835903	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016055430		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	1 Milliliter, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram, Unk		Not Reported

Celebrex	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	50 Milligram, Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Kineret	S	Unknown	100 Milligram	Not Reported
Methotrexate	S	Oral	1 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	1 Milliliter, Qwk	Not Reported
Methotrexate	S	Unknown	7.5 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	5 Milligram, Q2wk	Not Reported
Methotrexate	S	Unknown	7.5 Milligram, Q2wk	Not Reported
Methotrexate	S	Unknown	10 Milligram, Q2wk	Not Reported
Methotrexate	S	Unknown	25 Milligram, Q2wk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	100 Milligram, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported

Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	1 Milliliter, Qwk	Not Reported
Apo Celecoxib	S	Unknown	Unk	Not Reported
Apo Celecoxib	S			Not Reported
Celecoxib	S	Unknown	Unk	Not Reported
Celecoxib	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo	Not Reported
Orencia	S	Unknown	12.5 Milligram, Unk	Not Reported
Orencia	S	Unknown	12.5 Milligram, Q2wk	Not Reported
Orencia	S	Unknown	12.5 Milligram, Qwk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Prednisone	S	Oral	5 Milligram, Tid	Not Reported
Prednisone	S	Unknown	15 Milligram, Qd	Not Reported
Prednisone	S	Oral	5 Milligram, Unk	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	15 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram, Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Altace	C	Unknown	5 Milligram, Unk	Not Reported
Altace	C	Unknown	10 Milligram, Unk	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram, Unk	Not Reported

Apo-Gabapentin	C	Unknown	300 Milligram, Unk	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Q2wk	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Qd	Not Reported
Cipralex [Escitalopram]	C		20 Milligram, Unk	Not Reported
Citalopram Hydrobromide	C		20 Milligram, Unk	Not Reported
Conjugated Estrogens	C		20 Milligram, Unk	Not Reported
Conjugated Estrogens	C		0.625 Milligram, Unk	Not Reported
Cymbalta	C	Unknown	120 Milligram, Qd	Not Reported
Cymbalta	C		30 Milligram, Qid	Not Reported
Cymbalta	C		60 Milligram, Unk	Not Reported
Escitalopram	C	Unknown	10 Milligram, Unk	Not Reported
Estrace	C		0.5 Milligram, Unk	Not Reported
Gabapentin	C	Unknown	3000 Milligram, Unk	Not Reported
Gabapentin	C	Oral	100 Milligram, Unk	Not Reported
Hydrochlorothiazide	C		12.5 Milligram, Unk	Not Reported
Hydromorphone Hydrochloride	C	Oral	3.0 Milligram, Bid	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Milligram, Bid	Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	20 Milligram, Qd	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram	Not Reported
Taro-Mupirocin	C	Topical	Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15848989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016412978		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Ear Pain; Facial Paralysis; Insomnia; Nasopharyngitis; Pain In Jaw	Calcium Folinate	S	Oral	5 Mg, Daily (Qd)	Pfizer
	Enbrel	S		Unk	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Sulfasalazine	S		Unk	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly (Qwk)	Pfizer
	Arava	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Leflunomide	S	Oral	20 Mg, Daily (Qd)	Not Reported
	Prednisone	S	Oral	5 Mg, Daily (Qd)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Vitamin D2	C		Unk	Not Reported
	Vitamin B12 /00056201/	C	Oral	1 Df, Daily	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Desoximetasone	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Fentanyl	C	Unknown	1 Df, Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, 2x/Day (Bid)	Not Reported
	Metformin And Sitagliptin	C	Oral	Unk, 2x/Day	Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, 1x/Day (Qd)	Not Reported
	Rabeprazole	C	Oral	180 Mg, 1x/Day (Qd)	Not Reported
	Ranitidine	C	Oral	150 Mg, 1x/Day (Qd)	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Synthroid	C	Oral	1 Df, 1x/Day (Qd)	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Zopiclone	C	Oral	7.5 Mg, 1x/Day (Qd)	Not Reported
	Oxycodone Hydrochloride	C		Unk	Not Reported

	Sitagliptin			C		Unk, 2x/Day				Not Reported
	Acetaminophen			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15867657	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015173347		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		12.5 Mg, Unk		Pfizer
	Arava			S		200 Mg, 2x/Week		Not Reported
	Arava			S		10 Mg, 1x/Day		Not Reported
	Arava			S		10 Mg, Alternate Day		Not Reported
	Arava			S		10 Mg, Alternate Day		Not Reported
	Arava			S		10 Mg, 3x/Week		Not Reported
	Arava			S		10 Mg, 2x/Week		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Humira			S		40 Mg, Cyclic (Every Other Week)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Cyclic		Not Reported
	Rituxan			S		1000 Mg, Cyclic		Not Reported
	Plaquenil			S		Unk		Not Reported
	Tofacitinib			C		Unk		Not Reported

Xeljanz	C	Unk	Not Reported		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15964311	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013565		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen;Caffeine			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	20 Milligram, Qwk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15977844	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility	Orencia			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported

Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Oral	20 Mg, Qwk		Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Arava	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	15978204	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16089614	EXPEDITED (15-DAY)		CA, DE, OT	DE-MYLANLABS-2019M1023919			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	Unk		Not Reported
	Torasemide			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Metamizole			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan
	Ramipril			S	Transplacental	20 Mg, Unk (Exposure Duration 0-13+6 Weeks)		Mylan
	Rivaroxaban			S	Transplacental	Unk		Mylan
	Aliskiren			S	Transplacental	Unk		Mylan
	Nicotine			S	Transplacental	Unk		Mylan
	Enoxaparin			C	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16115681	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16216669	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE086173		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Iron Deficiency Anaemia; Live Birth; Maternal Exposure During Pregnancy; Premature Delivery; Premature Rupture Of Membranes; Product Use In Unapproved Indication; Pyrexia; Tachycardia; Twin Pregnancy	Prednisolone			S	Unknown	5 Mg, Qd		Novartis
	Cyclophosphamide			S	Unknown	13.9 G, Unk (Cumulative Dose 2.1g)		Not Reported
	Cyclophosphamide			S	Unknown	21.1 G, Unk		Not Reported
	Cyclophosphamide			S	Unknown	10.9 G, Unk (Cumulative Dose 2.1g)		Not Reported
	Azathioprine			S	Unknown	Unk Exposed At 1st Trimester		Not Reported
	Folic Acid			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Iron			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S				Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Maltofer (Ferric Hydroxide Polymaltose Complex)			S	Unknown	Unk		Not Reported
	Ferrum Hausmann (Ferrous Fumarate)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16386945	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2804939-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus Inadequate Control; Ear Infection; Ear Infection;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

Glycosylated Haemoglobin Increased; Retinal Injury

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16418886	EXPEDITED (15-DAY)		DE, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-037		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Leukopenia; Off Label Use; Pulmonary Embolism	Cyclophosphamide			S	Oral			Westward
	Prednisone			S	Oral			Westward
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16420735	EXPEDITED (15-DAY)		OT	PHHY2019FR132247		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lupus Nephritis; Nephrotic Syndrome; Phospholipidosis; Proteinuria; Renal Disorder	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Ramipril			S	Unknown	Unk		Not Reported
	Thalidomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16461966	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019105027		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anger; Crying;	Benlysta Solution For Injection In			S	Subcutaneous	Unk Unk, We		Glaxosmithkline

Eye Irritation; Fear; Feeling Abnormal; Multiple Allergies; Overdose; Pain Of Skin; Pruritus; Screaming; Skin Burning Sensation	Pre-Filled Syringe						
	Wellbutrin		S		Unk		Glaxosmithkline
	Plaquenil		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16462173	EXPEDITED (15-DAY)		OT	PHHY2019CA141091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Erelzi			S	Unknown			Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16463281	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1064928		11 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S				Teva
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16463282	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1064929		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Reversible Cerebral Vasoconstriction Syndrome	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S				Teva
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16463895	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1895		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatitis; Liver Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16463896	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1905		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Intolerance; Gout; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown	4 Doses		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16464549	EXPEDITED (15-DAY)		OT	PHHY2019US140479		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Epstein-Barr Virus Infection Reactivation; Face Oedema; Lymphadenopathy; Papule; Pyrexia; Rash; Skin Exfoliation; Skin Plaque; Transaminases Increased	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16465281	EXPEDITED (15-DAY)		HO, LT	CA-PFIZER INC-2014353870			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Pain; Pancytopenia; Product Complaint; Sepsis; Tongue Coated	Methotrexate Sodium			S	Oral	1 Df, 1x/Day		Pfizer
	Pro-Hydroxyquine-200			S	Oral	1 Df, 1x/Day		Not Reported
	Alendronate			C	Unknown	Unk		Not Reported
	Apo-Cal			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16465614	EXPEDITED (15-DAY)		OT	PHHY2019US142390		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiotoxicity; Dyspnoea; Hypertensive Cardiomyopathy; Skin Hyperpigmentation	Hydroxychloroquine			S	Unknown	400 Mg (5.4 Mg/Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16465621	EXPEDITED (15-DAY)		OT	PHHY2019DE139617			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Umbilical Hernia	Prednisolone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Cyclophosphamide			S	Transplacental	Maternal Dose: 13.9 G, Unk (Cumulative Dose 2.1g)		Not Reported
	Cyclophosphamide			S	Transplacental	Maternal Dose: 21.1 G, Unk		Not Reported
	Cyclophosphamide			S	Transplacental	Maternal Dose: (Cumulative Dose 2.1g)		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Mycophenolate Mofetil			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Belimumab			S	Transplacental	Unk		Not Reported
	Low Molecular Weight Heparin			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jun-2019	16465761	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015322040		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nasopharyngitis; Rash; Rheumatoid Arthritis; Vertigo	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, 1 Every 1 Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk (Solution Intraarterial)		Pfizer
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day		Not Reported

	Arava	S		20 Mg, Daily		Not Reported
	Norvasc	C	Oral	5 Mg, Daily		Not Reported
	Avelox	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2019	12913306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091788		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Off Label Use; Pyrexia	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jun-2019	16466263	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058483		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatitis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Off Label Use	Actemra	S	Subcutaneous	162 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	11365599	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015190582		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	200 Milligram		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	9 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, Die		Not Reported

	Apo-Prednisone	S	Unknown	9 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclic (Every 15 Days)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Acetaminophen	C		500 Mg, Unk	Not Reported
	Gabapentin	C		600 Mg, Tid	Not Reported
	Reactine [Cetirizine Hydrochloride]	C		10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	11801930	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015411810		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Sulfasalazine			S		500 Mg X 2, Unk		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Sulfasalazine			S		500 Mg X 2, Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	12398645	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016251953			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Ibuprofen			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	12447989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016284711		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Enbrel	S	Unknown	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium	S	Unknown	25 Milligram		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Lyrica	S	Unknown	Unk		Pfizer
	Leflunomide	S	Oral	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S		Unk		Not Reported
	Mirtazapine	S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	12691293	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016403931		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Drug Ineffective; Nodule; Pain	Enbrel			S	Parenteral	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Apo-Hydroxyquine			S	Oral	400 Mg, Daily		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	12696672	EXPEDITED (15-DAY)		HO, LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1458		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	12701649	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1485		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Hip Fracture; Intervertebral Disc Disorder; Nausea; Product Complaint; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Single		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	12875220	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2041		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Elbow Deformity; Jaw Fracture; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Toxicity To Various Agents	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13063176	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0488		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Intolerance; Mobility Decreased; Nausea; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Visual Impairment; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown	More Than 20 Mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Stelara			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported

	Apo-Sulfasalazine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13070799	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2790		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Methotrexate (Trade Name Unknown)			S	Oral	Dose Range From 20 Mg, 15 Mg, Than 10 Mg, Weekly		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Dose Range From 20, 15, Than 10 Mg, Weekly		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Remicade	S	Subcutaneous		Not Reported
Remicade	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Intravenous (not otherwise specified)	Monthly	Not Reported
Arava	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported
Infliximab	C	Unknown		Not Reported
Cortisone	C	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13117183	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2017015511		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Abatacept			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, 2x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actonel			C		135 Mg, Qwk		Not Reported
	Advair			C		500 Ug, Unk		Not Reported
	Amlodipine			C	Unknown	5 Mg, Qd		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Qd		Not Reported
	Aspirin			C	Unknown	81 Mg, Qd		Not Reported
	Calcium			C	Unknown	500 Mg, Bid		Not Reported
	Citalopram			C	Unknown	30 Mg, Qd		Not Reported
	Docusate Sodium			C		Unk		Not Reported
	Ergocalciferol			C	Unknown	3000 Df, Qd		Not Reported
	Ferrous Gluconate			C	Oral	300 Mg, Qd		Not Reported
	Folic Acid			C	Oral	5 Mg, Qd		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	2 Df, Qd		Not Reported
	Olmesartan Medoxomil			C	Unknown	40 Mg, Qd		Not Reported
	Oxybutynin			C	Unknown	2.5 Mg, Qd		Not Reported
	Prednisone			C	Unknown	9 Mg, Qd		Not Reported
	Rabeprazole			C	Unknown	20 Mg, Qd		Not Reported

Rabeprazole Sodium	C	Oral	20 Mg, Bid	Not Reported
Senna Alexandrina	C	Oral	Unk	Not Reported
Spiriva	C		Unk	Not Reported
Tiotropium Bromide	C	Unknown	18 Ug, 4x/Day	Not Reported
Tylenol	C	Unknown	Unk Unk, Qid	Not Reported
Vitamin B12	C	Unknown	1500 Mg, Qd	Not Reported
Zinc Gluconate	C	Unknown	25 Mg, Qd	Not Reported
Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported
Manganese Sulfate	C		Unk	Not Reported
Vitamin C	C	Oral	1000 Mg, Qd	Not Reported
Copper Sulfate	C		Unk	Not Reported
Omega 3	C		Unk	Not Reported
Coenzyme Q10	C		Unk	Not Reported
Dha	C		Unk	Not Reported
Epa	C		Unk	Not Reported
Fatty Acid	C		Unk	Not Reported
D-Alpha Tocopherol	C		Unk	Not Reported
Fish Oil	C		Unk	Not Reported
Docusate Sodium And Senna	C		Unk	Not Reported
Omega-3 Marine Triglycerides	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	Unk Unk, Qd	Not Reported
Magnesium Sulfate	C			Not Reported
Oxybutin	C		2.5 Milligram, Qd	Not Reported
Vitamin C Mse Matrix	C	Oral	1000 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13145122	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016393950		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Enbrel			S	Unknown	Unk		Pfizer

Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Codeine	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Ramipril	S	Unknown	1 Dosage Form, Qd	Pfizer
	Ramipril	S	Unknown	Unk, Unk, Qd	Pfizer
	Altace	S	Unknown	1 Dosage Form, Qd	Pfizer
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Qd	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk Unk, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	600 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Codeine Phosphate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day (Daily)	Not Reported
	Levothyroxine Sodium	S	Unknown	Unk Unk, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Cosopt	S	Unknown	Unk, 2x/Day	Not Reported
	Levothyroxine	S	Unknown	1 Df, 1x/Day	Not Reported
	Levothyroxine	S	Unknown	Unk	Not Reported

Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Prednisone	S	Unknown	Unk Unk, Qd	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	2 Df, 2x/Day	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Unk Unk, 2x/Day	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Daily	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Tylenol No.2	C		Unk	Not Reported
Acetaminophen	C	Oral	1000 Milligram	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Hydroxychloroquine Phosphate	C		Unk	Not Reported
Caffeine	C		Unk	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Unk	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Meprobamate	C		Unk	Not Reported
Phosphate [Phosphoric Acid Sodium]	C		Unk	Not Reported
Timolol Maleate	C	Unknown	2 Dosage Form, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13245840	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1026		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Therapy Non-Responder; Viral Upper Respiratory Tract Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Celebrex			S	Oral	As Required		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13297479	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1173		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13508197	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1263		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diabetes Mellitus; Drug Intolerance; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Humira	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13875435	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2497		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Bupropion	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Levothyroxine	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	13875567	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2511		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	14163774	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017477937		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Unknown
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Unk		Not Reported
	Orencia			S	Unknown	200 Milligram, Unk		Not Reported
	Prednisone			S	Unknown	20 Nanogram, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Gram, Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Gram, (Every 6 Months)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Gram, Q6mo		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Unk		Not Reported
	Apo-Prednisone			S	Unknown	20 Nanogram, Unk		Not Reported

		Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Unk			Not Reported
		Actonel			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	14166067	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017477647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Q2wk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Abatacept			C		Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported

	Leflunomide	C	Unknown	Unk		Not Reported
	Tofacitinib Citrate	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Prednisone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	14198647	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3616		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	2 Times/Week		Not Reported
	Enbrel			S	Unknown	2x/Week (2 Every 1 Week)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	14570765	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	14775749	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018159734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Abatacept			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15210067	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018304801		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Ml, Qwk		Pfizer
	Methotrexate Sodium			S	Intravenous (not	20 Ml, Weekly		Unknown

Incomplete; Therapy Non-Responder; Treatment Failure			otherwise specified)			
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Oral	20 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15220361	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2247		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Delayed	Leflunomide	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Rabeprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15568789	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0818		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Rituxan	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15607062	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015288022		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diabetes Mellitus; Drug Ineffective; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Q2wk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported

	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	15 Mg, 1x/Day	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	200 Milligram, Bid	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Tofacitinib	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15703431	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3623		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Product Use Issue; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Advil	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Ketorolac	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	15868061	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017031165		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Musculoskeletal Discomfort; Pharyngeal Oedema	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S		Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk			Not Reported
	Methotrexate			C	Unknown	Up To 20 Milligram Once Week			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported
	Arava			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16388622	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1575		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fall; Muscular Weakness; Pain In Extremity	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	More Than Or Equal To 2 Gm Daily For 3 Months		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467403	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2829531-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467716	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-036053			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Premature Separation Of Placenta	Esomeprazole			S	Oral	20 Milligram, Once A Day		Aurobindo
	Diffu-K			S	Oral	1 Dosage Form, Once Daily (Qd)		Not Reported
	Imurel			S	Oral	150 Milligram, Daily		Not Reported
	Cortancyl			S	Oral	1 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16467886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2339407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Tocilizumab			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Discontinued		Not Reported
	Xeljanz			S	Oral	5mg/Bid (2x/Day)		Not Reported
	Sulfasalazine			S	Unknown	Discontinued		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16468449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058879		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	640 Milligram, Q4wk		Not Reported

Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk	Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	400 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Piroxicam	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16470097	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2019SE90097			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature	Esomeprazole			S	Oral	20 Miligram Once Daily		Astrazeneca

Delivery; Premature Separation Of Placenta	Diffu-K	S	Oral			Not Reported
	Imurel	S	Oral	150 Milligram Daily		Not Reported
	Cortancyl	S	Oral	1 Df Once Daily		Not Reported
	Plaquenil	S	Oral	400 Milligram Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16471018	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1065802		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Naproxen Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jun-2019	16471643	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Cimzian Single Used Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Imuran	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	11827503	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015131851		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil			S	Oral	20 Milligram		Not Reported
	Plaquenil			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported

					Leflunomide	S	Unknown	Unk	Not Reported
					Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
					Orencia	S	Subcutaneous	125 Milligram	Not Reported
					Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
					Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
					Ciclosporin	S	Unknown	Unk	Not Reported
					Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	12323846	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016053912		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Q2wk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Apo-Hydroxyquine			S	Unknown	300 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	12580648	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015383958		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Sulfasalazine		S	Unknown	1500 Mg, Unk	Pfizer
	Actemra		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	200 Mg, 1x/Day Daily (Qd)	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, 1x/Day(Daily, (1 Every 24 Hours))	Not Reported
	Arava		S	Unknown	10 Mg, 1x/Day (Daily)	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Anakinra		C	Unknown	Unk	Not Reported
	Kineret		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	12764898	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076287		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Peripheral Swelling; Rash; Tendon Disorder	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	13373387	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0543		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	13571492	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1503		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Rheumatoid Factor Positive; Surgical Failure; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mobicox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	13929657	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2687		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	14167765	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3388		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	14176963	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2891		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Drug Ineffective; Lower Respiratory Tract Infection; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	14242115	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3930		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Qod	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	14326018	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSL2017168640		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass;	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

Restrictive Pulmonary Disease	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	300 Milligram, Qd	Not Reported
	Lipitor	S	Unknown	40 Milligram, Qd	Not Reported
	Zenhale	S	Unknown	200 Microgram, Bid	Not Reported
	Zenhale	S	Unknown	200 Microgram, Qd	Not Reported
	Spiriva	S	Unknown	2.5 Milligram, Bid	Not Reported
	Tiotropium Bromide Monohydrate	S	Unknown	5 Mg, Qd (2.5 Mg *2)	Not Reported
	Tiotropium Bromide Monohydrate	S	Unknown	2.5 Mg, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	14570652	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0534		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Vitamin D	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15048481	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015799		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15565600	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA023531			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	200 Milligram		Not Reported

Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	S	Oral	5 Mg, Daily	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	9 Mg, Daily	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Die	Not Reported
	Apo-Prednisone	S	Unknown	9 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclic (Every 15 Days)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cortisone	C		Unk	Not Reported
	Acetaminophen	C		500 Mg, Unk	Not Reported
	Dexamethasone	C	Unknown	Unk	Not Reported
	Gabapentin	C		600 Mg, Tid	Not Reported
	Gabapentin	C		600 Mg, Tid	Not Reported
	Reactine [Cetirizine Hydrochloride]	C		10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15629329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556365-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Codeine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Prednisone			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15681063	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574305-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15721384	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Discomfort; Joint Stiffness; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	L-Thyroxine			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15753256	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018181974		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15764467	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0567		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	20 To 25 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	15935460	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2657055-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16075887	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide	S	Oral	20 Mg, Every Day		Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Bid		Apotex
	Azathioprine	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Twice Weekly		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Imuran /00001501/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Every Day		Not Reported
	Tiaprofenic Acid	C	Unknown	300 Mg, Every Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16079887	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05894		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

					Plaquenil	S	Unknown	Unknown	Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
					Simponi	S	Subcutaneous	Unknown	Not Reported
					Sulfasalazine	S	Oral	Unknown	Not Reported
					Tocilizumab	S	Unknown	Unknown	Not Reported
					Desoximetasone	C	Unknown	Unknown	Not Reported
					Methotrexate	C	Unknown		Not Reported
					Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16138966	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0921			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16462890	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1910		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fall; Interstitial Lung Disease; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Pamidronate Disodium		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Doxycycline		S	Unknown	Not Reported
	Cyclosporin		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Stelara		S	Unknown	Not Reported
	Doxycycline Hyclate		S	Unknown	Not Reported
	6-Mercaptopurine Monohydrate		S	Unknown	Not Reported
	Dilaudid		S	Unknown	Not Reported
	Tenoxicam		S	Unknown	Not Reported
	Bromocriptine		S	Unknown	Not Reported
	Ustekinumab		S	Unknown	Not Reported
	Colchicine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472302	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-061691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Off Label Use; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Actemra			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472620	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058606			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16472913	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1957		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Stelara			S	Subcutaneous					Not Reported
	Cimzia			S	Unknown					Not Reported
	Otezla			S	Oral					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Leflunomide			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16473361	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16473518	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1968		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Methotrexate (Trade Name			S	Unknown			Not Reported

Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Unknown)			
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16473556	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019264243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Methotrexate Sodium			S		Unk		Pfizer
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S		Unk		Not Reported
	Imuran [Azathioprine Sodium]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Teva Mycophenolate (Mycophenolate Mofetil)			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16473562	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019266453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S		Unk		Not Reported
	Diclofenac			S		50 Mg, 2x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Hydroxychloroquine	S	Oral	400 Mg, 1x/Day		Not Reported
Indocid [Indometacin]	S		50 Mg, 3x/Day		Not Reported
Leflunomide	S	Oral	10 Mg, 1x/Day		Not Reported
Naproxen	S		500 Mg, 4x/Day		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16474794	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA168826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hepatitis Acute; Lymphoma	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16484162	DIRECT	Y	HO			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Blood Lactic Acid Increased; Drug Eruption; Hallucination; Headache; Pustular Psoriasis	Hydroxychloroquine		Y	S	Oral		1 MTH	Unknown
	Azithromycin			C				Not Reported
	Cephalexin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	13748190	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201707-004057		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Interstitial Lung Disease	Plaquenil Tablet	S	Oral		Concordia
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Unknown	Daily Dose: Unknown	Not Reported
	Leflunomide	S	Unknown	Daily Dose:Unknown	Not Reported
	Xeljanz	C			Not Reported
	Celebrex	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	13875457	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0556		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Product Complaint; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituxan	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Tofacitinib Citrate	S	Unknown	Mg		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	14173094	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Abatacept	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	14175956	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210519		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Sodium Aurothiomalate			S	Parenteral	50 Mg,Unk		Not Reported
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Hydroxychloroquine Sulfate			S		20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported

	Orencia			S		750 Mg,Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk			Not Reported
	Meloxicam			C	Unknown	Unk Unk,Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	14289786	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-110414		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	14616212	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018031333		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough;	Enbrel			S	Unknown	Unk		Amgen
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Novo-Rythro	S	Unknown	Unk	Not Reported
	Erythro Base	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Wellbutrin	S	Unknown	300 Milligram, Qd	Not Reported
	Wellbutrin	S	Unknown	Unk	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Risedronate	C	Unknown	Unk	Not Reported
	Orencia	C	Unknown	Unk	Not Reported
	Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Bupropion	C	Unknown	300 Milligram, Qd	Not Reported
	Bupropion	C			Not Reported
	Ergocalciferol	C	Unknown	4000 International Unit, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Celebrex	C	Unknown	200 Milligram, Bid	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	15569077	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3075		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Product Use	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	15887227	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0257		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Arava	S	Unknown	2x/Week		Not Reported
Arava	S	Unknown			Not Reported
Arava	S	Unknown	10 Mg, Alternate Day		Not Reported
Arava	S	Unknown	10 Mg, Alternate Day		Not Reported
Arava	S	Oral	3x/Week		Not Reported
Arava	S	Unknown	2x/Week		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Humira	S	Unknown	Every Other Week		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Cyclic		Not Reported
Rituxan	S	Unknown	Cyclic		Not Reported
Plaquenil	S	Unknown			Not Reported
Tofacitinib	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16361172	EXPEDITED (15-DAY)		OT	PHHY2019IT120328		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysphonia; Infection Reactivation; Sensation Of Foreign Body; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16402074	EXPEDITED (15-DAY)		OT	PHHY2019US125372		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Novartis

Retinal Toxicity; Visual Field Defect	Hydrochlorothiazide	C	Unknown		Not Reported
	Levoxyl	C	Unknown		Not Reported
	Allegra	C	Unknown		Not Reported
	Prilosec	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16416156	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019244637		40 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 3x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16465609	EXPEDITED (15-DAY)		OT	PHHY2019DE139619			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Premature Baby; Umbilical Hernia	Mycophenolate Mofetil			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	Maternal Dose 5 Mg/Day		Novartis
	Cyclophosphamide			S	Transplacental	Maternal Doe: 13.9 G, Unk (Cumulative Dose 2.1g) 21.1 G, Unk 10.9 G, Unk (Cumulative Dose 2.1g)		Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Folic Acid			S	Transplacental			Not Reported
	Iron			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Aspirin			S	Transplacental			Not Reported
	Low Molecular Weight Heparin			S	Transplacental			Not Reported
	Low Molecular Weight Heparin			S				Not Reported
	Low Molecular Weight Heparin			S				Not Reported

	Low Molecular Weight Heparin			S						Not Reported
	Belimumab			S	Transplacental					Not Reported
	Belimumab			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476659	EXPEDITED (15-DAY)		HO, LT	CA-ORION CORPORATION ORION PHARMA-TREX2014-0261			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jaundice; Pain; Pancytopenia; Platelet Transfusion; Product Complaint; Sepsis; Tongue Coated	Methotrexate			S	Oral	Strength: 2.5 Mg		Not Reported
	Pro-Hydroxyquine-200			S	Oral	Strength: 200		Not Reported
	Alendronate			C	Unknown			Not Reported
	Apo-Cal			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16476771	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477272	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pneumonia	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478301	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019268586		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oral Pain; Oropharyngeal Pain; Stomatitis	Methotrexate Sodium			S	Subcutaneous	200 Mg, 1 Every 2 Week (S)		Unknown
	Cimzia			S	Subcutaneous	200 Mg, 1 Every 2 Week (S)		Not Reported
	Plaquenil Sulfate			S	Oral	200 Mg, 2x/Day		Not Reported
	Benzylhydrochlorothiazide			C		Unk		Not Reported
	Coumadin			C		Unk		Not Reported
	Eltroxin			C		Unk		Not Reported

Metoprolol	C	Unk	Not Reported
Pravachol	C	Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478419	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015579			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Indomethacin			S	Unknown	50 Mg, Tid		Not Reported
	Indomethacin			S				Not Reported
	Celecoxib			S	Unknown	200 Mg, Qd		Apotex
	Zopiclone			S	Unknown	7.5 Mg, At Bed Time		Not Reported
	Sertraline			S	Unknown	25 Mg, Hs (At Bed Time)		Apotex
	Temazepam			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Toradol			S	Intramuscular	10 Mg, Unk		Apotex
	Toradol			S	Intramuscular	10 Unk, Unk		Apotex
	Methotrexate			S	Oral	10 Mg, U (Twice A Day On Every Friday)		Not Reported
	Prednisone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen /00256202/			C	Unknown	500 Mg, Bid		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Mg, Unk		Not Reported
	Lidocaine			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	50000 Iu, Q.Wk.		Not Reported
	Celecoxib			S	Unknown	200 Mg, Qd		Apotex
	Zopiclone			S	Unknown	7.5 Mg, Unk		Not Reported
	Temazepam			S	Unknown			Not Reported

	Leflunomide			S	Unknown	20 Mg, Unk				Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478988	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1057743			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Empyema	Methotrexate			S	Unknown	22.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Mylan
	Leflunomide			S	Unknown	10 Milligram		Mylan
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Mylan
	Sulfasalazine			S	Unknown	2000 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan

	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine	S	Unknown	200 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16480140	EXPEDITED (15-DAY)		OT	PHHY2016US102858			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Squamous Cell Carcinoma	Jakafi			S	Oral	15 Mg, Bid		Not Reported
	Jakafi			S	Oral	15 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis
	Procrit//Epoetin Alfa			S	Unknown	Unk		Not Reported
	Neupogen			C	Unknown			Not Reported
	Neupogen			C	Unknown			Not Reported
	Reclast			C	Unknown			Not Reported
	B Complex			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported

	Coq-10	C	Unknown		Not Reported
	Centrum	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Glucosamine	C	Unknown		Not Reported
	Potassium	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Aspirin	C	Unknown		Not Reported
	Plaquenil//Hydroxychloroquine Phosphate	C	Unknown		Not Reported
	Hydroxyurea	C	Unknown		Not Reported
	Anagrelide Hydrochloride	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16480393	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	11005341	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015088884		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Hydromorphone			C		Unk		Not Reported
	Hydromorph Contin			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	12579245	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016352305		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine	S	Endocervical	Die		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Unknown			Not Reported
	Cortisone	C	Unknown			Not Reported
	Dexamethasone	C	Unknown			Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Gabapentin	C	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	12752792	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1193		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
					Actemra	S	Intravenous (not otherwise specified)			Not Reported
					Orencia	S	Subcutaneous			Not Reported
					Cyclosporin	S	Unknown			Not Reported
					Leflunomide	S	Unknown			Not Reported
					Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	12772708	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076392			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Ibuprofen			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil S			S	Oral	200 Milligram, Qd		Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	13063466	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Intolerance; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	13394743	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1604		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prevacid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	13929682	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2697		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name			S	Unknown			Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Product Use Issue; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Unknown)					
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Humira	S	Subcutaneous	3/C G2		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Tocilizumab	C	Unknown			Not Reported
	Gold	C	Unknown			Not Reported
	Lyrica	C	Unknown			Not Reported
	Trazodone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	13952736	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2725		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	14171499	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA210817		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Amnesia; Bronchitis Chronic; Delirium; Dislocation Of Vertebra; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Drug Tolerance Decreased; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Infection; Knee Arthroplasty; Neck Pain; Neck Surgery; No Adverse Event; Rheumatoid Arthritis; Spinal Column Injury; Spinal Fusion Surgery; Surgical Failure; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			C	Unknown	500 Mg,Bid		Not Reported
	Naproxen			C	Unknown	Unk Unk,Unk		Not Reported
	Mobicox			C		15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	14193099	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017493947		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	22.5 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	22.5 Milligram, Qwk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	14341375	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3574		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lipitor			S	Unknown			Not Reported

	Spiriva	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Zenhale	S	Unknown	200 Ug		Not Reported
	Tiotropium Bromide Monohydrate	S	Unknown	5 Mg, Qd (2.5 Mg *2)		Not Reported
	Tiotropium Bromide Monohydrate	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15219907	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2240		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15220977	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016241833		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Enbrel		S	Subcutaneous	50 Mg, Weekly	Pfizer
	Methotrexate Sodium		S	Unknown	20 Mg, Qwk	Pfizer
	Methotrexate Sodium		S	Unknown	20 Milligram, Q2wk	Pfizer
	Sulfasalazine		S	Unknown	Unk	Pfizer
	Apo-Hydroxyquine		S	Unknown	300 Mg, Qd	Not Reported
	Simponi		S	Subcutaneous	50 Mg, Monthly	Not Reported
	Hydroxychloroquine		S	Unknown	300 Mg, 1x/Day	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15626914	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018469609		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin Hcl			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		1500 Mg, 2x/Day		Pfizer
	Azathioprine			S		Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Mycophenolate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15819408	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP005236		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea;	Piperacillin & Tazobactam			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Rosuvastatin			S	Unknown	Unk		Apotex
	Vancomycin			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	500 Mg, Unk,2x/Day		Not Reported
	Lasix /00032601/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk,2x/Day		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk,2x/Day		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Apo Amlo			C	Unknown			Not Reported
	Apo-K			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Epoetin Alfa			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported

Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Hydroxychloroquine	C	Unknown			Not Reported
	Insulin Lispro	C	Unknown			Not Reported
	Januvia	C	Unknown			Not Reported
	Kcl	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Methylprednisolone	C	Unknown			Not Reported
	Metoprolol	C	Unknown			Not Reported
	Pantoloc /01263201/	C	Unknown			Not Reported
	Pantoprazole	C				Not Reported
	Risedronate	C	Unknown			Not Reported
	Slow-K	C	Unknown			Not Reported
	Tylenol /00020001/	C	Unknown			Not Reported
	Ventolin /00139501/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15861331	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0180		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Influenza Like Illness	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Calcium Folinate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg Vial		Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Folic Acid	S	Unknown		Not Reported
	Vitamin D2	C	Oral	2000 Daily; Strength: 1000 Unit	Not Reported
	Vitamin B12	C	Unknown	Sub Daily; Strength: 1000 Ug	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Fentanyl	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Metformin And Sitagliptin	C	Unknown		Not Reported
	Perindopril Erbumine	C	Unknown		Not Reported
	Rabeprazole	C	Unknown		Not Reported
	Ranitidine	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Sitagliptin	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15929651	NON-EXPEDITED			US-SA-2019SA033733			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

			Enbrel		S	Unknown	Unk		Not Reported
			Humira		S	Unknown	Unk		Not Reported
			Actemra		S	Unknown	Unk		Not Reported
			Xeljanz		C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15983660	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0499			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo Ibuprofen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	15984024	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA018839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Actemra	S	Unknown	640 Mg, Weekly	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Azathioprine	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Tocilizumab	S	Unknown	640 Mg, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16038858	EXPEDITED (15-DAY)		OT	PHEH2019US009668			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulphate Sandoz			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16075592	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022716			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Ivax
	Ciclosporin	S	Unknown	Ivax
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported

	Orencia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16167665	EXPEDITED (15-DAY)		OT	IT-ACCORD-119229		80 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Hypotension; Medication Error	Hydrochlorothiazide			S	Oral	1 Df, Unk (Total)		Not Reported
	Lisinopril			S	Oral	1 Df, Unk (Total)		Accord
	Diltiazem			S	Oral	1 Df, Unk (Total)		Not Reported
	Hydroxychloroquine			S	Oral	1 Df, Unk (Total)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16368578	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2019095710		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysphonia; Infection Reactivation; Sensation Of Foreign Body; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Glaxosmithkline

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16463584	EXPEDITED (15-DAY)		OT	CA-SA-2019SA160742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Erythema; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Leflunomide		S	Unknown	Unk Unk, Unk		Sanofi
	Amlodipine		S	Unknown	Unk Unk, Unk		Not Reported
	Naproxen		S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate		S				Not Reported
	Sulfasalazine		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Oral	300 Mg, Qd		Sanofi
	Brenzys		S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16473611	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016594878		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Xeljanz			S	Oral	5.0 Miligram, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Haemophilus Influenzae Vaccine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Prevnar 13			C		Unk		Not Reported
	Tetanus Vaccine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16481428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2833864-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16481523	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15932			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16481538	NON-EXPEDITED			US-IPCA LABORATORIES LIMITED-IPC-2018-US-002124			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate 200mg Tablets, Usp			S	Unknown	200 Mg, Bid		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16481632	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2019-15901		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported

	Prednisone			C	Unknown	Unknown			Not Reported
	Xeljanz			C	Unknown	Unknown			Not Reported
	Ciclosporin			C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16481918	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome; Product Use In Unapproved Indication	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Teva Mycophenolate (Mycophenolate Mofetil)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16481936	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Indocid	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Naproxen	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482465	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026210		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482504	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019026192		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Methotrexate			C	Subcutaneous	7.5 Milligram, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482505	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019026209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Ucb
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16482927	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-UTRE2015-0494		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Nasopharyngitis; Rash; Rheumatoid Arthritis; Vertigo	Methotrexate (Manufacturer Unknown)			S	Oral			Not Reported
	Methotrexate (Manufacturer Unknown)			S	Oral			Not Reported
	Methotrexate (Manufacturer Unknown)			S	Intra-arterial			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Norvasc			C	Oral			Not Reported
	Avelox			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16483752	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1059382		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Epstein-Barr	Hydroxychloroquine			S	Unknown			Not Reported

Virus Infection
Reactivation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16484232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2345303		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16485193	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2090615-00		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Minocycline	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Stelera	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Rheumatrex	C		Not Reported
	Orencia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2019	16487956	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1059484		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Pruritic; Urticaria	Econazole			S	Vaginal	Unk		Not Reported
	Plaquenil Sulfate			S	Oral	400 Milligram, Qd		Mylan
	Pevaryl /00418501/			S	Vaginal	Unk		Mylan
	Voltarene Lp			S	Oral	75 Milligram, Qd		Mylan
	Esomeprazole Biogaran			S	Oral	20 Milligram, Qd		Mylan
	Levothyrox			C		Unk		Mylan
	Methylprednisolone Dakota			C		Unk		Mylan

	Dicloridrato De Levocetirizina	C	Unk	Mylan
	Symbicort	C	Unk,Turbuhaler	Mylan
	Ventoline /00139501/	C	Unk	Mylan
	Prozac	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	12674918	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0935		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	13822440	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016140935		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Feeling Abnormal; Groin Pain; Joint Swelling; Osteoporosis; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Risedronate			C		35 Mg, Qwk		Not Reported
	Risedronate			C				Not Reported
	Methacin			C		50 Mg, As Necessary		Not Reported
	Indometacin			C	Unknown	50 Milligram (As Required)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	14223798	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017152004		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Fatigue; Hypersensitivity; Malaise; Nasal Congestion; Neuralgia; Pain In Extremity; Productive Cough; Rheumatoid Arthritis; Vision Blurred; Visual Impairment	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			C	Oral	5 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown	Unk Unk, Qd		Not Reported
	Mtx			C	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			C	Oral	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	14334322	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017485679		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Product Use Issue; Pulmonary Mass; Restrictive Pulmonary Disease	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Lipitor			S	Unknown	40 Mg, Qd		Pfizer
	Spiriva			S	Unknown	2.5 Mg, Bid		Not Reported
	Tiotropium Bromide Monohydrate			S	Unknown	5 Mg, Qd (2.5 Mg *2)		Not Reported
	Tiotropium Bromide Monohydrate			S	Unknown	2.5 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Leflunomide	S	Oral	Unk		Not Reported
	Plaquenil	S	Oral	300 Mg, Qd		Not Reported
	Zenhale	S	Unknown	200 Microgram, Bid		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	14634127	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0729		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			C	Oral			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Risedronate			C	Oral			Not Reported
	Risedronate			C	Unknown			Not Reported

	Bupropion				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	15624538	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556577-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Urethral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	15709363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2583915-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Enteric Coated		Not Reported
	Topicort			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	15788090	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0212		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Unknown	Twice A Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

	Arava	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16051907	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA058832		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Nnk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16402082	EXPEDITED (15-DAY)		OT	PHHY2019IT126063			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Complement Factor C3 Decreased; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Thrombocytopenia Neonatal; Total	Hydroxychloroquine			S	Transplacental	Mother Dose 300 Mg, Qd		Novartis
	Acetylsalicylic Acid			S	Transplacental	Mother Dose 100 Mg, Qd Low-Dose		Not Reported
	Folic Acid			S	Transplacental			Not Reported
	Low Molecular Weight Heparin			S	Transplacental	Mother Dose 100 Iu/Kg,		Not Reported

Complement Activity Decreased					Bid	
	Eculizumab		S	Transplacental	Mother Dose 600 Mg, Unk	Not Reported
	Antithrombin Iii		S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16477234	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016178578		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prevnar 13			C	Intradermal			Not Reported
	Tetanus Vaccine			C	Unknown			Not Reported
	Haemophilus Influenza			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16489099	EXPEDITED (15-DAY)		OT	CA-ROCHE-2345299		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown	Solution For Injection		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown	Sustained-Release	Not Reported
	Loperamide	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Pantoprazole Sodium	C	Unknown		Not Reported
	Restasis	C	Unknown	Emulsion For Injection/Infusion	Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown		Not Reported
	Vagifem	C	Unknown	Vaginal Tablet	Not Reported
	Oxyneo	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown		Not Reported

Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16489776	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2772		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Haemophilus Influenzae Vaccine			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Tetanus Vaccine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16490546	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1971		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Intolerance; Interstitial Lung Disease; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	0.65 Ml Weekly (Injectable) (Reduced To 0.65 Ml Since Start On Xeljanz		Not Reported

Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Celebrex	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Kineret	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Cellcept	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported

	Apo Mycophenolate		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Anakinra		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16490964	EXPEDITED (15-DAY)		OT	IT-TAKEDA-2019TEU007452		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysphonia; Visceral Leishmaniasis	Lansoprazole			S	Unknown	Unk		Takeda
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16491299	EXPEDITED (15-DAY)		OT	NL-TEVA-2019-NL-1069731		77 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Oedema Peripheral	Hydroxychloroquine			S		200mg, 1x/D		Teva
	Foliumzuur			C		10mg, 1x/W		Not Reported
	Methotrexaat			C		25mg, 1x/W		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16492143	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15891		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation;	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported

Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Subcutaneous	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Azathioprine	C	Unknown	Unknown	Not Reported
	Ciclosporin	C	Unknown	Unknown	Not Reported
	Minocycline	C	Unknown	Unknown	Not Reported
	Penicillamine	C	Unknown	Unknown	Not Reported
	Prednisolone	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Tocilizumab	C	Unknown	Unknown	Not Reported
	Tocilizumab	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16493425	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026227		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Cimzia	S		Unk		Not Reported
	Apo-Leflunomide	S		20 Milligram		Not Reported
	Enbrel	S				Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
	Otezla	S		Unk		Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16493836	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026266			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Otezla			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16495049	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1059708		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure Acute; Cardiomyopathy; Cardiotoxicity; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion	Hydroxychloroquine	S	Unknown	5.4 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16496470	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170629		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Infection; Eye Inflammation; Rheumatoid Arthritis; Vulvovaginal Mycotic Infection	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S				Sanofi
	Enbrel			S				Not Reported
	Bupropion			C				Not Reported
	Diltiazem			C				Not Reported
	Irbesartan			C				Not Reported
	Levothyroxine			C				Not Reported
	Omeprazole			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16496987	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170640		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Haemoglobin Decreased;	Arava			S	Oral	10 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Gold			S		Unk		Not Reported

Mean Cell Volume Decreased; Rash; Red Cell Distribution Width Increased; Swelling Face

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497352	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Cimzia			S				Not Reported
	Arava			S				Not Reported
	Cosentyx			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497609	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170698			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Doxycycline			S	Unknown	50 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

	Abatacept			S	Unknown	Unk			Not Reported
	Enbrel			S	Unknown	Unk			Not Reported
	Methotrexate			C					Not Reported
	Prednisone			C					Not Reported
	Simponi			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497610	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170694		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497611	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170716		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Inflammation; Rheumatoid Arthritis; Vulvovaginal Mycotic Infection	Arava			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Bupropion			C		Unk Unk, Unk		Not Reported
	Diltiazem			C		Unk Unk, Unk		Not Reported
	Irbesartan			C		Unk Unk, Unk		Not Reported
	Levothyroxine			C		Unk Unk, Unk		Not Reported
	Omeprazole			C				Not Reported
	Trazodone			C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497622	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170695		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Cough; Drug Ineffective; Hypoaesthesia; Intraocular Pressure Test Abnormal; Malnutrition; Migraine; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Platelet Count Decreased; Vision Blurred; Visual Impairment; Weight Increased	Leflunomide			S	Unknown	20 Mg, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16497879	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026229		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Breast Feeding; Off Label Use; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	400 Milligram		Ucb
	Cimzia			S		200 Milligram, Weekly (Qw)		Ucb
	Cimzia			S	Subcutaneous	200 Mg		Ucb
	Enbrel			S		Unk Unk, Weekly (Qw)		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Subcutaneous	20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2019	16498110	NON-EXPEDITED			PHEH2019US027386			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2019	14311739	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017188879		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Unknown	15 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Milligram, Qd		Not Reported
	Lansoprazole			C	Unknown	30 Milligram, Unk		Not Reported
	Atorvastatin			C	Unknown	20 Milligram, Qd		Not Reported
	Gabapentin			C	Unknown	100 Milligram, Qd		Not Reported
	Symbicort			C		Unk, Turbuhaler, Powder		Not Reported
	Plaquenil			C		Unk		Not Reported
	Plaquenil			C		200 Mg, Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2019	15556413	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016071038		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate Sodium	S	Unknown	25 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Mirtazapine	S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2019	16498506	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-036755			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis; Renal Disorder	Ramipril			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Not Reported
	Thalidomide			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	375 Milligram/Sq. Meter (Four Injections)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2019	16498812	EXPEDITED (15-DAY)		OT	CA-ROCHE-2345298		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Failure	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Potassium Chloride		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2019	16498814	EXPEDITED (15-DAY)		OT	CA-ROCHE-2345302		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jun-2019	16498981	NON-EXPEDITED			US-TEVA-2019-US-1064290		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Flushing; Malaise; Reaction To Excipient; Urticaria	Hydroxychloroquine			S	Unknown	Obtained From Local Pharmacy, Which Contained The Excipient Microcrystalline Cellulose		Teva

							Obtained F...			
	Hydroxychloroquine			S						Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	11580709	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1471671-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Cutaneous Lupus Erythematosus; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Skin Wound; Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Oral	Enteric Coated		Not Reported
	Apo-Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported

Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure	Apo Prednison	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Topicort Mild (Hydrocortisone Acetate)	S	Oral	Not Reported
	Topicort Mild (Hydrocortisone Acetate)	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Stelara	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Zyrtec-D	S	Unknown	Not Reported
	Cortisone	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Atasol (Acetaminophen)	C		Not Reported
	Salazopyrine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	11848521	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015135019		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Gastrointestinal Disorder; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Prednisone			C		5 Milligram		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	11997367	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016010536		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated	Enbrel			S	Unknown	Unk		Amgen

Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	15 Milligram, Qwk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk Unk, Qd	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	125 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	15 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	1 Dosage Form	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	12459300	EXPEDITED (15-DAY)		DS, OT	CA-AMGEN-CANSP2016072276		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury;	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	20 Milligram, Qd		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk		Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
	Celebrex	C	Oral	200 Milligram, Qd		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	12562777	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015105993		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cortisone			C	Oral	5 Milligram		Not Reported
	Desoximetasone			C	Oral	5 Milligram		Not Reported

Desoximetasone	C	Oral	5 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	12596989	EXPEDITED (15-DAY)		OT	US-INCYTE CORPORATION-2016IN004581			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Squamous Cell Carcinoma	Jakafi			S	Oral	15 Milligram, Bid		Incyte
	Jakafi			S	Oral	15 Milligram, Bid		Incyte
	Procrit			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Neupogen			C	Unknown			Not Reported
	Reclast			C	Unknown			Not Reported
	B Complex /00322001/			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Coq-10			C	Unknown			Not Reported
	Centrum /02217401/			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Glucosamine			C	Unknown			Not Reported
	Potassium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Hydroxyurea			C	Unknown			Not Reported
	Anagrelide Hydrochloride			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	13286950	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017029027		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chills; Drug Ineffective; Dyspnoea; Mobility Decreased; Movement Disorder; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Sensitivity To Weather Change; Swelling Face	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C		7.5 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	14115615	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017158505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	14169113	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebrovascular Accident; Drug Ineffective; Memory Impairment; Musculoskeletal Pain; Myocardial Infarction; Peripheral Swelling	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	14625232	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018032035		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Leflunomide			C		Unk		Not Reported

			Hydroxychloroquine		C	Unknown	400 Milligram		Not Reported
			Hydroxychloroquine		C	Unknown	Unk		Not Reported
			Amoxicillin		C		Unk		Not Reported
			Amoxicillin Trihydrate;Clavulanate Potassium		C		Unk		Not Reported
			Amoxil [Amoxicillin]		C		Unk		Not Reported
			Bcg		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15209523	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018100948		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15230305	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2276		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Intolerance; Infection; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15589814	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018154303		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Unknown	50 Milligram		Amgen
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide		S	Unknown	5 Milligram	Not Reported
	Apo-Leflunomide		S	Oral	10 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	5 Milligram	Not Reported
	Prednisone		C		Unk, Qwk, (Endocervical Route),	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15596315	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1051		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Procytox			S	Intravenous (not otherwise specified)	2000mg/Vial		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15658692	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2018167793		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Laboratory Test Abnormal; Nasopharyngitis; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15727248	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017094500		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15791137	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019001808		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase	Vancomycin Hcl			S	Unknown	Unk		Pfizer
	Piperacillin/Tazobactam			S	Unknown	Unk		Unknown

Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid	Ceftazidime	S	Unknown	Unk	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	500 Mg, 2x/Day	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	500 Mg, 2x/Day	Not Reported
	Lasix [Furosemide]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2x/Day	Not Reported
	Prednisone	S	Unknown	10 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	7.5 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk	Not Reported
	Actonel	C		Unk	Not Reported
	Apo Amlo	C		Unk	Not Reported
	Apo-K	C		Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Epoetin Alfa	C		Unk	Not Reported
	Escitalopram	C	Unknown	10 Mg, Unk	Not Reported
	Hydrochlorothiazide	C		Unk	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported
	Insulin Lispro	C		Unk, 3x/Day	Not Reported
	Januvia	C		Unk	Not Reported
	Kcl	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported

Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Metoprolol	C		Unk		Not Reported
	Pantoloc [Pantoprazole]	C		40 Mg, 1x/Day		Not Reported
	Pantoprazole	C		Unk		Not Reported
	Risedronate	C		35 Mg, Weekly		Not Reported
	Slow-K	C		Unk		Not Reported
	Tylenol [Paracetamol]	C		Unk		Not Reported
	Ventolin [Salbutamol Sulfate]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15897388	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-002607		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus	Diclofenac Sodium Ophthalmic Solution 0.1%			S	Unknown			Bausch And Lomb
	Cortisone Acetate			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Erythematosus; Wound	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Duration: 365 (Unspecified)	Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	Duration: 365 (Unspecified)	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo Folic	S	Unknown		Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Apo Prednison	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	15899170	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-002614		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Topicort Mild (Desoximetasone)			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Antibody Positive; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/ Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Duration: 365	Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported

Sulfasalazine	S	Oral	Duration: 365		Not Reported
Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16048874	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatitis; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Tiw (For 18 Months)		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Qow		Sanofi
	Actemra			S	Subcutaneous	162 Mg		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Orencia			S				Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16050129	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058750		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

					Orencia		S	Unknown	Unk Unk, Unk	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
					Mobicox		C	Unknown	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16051260	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058843		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Surgical Failure	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S				Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Mobicox			C		15 Mg, Qd		Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16465680	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016243310		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel Mini With Autotouch			S	Subcutaneous	25 Milligram, Q2wk		Pfizer
	Enbrel Mini With Autotouch			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel Mini With Autotouch			S	Unknown	1 Milliliter, Qwk		Pfizer
	Celebrex			S	Unknown	200 Milligram, Unk		Pfizer

Celebrex	S		Unk	Pfizer
Methotrexate Sodium	S	Unknown	1 Milliliter, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	1 Ml, Qwk (1 Every 1 Week (S))	Pfizer
Methotrexate Sodium	S	Oral	1 Milligram, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	7.5 Milligram, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	5 Milligram, Q2wk	Pfizer
Methotrexate Sodium	S	Unknown	7.5 Milligram, Q2wk	Pfizer
Methotrexate Sodium	S	Unknown	10 Milligram, Q2wk	Pfizer
Methotrexate Sodium	S	Unknown	25 Milligram, Q2wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	1 Ml, Weekly	Unknown
Celecoxib	S	Unknown	Unk	Pfizer
Celecoxib	S			Pfizer
Sulfasalazine	S	Oral	500 Milligram, Unk	Pfizer
Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	50 Milligram, Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Kineret	S	Unknown	100 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	7.0 Mg, Qd	Not Reported
Prednisone	S	Oral	5 Milligram, Tid	Not Reported
Prednisone	S	Unknown	15 Milligram, Qd	Not Reported
Prednisone	S	Oral	5 Milligram, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Qd	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	15 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram, Unk	Not Reported
Anakinra	S	Unknown	100 Milligram	Not Reported
Anakinra	S	Unknown	100 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo Celecoxib	S	Unknown	Unk	Not Reported
Apo Celecoxib	S		Unk	Not Reported
Cimzia	S	Unknown	Solution Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo	Not Reported
Orencia	S	Unknown	12.5 Milligram, Unk	Not Reported
Orencia	S	Unknown	12.5 Milligram, Q2wk	Not Reported
Orencia	S	Unknown	12.5 Milligram, Qwk	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported

Altace	C	Unknown	5 Milligram, Unk	Not Reported
Altace	C	Unknown	10 Milligram, Unk	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram, Unk	Not Reported
Apo-Gabapentin	C	Unknown	300 Milligram, Unk	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Q2wk	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Qd	Not Reported
Cipralex [Escitalopram]	C		20 Milligram, Unk	Not Reported
Citalopram Hydrobromide	C		20 Milligram, Unk	Not Reported
Conjugated Estrogens	C		20 Milligram, Unk	Not Reported
Conjugated Estrogens	C		0.625 Milligram, Unk	Not Reported
Cymbalta	C	Unknown	120 Milligram, Qd	Not Reported
Cymbalta	C		30 Milligram, Qid	Not Reported
Cymbalta	C		60 Milligram, Unk	Not Reported
Escitalopram	C	Unknown	10 Milligram, Unk	Not Reported
Estrace	C		0.5 Milligram, Unk	Not Reported
Gabapentin	C	Unknown	3000 Milligram, Unk	Not Reported
Gabapentin	C	Oral	100 Milligram, Unk	Not Reported
Hydrochlorothiazide	C		12.5 Milligram, Unk	Not Reported
Hydromorphone Hydrochloride	C	Oral	3.0 Milligram, Bid	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Milligram, Bid	Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	20 Milligram, Qd	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram	Not Reported
Taro-Mupirocin	C	Topical	Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16477928	EXPEDITED (15-DAY)		OT	IT-ACCORD-135024		61 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Intramuscular	Strength: 15 Mg / 2 Ml, Solution For Injection. Solution For Injection In Pre-Filled Syringe		Accord
	Plaquenil			S	Oral			Not Reported
	Salazopyrin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499094	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001612		51 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vein Occlusion	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Cellcept			C				Not Reported
	Prednisolone			C				Not Reported
	Warfarin			C				Not Reported
	Magmitt			C				Not Reported
	Sodium Rabeprazole			C				Not Reported
	Sodium Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499095	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

Intolerance; Hepatitis Acute; Lymphoma	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499096	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001614		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiotoxicity; Dyspnoea	Hydroxychloroquine			S	Unknown	5.4 Mg/Kg Without Periodic Monitoring		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499442	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170815		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499718	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported

	Methotrexate			S	Oral	20 Mg, Qw			Not Reported
	Actemra			S		Unk Unk, Unk			Not Reported
	Tylenol [Paracetamol]			C		Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499727	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170715		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Musculoskeletal Pain; Pancytopenia	Leflunomide			S		Unk Unk, Unk		Sanofi
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Sanofi
	Metoprolol			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499729	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170655		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Prednisone			S		5 Mg		Not Reported
	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499839	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Finger Deformity; Malaise; Pain; Pulmonary Fibrosis	Leflunomide	S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd		Sanofi
	Sulfasalazine	C	Oral	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499840	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA170776		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Gallbladder Disorder; Groin Pain; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	Q25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Lorazepam			S	Unknown	1 Mg, Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Celebrex			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Citalopram			C	Unknown	10 Mg, Qd		Not Reported
	Pantoprazole			C		40 Mg, Bid		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499843	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170756		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide		S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate		S	Oral	Unk	Sanofi
	Methotrexate		S	Oral	12.5 Mg, Qw	Not Reported
	Sulfasalazine		S	Rectal	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Gold		S	Intramuscular	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499850	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170781		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bladder Prolapse; Cardiac Disorder; Localised Infection	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499891	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170789		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, 11 Years		Not Reported
	Gold			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, 5 Months		Not Reported
	Hydrochlorothiazide;Lisinopril			C	Unknown	Unk Unk, Unk		Not Reported

	Hydrochlorothiazide;Lisinopril Dihydrate		C	Unknown	Unk Unk, Unk			Not Reported
	Prednisone		C	Unknown	5 Mg, Qd			Not Reported
	Rituxan		C	Unknown	Unk Unk, Unk			Not Reported
	Tylenol Extra Strength		C	Unknown	Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499893	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA170792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S		15 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Infliximab			S		5 Mg/Kg, Q8w		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499901	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170800		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Arava			S	Unknown	20 Mg, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16499902	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170806			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1000 G, Bid		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16500276	EXPEDITED (15-DAY)		OT	JP-ASTELLAS-2019JP013098		38 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Off Label Use	Tacrolimus			S	Oral	Unk Unk, Unknown Freq.		Astellas
	Predonine /00016201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Predonine /00016201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Predonine /00016201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Predonine /00016201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Predonine /00016201/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16502659	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE149909		55 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Drug Intolerance; Dyspnoea; Interstitial Lung Disease; Lung Disorder; Product Use In Unapproved Indication	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Novartis
	Mycophenolate Mofetil			S				Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16505825	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170787		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral	20 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	40 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4w		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jul-2019	16509689	EXPEDITED (15-DAY)		HO	PHHY2019ES145959		8 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Infection	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qd		Novartis
	Metilprednisolona			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Dolquine			S	Oral	100 Mg, Qd		Not Reported
	Amlodipino			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	13875527	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	14241809	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021765		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Celecoxib			S	Oral	Unk		Apotex
	Fentanyl			S	Unknown	Unk		Apotex
	Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q.3w		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk, Every 4 Week		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Celebrex			S	Occlusive dressing technique	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	1 Df, Unk		Not Reported
	Actonel			C	Unknown	36 Mg, Q.Wk.		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	2.5 Mg, Qd		Not Reported
	Ergocalciferol			C	Unknown	400 Iu, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	40 Mg, Bid		Not Reported
	Esomeprazole			C	Unknown	400 Mg, Bid		Not Reported

Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every Four Weeks	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06852001/	C	Unknown	1200 Mg, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hcl	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hcl	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported

	Vitamin D /00107901/			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	14777509	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1150		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	14797823	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1232		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis Noninfective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Nexium	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	L-Thyroxine	C	Unknown		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	15301936	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-04			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise;	Mobicox			S	Unknown			Boehringer Ingelheim
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Dosage Form: Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Dosage Form: Solution Subcutaneous		Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	15308652	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-04		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness;	Mobicox			S	Unknown			Boehringer Ingelheim
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: -59.0		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Depo-Medrol			C	Other	Form: Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Pantoprazole Magnesium	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	15599232	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018458049		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Unknown	5 Mg, Unk		Pfizer
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	5 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	5 Mg, Unk		Not Reported
	Prednisone	C	Unknown	50 Mg, 1x/Day		Not Reported
	Prednisone	C		Qwk, (Endocervical Route)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	15605754	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3228		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	15664904	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016045701		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Qd		Pfizer
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk Unk, 1x/Day		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	1 Df, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	15677810	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017081107		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Ineffective; Dyspnoea; Mobility Decreased; Movement Disorder; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Sensitivity To Weather Change; Swelling Face	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16476393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594509-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16509060	EXPEDITED (15-DAY)		HO	ES-ACCORD-136106		8 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Skin Infection	Methotrexate			S	Subcutaneous			Accord
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)		
	Dolquine	S	Oral	200 Mg Coated Tablets, 30 Tablets		Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16509108	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16509143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346126		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Methotrexate	C	Subcutaneous		Not Reported
Methotrexate	C	Oral		Not Reported
Naproxen	C	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Lyrica	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16509963	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-212465		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Epstein-Barr Virus Infection Reactivation	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16512825	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	1 Df, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Sulfasalazine			C	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16513519	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1069155		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown			Teva
	Bisoprolol			S	Unknown			Teva
	Erythromycin			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Methotrexate Sodium			S	Oral			Barr
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex 200mg			S	Oral	200 Milligram Daily;		Not Reported
	Demerol			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Humira (Adalimumab)			S				Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride Injection Usp			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16514476	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071552			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16514616	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2838916-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jul-2019	16518431	NON-EXPEDITED			US-PFIZER INC-2019279979			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S				Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	11837544	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015337333		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid)		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

						otherwise specified)				
		Desoximetasone			S	Unknown	Unk			Not Reported
		Desoximetasone			S	Oral	5 Mg, Unk			Not Reported
		Cortisone			C	Oral	5 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	11853118	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015449329		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Ineffective; Fear Of Injection; Gastrointestinal Disorder; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Sarcoidosis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly(Qwk)		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Cyclic (Every 2 Weeks)		Not Reported
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Leflunomide			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	13134947	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016288728		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Oral	1 G, Bid		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, Bid		Pfizer
	Arava			S	Oral	20 Mg, Qd (Daily)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Celebrex			C	Oral	200 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	14635310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018104248		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg, Bid		Pfizer
	Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, Unk		Not Reported
	Apo-Azathioprine	S	Unknown	100 Mg, Unk		Not Reported
	Hydroxychloroquine	C	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine	C	Unknown	400 Mg, Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Amoxil	C		Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]	C		Unk		Not Reported
	Amoxicillin	C		Unk		Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium	C		Unk		Not Reported
	Bcg	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	15981282	EXPEDITED (15-DAY)		HO, OT	PHHY2019IT033283		33 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Haemorrhage; Labelled Drug-Drug Interaction Medication Error; Maternal Exposure During Pregnancy; Premature Delivery; Product Administration Error; Product Use In Unapproved Indication; Proteinuria; Renal Impairment; Thrombocytopenia	Acetylsalicylic Acid			S	Unknown	100 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	300 Mg, Qd		Novartis
	Folic Acid			S	Unknown			Not Reported
	Low Molecular Weight Heparin			S	Unknown	100 Iu/Kg, Qd		Not Reported
	Antithrombin Iii			S	Intravenous drip	1.7 Iu/Kg, Qh		Not Reported
	Eculizumab			S	Intravenous drip	600 Mg, Unk		Not Reported
	Eculizumab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16048330	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebrovascular Accident; Drug Ineffective; Memory Impairment; Musculoskeletal Pain; Myocardial Infarction; Peripheral Swelling	Arava			S		Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Enbrel			S		Unk Unk, Unk		Not Reported
	Gold			S		Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16067915	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1023043			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrocalcinosis; Cutaneous Vasculitis; Deep Vein Thrombosis Postoperative; Fall; Femur Fracture; Leukopenia; Rheumatoid Arthritis; Rib Fracture	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram		Mylan

	Erelzi		S	Unknown	50 Milligram			Mylan
	Leflunomide		S	Unknown	10 Milligram			Mylan
	Leflunomide		S	Unknown	10 Milligram			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16124861	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018490576		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Laboratory Test Abnormal; Nasopharyngitis; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16296936	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK081498		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal	Salbutamol Sulphate			S		100 Ug, Prn		Glaxosmithkline
	Incruse Ellipta			S		62.5 Ug, Unk		Glaxosmithkline
	Ivermectin			S		Unk		Glaxosmithkline
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Prednisone			S	Oral	50 Mg, Unk		Not Reported
	Zenhale			S		2 Df, Bid		Not Reported
	Pantoloc			S		40 Mg, Unk		Not Reported
	Omnaris			S		50 Ug, Unk		Not Reported
	Alvesco			S		200 Ug, Qd		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			C		Unk		Not Reported

Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Sulfasalazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16522552	NON-EXPEDITED			US-PFIZER INC-2019276771			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Sulfasalazine			S		Unk		Pfizer
	Plaquenil Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira Ac			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16522648	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Enbrel			S	Unknown	1000 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16523490	EXPEDITED (15-DAY)		OT	PL-ROCHE-2346668		58 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methylprednisolone			C	Unknown	Up To 32 Mg		Not Reported
	Venlafaxine			C	Unknown	Dose: 75 Mg/D		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16523529	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346763		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]				
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16524310	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177675			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Naproxen			S				Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk,		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Vioxx			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16524371	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177768			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16524403	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2019-038311			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Losartan Hydrochlorothiazide Film-Coated Tablets 50m			S	Unknown	Unk		Aurobindo
	Dobupal			S	Unknown	Unk, 1/24		Not Reported
	Eutirox			S	Unknown	Unk, 1/24		Not Reported
	Dolquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16524505	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-019034		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Wellbutrin			S	Unknown	Extended Release		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

					Methotrexate		S	Unknown			Not Reported
					Methotrexate		S	Unknown			Not Reported
					Orencia		S	Unknown			Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)			Not Reported
					Sulfasalazine		C	Unknown			Not Reported
					Xeljanz		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16526286	EXPEDITED (15-DAY)		OT	CA-SA-2019SA176749			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Malaise; Nausea; Retinal Toxicity; Vomiting	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			C	Oral	10 Mg, Qw		Not Reported
	Methotrexate			C		25 Unk		Not Reported
	Azathioprine			C	Oral	100 Mg, Qd, 6 Months		Not Reported
	Prednisone			C		5 Mg, Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16526423	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1061216		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure; Hypercalcaemia; Lymphoproliferative Disorder; Off Label Use; Pancytopenia	Methotrexate			S	Unknown	Initial Dose Not Stated; Three Months Prior To Presentation, Dose Increased To 15 Mg Weekly		Not Reported
	Methotrexate			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Mycophenolate Mofetil	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16526554	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017193445		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Milligram (1-2 Tablet Four Time Per Day)		Not Reported
	Rituxan			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16526832	EXPEDITED (15-DAY)		OT	PHHY2019CA150865		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Erelzi			S	Unknown	Unk		Novartis
	Tocilizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	300 Mg, Unk		Not Reported

	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16527563	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-019032		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Wellbutrin			S	Unknown	Extended Release		Not Reported
	Erythromycin			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16527807	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis;	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported
	Levofloxacin			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported

Treatment Failure	Benadryl	S	Unknown			Not Reported
	Celebrex	S	Oral			Not Reported
	Cimzia Single-Use Prefilled	S	Unknown			Not Reported
	Demerol	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Imuran	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Procytox	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Ezetrol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16527853	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk Unk, Unk		Sanofi
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jul-2019	16529665	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2841284-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	9747187	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2013086453		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Myfortic			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Qd		Not Reported
	Mycophenolate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Oral	40 Milligram, Qd		Not Reported
	Prednisone			C	Oral	3 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	14016062	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017402680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Unknown
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day (Od)		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	14167697	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006269		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Amnesia; Bronchitis Chronic; Delirium; Dislocation Of Vertebra; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Drug Tolerance Decreased; Drug Tolerance Decreased; Hip Arthroplasty; Hip Arthroplasty; Infection; Infection; Knee Arthroplasty; Neck Pain; Neck Surgery; No Adverse	Hydroxychloroquine Tablet			S	Oral			Concordia
	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Event; Rheumatoid Arthritis; Spinal Column Injury; Spinal Fusion Surgery; Surgical Failure; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide		S	Unknown		Not Reported
	Naprosyn		C			Not Reported
	Sulfasalazine		C			Not Reported
	Mobicox		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	14172667	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebrovascular Accident; Drug Ineffective; Memory Impairment; Musculoskeletal Pain; Myocardial Infarction; Peripheral Swelling	Plaquenil Tablet			S	Oral			Concordia
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	14415480	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000266		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	15241376	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002769		51 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Bredinin			C				Not Reported
	Loxoprofen			C				Not Reported
	Aspara Potassium			C				Not Reported
	Pravastatin Na			C				Not Reported
	Urso			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Rozerem			C				Not Reported
	Amitiza			C				Not Reported

	Bonalon	C	Not Reported
	Nexium	C	Not Reported
	Micardis	C	Not Reported
	Lunesta	C	Not Reported
	Furosemide	C	Not Reported
	Flunitrazepam	C	Not Reported
	Quetiapine	C	Not Reported
	Etizolam	C	Not Reported
	Alfacalcidol	C	Not Reported
	Nifedipine	C	Not Reported
	Nauzelin	C	Not Reported
	Calonal	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	15600591	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-973801			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib			S	Unknown	200 Milligram Daily;		Teva
	Citalopram			S	Unknown	20 Milligram Daily;		Actavis
	Indomethacin			S	Unknown	150 Milligram Daily;		Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Temazepam			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Toradol			S	Intramuscular			Not Reported
	Toradol			S				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lidocaine			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Naproxen/00256202/			C		1000 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

	Vitamin D /00107901/			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	15679506	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2018-CA-981583			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	15680443	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-981578			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	15683672	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0651		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Ineffective; Dyspnoea; Mobility Decreased; Movement Disorder; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Sensitivity To Weather Change; Swelling Face	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	15888416	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1006025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Levofloxacin			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Benadryl			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Imuran	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Pms-Azithromycin	S	Unknown	250 Milligram Daily;		Not Reported
	Procytox 2000mg/Vial	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Azithromycin	S	Unknown	250 Milligram Daily;		Not Reported
	Procytox	S	Unknown			Not Reported
	Ezetrol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16527387	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2019-018796		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Heart Transplant; Nephrotic Syndrome; Renal Transplant	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16529912	NON-EXPEDITED		OT	US-TEVA-2019-US-1070470		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute;	Hydroxychloroquine			S	Unknown	5.4 Mg/Kg		Teva

Cardiomyopathy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16529913	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1070450		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Epstein-Barr Virus Infection Reactivation	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16530325	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-212718		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Acute; Cardiotoxicity; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16530361	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177463			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Oral			Not Reported
	Citalopram Hydrobromide	C		40 Ug		Not Reported
	Prednisone	C		10 Ug		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16530894	EXPEDITED (15-DAY)		HO, OT	PHHY2019FR148948		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Nephrotic Syndrome	Prednisolone			S	Unknown	10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	5000 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	2 Mg/Kg, Qd		Not Reported
	Ramipril			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16531562	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1071523			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)		
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral	1000 Milligram Daily;	Not Reported
	Hydromorphone		C	Unknown		Not Reported
	Prednisone		C	Unknown	2 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16533668	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-018951		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Cutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown	Form: Not Specified		Bausch And Lomb
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown	Form: Not Specified	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jul-2019	16534036	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201904-001265		42 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema Multiforme; Pyrexia	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Daiphen			C				Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	15237821	EXPEDITED (15-DAY)		CA, DE	DE-ROCHE-2162345			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rituximab			S	Transplacental			Not Reported
	Dalteparin Sodium			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torem [Torasemide]			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 100		Not Reported

			Mg, Frequency: Once Daily From	
Acetylsalicylic Acid	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily100 Mg	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental		Not Reported
Clexane	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 200 Mg, Frequency: Once Daily From	Not Reported
Ramipril	S	Transplacental	From Gestational Week 0-113+6	Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental		Not Reported
Delix (Ramipril)	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 20 Mg, Frequency: Once Daily	Not Reported
Prednisolon [Prednisolone]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 10 Mg, Frequency: Every 2 Days From	Not Reported
Advagraf	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 6 Mg,	Not Reported

			Frequency: Once Daily	
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Simvastatin	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S			Not Reported
Salbutamol	S	Transplacental	Frequency: Daily From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Heparin Lmw	S	Transplacental		Not Reported
Enoxaparin	S	Transplacental	From Gestational Week 0-14	Not Reported
Rasilez	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 17/Jan/2012 Dose: 300 Mg, Frequency: Once Daily	Not Reported
Pantozol [Pantoprazole Sodium Sesquihydrate]	S	Transplacental	From Gestational Week 0-14	Not Reported
Quensyl	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 400 Mg, Frequency: Once Daily	Not Reported
Pantozol [Pantoprazole Sodium Sesquihydrate]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 40 Mg, Frequency: Once Daily	Not Reported

Cytotec	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012		Not Reported
Mifegyne	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012		Not Reported
Cyclophosphamide	C	Transplacental	3000 Mg Cumulative Start Date, Cessation Date: /Aug/2011		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	15681249	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1540		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	15697669	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-17P-028-1856583-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16468683	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019266229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Etanercept			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

	Cimzia			S	Subcutaneous	Unk	Not Reported
	Humira			S	Subcutaneous	Unk	Not Reported
	Orencia			S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi			S	Subcutaneous	Unk	Not Reported
	Tocilizumab			S		160 Mg, Unk	Not Reported
	Azathioprine			C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16531205	EXPEDITED (15-DAY)		OT	PHHY2019CA149819		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyarthritis	Prednisone			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16534071	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1071610		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme	Levofloxacin			S	Unknown			Teva
	Methotrexate			S	Oral			Barr
	Metronidazole			S	Unknown			Actavis
	Apo Sulfasalazine Tab 500 Mg			S	Unknown			Not Reported

Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Apo-Bisoprolol		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Apo-Norflox - 400mg		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Arthrotec		S	Unknown		Not Reported
	Ceclor		S	Unknown		Not Reported
	Celebrex		S	Oral	200 Milligram Daily;	Not Reported
	Demerol		S	Unknown		Not Reported
	Erythromycin		S	Unknown		Not Reported
	Humira (Adalimumab)		S	Subcutaneous		Not Reported
	Lyrica		S	Unknown		Not Reported
	Meperidine		S	Unknown		Not Reported
	Plaquenil		S	Oral	400 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16534414	EXPEDITED (15-DAY)		OT	CA-ROCHE-2348277		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16535053	NON-EXPEDITED			PHEH2019US028005			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16535214	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2225		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel Mini With Autotouch			S	Subcutaneous			Not Reported
	Enbrel Mini With Autotouch			S	Subcutaneous			Not Reported
	Enbrel Mini With Autotouch			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported

Celebrex	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S		Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Kineret	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

Apo-Hydroxyquine	S	Unknown	Not Reported
Apo Celecoxib	S	Unknown	Not Reported
Apo Celecoxib	S		Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Apo-Gabapentin	C	Unknown	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
Cipralex	C	Unknown	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Escitalopram	C	Unknown	Not Reported
Estrace	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Mupirocin	C	Unknown	Not Reported

		Pantoloc			C	Unknown				Not Reported
		Shark Liver Oil			C	Unknown				Not Reported
		Tapentadol Hydrochloride			C	Unknown				Not Reported
		Taro-Mupirocin			C	Unknown				Not Reported
		Tramacet			C	Unknown				Not Reported
		Tramadol Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16535824	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2019-018791		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Prednisolone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jul-2019	16536002	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071528			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib			S	Unknown	200 Milligram Daily;		Teva
	Citalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Indometacin			S	Unknown	150 Milligram Daily;		Actavis
	Indometacin			S				Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Temazepam			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Toradol			S	Intramuscular			Not Reported

Virus Infection
Reactivation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2019	16536658	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1071545			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown			Ivax
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2019	16536659	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1071534		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Pancreatitis;	Celecoxib			S	Unknown			Teva
	Ciclosporin			S	Unknown			Ivax
	Lorazepam			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported

Photosensitivity Reaction; Rheumatoid Arthritis; Sleep Disorder	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Citalopram	C	Unknown			Not Reported
	Gold	C	Unknown			Not Reported
	Morphine	C	Unknown			Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	13058435	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015741		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Leflunomide			S	Unknown			Apotex
	Azathioprine			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

	Methyl Salicylate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	13141381	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0492		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	13762278	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1218		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis; Sarcoidosis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Plaquenil		S	Oral		Not Reported
	Cimzia		S	Subcutaneous	Cyclic	Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Arava		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Morphine Sulfate		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	14495953	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Off Label Use; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported

	Xeljanz			C	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	14599594	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP007040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1.5 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	14634521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020000			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

	Leflunomide			C	Unknown	Unk				Not Reported
	Sulfasalazine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	15643371	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978321		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Oral			Barr
	Rosuvastatin Calcium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16198890	EXPEDITED (15-DAY)		HO	PHHO2018US009028		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Not Reported
	Gsk2118436			S	Oral	150 Mg, Bid		Not Reported
	Gsk2118436			S	Oral	150 Mg, Bid		Not Reported
	Gsk1120212			S	Oral	2 Mg, Qd		Not Reported
	Gsk1120212			S	Oral	2 Mg, Qd		Not Reported

	Zonisamide	S	Oral	100 Mg, Bid		Not Reported
	Atorvastatin	C	Oral	80 Mg, Qd		Not Reported
	Levothyroxine	C	Oral	125 Ug, Qd		Not Reported
	Solumedrol	C	Unknown	Pulse Dose X 5 Days		Not Reported
	Olanzapine	C	Oral	10 Mg, Qd		Not Reported
	Lacosamide	C	Oral	250 Mg, Bid		Not Reported
	Lamictal	C	Oral	300 Mg, Bid		Not Reported
	Clobazam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16529224	EXPEDITED (15-DAY)		OT	PHHY2019FR148941		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16532066	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2844164-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
		Plaquenil			S	Unknown				Not Reported
		Actemra			C					Not Reported
		Arava			C					Not Reported
		Xeljanz			C					Not Reported
		Hydroxychloroquine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16532494	EXPEDITED (15-DAY)		OT	PHHY2019FR148944		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Induced Labour; Maternal Exposure During Pregnancy; Proteinuria	Prednisolone			S	Unknown	10 Mg		Novartis
	Azathioprine			S	Unknown	2 Mg/Kg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16537619	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2844253-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change	Humira			S	Subcutaneous	365 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	365 Days		Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16537906	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA177580		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, 2 Every 1 Day		Sanofi
	Methotrexate			S	Subcutaneous	0.8 Ml, Qw		Not Reported
	Leflunomide			S	Unknown	Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk, Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, 2 Every 1 Day		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, 2 Every 1 Day		Not Reported
	Actemra			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16538298	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 1 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported

	Meloxicam			C	Unknown					Not Reported
	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16538432	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063572		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16538804	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201907307		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercalcaemia;	Methotrexate (Manufacturer			S	Unknown	For The Past 7 Years, And		Fresenius Medical

Lymphoproliferative Disorder; Pancytopenia	Unknown)				The Dose Increased To 15mg Weekly Three Months Ago,	Care
	Methotrexate (Manufacturer Unknown)		S			Fresenius Medical Care
	Mycophenolate Mofetil		S			Not Reported
	Mycophenolate Mofetil		S			Not Reported
	Hydroxychloroquine		S			Not Reported
	Hydroxychloroquine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16538963	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071519		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Celecoxib			S	Unknown			Teva
	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown	1 Ml 1 Every 1 Weeks		Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16539411	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-018959			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Bausch And Lomb
	Cortisone Acetate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16541685	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR120783		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression	Benlysta Powder For Infusion			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	100 Mg, Qd		Glaxosmithkline
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16541944	EXPEDITED (15-DAY)		HO, LT, OT	US-MEDAC PHARMA, INC.-2070483		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia; West Nile Viral Infection	Methotrexate			S				Medac
	Hydroxychloroquine Sulfate			S				Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S				Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Sulfamethoxazole And Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2019	16541952	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2019-018797		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Induced Labour; Maternal Exposure During Pregnancy; Proteinuria	Prednisolone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	12356343	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015288052		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug	Enbrel			S	Unknown	25 Milligram, Unk		Pfizer

Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk	Pfizer
	Ibuprofen	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Plaquenil	S	Oral	200 Mg, Qd	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S		Unk	Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Folic Acid	S		5 Milligram, Unk	Not Reported
	Apo-Ibuprofen	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	12888352	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013302		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown			Apotex
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Bid		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold	S	Intramuscular	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Etanercept	S	Unknown	25 Mg, Bid		Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	14599596	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	400 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	15568779	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1419		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Finger Deformity; No Adverse Event; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported

	Bisoprolol	C	Unknown	Not Reported
	Digoxin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Nifedipine	C	Unknown	Not Reported
	Palafer	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Toloxin	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Xarelto	C	Unknown	Not Reported
	Zinc Citrate	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16345012	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2793410-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Sleep Disorder	Humira			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Enbrel		S	Unknown		Not Reported
	Celecoxib		S	Unknown		Not Reported
	Dilaudid		S	Unknown		Not Reported
	Lorazepam		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Pantoloc		C			Not Reported
	Gold		C	Unknown		Not Reported
	Citalopram		C	Unknown		Not Reported
	Morphine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16431043	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819807-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16533444	NON-EXPEDITED			US-PFIZER INC-2019288394			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

	Humira			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16535793	NON-EXPEDITED			PHEH2019US028219			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Duloxetine Hcl			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16542551	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2845331-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16542560	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001622		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus Inadequate Control; Ear Infection; Ear Infection; Glycosylated Haemoglobin	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous	Strength: 40mg/0.8ml		Not Reported

Increased; Retinal Injury

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16542564	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001630		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Epstein-Barr Virus Infection Reactivation; Face Oedema; Leukocytosis; Oedema Peripheral; Pyrexia; Rash; Rash; Rash; Rash Pruritic; Rebound Effect; Transaminases Increased	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Oral	Unknown (Tapered To Oral Methylprednisolone)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16543048	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011280		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16543085	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022600		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug	Azathioprine			S	Unknown	100 Mg, Qd		Apotex

Ineffective; Rheumatoid Arthritis	Hydroxychloroquine		S	Unknown	400 Mg, Unknown	Apotex
	Meloxicam		S	Unknown	15 Mg, Unknown	Apotex
	Meloxicam		S	Unknown	Unk	Apotex
	Methotrexate		S	Unknown	25 Mg, Unknown	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Qd	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Atorvastatin		C	Unknown	20 Mg, Qd	Not Reported
	Gabapentin		C	Unknown	100 Mg, Qd	Not Reported
	Lansoprazole		C	Unknown	30 Mg, Unk	Not Reported
	Symbicort Tu		C	Unknown	Unk	Not Reported
	Plaquenil /00072602/		C	Unknown	Unk	Not Reported
	Plaquenil /00072602/		C	Endocervical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16543306	EXPEDITED (15-DAY)		OT	US-FDC LIMITED-2070513		43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Psychosis; Drug Interaction; Toxicity To Various Agents	Ciprofloxacin			S	Unknown			Fdc
	Hydroxychloroquine			S	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16543318	EXPEDITED (15-DAY)		HO, OT	JP-IPCA LABORATORIES LIMITED-IPC-2019-JP-000806			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pustular Psoriasis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Ipca

	Prednisolone	C	Unknown	13 Mg, Qd		Not Reported
	Prednisolone	C	Unknown	58 Mg, Qd		Not Reported
	Tacrolimus	C	Unknown	3 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16543685	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-123277		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Nausea; Rash; Therapeutic Product Effect Decreased	Avelox			S				Bayer
	Cipro			S		Unk		Bayer
	Arava			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Cephalexin Monohydrate			S		Unk		Not Reported
	Clindamycin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Gold			C		Unk		Not Reported
	Hydralazine Hydrochloride			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported
	Iron Sucrose			C		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Losartan			S		Unk		Not Reported
	Methotrexate			S		10 Mg		Not Reported
	Metoprolol Tartrate			S		Unk		Not Reported
	Pantoprazole Magnesium			S		Unk		Not Reported

Pariet	S	Unk	Not Reported
Penicillin Nos	S	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Prednisone	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16544291	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS COMPANY GMBH-2019AGH0004		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Epstein-Barr Virus Infection	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal
	Hydroxychloroquine Sulfate			S				Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16545146	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1073069		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D Deficiency	Amlodipine Besilate			S	Oral			Teva
	Methotrexate			S	Subcutaneous			Barr
	Asacol			S	Oral	2400 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported

			Depo-Medrol			C	Unknown			Not Reported
			Ferrous Gluconate			C	Unknown			Not Reported
			Folic Acid			C	Unknown			Not Reported
			Tylenol/00020001/			C	Unknown			Not Reported
			Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16548478	EXPEDITED (15-DAY)		OT	US-ANIPHARMA-2019-US-010567		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Anastrozole			S				Ani
	Hydroxychloroquine			S		400 Mg Daily		Not Reported
	Docetaxel			S				Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2019	16548561	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1073722		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Ramipril			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	S	Unknown	7 Milligram Daily;		Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	C				Not Reported
	Caffeine	C				Not Reported
	Plaquenil	C	Unknown			Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	13915916	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2017128281		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Oral	37.5 Milligram, Qd		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Folic Acid			C		12.5 Milligram, Qd		Not Reported
	Hydrodiuril			C	Unknown	12.5 Milligram, Qd		Not Reported
	M-Eslon			C		10 Milligram, Bid		Not Reported
	Morphine			C		Unk		Not Reported
	Statex			C		5 Milligram		Not Reported
	Morphine Sulfate			C		5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	15699225	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580788-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	15805073	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617549-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Pms Azithromycin			S	Unknown			Not Reported
	Procytox			S	Unknown	2000mg/Vial		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Benadryl	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Demerol	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Ezetrol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16050125	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058841		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown	20 Mg, Unk		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16550309	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2847062-00		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16550820	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-137781		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Tachycardia; West Nile Viral Infection	Methotrexate			S				Accord
	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported
	Prednisone			S		Part Of A Regimen That Involved Tapering Of The Dose		Not Reported
	Methylprednisolone			S				Not Reported
	Rituximab			S				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16550848	EXPEDITED (15-DAY)		HO, LT, OT	US-ORION CORPORATION ORION PHARMA-19_00006511		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Tachycardia; West Nile	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Viral Infection	Prednisone		S	Unknown	Part Of A Regimen That Involved Tapering Of The Dose	Not Reported
	Methylprednisolone		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Mycophenolate Mofetil		S	Unknown		Not Reported
	Sulfamethoxazole, Trimethoprim		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16551419	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2847468-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Disorder; Nervous System Disorder; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gadolinium			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Escitalopram Oxalate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16551611	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2846987-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective;	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Drug Intolerance; Interstitial Lung Disease; Therapeutic Product Effect Decreased	Procytox	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Ezetrol	C			Not Reported
	Methotrexate	C			Not Reported
	Celebrex	C			Not Reported
	Azithromycin	C			Not Reported
	Arava	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16551724	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1073000			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Asacol			S	Oral	2400 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Atacand Plus			C	Unknown			Not Reported

	Bisoprolol Fumarate		C	Unknown		Not Reported
	Ferrous Gluconate		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Omega Allergenic Extracts		C	Unknown		Not Reported
	Tylenol		C			Not Reported
	Vitamin D3		C	Unknown		Not Reported
	Amlodipine Besilate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16552620	NON-EXPEDITED			US-PFIZER INC-2019290381			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Naproxen			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16555236	EXPEDITED (15-DAY)		OT	PHHY2019KR150211		50 YR	Male	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Escherichia Infection; Pyrexia; Splenic Abscess; Splenic Cyst	Methotrexate			S	Unknown	Unk		Novartis
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2019	16748946	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Impairment	Plaquenil		Y	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	14878384	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2346040-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	15953101	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014247			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	15975313	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016164			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Eye Disorder; Gastrointestinal Disorder; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	15985272	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017162			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16016694	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-020387			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

White Blood Cell Count Decreased	Plaquenil /00072603/			S	Unknown	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported
	Xeljanz Xr			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16016786	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-020376			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hypersensitivity; Influenza Like Illness; Sinusitis	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16016800	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-020380			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16218663	EXPEDITED (15-DAY)		HO, OT	JP-JNJFOC-20190431065		31 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy; Infection; Infectious Pleural Effusion; Off Label Use; Product Use In Unapproved Indication; Systemic Lupus Erythematosus	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Tacrolimus Monohydrate	S	Unknown	Not Reported
	Predonine	S	Oral	Not Reported
	Predonine	S	Oral	Not Reported
	Predonine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prograf	S	Oral	Not Reported
	Novorapid	C	Subcutaneous	Not Reported
	Takepron	C	Oral	Not Reported
	Magnesium Oxide	C	Oral	Not Reported
	Alfarol	C	Oral	Not Reported
	Bufferin	C	Oral	Not Reported
	Xyzal	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16346937	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027470			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Venlafaxine			S	Oral	37.5 Milligram, Daily		Aurobindo
	Venlafaxine			S	Unknown	Unk		Aurobindo
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Folic Acid			C	Unknown	12.5 Milligram, Daily		Not Reported

Meslon	C	Unknown	10.0 Milligram, Two Times A Day		Not Reported
Morphine	C	Unknown	Unk		Not Reported
Morphine Sulphate	C	Unknown	5.0 Milligram		Not Reported
Statex	C	Unknown	5 Milligram, Unk		Not Reported
Hydrodiuril	C	Unknown	12.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16492309	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001620			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Hydroxychloroquine			S	Oral			Concordia
	Leflunomide			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Brenzys			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16556618	EXPEDITED (15-DAY)		OT	US-UNITED THERAPEUTICS-UNT-2019-011499		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoperitoneum; Pulmonary Artery Aneurysm; Thrombosis; Vascular Pseudoaneurysm	Remodulin Sq			S	Subcutaneous	Unk, Continuing		United Therapeutics
	Tadalafil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16556945	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001647			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557072	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-CELLTRION INC.-2018DE021971			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rituximab (Unknown)			S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional		Not Reported
	Dalteparin Sodium			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Delix [Ramipril]			S	Transplacental	20 Mg, Qd		Not Reported
	Tacrolimus			S	Transplacental	6 Mg		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd, From Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Not Reported
	Metamizole Sodium			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported

Prednisolone	S	Transplacental	10 Mg, Qod	Not Reported
Enoxaparin	S	Transplacental		Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Advagraf	S	Transplacental	6 Mg, Qd	Not Reported
Advagraf	S	Unknown	Unk	Not Reported
Advagraf	S			Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	Unk	Not Reported
Ramipril	S	Transplacental	20 Mg Unk From Gestational Week 0-113+6	Not Reported
Ramipril	S			Not Reported
Salbutamol Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Salbutamol Sulfate	S	Transplacental	Unk	Not Reported
Torem [Torasemide]	S	Transplacental	100 Mg, Qd	Not Reported
Torem [Torasemide]	S	Unknown	Unk	Not Reported
Clexane	S	Transplacental	200 Mg, Qd	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	100 Mg, Qd, From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	S			Not Reported
Novaminsulfon	S	Transplacental	300 Mg, Qd	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported

Torasemide	S	Transplacental	100 Mg, From Gestational Week 0-14		Not Reported
Heparin	S	Transplacental	Unk		Not Reported
Heparin Lmw	S	Transplacental	Unk		Not Reported
Cytotec	C	Transplacental	Gestation Period At Time Of Exposure: 13 Wk		Not Reported
Enoxaparin Sodium	C	Transplacental	From Gestational Week 0-14		Not Reported
Mifegyne	C	Transplacental	Gestation Period At Time Of Exposure: 13 Wk		Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported
Cyclophosphamide	C	Transplacental	300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557153	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-200825		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinal Disorder; Chorioretinopathy; Exposure During Pregnancy; Retinal Pigment Epitheliopathy; Subretinal Fluid	Hydroxychloroquine			S	Unknown	200 Milligram, Daily (400 Mg/Sunday)		Sun
	Prednisone			S	Unknown	15 Milligram, Daily		Mutual
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557176	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001653		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tendon Rupture	Hydroxychloroquine			S	Unknown			Concordia

	Enbrel			S	Unknown					Not Reported
	Hydroxychloroquine			C						Not Reported
	Chloroquine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557633	EXPEDITED (15-DAY)		DE	PHHY2019AU158402		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Ataxia; Dysarthria; Holmes Tremor; Jc Virus Granule Cell Neuronopathy; Nystagmus; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Prednisolone			S	Unknown	12 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16557955	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-038620			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Disorder; Weight Decreased	Venlafaxine			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Every Week		Not Reported
	Naproxen			S	Unknown	500 Milligram, Two Times A Day		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558307	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1073743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand	Dorzolamide Hydrochloride W/Timolol Maleate			S	Unknown			Actavis

Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Dorzolamide Hydrochloride W/Timolol Maleate		S	Unknown	2 Dosage Forms Daily;	Actavis
	Methotrexate		S	Unknown		Barr
	Prednisone		S	Unknown		Actavis
	Ramipril		S	Oral		Actavis
	Ramipril		S	Oral		Actavis
	Actemra		S	Unknown		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Levothyroxine		S	Unknown		Not Reported
	Levothyroxine		S	Unknown		Not Reported
	Plaquenil		S	Unknown	400 Milligram Daily;	Not Reported
	Tylenol		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558353	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038682			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Venlafaxine			S	Oral	100 Milligram, Once A Day		Aurobindo
	Enbrel			S	Subcutaneous	Unk Unk, Every Week		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown	10 Milligram, Once A Day		Not Reported
	Ultram			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558406	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038659			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use Issue; Rheumatoid Arthritis	Venlafaxine	S	Oral	37.5 Milligram, Once A Day	Aurobindo
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydrodiuril	C	Unknown	12.5 Milligram, Once A Day	Not Reported
	M-Eslon	C	Unknown	10 Milligram, Two Times A Day	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Statex	C	Unknown	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558408	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038651			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Venlafaxine			S	Oral	37.5 Milligram, Once A Day		Aurobindo
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Hydrodiuril			C	Unknown	12.5 Milligram, Once A Day		Not Reported

	M-Eslon	C	Unknown	10.0 Milligram, Two Times A Day		Not Reported
	Morphine	C	Unknown	Unk		Not Reported
	Statex	C	Unknown	5 Milligram		Not Reported
	Venlafaxine Hydrochloride	C	Oral	37.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16558425	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1073755		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Atenolol			S	Unknown	25 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral	1000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoloc			S	Unknown	40 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16559241	EXPEDITED (15-DAY)		OT	CA-ROCHE-2350759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes	Actemra			S	Unknown			Not Reported

Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Arava	C	Unknown	Not Reported
	Arava	C		Not Reported
	Ativan	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Darifenacin	C	Unknown	Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C		Not Reported
	Dilaudid	C	Unknown	Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Loperamide	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Omnaris	C		Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Pantoprazole Sodium	C		Not Reported
	Plantago Ovata	C	Unknown	Not Reported
	Plantago Ovata	C		Not Reported
	Synthroid	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Vagifem	C	Vaginal	Not Reported

	Vagifem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16559251	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1073931		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Amlodipine Besilate			S	Oral			Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Asacol			S	Unknown	2400 Milligram Daily;		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Vitamin D3			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Ebastine			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported

	Depo-Medrol	C	Intra-articular		Not Reported
	Crestor	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Atacand Plus	C			Not Reported
	Amlodipine Besilate	C			Not Reported
	Acetaminophen	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16559799	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN004927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Merck
	Actemra			S	Unknown			Not Reported
	Apo Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort (Desoximetasone)			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16559974	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1063277			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Foot Fracture	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S		15 Milligram		Not Reported
	Methotrexate			S		15 Milligram		Not Reported
	Methotrexate			S		15 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	150 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram		Mylan
	Cimzia			S	Unknown	200 Milligram, Unk		Mylan
	Roactemra			S	Unknown	600 Milligram, Unk		Mylan
	Enbrel			S	Unknown	50 Milligram		Mylan

	Humira			S	Unknown	40 Milligram				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16560686	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1063297		37 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Pregnancy; Coagulation Test Abnormal; Complement Factor C3 Decreased; Complement Factor C4 Decreased; Hyponatraemia; Maternal Exposure During Pregnancy; Postpartum Haemorrhage; Proteinuria; Thrombocytopenia	Prednisone			S	Oral	2.5 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Mylan
	Bemiparin Sodium			S	Unknown	2500 International Unit, Qd		Mylan
	Aspirin /00002701/			S	Unknown	100 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561061	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005162			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre- Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intreavenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561223	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561419	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005147			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single-Use-Pre-Filled Syringe, Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Prednisone	S	Unknown	Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561500	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-019230		5 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Morphoea; Product Use In Unapproved Indication	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S				Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16561502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351627		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16562314	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1074062		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure; Hypercalcaemia; Lymphoproliferative Disorder; Off Label Use; Pancytopenia	Methotrexate			S	Unknown	Initial Dose Not Stated; Three Months Prior To Presentation, Dose Increased To 15 Mg Weekly		Barr
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	2000 Milligram Daily;		Teva
	Mycophenolate Mofetil			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16562632	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Liver Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Diclofenac Sodium			S	Unknown			Actavis
	Pantoprazole Sodium Anhydrous			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16562773	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16563139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351570		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16563140	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2019	16563240	EXPEDITED (15-DAY)		HO	PHHY2019US154650		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Calciphylaxis; Hyperparathyroidism Secondary; Pain In Extremity; Skin Ulcer	Prednisone			S	Unknown	80 Mg, Qd		Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Azathioprine			S	Unknown	150 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported

	Apixaban				S	Unknown	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	15979303	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014059			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	15980474	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016692			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	15984746	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017744			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	15985570	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017705			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Hypersensitivity	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rasuvo			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16009921	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016141			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563402	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Oral	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563463	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005092		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednisone			S	Unknown	5.0 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe		Not Reported

Erythematosus	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	500.0 Milligram	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400.0 Milligram, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Solution, 25.0 Milligram	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 .0 Milligram, 1 Every 1 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1.0 Gram, 2 Every 1 Day	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563488	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN004899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

						Cortisone Acetate	S	Topical		Not Reported
						Enbrel	S	Subcutaneous		Not Reported
						Folic Acid	S	Unknown		Not Reported
						Humira	S	Subcutaneous		Not Reported
						Hydroxychloroquine Sulfate	S	Unknown		Not Reported
						Methotrexate	S	Unknown		Not Reported
						Orencia	S	Intravenous (not otherwise specified)		Not Reported
						Phthalylsulfathiazole	S	Unknown		Not Reported
						Prednisone	S	Intravenous (not otherwise specified)		Not Reported
						Remicade	S	Intravenous (not otherwise specified)		Not Reported
						Rituxan	S	Intravenous (not otherwise specified)		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
12-Jul-2019	16563536	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005049			Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Unknown	Unk		Merck		
	Actemra			S	Unknown	Unk		Not Reported		
	Arava			S	Unknown	Unk		Not Reported		
	Cimzia			S	Subcutaneous	Unk		Not Reported		
	Enbrel			S	Subcutaneous	Unk		Not Reported		
	Folic Acid			S	Unknown	Unk		Not Reported		
	Humira			S	Subcutaneous	Unk		Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported		
	Methotrexate			S	Unknown	Unk		Not Reported		
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported		

					Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
					Prednisone	S	Unknown	Unk	Not Reported
					Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563591	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563682	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038616			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Venlafaxine			S	Unknown	Unk		Aurobindo
	Venlafaxine			S	Oral	37.5 Milligram, Once A Day		Aurobindo
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Hydrodiuril			C	Unknown	12.5 Milligram, Once A Day		Not Reported
	M-Eslon			C	Unknown	10 Milligram, Two Times A Day		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	5 Milligram		Not Reported
	Statex			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563757	EXPEDITED (15-DAY)		HO, OT	ES-ROCHE-2348932			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Atrial Fibrillation; Cytopenia; Intentional Product Use Issue; Off Label Use; Pneumonia; Sepsis	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Rituximab			S				Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Mycophenolate Mofetil	S			Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Tacrolimus	S	Unknown		Not Reported
	Tacrolimus	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16563979	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN004987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hypersensitivity; Infusion Related Reaction; Pericarditis; Swelling; Wound	Fosamax			S	Oral	Unk		Merck
	Simponi			S	Subcutaneous	Unk		Merck
	Apo Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride (+) Phenylephrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, 40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16564118	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-17685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16564750	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN004999			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydrocortisone Acetate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16564764	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038820			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes	Rosuvastatin			S	Oral	5 Milligram, Two Times A		Aurobindo

Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure					Day				
	Rosuvastatin			S	Unknown	Unk			Aurobindo
	Actemra			S	Unknown	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported
	Enbrel			S	Subcutaneous	Unk			Not Reported
	Gold			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Methotrexate			C	Oral	Unk			Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16565485	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-17698			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

	Ciclosporin			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16565915	NON-EXPEDITED			US-PFIZER INC-2019296739		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Sumatriptan Succinate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16566289	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN004934			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Formulation: Solution Subcutaneous; 40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Prednisone		S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Formulation: Powder For Solution Intravenous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Formulation: Solution Intravenous	Not Reported
	Simponi		S	Subcutaneous	Formulation: Solution Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16566460	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Unknown			Merck
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Dosage Form: Solution Subcutaneous, Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Dosage Form: Not Specified		Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Route: Intravenous (Not Otherwise Specified)		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown	Dosage Form: Not Specified		Not Reported

					Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous, Route: Intravenous (Not Otherwise Specified)	Not Reported
					Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous, Route: Intravenous (Not Otherwise Specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16566717	EXPEDITED (15-DAY)		DE, DS, OT	AU-MYLANLABS-2019M1065083		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ataxia; Coordination Abnormal; Diplopia; Dysarthria; Holmes Tremor; Infection Reactivation; Jc Virus Granule Cell Neuronopathy; Nystagmus; Oscillopsia	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Prednisolone			S	Unknown	12 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Folic Acid			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16566752	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005080		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Dosage Form:Solution Subcutaneous, Single Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported

Erythematosus	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, 1every1day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	1.0 Gram, 2 Every 1 Day	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16566926	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074783		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Potassium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16567275	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005139		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Fosamax			S	Oral	Unk		Merck
	Prednisone			S	Unknown	Unk		Merck
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, 1 Every 1 Day(S)		Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, 2 Every 1 Day(S)		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16567807	EXPEDITED (15-DAY)		DE	CA-GLAXOSMITHKLINE-CA2019AMR122750		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Flovent			S		Unk		Glaxosmithkline
	Losec			S		20 Mg, Unk		Glaxosmithkline
	Metformin			S		500 Mg, Bid		Glaxosmithkline
	Salmeterol Xinafoate			S		Unk		Glaxosmithkline
	Alendronate Sodium			S		70 Mg, We		Not Reported
	Ipratropium Bromide + Salbutamol Sulphate			S		Unk		Not Reported
	Lasix			S		40 Mg, Unk		Not Reported
	Lipitor			S		10 Mg, Unk		Not Reported
	Nitrazadon			S		10 Mg, Unk		Not Reported
	Plaquenil			S		300 Mg, Qd		Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Tylenol			S		500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16568033	EXPEDITED (15-DAY)		HO	FR-SA-2019SA186387		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Lovenox			S	Subcutaneous	0.4 Ml, Qd		Sanofi
	Plaquenil			S	Oral	600 Mg, Qd		Sanofi
	Bisoprolol Fumarate			S	Oral	2.5 Mg, Qd		Not Reported
	Flagyl			S	Oral	1500 Mg, Qd		Sanofi
	Doxycycline			S	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jul-2019	16568561	EXPEDITED (15-DAY)		HO	PHHY2019DE157846		80 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Depressed Level Of Consciousness; General Physical Health Deterioration; Pyrexia	Prednisolon			S	Oral	5 Mg, Qd (1-0-0-0)		Novartis
	Quensyl			S	Oral	200 Mg, Qd (1-0-0-0)		Not Reported
	Mucofalk			C	Oral	3.25 G, Qd (0.5-0-0-0)		Not Reported
	Toujeo			C	Subcutaneous	Unk (Schema, Injektions-/Infusionslösung)		Not Reported
	Apidra			C	Subcutaneous	Unk		Not Reported
	Pantozol			C	Oral	40 Mg, Qd (1-0-0-0)		Not Reported
	Metronidazole			C	Oral	400 Mg, Bid (1-0-1-0)		Not Reported
	Allopurinol			C	Oral	100 Mg, Qd (100 Mg, 1-0-0-0, Tabletten)		Not Reported
	Amlodipin			C	Oral	5 Mg, Qd (5 Mg, 0-0-1-0, Tabletten)		Not Reported
	Simvastatin			C	Oral	20 Mg, Qd (20 Mg, 0-0-1-0, Tabletten)		Not Reported
	Furosemid			C	Oral	125 Mg, Bid (1-1-0-0)		Not Reported
	Lyrica			C	Oral	25 Mg, Bid (25 Mg, 1-0-1-0, Kapseln)		Not Reported
	Ass			C	Oral	100 Mg, Qd (100 Mg, 1-0-0-0, Tabletten)		Not Reported
	L-Thyroxin			C	Oral	50 Ug, Qd (50 Mg, 1-0-0-0, Tabletten)		Not Reported
	Nebivolol			C	Oral	5 Mg, Bid (5 Mg, 1-0-1-0, Tabletten)		Not Reported
	Fentanyl			C	Transdermal	25 Ug, Qd (25 ?G / Tag, Alle 3 Tage, Zuletzt Am 21.02.18, Pflaster Transdermal)		Not Reported
	Ramipril			C	Oral	2.5 Mg, Qd (2.5 Mg, 1-0-0-		Not Reported

							0, Tabletten)			
		Dekristol			C	Oral	1 Df, Qw ((20000 Ie / Woche, 1-0-0-0, Kapseln))			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2019	16569134	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074785		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	13393116	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP008815			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

						otherwise specified)				
		Prednisone			C	Unknown	2 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	13921728	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017374858		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Venlafaxine Hcl			S	Oral	37.5 Milligram, Qd		Pfizer
	Venlafaxine Hcl			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Folic Acid			C		12.5 Milligram, Qd		Not Reported
	Hydrodiuril			C	Unknown	12.5 Mg, Qd		Not Reported
	M-Eslon			C		10 Mg, Bid		Not Reported
	Morphine			C		Unk		Not Reported
	Statex			C		5 Mg, Unk		Not Reported
	Venlafaxine Hydrochloride			C	Oral	37.5 Mg, Qd		Not Reported
	Morphine Sulfate			C		5 Mg, Unk		Not Reported
	Morphine Sulfate			C		5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	14281329	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP022296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition	Celecoxib			S	Oral	200 Mg, Bid		Apotex

Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	15114781	EXPEDITED (15-DAY)		OT	ES-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-059571			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Infection; Leukopenia; Lymphopenia; Neutropenia; Off Label Use; Rheumatoid Arthritis	Abatacept			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Unknown			Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Dolquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			C	Unknown	50 Mg, Unk		Not Reported
	Paracetamol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Lornoxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16540717	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019279753			Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Distress Syndrome; Foetal Growth Restriction; Premature Baby	Methylprednisolone Sodium Succinate			S	Transplacental	60 Mg, Daily		Pfizer
	Azathioprine			S	Transplacental	100 Mg, Daily		Not Reported
	Magnesium Sulfate			S	Transplacental	Bolus Dose Of 2 G, Followed By Infusion Of 1.5 G/H		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Mg, Daily		Not Reported
	Labetalol			S	Transplacental	50-100 Mg, 3x/Day (Every 8 Hours)		Not Reported
	Vitamin D [Ergocalciferol]			C	Transplacental	Unk		Not Reported
	Folic Acid			C	Transplacental	Unk		Not Reported
	Betamethasone			C	Transplacental	Unk		Not Reported
	Iron			C	Transplacental	Unk		Not Reported
	Prednisone			C	Transplacental	5-10 Mg, Daily		Not Reported
	Prednisone			C	Transplacental	5 Mg, Daily		Not Reported
	Calcium			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16550917	EXPEDITED (15-DAY)		DE, DS, OT	AU-ORION CORPORATION ORION PHARMA-19_00006517		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Infection Reactivation; Jc Virus Granule Cell Neuronopathy; Lymphopenia; Product Use In Unapproved Indication	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16569842	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039175			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16570355	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-038677		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Breath Sounds Abnormal; Chills; Cough; Decreased Appetite; Hilar Lymphadenopathy; Hypercalcaemia; Hypovolaemia; Lung Consolidation; Lymphadenopathy Mediastinal; Lymphoproliferative Disorder; Off Label Use; Pulmonary Mass; Pyrexia; Vasoconstriction; Weight Decreased	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Mycophenolic Acid			S	Unknown			Zydus Pharm
	Mycophenolic Acid			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16570659	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-17729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Infliximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16570667	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-17738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16571237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1075023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Diclofenac			S	Unknown	100 Milligram Daily;		Actavis
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Naproxen			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Indocid			S	Unknown	150 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16572693	EXPEDITED (15-DAY)		OT	ES-PROVELL PHARMACEUTICALS-2070821		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Euthyrox			S				Provell Pharmaceuticals
	Dobupal			S				Not Reported
	Hyzaar			S				Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16574550	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351569		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16574885	EXPEDITED (15-DAY)		DS	PHHY2019FR159267		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hypertrophic Cardiomyopathy	Prednisone			S	Oral	8 Mg, Qd		Novartis
	Imurel			S	Oral	2 Mg/Kg, Qd		Not Reported
	Lyrica			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Endoxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16574925	EXPEDITED (15-DAY)		HO	PHHY2019FR157775		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Bisoprolol Fumarate			S	Oral	2.5 Mg, Qd		Not Reported
	Doxycycline			S	Oral	200 Mg, Qd		Novartis
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported

	Lovenox			S	Subcutaneous	0.4 Ml, Qd				Not Reported
	Flagyl			S	Oral	1500 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16574990	EXPEDITED (15-DAY)		HO, OT	PHHY2019TR152610		75 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lymphoma; Diffuse Large B-Cell Lymphoma; Fibrosis; Hydrocele; Lymphadenopathy; Nodule; Ocular Lymphoma; Pleural Effusion; Pyrexia; Rheumatoid Arthritis; Systemic Bacterial Infection	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16574992	EXPEDITED (15-DAY)		CA, OT	PHHY2019EG160311			Male	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Atrial Septal Defect; Cardiac Ventricular Thrombosis; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Mitral Valve Incompetence; Neonatal Lupus Erythematosus; Patent Ductus Arteriosus; Platelet Count Decreased; Rash Macular; Thrombocytopenia; Tricuspid Valve Incompetence	Hydroxychloroquine			S	Transplacental	(Maternal Dose 200 Mg Qd)		Novartis
	Levothyroxine			S	Transplacental	(Maternal Dose 100 Ug, Qd)		Not Reported
	Aspirin			S	Transplacental	(Maternal Dose 81mg Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jul-2019	16575115	EXPEDITED (15-DAY)		HO	PHHY2019DE157952		80 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pain; Pyrexia	Prednisolon			S	Oral	5 Mg, Qd		Novartis
	Quensyl			S	Oral	200 Mg, Qd		Not Reported
	Furosemid			C	Oral	125 Mg, Bid (1-1-0-0)		Not Reported
	Apidra			C	Subcutaneous	Unk		Not Reported
	Nebivolol			C	Oral	5 Mg, Bid (1-0-1-0)		Not Reported
	Mucofalk			C	Oral	0.5 Df, Qd		Not Reported
	Simvastatin			C	Oral	20 Mg, Qd (0-0-1-0)		Not Reported
	Ramipril			C	Oral	2.5 Mg, Qd		Not Reported
	L-Thyroxin			C	Oral	50 Ug, Qd		Not Reported
	Lyrica			C	Oral	25 Mg, Bid		Not Reported
	Pantozol			C	Oral	40 Mg, Qd		Not Reported
	Ass			C	Oral	100 Mg, Qd		Not Reported
	Fentanyl			C	Transdermal	25 Ug/Hr, Q72h		Not Reported
	Toujeo			C	Subcutaneous	Unk		Not Reported
	Dekristol			C	Oral	20000 Iu, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	12639830	EXPEDITED (15-DAY)		DS	FR-ROCHE-1810927		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Bactrim			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral	Dose Decreased		Not Reported
	Advagraf			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]				
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Temerit	S	Unknown		Not Reported
	Cortancyl	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	12651566	EXPEDITED (15-DAY)		DS, OT	FR-ASTELLAS-2016US031007		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral; Product Use In Unapproved Indication; Vestibular Disorder	Advagraf			S	Oral	5 Mg, Once Daily (In The Morning)		Astellas
	Cellcept /01275102/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Cellcept /01275102/			S	Oral			Not Reported
	Cellcept /01275102/			S	Oral	250 Mg, Twice Daily (Morning And Evening)		Not Reported
	Temerit			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Twice Daily (Morning And Evening)		Not Reported
	Bactrim			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Cortancyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	14238407	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021637		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Decreased Appetite; Disability; Drug	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Indomethacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	25 Mg, Qd		Apotex
	Prednisone			S	Oral	3 Mg, Qd		Apotex

Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Prednisone	S	Oral	50 Mg, Unk	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Apo-Prednisone	S	Oral	3 Mg, Qd	Apotex
	Apo-Prednisone	S	Oral	50 Mg, Qd	Apotex
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Indocid /00003801/	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	30 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cymbalta	C	Oral	30 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C	Oral	Unk, Q.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	15698621	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1526		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	15732814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2053047-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Crohn'S Disease; Drug Ineffective; Elbow Operation; Fatigue; Neck Pain; Pain In Extremity; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	15928898	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019NL025314		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Condition Aggravated; Drug Ineffective; Lupus Myocarditis; Lupus Nephritis; Myocarditis; Off Label Use; Renal Tubular Necrosis; Respiratory Failure; Systemic Lupus Erythematosus; Thrombocytopenia	Bortezomib			S	Subcutaneous	1.3 Mg/M2,Q3w, Days 1, 4, 8 And 11 (Misuse)		Not Reported
	Bortezomib			S				Not Reported
	Bortezomib			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	(1000 Mg, Bid, Maintenance Therapy) (Misuse)		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16015874	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-019149			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16533273	EXPEDITED (15-DAY)		DE, OT	AU-PFIZER INC-2019288524		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Jc Virus Granule Cell Neuronopathy	Methotrexate			S		20 Mg, Weekly		Pfizer
	Methotrexate			S				Pfizer
	Prednisolone			S		12 Mg, Daily		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16567310	EXPEDITED (15-DAY)		HO, OT	CA-009507513-1907CAN005277		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Fosamax			S	Unknown	70 Milligram, Qw		Merck
	Actemra			S	Unknown	680 Milligram, Qm		Not Reported
	Actemra			S	Unknown	360 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	25 Milligram, 2 Every 1 Week (S); Qw		Not Reported
	Etanercept			S	Unknown	50 Milligram, Qw		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qw		Not Reported

Skin Ulcer; Ulcer	Methotrexate	S	Unknown	12 Milligram, Qw	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qw	Not Reported
	Myochrysine	S	Unknown	Unk;(Formulation: Solution Intramuscular)	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16575363	EXPEDITED (15-DAY)		OT	PHHY2019PL160571		58 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Novartis
	Tocilizumab			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Venlafaxine			C	Unknown	75 Mg/Dl, Unk		Not Reported
	Methylprednisolone			C	Unknown	Upto 32 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16575633	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-459		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia; West Nile Viral Infection	Methotrexate			S	Unknown	()		Westward
	Hydroxychloroquine			S	Unknown	()		Not Reported
	Prednisone			S	Unknown	Part Of A Regimen That		Not Reported

							Involved Tapering Of The Dose			
			Methylprednisolone		S	Unknown	()			Not Reported
			Rituximab		S	Unknown	()			Not Reported
			Mycophenolate Mofetil		S	Unknown	()			Not Reported
			Sulfamethoxazole, Trimethoprim		C	Unknown	()			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16575711	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039021			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Ineffective; Enthesopathy; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Inflammation; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Tenosynovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Meloxicam			S	Unknown	75 Milligram, Once A Day		Aurobindo
	Enbrel			S	Unknown	500 Milligram, Every Week		Not Reported
	Flurbiprofen			S	Unknown	100 Milligram, Two Times A Day		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Every Week		Not Reported
	Mobicox			S	Unknown	75 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Concerta			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	200 Milligram		Not Reported

	Procaine Hydrochloride	C	Unknown	Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk		Not Reported
	Xanax	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16575741	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039069			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Dysgeusia; Fluid Retention; Lower Respiratory Tract Infection; Musculoskeletal Pain; Pain In Extremity	Meloxicam			S	Unknown	15 Milligram, Once A Day		Aurobindo
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	1 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576322	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039031			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise;	Meloxicam			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	160 Milligram, Every Week		Not Reported
	Depo-Medrol			C		80 Milligram		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Humira			C				Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576325	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039177			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bone Pain; Drug Ineffective; Fibromyalgia; Immunodeficiency; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Sacroiliitis; Somnolence; Treatment Failure	Meloxicam			S	Unknown	Unk		Aurobindo
	Amitriptyline			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	15 Milligram, Every Week		Not Reported
	Folic Acid			C	Unknown	5 Milligram		Not Reported
	Naproxen			C	Unknown	500 Milligram, Once A Day		Not Reported
	Pantoprazole			C	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576326	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039147			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Blood Creatinine Increased; Nasopharyngitis; Therapeutic Product Effect Incomplete	Meloxicam		S	Unknown	Unk	Aurobindo
	Methotrexate		S	Unknown	0.6 Milliliter, Every Week	Not Reported
	Methotrexate		S	Unknown	0.4 Milliliter	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	0.2 Milliliter	Not Reported
	Methotrexate		S	Unknown	0.6 Milliliter, Every Week	Not Reported
	Methotrexate		S	Unknown	0.6 Milliliter	Not Reported
	Methotrexate		S	Unknown	0.4 Milliliter	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Xeljanz		S	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576336	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039040			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthritis; Back Pain; Bone Pain; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Joint Swelling; Kyphoscoliosis; Laboratory Test Abnormal; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Sacroiliitis; Somnolence; Spinal Osteoarthritis; Spinal X-	Meloxicam			S	Unknown	Unk		Aurobindo
	Amitriptyline			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	500 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

Ray Abnormal; Spondyloarthropathy; Therapeutic Product Effect Incomplete	Pantoprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576588	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1077159		80 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Depressed Level Of Consciousness; General Physical Health Deterioration; Pyrexia	Prednisolon			S	Oral	5 Mg, 1-0-0-0, Tablets		Teva
	Quensyl			S	Oral	200 Mg, 1-0-0-0, Tablets		Not Reported
	Mucofalk 3,25g/Beutel			C	Oral	3.25 G, 0.5-0-0-0, Bag		Not Reported
	Toujeo 300einheiten/Ml Solostar 1,5ml Pen			C	Subcutaneous	Scheme, Solution For Injection/Infusion		Not Reported
	Apidra			C	Subcutaneous	Scheme, Solution For Injection/Infusion		Not Reported
	Pantozol			C	Oral	40 Mg, 1-0-0-0, Tablets		Not Reported
	Metronidazol			C	Oral	400 Mg, 1-0-1-0, Tablets		Not Reported
	Amlodipin			C	Oral	5 Mg, 0-0-1-0, Tablets		Not Reported
	Allopurinol			C	Oral	100 Mg, 1-0-0-0, Tablets		Not Reported
	Dekristol 20000i.E.			C	Oral	20000 Iu / Week, 1-0-0-0, Capsules		Not Reported
	Ramipril			C	Oral	2.5 Mg, 1-0-0-0, Tablets		Not Reported
	Simvastatin			C	Oral	20 Mg, 0-0-1-0, Tablets		Not Reported
	Furosemid			C	Oral	125 Mg, 1-1-0-0, Tablets		Not Reported
	Lyrica 25mg			C	Oral	25 Mg, 1-0-1-0, Capsules		Not Reported
	Ass 100			C	Oral	100 Mg, 1-0-0-0, Tablets		Not Reported
	L-Thyroxin 50			C	Oral	50 Mg, 1-0-0-0, Tablets		Not Reported
	Nebivolol			C	Oral	5 Mg, 1-0-1-0, Tablets		Not Reported
	Fentanyl			C	Transdermal	25 Ug / Day, Every 3 Days, Last On 21.02.18, Plaster Transdermal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576629	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039143			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Moxifloxacin			S	Oral	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16576795	EXPEDITED (15-DAY)		OT	FR-SA-2019SA178919			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Function Abnormal; Nausea; Off Label Use; Off Label Use; Vomiting	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Prednisone			C	Oral	1 Mg/Kg, Qd		Not Reported
	Prednisone			C		Dose Tapered And Then Stopped		Not Reported
	Prednisone			C		Gradually Increased Over Time From 2006 To 2016, From 8mg/D Of Prednisone To More Than 20 Mg/D		Not Reported
	Prednisone			C		Gradually Increased Over Time From 2006 To 2016, From 8mg/D Of Prednisone To More Than 20 Mg/D		Not Reported
	Prednisone			C		More Than 20 Mg/D		Not Reported
	Azathioprine			C		Unk		Not Reported
	Infliximab			C		Unk		Not Reported

	Adalimumab	C		Unk		Not Reported
	Hydroxyurea	C				Not Reported
	Ruxolitinib	C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16577197	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039035			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Other	80 Milligram		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16577202	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039305			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam	S	Oral	7.5 Milligram		Aurobindo
	Actemra	S	Subcutaneous	Unk Unk, 1 Every 1 Week		Not Reported
	Arava	S	Unknown	20 Milligram, Once A Day		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	20 Milligram, 1 Every 1 Week		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16577207	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-039538			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Meloxicam			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Abatacept			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16577252	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039533			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Meloxicam			S	Unknown	15 Milligram		Aurobindo
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Atorvastatin Calcium			C	Unknown	20 Milligram		Not Reported
	Budesonide;Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	100 Milligram		Not Reported

	Lansoprazole			C	Unknown	30 Milligram			Not Reported
	Plaquenil			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16580031	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1077128		80 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Pain; Pyrexia	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1-0-0-0, Tabletten		Teva
	Prednisolone			S	Oral	5 Mg, 1-0-0-0, Tabletten		Not Reported
	Furosemid			C	Oral	125 Mg, 1-1-0-0, Tabletten		Not Reported
	Apidra			C	Subcutaneous	Schema, Injektions-/Infusionslösung		Not Reported
	Nebivolol			C	Oral	5 Mg, 1-0-1-0, Tabletten		Not Reported
	Simvastatin			C	Oral	20 Mg, 0-0-1-0, Tabletten		Not Reported
	Mucofalk 3,25g/Beutel			C	Oral	3.25 G, 0.5-0-0-0, Beutel		Not Reported
	Ramipril			C	Oral	2.5 Mg, 1-0-0-0, Tabletten		Not Reported
	L-Thyroxin 50			C	Oral	50 Mg, 1-0-0-0, Tabletten		Not Reported
	Toujeo 300einheiten/Ml Solostar 1,5ml Pen			C	Subcutaneous	Schema, Injektions-/Infusionslösung		Not Reported
	Dekristol 20000i.E.			C	Oral	20000 Ie / Woche, 1-0-0-0, Kapseln		Not Reported
	Lyrica 25mg			C	Oral	25 Mg, 1-0-1-0, Kapseln		Not Reported
	Pantozol			C	Oral	40 Mg, 1-0-0-0, Tabletten		Not Reported
	Ass 100			C	Oral	100 Mg, 1-0-0-0, Tabletten		Not Reported
	Fentanyl			C	Transdermal	25 Mg/H, Alle 3 Tage, Zuletzt Am 21.02.18, Pflaster Transdermal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16580099	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1077400		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Bisoprolol (Fumarate De)			S	Oral			Teva
	Doxycycline			S	Oral			Actavis
	Flagyl			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lovenox			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2019	16581877	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	13985085	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005262		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	15620391	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556101-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Toxicity To Various Agents; Upper Limb Fracture	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Procytox		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	15961326	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-015708			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Tolerance Decreased; Oedema	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16009369	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2675291-00		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Erythroid Maturation Arrest; Nausea; Retinal Oedema	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16011957	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-019521			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Nausea	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16019029	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-020492			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Gastrointestinal Disorder; Rash; Sinusitis; Treatment Failure; Urinary Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16020907	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-021154			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16031059	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-022380			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Therapeutic Response Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Nsaids			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16031108	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059233			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Leflunomide			S		20 Mg, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd, Tablet		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk, Solution Intravenous		Not Reported
	Acetaminophen			C		2 Tablet Of 500 Mg, Qid		Not Reported
	Hydromorphone			C				Not Reported
	Hydrocortisone Valerate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Lyderm [Fluocinonide]			C				Not Reported
	Myocrisin			C	Unknown	Unk Unk, 1 Every 2 Week		Not Reported
	Naproxen			C	Unknown	250 Mg, Qd		Not Reported
	Naproxen			C		Unk Unk, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Aurothiomalate De Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16155689	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728550-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16374128	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1055738		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16494262	EXPEDITED (15-DAY)		HO, LT, OT	FR-SA-2019SA174472		39 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Altered State Of Consciousness; Cardiac Failure; Cardiogenic Shock; Depressed Level Of Consciousness; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram St Segment Depression; Electrocardiogram T Wave	Hydroxychloroquine			S	Oral	12 G, 1x		Sanofi
	Bromazepam			S	Oral	Unk Unk, 1x		Not Reported
	Paroxetine Hydrochloride			S	Oral	Unk Unk, 1x		Not Reported
	Zolpidem Tartrate			S	Oral	Unk Unk, 1x		Sanofi

Amplitude Decreased; Haemodynamic Instability; Hepatocellular Injury; Hyperlactacidaemia; Hypokalaemia; Hypotension; Loss Of Consciousness; Metabolic Acidosis; Overdose; Prothrombin Time Shortened; Supraventricular Tachycardia; Systolic Dysfunction; Ventricular Arrhythmia; Ventricular Fibrillation

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16582356	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000868			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Ipca
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16582641	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-213477		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Losartan/Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Dobupal 75 Mg Comprimidos, 60 Comprimidos			S	Unknown	1/24 ()		Not Reported
	Eutirox 100 Microgramos Comprimidos			S	Unknown	1/24 ()		Not Reported
	Dolquine 200 Mg Comprimidos			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16583431	NON-EXPEDITED			US-PFIZER INC-2019303448		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jul-2019	16586835	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019299741		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	11923404	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-16K-028-1539270-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Deafness; Decreased Appetite; Dizziness; Ear Infection; Gastrointestinal Disorder; Headache; Mobility Decreased; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight	Humira			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	12913686	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092883		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Abatacept			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Anakinra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo Warfarin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Mg (Titer)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	13520892	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1965769-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid W/Clopidogrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous				Not Reported
	Gold			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Naprosyn			S	Unknown				Not Reported
	Plaquenil			S	Oral				Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown				Not Reported
	Diclofenac Potassium			S	Unknown				Not Reported
	Motrin			S	Unknown				Not Reported
	Sodium Aurothiomalate			S	Parenteral				Not Reported
	Aspirin			S	Oral				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Tramadol Hydrochloride			S	Unknown				Not Reported
	Voltaren			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	15854346	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2633478-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia;	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting	Sodium Aurothiomalate		S	Parenteral	Bp		Not Reported
	Sodium Aurothiomalate		S	Parenteral			Not Reported
	Sulfamethoxazole And Trimethoprim		S	Unknown			Not Reported
	Vitamin C		S	Unknown			Not Reported
	Gold (198 Au)		S	Other			Not Reported
	Ibuprofen		S	Unknown			Not Reported
	Hydroxychloroquine Sulfate		S	Unknown			Not Reported
	Tramadol Hydrochloride		C	Unknown			Not Reported
	Tramadol		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	15941795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2659053-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Gold			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16040051	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-023379			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Nausea	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16046592	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059191		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			C	Subcutaneous	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16047613	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-023028			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Treatment Failure	Orencia	S	Unknown			Bristol Myers Squibb
	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Nsaids	S	Unknown			Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16048334	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16048341	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059242		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi

				otherwise specified)		
	Xeljanz	S	Oral	2 Every 1 Day		Not Reported
	Amoxil [Amoxicillin]	C		Unk Unk, Unk		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potassium	C				Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported
	Leflunomide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16098406	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2709653-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16221187	EXPEDITED (15-DAY)		OT	FR-CELLTRION INC.-2019FR020469			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Product Use In Unapproved Indication; Therapeutic Product Effect Variable	Rituximab (Unknown)	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	120 Mg, Qd		Not Reported
	Prednisone	S	Unknown	2.5 Mg, Qd		Not Reported
	Cyclosporine	S				Not Reported
	Immunoglobulin I.V	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Erythropoietin	S				Not Reported
	Tn Unspecified (Hydroxychloroquine)	S	Unknown	Unk		Not Reported
	Tn Unspecified (Ciclosporin)	S	Unknown	Unk		Not Reported
	Tn Unspecified (Erythropoietin)	S	Unknown	Unk		Not Reported
	Tn Unspecified (Intravenous Immunoglobulin)	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tn Unspecified (Blood, Whole)	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16231006	EXPEDITED (15-DAY)		OT	FR-CELLTRION INC.-2019FR020569			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Product Use In Unapproved Indication; Therapeutic Product Effect Variable	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Blood, Whole			S	Unknown	Unk		Not Reported
	Prednisone Nos			S	Unknown	50 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	1 G/3 D		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16231334	EXPEDITED (15-DAY)		OT	FR-CELLTRION INC.-2019FR020571			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Dependence; Drug Ineffective; Product Use In Unapproved Indication	Rituximab (Unknown)		S	Unknown	Unk	Not Reported
	Prednisone Nos		S	Unknown	70 Mg, Qd	Not Reported
	Prednisone Nos		S	Unknown	50 Mg, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Blood, Whole		S	Unknown	Unk	Not Reported
	Erythropoietin		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		C	Unknown	Unk	Not Reported
	Immunoglobulins (Immunoglobulin Anti Respiratory Syncytial Vir)		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16350189	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2793861-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Voltaren			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aspirin			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo Hydroxychloroquine			S	Unknown			Not Reported
	Apo Diclofenac Ophthalmic			S	Unknown			Not Reported
	Sulfametoxazol/Trimetoprim			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

		Tramadol Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16366041	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2800051-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Acetylsalicylic Acid W/Clopidogrel			S	Unknown			Not Reported
	Mortin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Apo Asa			S	Unknown			Not Reported
	Apo-Diclofenac			S	Unknown			Not Reported
	Tramadol Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16578122	EXPEDITED (15-DAY)		OT	FI-ORION CORPORATION ORION PHARMA-DIUR2019-0001		80 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Stenosis; Blood Pressure Decreased; Cerebral Infarction; Dizziness; Drug Interaction; Labelled Drug-Drug Interaction Medication Error; Pain In Extremity; Rheumatoid Arthritis	Diurex Mite			S	Oral			Not Reported
	Diurex Mite			S	Oral	On Alternating Days With Cardace		Not Reported
	Trexan			S	Oral	Strength: 2.5 Mg		Not Reported
	Primaspan			S	Oral	In The Morning, Strength: 100 Mg		Not Reported
	Oxiklorin			S	Oral	Strength: 300 Mg		Not Reported
	Cardace (Ramipril)			S	Unknown	Strength: 2.5.Mg		Not Reported
	Cardace (Ramipril)			S	Unknown	Strength: 2.5.Mg, On Alternating Days With Diurex Mite		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16588536	EXPEDITED (15-DAY)		HO	DE-AMGEN-DEUSP2019114909		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tendon Rupture	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Quensyl			S	Unknown	Unk		Not Reported
	Chloroquine			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16588662	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1078657		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaplastic Large Cell Lymphoma T- And Null-Cell Types	Azathioprine			S	Unknown	100 Milligram Daily;		Not Reported
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Hydroxychloroquine			S	Unknown	150 Milligram Daily;		Not Reported
	Rivaroxaban			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16588864	EXPEDITED (15-DAY)		OT	CH-TEVA-2019-CH-1079481		24 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Enzyme Increased	Doxycycline			S	Oral			Actavis
	Marcoumar			S	Oral	Dosage According To Inr		Not Reported
	Plaquenil			S	Oral			Not Reported
	Sintrom			S	Oral	Dose According To Inr (3-5 Mg Daily)		Not Reported
	Pantoprazol			C	Oral			Not Reported
	Clexane			C	Subcutaneous	100 Mg/1 Ml Twice Daily		Not Reported
	Eliquis			C	Oral	5 Mg 1-0-1-0 (Exact Date Unknown)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16589044	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1077482		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Cardiac Disorder; Weight Decreased	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Venlafaxine Hydrochloride			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16589604	EXPEDITED (15-DAY)		HO, OT	NL-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-213800		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Bortezomib			S	Subcutaneous	1.3 Milligram/Sq. Meter,		Novartis

Cardiac Failure; Lupus Nephritis; Off Label Use; Thrombocytopenia					Days 1, 4, 8 And 11; Every Three Weeks	
	Hydroxychloroquine	S	Unknown	Unk		Sun
	Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	S	Unknown	1000 Milligram, Bid		Not Reported
	Prednisolone	S	Unknown	Unk		Taro
	Prednisolone	S				Taro
	Methylprednisolone	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Cyclophosphamide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16591142	EXPEDITED (15-DAY)		OT	US-SWEDISH ORPHAN BIOVITRUM-2018US0519			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Kineret			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S				Not Reported
	Plaquenil			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16591731	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057930			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi

	Enbrel	S		Unk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Leflunomide	C				Not Reported
	Prednisone	C				Not Reported
	Sulfasalazine	C	Unknown	500 Mg, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jul-2019	16595274	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-041224			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Doxycycline			S	Oral	200 Milligram, Once A Day		Not Reported
	Bisoprolol			S	Oral	2.5 Milligram, Once A Day		Aurobindo
	Flagyl			S	Oral	1500 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	0.4 Milliliter, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	13035123	EXPEDITED (15-DAY)		DS, OT	FR-PFIZER INC-2016573920		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hypertrophic Cardiomyopathy	Lyrica			S	Oral	Unk		Pfizer
	Endoxan [Cyclophosphamide]			S	Intravenous (not otherwise specified)	3 Courses In Total		Not Reported
	Imurel [Azathioprine]			S	Oral	2 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	8 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	14498031	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007133		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	15856020	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000131		52 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinal Dystrophy	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Cellcept			C				Not Reported
	Arotinolol Hydrochloride			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Takecab			C				Not Reported
	Rivotril			C				Not Reported
	Bonoteo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16067781	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025261			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Administered; Drug Ineffective	Actemra			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16068052	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025300			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16071676	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025364			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16079290	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025541			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Hepatic Enzyme Increased; Injection Site Reaction	Orencia	S	Unknown	Unk		Bristol Myers Squibb
	Humira	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16359297	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001454		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhegmatogenous Retinal Detachment; Visual Acuity Reduced	Plaquenil 200 Mg Tablet			S	Oral	Daily Dose: Unknown		Concordia
	Plaquenil 200 Mg Tablet			S				Concordia
	Prednisolone			C				Not Reported
	Tacrolimus			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16388008	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-030071			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	2.68 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, 1 Every 1 Week	Not Reported
	Enbrel	S	Unknown	25 Milligram, 1 Every 2 Week	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown	25 Milligram, 1 Every 1 Week	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Week	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, 1 Every 4 Week	Not Reported
	Methotrexate	S	Unknown	15 Milligram, 1 Every 4 Week	Not Reported
	Methotrexate	S	Unknown	15.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 4 Week	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported

Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Myochrysine	S	Parenteral	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S			Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, 1 Every 1 Week	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	760 Milligram, Every Week	Not Reported
Orencia	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
	Tocilizumab	S	Unknown	380 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram, 1 Every 4 Week	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16564055	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2848757-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness;	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Risedronate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Cimziasingle	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16570958	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-019682		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Doxycycline			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Bisoprolol (Fumarate De)			S	Oral			Not Reported
	Flagyl			S	Oral			Not Reported
	Enoxaparin			S	Unknown	Pre-Filled Syringe		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16595417	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040557			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D Deficiency	Amlodipine			S	Unknown	Unk		Aurobindo
	Amlodipine			S	Oral	5 Milligram		Aurobindo
	Asacol			S	Oral	800 Milligram, 3 Times A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Omega Allergenic Extracts			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16595543	EXPEDITED (15-DAY)		DE	CA-AUROBINDO-AUR-APL-2019-040268			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Atorvastatin Tablets			S	Unknown	10 Milligram		Not Reported
	Metformin			S	Unknown	500 Milligram, Two Times		Aurobindo

				A Day	
	Omeprazole	S	Oral	20 Milligram	Aurobindo
	Flovent	S	Unknown	Unk	Not Reported
	Ipratropium Bromide;Salbutamol Sulfate	S	Unknown	Unk	Not Reported
	Lasix	S	Unknown	40 Milligram	Not Reported
	Nitrazadon	S	Unknown	10 Milligram	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	5 Milligram, Once A Day	Not Reported
	Salmeterol Xinafoate	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16595943	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040387			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Amlodipine			S	Oral	5 Milligram		Aurobindo
	Asacol			S	Oral	800 Milligram, 3 Times A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 2 Weeks		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

	Tylenol			C	Unknown	Unk				Not Reported
	Vitamin D3			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16596689	EXPEDITED (15-DAY)		HO, LT, OT	DE-ACCORD-139309		59 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Methotrexate			S				Accord
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16596719	EXPEDITED (15-DAY)		LT, OT	US-ACCORD-139083		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Toxicity To Various Agents	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Fluocinonide			C	Topical	To Apply To To Scalp Daily		Not Reported
	Folic Acid			C	Oral			Not Reported
	Triamcinolone			C	Topical	To Apply To The Affected Skin Or The Trunk Daily		Not Reported
	Hydrocortisone			C	Topical	To Apply To All Affected Areas Of The Face Daily		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16597045	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001704			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oral Herpes; Pollakiuria; Squamous Cell Carcinoma Of Skin	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Tritace			C				Not Reported
	Amlodipine			C				Not Reported
	Prednisolone			C				Not Reported
	Panadol Osteo			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16599507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351681		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported

	Leflunomide	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jul-2019	16600055	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2019302000		58 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Infliximab Hospira			S		Unk		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Tocilizumab			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported
	Venlafaxine			C		Dose: 75 Mg/D		Not Reported
	Methylprednisolone			C		Up To 32 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16600155	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068155		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported

	Ergocalciferol	C	Unknown	Unk, Qwk	Not Reported
	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Furosemide	C	Unknown	40 Milligram	Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown	1500.0 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320.0 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jul-2019	16609231	DIRECT					52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Exaggerated Startle Response; Incorrect Dose Administered; Palpitations; Panic Attack; Product Prescribing Issue	Hydroxychloriquine 200m Generic For Plaquen L			S	Oral	Quantity:2 Tablet(S);		Sandoz
	Citirizine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	14294963	EXPEDITED (15-DAY)		OT	CA-ROCHE-2040487		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

		Sulfate]								
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Gold			S	Intramuscular				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	14996566	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2018M1037863		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteriuria; Breast Cancer; Deep Vein Thrombosis; Foot Fracture; Fracture; Hypogammaglobulinaemia ; Immunoglobulins Decreased; Intervertebral Disc Protrusion; Mucosal Inflammation; Osteopenia; Radiculopathy; Rotator Cuff Syndrome; Secondary Immunodeficiency; Spinal Osteoarthritis; Stenosis; Stomatitis; Vitamin D Deficiency	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	1000 Milligram		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	Last Administration On May/2016		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1000 Milligram		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1000 Milligram		Mylan
	Mabthera			S	Intravenous (not otherwise specified)	1000 Milligram		Mylan
	Leflunomide			S	Unknown	15 Mg, Unk		Mylan
	Leflunomide			S	Unknown	Unk		Mylan
	Humira			S	Subcutaneous	40 Mg, Unk Most Recent Dose: /Jan/2015		Mylan
	Quensyl			S	Unknown	400 Milligram, Unk (Given 2017,2018)		Mylan
	Quensyl			S	Unknown	400 Milligram, Unk (Given 2017,2018)		Mylan

	Sulfasalazin	S	Unknown	2000 Dosage Form	Mylan
	Sulfasalazin	S	Unknown	3000 Dosage Form	Mylan
	Sulfasalazin	S	Unknown	2000 Dosage Form	Mylan
	Cyanocobalamin W/Folic Acid	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Unknown	400 Milligram	Mylan
	Celecoxib	C	Unknown	200 Milligram	Mylan
	Cotrimoxazole	C	Unknown	960 Milligram	Mylan
	Folinic Acid	C	Unknown	5 Milligram	Mylan
	Tapentadol	C	Unknown	50 Milligram	Mylan
	Anastrozol	C	Unknown	1 Milligram	Mylan
	Prednisolon /00016201/	C	Unknown	20 Milligram	Mylan
	Pantozol /01263204/	C	Unknown	20 Milligram	Mylan
	Colecalciferol	C	Unknown	1000 International Unit	Mylan
	Leflunomide	C		15 Milligram	Mylan
	Hydroxychloroquine	C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16092046	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026507			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Contraindicated Product Administered	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown	Unk		Unknown
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Kevzara			S	Unknown	Unk			Not Reported
	Simponi			S	Unknown				Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Leflunomide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16387082	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-031097			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	2 Milligram, Once A Day		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16387141	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029825			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine	Celecoxib Capsules			S	Oral	Unk		Aurobindo

Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Renal Impairment; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Gabapentin	S	Oral	100 Milligram, Two Times A Day	Aurobindo
	Gabapentin	S	Unknown	100 Milligram	Aurobindo
	Abatacept	S	Intravenous (not otherwise specified)	75 Milligram, Monthly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Every Month	Not Reported
	Apo Celecoxib	S	Oral	Unk	Not Reported
	Apo Gabapentin	S	Oral	100 Milligram, Two Times A Day	Not Reported
	Apo Gabapentin	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Once A Day	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S			Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, One Every Month	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Unknown	2.5 Gram, Daily	Not Reported

Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
Oxycodone;Paracetamol	C	Unknown	Unk	Not Reported
Oxycodone;Paracetamol	C	Unknown	1 Dosage Form	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Every Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram	Not Reported
Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Every Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, Daily	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Daily	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Two Times A Day	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Daily	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A	Not Reported

			Day	
Esomeprazole Magnesium Trihydrate	C	Unknown	400 International Unit, Once A Day	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Daily	Not Reported
Fish Oil	C	Unknown	1200 Milligram, Daily	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	Unk, Two Times A Day	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
Nexium	C	Unknown	4 Milligram, Two Times A Day	Not Reported
Nicotinamide	C	Unknown		Not Reported
Nortriptyline Hydrochloride	C	Unknown	10 Milligram, Cyclical	Not Reported
Nortriptyline Hydrochloride	C	Unknown	10 Milligram	Not Reported
Omega 3	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	400 Milligram, Daily	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Daily	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Daily	Not Reported

Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Cyclical	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Daily	Not Reported
Tylenol	C	Oral	1000 Milligram, Daily	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Retinol	C	Unknown	Unk	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Vitamin D	C	Unknown	400 Dosage Form, Daily	Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Milligram, Daily	Not Reported
Xeljanz	C	Unknown	5 Milligram	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16610192	EXPEDITED (15-DAY)		OT	PL-JNJFOC-20190713697		58 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Infliximab, Recombinant Solution For Infusion			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Venlafaxine			C	Unknown	Dose: 75 Mg/D			Not Reported
		Methylprednisolone			C	Unknown	Up To 32 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16610534	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1079560		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Miliaria; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Sleep Disorder; Stomatitis	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Lorazepam			S	Unknown			Actavis
	Lorazepam			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Celecoxib			S	Unknown	400 Milligram Daily;		Teva
	Dilaudid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Citalopram			C		10 Milligram Daily;		Not Reported
	Gold			C	Unknown			Not Reported
	Gold			C				Not Reported
	Morphine			C	Unknown			Not Reported
	Pantoloc			C		80 Milligram Daily;		Not Reported
	Pantoloc			C				Not Reported

Prednisone	C	10 Milligram Daily;	Not Reported		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16611329	NON-EXPEDITED			PHEH2019US029924			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jul-2019	16612114	EXPEDITED (15-DAY)		CA	PHHY2019FR164694		3 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Decreased; Blood Immunoglobulin M Decreased; Monoclonal B-Cell Lymphocytosis	Neoral			S	Transplacental	Maternal Dose: 300 Mg, Qd		Novartis
	Neoral			S	Transplacental	Maternal Dose: 300 Mg, Qd		Novartis
	Rituximab			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Plaquenil			S	Transplacental	Maternal Dose: 400 Mg, Qd		Not Reported
	Plaquenil			S	Transplacental	Maternal Dose: 400 Mg, Qd		Not Reported
	Aspirine			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported
	Aspirine			S	Transplacental	Maternal Dose: 100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	14205422	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201711-006424		45 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Nephritis	Plaquenil 200 Mg Tablet			S	Oral			Concordia

		Prednisolone			C						Not Reported
		Mycophenolate Mofetil			C						Not Reported
		Tacrolimus Monohydrate			C						Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
23-Jul-2019	14361157	EXPEDITED (15-DAY)		HO		JP-CONCORDIA PHARMACEUTICALS INC.-GSH201801-000048		35 YR	Female	JPN	
Preferred Term		**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**	
Serum Sickness		Plaquenil 200 Mg Tablet			S	Oral				Concordia	
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported	
		Prednisone			C					Not Reported	
		Tacrolimus Monohydrate			C					Not Reported	
		Edirol			C					Not Reported	
		Fluitran			C					Not Reported	
		Furosemide			C					Not Reported	
		Pralia			C					Not Reported	
		Takecab			C					Not Reported	
		Takecab			C					Not Reported	
		Predonine			C					Not Reported	
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
23-Jul-2019	15556653	EXPEDITED (15-DAY)		HO		CA-TEVA-2018-CA-965534		58 YR	Female	CAN	
Preferred Term		**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug		Alendronate Sodium			S	Unknown				Actavis	
		Codeine			S	Unknown				Not Reported	
		Leflunomide			S	Unknown				Barr	
		Methotrexate			S	Unknown				Barr	
		Methotrexate			S	Unknown				Barr	
		Methotrexate			S	Unknown				Barr	
		Methotrexate			S	Unknown				Barr	
		Methotrexate			S	Subcutaneous				Barr	

Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Alendronate	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab Gp2013	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	15948634	EXPEDITED (15-DAY)		HO, LT, OT	NL-TAKEDA-2019TUS005687		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Condition Aggravated; Drug Ineffective; Lupus Myocarditis; Lupus Nephritis; Off Label Use; Product Use In Unapproved Indication; Renal Tubular Necrosis; Respiratory Failure; Systemic Lupus Erythematosus; Thrombocytopenia	Velcade			S	Subcutaneous	1.3 Milligram/Sq. Meter, 3/Week		Takeda
	Velcade			S				Takeda
	Velcade			S				Takeda
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Milligram, Q12h		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Milligram, Q12h		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Milligram, Q12h		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16198298	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006267		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use	Fosamax			S	Unknown	Unk		Merck
	Acetazolamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported

	Iron Polymaltose	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Infliximab	S	Unknown	Unk, 1 Every 1 Month		Not Reported
	Infliximab	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16568296	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-019884		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Reactivation; Jc Virus Granule Cell Neuronopathy	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16614172	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019307256		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Injury	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16614421	EXPEDITED (15-DAY)		HO, OT	GR-ROCHE-2360041		11 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Intentional Product Use Issue; Measles; Off Label Use	Mycophenolate Mofetil	S	Unknown			Not Reported
	Belimumab	S	Unknown			Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	3 Pulses		Not Reported
	Cyclophosphamide	S	Unknown	500 Mg/M2		Not Reported
	Prednisolone	S	Unknown	0.3 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Enoxaparin	C	Unknown			Not Reported
	Salmeterol	C	Respiratory (inhalation)			Not Reported
	Fluticasone	C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16615405	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-03497			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Minocycline			S	Unknown	Unk		Alkem
	Minocycline			S				Alkem
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16615413	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-03406			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Leukopenia	Mycophenolate Mofetil	S	Unknown	Unk	Alkem
	Minocycline	S	Unknown	Unk	Alkem
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Taper Below 15 Mg/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16615469	EXPEDITED (15-DAY)		HO, LT	JP-ROCHE-2359089		25 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Computerised Tomogram Thorax Abnormal; Cytomegalovirus Test Positive	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Oral	Dose Interval Uncertainty (Twice)		Not Reported
	Prograf			S	Oral			Not Reported
	Prograf			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Losartan Potassium			S	Oral			Not Reported
	Losartan Potassium			S	Oral			Not Reported
	Itraconazole			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

		Predonine [Prednisolone]			C	Oral	The First Time Dosage: 15mg The Second Time Dosage: 10mg			Not Reported
		Amitiza			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16615845	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-042815			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Joint Swelling; Peripheral Swelling; Skin Laceration; Skin Ulcer; Treatment Failure	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Allopurinol			C	Unknown	200 Milligram, Daily		Not Reported
	Prednisone			C	Unknown	Unk (Two Times A Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16616666	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001707		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Pruritus; Squamous Cell Carcinoma	Hydroxychloroquine	S	Unknown	Concordia
	Jakafi	S	Oral	Not Reported
	Jakafi	S	Oral	Not Reported
	Procrit	S	Unknown	Not Reported
	Neupogen	C		Not Reported
	Reclast	C		Not Reported
	B Complex	C		Not Reported
	Calcium	C		Not Reported
	Coq-10	C		Not Reported
	Centrum	C		Not Reported
	Furosemide	C		Not Reported
	Glucosamine	C		Not Reported
	Potassium	C		Not Reported
	Folic Acid	C		Not Reported
	Aspirin	C		Not Reported
	Plaquenil	C		Not Reported
	Hydroxyurea	C		Not Reported
	Anagrelide Hydrochloride	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16617642	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190717399		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab, Recombinant			S				Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16618478	EXPEDITED (15-DAY)		DS	CA-SA-2019SA110385		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Loss Of Personal Independence In Daily Activities; Nausea	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Arava			S		20 Mg		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16618928	EXPEDITED (15-DAY)		HO	PHHY2019US170198		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Preterm Premature Rupture Of Membranes; Product Use In Unapproved Indication; Vaginal Haemorrhage	Prednisone			S	Unknown			Novartis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16621322	EXPEDITED (15-DAY)		CA, DE, OT	PHHY2019US170200			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Cavity Infection;	Prednisone			S	Transplacental	Unk		Novartis

Cerebral Haemorrhage Neonatal; Congenital Pneumonia; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Psittacosis	Hydroxychloroquine	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jul-2019	16622971	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1080033		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone (Mah Unknown)			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	12641253	NON-EXPEDITED			US-PFIZER INC-2016360015			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Oral Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Albumin			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	15556660	EXPEDITED (15-DAY)		HO	CA-TEVA-2018-CA-965516		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash	Alendronate Sodium			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr

Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Etanercept	S	Unknown			Not Reported
	Etanercept	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp	S	Oral			Not Reported
	Rituximab Gp2013	S	Unknown			Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	15702980	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-984827		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered;	Ciclosporin			S	Unknown			Ivax

Dermatitis; Drug Ineffective; Gallbladder Disorder; Groin Pain; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis	Lorazepam	S	Unknown			Actavis
	Methotrexate	S	Subcutaneous			Barr
	Arava	S	Unknown			Not Reported
	Celebrex	S	Unknown	400 Milligram Daily;		Not Reported
	Dilaudid	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Citalopram	C	Unknown	10 Milligram Daily;		Not Reported
	Gold	C	Unknown			Not Reported
	Pantoloc /01263201/	C	Unknown	80 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16314682	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2018M1005299		74 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Helicobacter Gastritis; Hypokalaemia; Hyponatraemia; Renal Failure; Urinary Tract Infection	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Mylan
	Rituximab			S	Unknown	1000 Mg, Unk (Last Cycle Of Rituximab Was Administered On 06/Sep/2016)		Mylan
	Dytide			C		Unk		Mylan
	Tilidin			C		Unk		Mylan
	Metoprolol			C		Unk		Mylan
	Omeprazol /00661201/			C		Unk		Mylan

Prednisolone	C	Unk	Mylan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16462587	EXPEDITED (15-DAY)		OT	CA-SA-2019SA151700			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Hypersensitivity; Drug Intolerance; Infection; Pancytopenia; Rash	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	7.5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Unknown	40 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16623924	EXPEDITED (15-DAY)		OT	GB-ABBVIE-19K-167-2863778-00			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported

	Meperidine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Levofloxacin		S	Unknown		Not Reported
	Lyrica		S	Unknown		Not Reported
	Erythro Base		S	Unknown		Not Reported
	Apo Leflunomida		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Celebrex		S	Oral	200 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16624959	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1079914		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16624974	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1080422		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Hepatotoxicity; Loss Of Consciousness; Mobility Decreased; Pain	Codeine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16625349	EXPEDITED (15-DAY)		HO	PHHY2019FR168279		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Spironolactone			S	Oral	25 Mg, Qd		Not Reported
	Doxycycline			S	Oral	200 Mg, Qd		Novartis
	Ramipril			S	Oral	5 Mg, Qd		Not Reported
	Lansoprazole			S	Oral	15 Mg, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	5 Mg, Qd		Not Reported
	Plaquenil			S	Oral	3 Df, Qd		Not Reported
	Tardyferon			S	Oral	2 Df, Qd		Not Reported
	Coumadine			S	Oral	5 Mg Et 6 Mg 1 Jour Sur 2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16625579	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2863484-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apoleflunomide			S	Oral			Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Viread			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626023	EXPEDITED (15-DAY)		OT	PHHY2019AU169102			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Chronic Spontaneous Urticaria; Osteoporosis; Rash Vesicular	Xolair			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Novartis
	Montelukast Sodium			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626366	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1080415		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug	Codeine			S	Unknown			Not Reported

Ineffective; Hepatotoxicity; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown		Barr
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626384	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP006981			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Cyclophosphamide			C	Oral	50 Mg		Not Reported
	Cyclophosphamide			C	Oral	150 Mg		Not Reported
	Prednisone			C	Unknown	75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626415	NON-EXPEDITED		DE	US-STRIDES ARCOLAB LIMITED-2018SP005618			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Progressive Multifocal Leukoencephalopathy	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Strides

	Cyclophosphamide			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626424	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2019SP002033		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Dose Tapered Off		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Mycophenolate Mofetil			S	Unknown	Dose Tapered Off		Strides
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Sodium Thiosulfate			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626426	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP006978			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Prednisolone			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Immunoglobulin /00025201/			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16627004	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1080950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Swelling; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16627487	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1080416		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma	Alendronate Sodium			S	Unknown			Actavis
	Alendronic Acid			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr

Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	13518838	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037971		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Qmo	Bristol Myers Squibb
	Orencia	S	Subcutaneous	125 Milligram	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	13976560	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166703			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Arava			S	Oral	20 Mg,Unk		Sanofi
	Hydroxychloroquine			S		200 Mg,Unk		Sanofi
	Methotrexate			S	Unknown	22.5 Mg,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C	Unknown	20 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	14633591	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1.5 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	14657700	EXPEDITED (15-DAY)		DS, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000984		73 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial;	Plaquenil 200 Mg Tablet			S	Oral			Concordia

Condition Aggravated; Osteoarthritis; Thrombocytopenia	Plaquenil 200 Mg Tablet		S	Oral	Concordia
	Plaquenil 200 Mg Tablet		S	Oral	Concordia
	Methylprednisolone		S	Intravenous (not otherwise specified)	Not Reported
	Artz		S	Intra-articular	Not Reported
	Baktar		C		Not Reported
	Rabeprazole Na		C		Not Reported
	Trazenta		C		Not Reported
	Bonoteo		C		Not Reported
	Humalog		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	15311483	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-002969		34 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iron Deficiency Anaemia; Pneumonia Bacterial	Plaquenil 200 Mg Tablet			S	Oral	(On Consecutive Days)		Concordia
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported
	Methylprednisolone			S	Oral			Not Reported

						Methylprednisolone		S	Oral	Not Reported
						Methylprednisolone		S	Oral	Not Reported
						Methylprednisolone		S	Oral	Not Reported
						Mycophenolate Mofetil		S	Oral	Not Reported
						Amlodipine		C		Not Reported
						Valsartan		C		Not Reported
						Valsartan		C		Not Reported
						Tramcet		C		Not Reported
						Metoclopramide		C		Not Reported
						Lansoprazole		C		Not Reported
						Benet		C		Not Reported
						Baktar		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	15634981	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16016667	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017691			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16048339	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059157			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Arava			S	Unknown	20 Mg		Sanofi
	Methotrexate			S	Unknown	22.5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Actemra			S	Unknown			Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16148361	EXPEDITED (15-DAY)		OT	CA-009507513-1903CAN012780		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Zenhale			S	Unknown	200 Microgram, 1 Every 1 Day(S)		Merck
	Zenhale			S	Unknown	200 Milligram, 2 Every 1 Day(S)		Merck
	Leflunomide			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Day(S)		Not Reported
	Lipitor			S	Unknown	40 Milligram, 1 Every 1		Not Reported

					Day(S)	
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	300 Milligram, 1 Every 1 Day(S)		Not Reported
	Spiriva	S	Unknown	2.5 Milligram, 2 Every 1 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16271434	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201905-001303		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Erythroid Maturation Arrest; Nausea; Retinal Oedema	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16628844	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1080412		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache;	Alendronate Sodium			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown		Barr
	Apo-Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Apremilast	S	Unknown	120 Milligram Daily;	Not Reported
	Apremilast	S	Unknown		Not Reported
	Apremilast	S			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Motrin	S	Oral	600 Milligram Daily;	Not Reported
	Motrin	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Benadryl	C			Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C			Not Reported

	Febuxostat	C				Not Reported
	Folic Acid	C				Not Reported
	Gravol	C				Not Reported
	Mogadon	C	Oral			Not Reported
	Nitrazepam	C				Not Reported
	Oxycodone	C				Not Reported
	Prednisone	C				Not Reported
	Uloric	C		160 Milligram Daily;		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629069	NON-EXPEDITED			IL-LAURUS LABS LIMITED-201900270			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Hydroxychloroquine Sulfate			S	Unknown	Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629083	NON-EXPEDITED		OT	IL-LAURUS LABS LIMITED-201900271			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Field Defect	Hydroxychloroquine Sulfate			S	Unknown	Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629138	NON-EXPEDITED			IL-LAURUS LABS LIMITED-201900272			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Hyperpigmentation	Hydroxychloroquine Sulfate			S	Unknown	Per Day		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629179	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2019SP002034		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use	Prednisolone		S		Unk		Not Reported
	Prednisolone		S				Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk		Strides
	Mycophenolate Mofetil		S				Strides
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629376	EXPEDITED (15-DAY)		HO	CA-ROCHE-2356023			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16629424	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2356022		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Indomethacin [Indometacin]		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Prednisone		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Cymbalta		C	Oral	Not Reported
	Folic Acid		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16630418	EXPEDITED (15-DAY)		DE, OT	CN-ROCHE-2358454			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis Orbital; Fungal Infection; Gastrointestinal Infection; Growth Retardation; Herpes Zoster; Hyperglycaemia; Keratitis; Ocular Hypertension; Osteoporosis; Otitis Media; Parotitis; Periodontitis; Pneumonia; Pulmonary Tuberculosis; Renal Failure; Respiratory Failure; Urinary Tract Infection	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cyclosporin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16630563	EXPEDITED (15-DAY)		DS, HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-MAPI_00011462		34 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Unilateral	Plaquenil			S	Oral			Concordia
	Advagraf			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Bactrim			S	Unknown			Not Reported
	Temerit			S	Unknown			Not Reported
	Cortancyl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16631230	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923291			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Gammagard Liquid			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, 2x A Week		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 1x/2wks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, 1x/Day:Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week		Not Reported
	Infliximab			S	Unknown	5 Unk		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, 1x/Week		Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month		Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16631252	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1082276		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16632292	EXPEDITED (15-DAY)		OT	TR-JNJFOC-20190733525		13 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Osteonecrosis	Risperdal			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16632843	EXPEDITED (15-DAY)		DE	AU-APPCO PHARMA LLC-2071299		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Virus Granule Cell Neuronopathy; Jc Virus Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16633556	DIRECT	Y	HO			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Hydroxychloroquine			S	Oral			Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16633560	DIRECT	Y	OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S	Oral			Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2019	16633754	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mouth Ulceration; Rash	Hydroxychloroquine			S	Oral			Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	12929735	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown	125 Mg, Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Qwk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Actonel			C	Unknown	35 Mg, Qwk		Not Reported
	Folate			C	Unknown	1 Mg, Qd		Not Reported
	Prevacid			C	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	13045204	EXPEDITED (15-DAY)		DS, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006461		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hypertrophic Cardiomyopathy	Plaquenil			S	Oral			Concordia
	Prednisone			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	14493419	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine /00884302/			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Diclofenac	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	14632744	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020016		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Off Label Use; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prolia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	15076471	EXPEDITED (15-DAY)		OT	CA-ROCHE-2143243		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Prednisone	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Alendronate Sodium	C			Not Reported
	Fosamax	C	Unknown		Not Reported
	Ibuprofen	C			Not Reported
	Lisinopril	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	15383755	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082928			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Cirrhosis; Off Label Use; Synovitis; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	15710332	EXPEDITED (15-DAY)		DE, OT	CA-ABBVIE-18K-028-2587400-00		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gait Disturbance;	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	15974800	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine /00884302/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Arava	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Cetirizine Hydrochloride	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16339149	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-046216		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Pregabalin			C	Oral	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16444037	EXPEDITED (15-DAY)		HO, LT, OT	US-ACCORD-133488		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Epstein-Barr Virus Antibody Positive; Hypercalcaemia; Lymphoproliferative Disorder; Off Label Use;	Methotrexate			S		For 7 Years		Accord
	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported

Pancytopenia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16466287	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16466410	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-060579		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Cimzia			S	Subcutaneous				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16477247	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001606			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Hypersensitivity; Drug Intolerance; Infection; Pancytopenia; Rash	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Daily Dose: Unknown		Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16534763	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1070668		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased;	Fentanyl Matrix Patch			S	Unknown			Actavis
	Gabapentin			S	Oral	200 Milligram Daily;		Ivax
	Methotrexate			S	Subcutaneous			Barr
	Nortriptyline			S				Teva

Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celecoxib	S	Oral		Teva
	Celecoxib	S			Teva
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Gabapentin	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/	S	Unknown	400 Milligram Daily;	Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram Daily;	Not Reported
	Acetaminophen	C			Not Reported
	Aclasta	C			Not Reported
	Actonel	C			Not Reported
	Ascorbic Acid(Vitamin C)	C			Not Reported
	Biotin	C			Not Reported
	Calcium	C			Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Fentanyl	C	Unknown		Not Reported
	Ferrous Gluconate	C			Not Reported
	Fish Oil	C			Not Reported
	Genteal	C			Not Reported
	Lomotil	C			Not Reported
	Lomotil	C			Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Nexium	C			Not Reported
	Nortriptyline	C			Not Reported
	Omega - 3	C			Not Reported

	Omega 3-6-9	C	Not Reported
	Oxycodone	C	Not Reported
	Oxycodone-Acetaminophen	C	Not Reported
	Oxycodone-Acetaminophen	C	Not Reported
	Pantoprazole	C	Not Reported
	Prednisone	C	Not Reported
	Pyridoxine	C	Not Reported
	Sodium	C	Not Reported
	Thiamine Hcl	C	Not Reported
	Trazodone	C	Not Reported
	Trazodone /00447702/	C	Not Reported
	Tylenol	C	Not Reported
	Vitamin A	C	Not Reported
	Vitamin B 3	C	Not Reported
	Vitamin B12	C	Not Reported
	Vitamin D	C	Not Reported
	Vitamin D3	C	Not Reported
	Vitamin E	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16588836	EXPEDITED (15-DAY)		LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001673		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pancytopenia; Toxicity To Various Agents	Plaquenil			S	Oral			Concordia
	Methotrexate			S	Oral			Not Reported
	Folate			C	Oral			Not Reported
	Hydrocortisone Butyrate			C	Topical	Apply To All Affected Areas Of The Face Daily		Not Reported
	Triamcinolone Acetonide Lotion			C	Topical	Apply To The Affected Skin Or The Trunk Daily		Not Reported
	Fluocinonide Acetonide			C	Topical	Apply To Scalp Daily		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16626042	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019031229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Ucb
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S		10 Milligram		Not Reported
	Cortisone Acetate			S		Tab 25mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Ucb
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Ucb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Pseudoephedrine Hcl			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Prednisone			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634265	EXPEDITED (15-DAY)		OT	AU-ROCHE-2363092			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Chronic Spontaneous Urticaria; Osteoporosis; Rash Vesicular	Xolair			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Montelukast Sodium			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634287	EXPEDITED (15-DAY)		OT	CA-ROCHE-2357002		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634366	EXPEDITED (15-DAY)		OT	CA-ROCHE-2358740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Tinnitus	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634575	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2459		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634679	EXPEDITED (15-DAY)		HO	CA-ROCHE-2356019		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituxan			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Arava			C	Unknown					Not Reported
	Naproxen			C	Unknown					Not Reported
	Viread			C	Unknown					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634734	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1081730		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634744	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1081854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Oral			Teva
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

Cell Sedimentation Rate Abnormal; Synovitis	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Folic Acid		C			Not Reported
	Hydroxychloroquine Sulfate		C			Not Reported
	Methotrexate		C	Unknown		Not Reported
	Plaquenil		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634745	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081720		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Ferrous Fumarate			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Pantoprazole			S	Unknown	40 Milligram Daily;		Teva
	Abatacept			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Ascorbic Acid (Vitamin C)			S	Unknown			Not Reported
	Atenolol (Prempharm)			S		25 Milligram Daily;		Not Reported
	Co Atenolol			S		20 Milligram Daily;		Not Reported
	Co Atenolol			S	Unknown	25 Milligram Daily;		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported

	Humira (Adalimumab)	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S		40 Milligram Daily;	Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;	Not Reported
	Naproxen	S	Oral	100 Milligram Daily;	Not Reported
	Naproxen	S	Oral	1000 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Palafer	S	Unknown		Not Reported
	Pantoloc	S		40 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Palafer Cf	S	Unknown		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Celebrex	C	Oral	200 Milligram Daily;	Not Reported
	Celecoxib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16634746	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1081736		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635052	EXPEDITED (15-DAY)		OT	CA-ROCHE-2357001		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol [Paracetamol]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635331	EXPEDITED (15-DAY)		OT	CA-SA-2019SA196624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus;	Arava			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Myochrysine			S	Intramuscular	Unk Unk, Unk		Not Reported

Transaminases Increased; Treatment Failure	Sulfasalazine	S	Unknown	For Months	Not Reported
	Imuran [Azathioprine]	S	Unknown	3-4/12	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Folic Acid	C	Unknown	5 Mg, Qd	Not Reported
	Pariet	C	Unknown	20 Mg, Qd Am	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635420	EXPEDITED (15-DAY)		HO	FR-ACCORD-148925		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Spironolactone			S	Oral			Accord
	Ramipril			S	Oral			Accord
	Bisoprolol			S	Oral			Not Reported
	Tardyferon			S	Oral	80 Mg, Coated Tablet		Not Reported
	Doxycycline			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Plaquenil			S	Oral	200 Mg Film-Coated Tablets		Not Reported
	Coumadine			S	Oral	5 Mg Et 6 Mg 1 Jour Sur 2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635755	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-071178		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Gadolinium Zeolite			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate	S	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Escitalopram Oxalate	C	Oral	10 Milligram, Qd	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635786	EXPEDITED (15-DAY)		HO	CA-ROCHE-2357091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16635905	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	10 Mg, Qd, 1 Every 24 Hour(S)		Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16636342	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019315039			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Premature Baby	Methotrexate Sodium			S	Transplacental	Unk		Pfizer
	Prednisone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Gammagard			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16636750	EXPEDITED (15-DAY)		OT	PHHY2019AU173357			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16637381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-071015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638107	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-071308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous	162 Milligram, Q2wk	Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram 2 Every 1 Week	Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram 3 Every 1 Week	Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Leflunomide			C	Unknown	Unk	Not Reported
	Prednisone			C	Unknown	20 Milligram, Qd	Not Reported
	Sulfasalazine			C	Unknown	Unk	Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638230	EXPEDITED (15-DAY)		HO, LT, OT	SA-BAUSCH-BL-2019-021000		8 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Embolism	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	Low Dose		Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown	Pulse Dose		Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638607	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019SA169749		8 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Not Reported

Indication; Pulmonary Embolism	Prednisolone	S	Oral	2 Mg/Kg, Qd		Novartis
	Prednisolone	S	Oral	Low Dose		Novartis
	Prednisolone	S	Oral	10 Mg, Unk		Novartis
	Prednisolone	S	Oral	20 Mg, Unk		Novartis
	Methylprednisolone	S	Unknown	Pulse Dose		Not Reported
	Azathioprine	S	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638744	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019032024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S		Unk		Not Reported
	Diclofenac Sodium			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous			Ucb
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Ucb
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisone			S				Not Reported

	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638802	EXPEDITED (15-DAY)		HO, OT	FR-TAKEDA-2019TEU008672		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Lansoprazole			S	Oral	15 Milligram, Qd		Takeda
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Not Reported
	Tardyferon			S	Oral	160 Milligram, Qd		Not Reported
	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Ramipril			S	Oral	5 Milligram, Qd		Not Reported
	Coumadine			S	Oral	Unk		Not Reported
	Bisoprolol /00802602/			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638879	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1081539		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16638888	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081862			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Methotrexate			S	Intra-articular			Barr
	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639356	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Naproxen			S	Oral	1000 Milligram Daily;		Teva
	Prednisone			S	Oral			Actavis
	Arava			S	Oral	10 Milligram Daily;		Not Reported

		Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;			Not Reported
		Prednisone			S	Subcutaneous	1.5 Milligram Daily;			Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Xeljanz			S	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639372	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1082408			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2019	16639453	EXPEDITED (15-DAY)		OT	PHHY2019AU173342			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myocarditis; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown			Novartis
	Mycophenolate Mofetil			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Hydroxychloroquine			S					Not Reported
		Cyclophosphamide			S	Unknown				Not Reported
		Cyclophosphamide			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2019	16639763	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2019	16639862	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2867392-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz Xr			C				Not Reported
	Xeljanz			C				Not Reported
	Infliximab			C				Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2019	16640086	EXPEDITED (15-DAY)		OT	PHEH2019US030917			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus-Like Syndrome	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	12913468	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092887		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	15101719	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-AUROBINDO-AUR-APL-2018-033608			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Once A Day		Not Reported
	Ezetimibe Tablets			S	Transplacental	Unk		Aurobindo
	Pantoprazole			S	Transplacental	Unk		Aurobindo
	Pantoprazole			S	Transplacental	40 Milligram, Once A Day		Aurobindo
	Simvastatin			S	Transplacental	Unk		Aurobindo
	Delix (Ramipril)			S	Transplacental	Maternal Dose 20 Mg, Unk		Not Reported
	Delix (Ramipril)			S	Transplacental	20 Milligram, Once A Day		Not Reported
	Xarelto			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Torem			S	Transplacental	Unk		Not Reported
	Torem			S	Transplacental	100 Milligram, Once A Day		Not Reported
	Advagraf			S	Transplacental	Unk		Not Reported
	Advagraf			S	Transplacental	6 Milligram, Once A Day		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported
	Aliskiren			S	Transplacental	Unk		Not Reported
	Dipyrone			S	Transplacental	Unk		Not Reported

	Prednisolone	S	Transplacental	Unk	Not Reported
	Prednisolone	S	Transplacental	10 Milligram, Two Times A Day	Not Reported
	Clexane	S	Transplacental	Unknown	Not Reported
	Clexane	S	Transplacental	200 Milligram, Once A Day	Not Reported
	Novaminsulfon	S	Transplacental	Unknown	Not Reported
	Novaminsulfon	S	Transplacental	300 Milligram, Once A Day	Not Reported
	Dalteparin Sodium	S	Unknown	Unk	Not Reported
	Rituximab	S	Transplacental	Unk	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Mifegyne	C	Transplacental	Unk	Not Reported
	Cyclophosphamide	C	Transplacental	300 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	15988283	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-017179			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16066327	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014095166		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma	Etanercept			S		25 Mg, Weekly		Pfizer
	Infliximab Hospira			S		400 Mg, Single (One Dose)		Not Reported

	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S	Endocervical	Unk	Pfizer
	Medroxyprogesterone Acetate	S	Unknown	Unk	Pfizer
	Sulfasalazine	S		Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Azathioprine	S		Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Ciclosporin	S		Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naprosyn [Naproxen Sodium]	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituximab	S		Unk, 2 Doses	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Depo-Provera	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16443729	EXPEDITED (15-DAY)		HO, LT, OT	US-ORION CORPORATION ORION PHARMA-19_00006384		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure; Hypercalcaemia; Immunosuppression; Lymphoproliferative Disorder; Pancytopenia	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Mycophenolate Mofetil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16465676	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016225143		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16597435	NON-EXPEDITED			US-PFIZER INC-2019305500		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Weight Decreased	Sildenafil Citrate			S		Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg Ec, Daily (Daily For 1 Week)		Pfizer
	Sulfasalazine			S	Oral	Unk, 2x/Day(Tablet By Mouth Twice Daily For 1 Week)		Pfizer
	Sulfasalazine			S		Unk, 3x/Day(T Tablet Three Times Daily For 1 Week)		Pfizer
	Sulfasalazine			S		Unk, 2x/Day(2 Tablets In The Morning And 2 Tablets In The Evening)		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16619619	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2019314413			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Occupational Exposure To Product; Strongyloidiasis	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16619621	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2019314194			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Occupational Exposure To Product; Strongyloidiasis	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Prednisolone			S		Unk		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16636334	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019315048		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gammagard			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16640670	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2019SP003337		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	High-Dose		Not Reported
	Psoralen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16640699	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP010610			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	1500 Mg At 8.00 Am In Morning And 1000 Mg At 2.00 Am In The Afternoon		Strides
	Prednisolone			S	Unknown	5 Mg Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg Twice Day		Not Reported
	Vitamin D /00107901/			S	Unknown	50,000 Units Weekly		Not Reported
	Calcium			S	Unknown	1 Tablet Daily		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16640990	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-070643		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16641472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2363942			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16641493	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-214444			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pustular Psoriasis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16641767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2363029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported

	Enbrel			S	Unknown				Not Reported
	Fosamax			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Folic Acid			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16641843	EXPEDITED (15-DAY)		CA	FR-ROCHE-2358501		3 DAY	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Decreased; Blood Immunoglobulin M Decreased; Foetal Exposure During Pregnancy; Monoclonal B-Cell Lymphocytosis	Rituximab			S	Transplacental			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Transplacental			Not Reported
	Aspirine			S	Transplacental			Not Reported
	Neoral			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642126	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product	Plaquenil			S		200 Mg, Bid		Sanofi
	Paracetamol			S				Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Arava	S		20 Mg, Qd	Sanofi
	Hydroxychloroquine	S		200 Mg, Bid	Sanofi
	Methotrexate	S		25 Df, Qw	Not Reported
	Methotrexate	S		20 Mg, Qw	Not Reported
	Sulfasalazine	S	Oral	2000 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		750 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg, Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk, Soluition Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Meloxicam	C			Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642139	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202228			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Rash; Treatment Failure	Hydroxychloroquine Sulfate			S		1 Df		Sanofi
	Leflunomide			S				Sanofi
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	1 Df		Not Reported
	Orencia			S	Subcutaneous	125 Df, Qw		Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642141	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neutropenia	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642142	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S		50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg; Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S		1000 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642143	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202266		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi

Incomplete	Celecoxib	S		200 Mg, Bid		Not Reported
	Methotrexate	S		20 Mg		Not Reported
	Enbrel	S				Not Reported
	Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642144	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202168		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Hydroxychloroquine			S	Subcutaneous	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Leflunomide			S	Oral	20 Mg		Sanofi
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642146	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202260		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S				Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Qow		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Qw		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Qow		Not Reported

	Enbrel			S		Unk Unk, Qw				Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642147	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202188			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Erosion; Drug Ineffective; Drug Intolerance; Joint Swelling; Nausea; Osteoarthritis; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Thrombocytosis; Thrombosis; Weight Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Actonel			C	Oral	35 Mg, Qw		Not Reported
	Codeine			C				Not Reported
	Ergocalciferol			C	Oral	2000 Iu, Qd		Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642152	EXPEDITED (15-DAY)		HO, LT	CA-SA-2019SA202170			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Actemra			S				Not Reported
	Anakinra			S				Not Reported

	Anakinra	S				Not Reported
	Enbrel	S				Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Ilaris	S				Not Reported
	Ilaris	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S		Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202431		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk, Solution		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk, Solution		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported

	Folic Acid		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642154	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202250		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S		500 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C		10 Mg, Qd		Not Reported
	Diclofenac			C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642157	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202259		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Discomfort; Drug Ineffective; Erythema; Joint Swelling; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S	Oral			Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S		Unk		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642158	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	200 Mg, Bid [2 Every 1 Days(S)]		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd [1 Every 1 Days(S)]		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Arava			S	Oral	20 Mg		Sanofi
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642498	NON-EXPEDITED			US-PFIZER INC-2019318210			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxepin Hcl			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Piroxicam			S		Unk		Pfizer
	Lodine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

	Lexapro	S	Unk		Not Reported
	Savella	S	Unk		Not Reported
	Nucynta	S	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642880	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019030839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			S		Unk		Not Reported
	Demerol			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine]			S		Unk		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Azithromycin			S		250 Milligram, Once Daily (Qd)		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Ezetrol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16642881	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202264		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Hydroxychloroquine			S		200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Prednisone			S		20 Ng		Not Reported
	Sulfasalazine			S		2 Df, Qd		Not Reported
	Sulfasalazine			S		2 Df, Qd		Not Reported
	Arava			S		10 Mg		Sanofi
	Orencia			S		200 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qw		Not Reported
	Humira			S	Subcutaneous	1 Df, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Df, Q6m		Not Reported
	Actonel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16643169	NON-EXPEDITED			US-PFIZER INC-2019319959		64 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Plaquinol			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644169	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-071056		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Coumadine			S	Oral	5 Mg And 6 Mg 1 Day Out Of 2		Bristol Myers Squibb
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	3 Dosage Form, Qd		Not Reported
	Tardyferon			S	Oral	2 Dosage Form, Qd		Not Reported
	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Ramipril			S	Oral	5 Milligram, Qd		Not Reported
	Lansoprazole			S	Oral	15 Milligram, Qd		Not Reported
	Bisoprolol Fumarate			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644313	EXPEDITED (15-DAY)		OT	PHHY2019GB173164			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

	Norfloxacin			S	Unknown	Unk			Not Reported
	Meperidine			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk			Not Reported
	Lyrica			S	Unknown	Unk			Not Reported
	Erythro Base			S	Unknown	Unk			Not Reported
	Apo Leflunomida			S	Unknown	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported
	Celebrex			S	Oral	200 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644345	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019030682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Procytox			S		Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Ezetrol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16644855	NON-EXPEDITED			US-SA-2019SA201782		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Density Decreased; Dyspepsia; Foot Fracture; Gastrooesophageal Reflux Disease; Weight Increased	Arava	S	Unk	Sanofi
	Plaquenil	S	200 Mg, Qd	Sanofi
	Xeljanz	S	20 Mg, Qd	Not Reported
	Xeljanz	S		Not Reported
	Align	C	1 Df	Not Reported
	Vitamin D [Colecalciferol]	C	Unk Unk, Qw	Not Reported
	Advil [Ibuprofen]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16645092	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1082834		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

		Tofacitinib Citrate			C	Unknown				Not Reported
		Viread			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jul-2019	16645141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2364037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration-195 Days		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Therapy Duration- 6.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration- 6.0 Years		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

	Asa			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	12913911	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092750		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cortisone			S	Oral	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	12916483	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091700		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective;	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Fatigue; Glossodynia; Hypersensitivity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure			otherwise specified)		
	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Folic Acid	S	Unknown	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram		Not Reported
	Winpred	S	Oral	Unk		Not Reported
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown	Unk		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported
	Diclofenac	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	14149901	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-095385		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Off Label Use; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	14178731	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-098530		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hypersensitivity; Off Label Use	Orencia			S	Unknown	125 Mg, Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported

Sulfasalazine	S	Unknown	1 G, Unk		Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Unk		Not Reported
Leflunomide	S	Oral	20 Mg, Qd		Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk		Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	14632990	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019940		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Rash	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	14633054	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Rituximab			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Levothyroxine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	14921791	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044363			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pruritus; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	14955003	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2018SP004258		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown	Unk		Strides
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unknown		Not Reported

	Plaquenil /00072603/	S	Oral	400 Mg, Unknown	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Demerol	S		Solution For Injection	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	15631632	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2018-CA-978035		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S				Teva
	Prednisone			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown	15 Milligram Daily;		Actavis
	Prednisone Acetate			S				Actavis
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

	Hydroxychloroquine	S				Not Reported
	Rituximab	S	Unknown			Not Reported
	Rituximab	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	15948962	EXPEDITED (15-DAY)		HO, LT, OT	NL-ACCORD-106757		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Drug Ineffective; Lupus Nephritis; Myocarditis; Off Label Use; Renal Tubular Necrosis; Respiratory Failure; Systemic Lupus Erythematosus	Mycophenolic Acid			S		1000 Mg, Bid, Maintenance Therapy		Accord
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S				Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S				Not Reported
	Azathioprine/Azathioprine Sodium			S				Not Reported
	Rituximab			S				Not Reported
	Methylprednisolone			S		Also Received In 2013		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	15978255	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013815		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Contraindicated Product Administered	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Qmo		Not Reported
	Apo-Gabapentin			S	Oral	100 Mg, Bid		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported

Myochrysine	S	Intramuscular	50 Mg, Q3wk	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Qmo	Not Reported
Actonel	C	Unknown	36 Mg, Qwk	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1200 Mg, Bid	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qwk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Unknown	Unk Unk, Bid	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5.0 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16444991	EXPEDITED (15-DAY)		CA, DE	FR-TEVA-2019-FR-1063232			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of	Esomeprazole			S	Transplacental	20 Milligram Daily;		Teva
	Plaquenil 200 Mg, Coated Tablet			S	Transplacental	Plaquenil 200 Mg, Coated Tablet		Not Reported
	Diffu K, Capsule			S	Transplacental	1 Dosage Forms Daily;		Not Reported
	Cortancyl 5 Mg Tablet			S	Transplacental	1 Dosage Forms Daily;		Not Reported

Placenta	Imurel	S	Transplacental	150 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16456054	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016547		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin			S	Unknown	Unk		Apotex
	Enalapril			S	Unknown	Unk		Apotex
	Clindamycin			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Hydralazine			S	Unknown	Unk		Apotex
	Losartan			S	Unknown	Unk		Apotex
	Moxifloxacin			S	Unknown	Unk		Apotex
	Metoprolol			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q.Wk., 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Keflex /00145501/			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Penicillin G /00000901/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

	Cipro /00697201/	C	Unknown	Unk		Not Reported
	Esomeprazole	C	Unknown	Unk		Not Reported
	Gold	C	Unknown	Unk		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported
	Iron Sucrose	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	8.5 Mg, Qd, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16581754	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001665		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
West Nile Viral Infection	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown	Part Of A Regimen That Involved Tapering Of The Dose		Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Unknown	High Dose		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfamethoxazole-Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16645866	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi

Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium	S	Unknown			Not Reported
	Folic Acid	S	Unknown	1 Mg		Not Reported
	Prednisone	S	Unknown			Not Reported
	Alendronate Sodium	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16645867	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16645869	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16645870	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202595			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		Solution Intravenous		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Desoximetasone			C		Not Specified		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16645963	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202634		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646353	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-073754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance; Intentional Product Use Issue	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646687	EXPEDITED (15-DAY)		OT	CA-ROCHE-2361966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646741	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S		200 Mg, Biw		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Tiw		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

	Orencia	S		Unk		Not Reported
	Prednisone	C		20 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646742	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202696		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	Unk, Qow		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk, Duration: 129		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported
	Prednisone			C	Oral	6 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported
	Mefenamic Acid			C				Not Reported
	Dequalinium Chloride			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646745	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202640			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S		200 Mg, 2 Every 1 Day		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	2 Df, Qd, 200 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S				Not Reported
	Azathioprine			S	Unknown	Unk, Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	2 Df, Qw, 25 Mg		Not Reported
	Gold			S	Unknown	Unk, Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Unk		Not Reported
	Tiaprofenic Acid			C	Unknown	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646747	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis;	Plaquenil			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi

Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Naproxen	C	Unknown	500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646748	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204160		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Diarrhoea; Dizziness; Drug Intolerance; Hypersensitivity; Lung Disorder; Malaise; Pulmonary Toxicity; Rheumatoid Arthritis	Plaquenil			S	Oral			Sanofi
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral	Unk		Sanofi
	Arava			C				Not Reported
	Depo-Medrol			C		80 Mg, Suspension Intra-Articular		Not Reported
	Diclofenac			C		50 Mg, Bid		Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646786	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202522		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder;	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported

Thrombocytopenia	Advil [Ibuprofen]	C				Not Reported
	Folic Acid	C				Not Reported
	Ketorolac	C				Not Reported
	Naproxen	C				Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646787	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202262		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Hydroxychloroquine			S	Subcutaneous	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Mg		Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Apo-Leflunomide			S		20 Mg		Not Reported
	Cimzia			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646788	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA202623		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)		
	Simponi		S	Subcutaneous		Not Reported
	Actemra		S	Unknown		Not Reported
	Anakinra		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Sanofi
	Cellcept [Mycophenolate Mofetil Hydrochloride]		S	Unknown		Not Reported
	Celebrex		C	Unknown		Not Reported
	Prednisone		C	Intravenous (not otherwise specified)	7 Mg, Qd	Not Reported
	Humira		C	Subcutaneous		Not Reported
	Methotrexate		C	Unknown	1 Ml, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646792	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202611		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Hydroxychloroquine			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646793	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202251		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Anakinra			S				Not Reported

			Apo-Azathioprine		S					Not Reported
			Enbrel		S	Subcutaneous	Unk			Not Reported
			Remicade		S	Intravenous (not otherwise specified)				Not Reported
			Rituxan		S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Hypospadias; Low Birth Weight Baby; Premature Baby	Methotrexate (Trade Name Unknown)			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Gammagard			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16646964	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2527		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Placental Insufficiency; Premature Delivery; Product Use In Unapproved Indication	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648244	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203400		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Plaquenil	S	Oral	200 Mg, Bid		Sanofi
	Methotrexate	S	Oral	20 Mg, Qw		Not Reported
	Leflunomide	S	Oral			Sanofi
	Leflunomide	S	Oral	20 Mg, Qd		Sanofi
	Cimzia	S	Subcutaneous			Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Orencia	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648247	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648248	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202627		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Hydroxychloroquine Sulfate			S	Oral			Sanofi

Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Sanofi
	Plaquenil	S			Sanofi
	Sulfasalazine	S	Oral		Not Reported
	Leflunomide	S			Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Ciclosporin	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Mg, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648249	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA202831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Sanofi

Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown	Unk Unk, Unk	Sanofi
	Prednisone	S	Unknown	Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Naproxen	S	Unknown	Unk Unk, Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk Unk, Unk	Not Reported
	Folic Acid	C	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	C	Unknown	Unk Unk, Unk	Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648251	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202330		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Prednisone			S	Oral	2 Df		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg Solution Subcutaneous		Not Reported
	Folic Acid			S		Unk Unk, Qw		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz			S	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648254	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil			S	Unknown	400.0 Mg, Unk		Sanofi
	Methotrexate			S	Subcutaneous	25.0 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Apo-Azathioprine			S	Unknown	100mg, Unk		Not Reported
	Apo-Minocycline			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	5.0 Mg, Bid		Not Reported
	Leflunomide			C	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648256	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported

	Infliximab			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Pantoprazole Sodium Anhydrous			C		Unk			Not Reported
	Atorvastatin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648259	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202722		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Swelling	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Naproxen			S		2 Df, Qd		Not Reported
	Leflunomide			S				Sanofi
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648293	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202693		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia ; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648380	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2872261-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Partial Responder	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648566	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019136361			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Sulfasalazine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648638	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Methotrexate			C	Unknown	Unk Unk, Qw		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648752	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1082896			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Ibuprofen			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Ibuprofen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral	200 Milligram Daily;		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

		Prednisone			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16648887	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1082832		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Tofacitinib Citrate			C				Not Reported
	Amlodipine			C				Not Reported
	Arava			C				Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Viread			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16649189	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1082839		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Cefazolin	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Barr
	Leflunomide	S	Oral	Barr
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Benadryl /00000402/	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16649249	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1082951		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of	Ibuprofen			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported

Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Enbrel	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Naprosyn	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Oral	200 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jul-2019	16649356	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084347			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Mycophenolate Mofetil			S	Unknown			Teva
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	10606970	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014322620		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cheilitis; Condition Aggravated; Rheumatoid Arthritis; Stomatitis	Methotrexate Sodium			S				Pfizer
	Folic Acid			S				Pfizer
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Fentanyl			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	13168077	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005387			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk, Cyclical		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	13408209	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-028353		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Hypersensitivity; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Milligram, Bid		Not Reported

Decreased	Kevzara	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Triatec /00116401/	C	Unknown	Unk	Not Reported
	Atasol /00020001/	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	650 Milligram, Bid	Not Reported
	Atacand	C	Unknown	Unk	Not Reported
	Hydrodiuril	C	Unknown	Unk	Not Reported
	Vitamin D /00107901/	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Neurontin	C	Unknown	600 Milligram, Tid	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Aluminium Acetate;Benzethonium Chloride	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Benzethonium Chloride	C	Unknown		Not Reported
	Aluminum Acetate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	13878964	EXPEDITED (15-DAY)		OT	CA-SA-2017SA134394			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi

Condition, Insomnia Type; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Unk Unk,Unk		Not Reported
	Benzylpenicillin	S	Unknown	Unk Unk,Unk		Not Reported
	Acetylsalicylic Acid	S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Unknown	Unk Unk,Unk		Not Reported
	Paracetamol	C	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15133020	EXPEDITED (15-DAY)		DS, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002332		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Autoimmune Retinopathy; Hepatic Cirrhosis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Mycophenolate Mofetil			S	Oral			Not Reported
	Daiphen			C				Not Reported
	Daiphen			C				Not Reported
	Juvela			C				Not Reported
	Lansoprazole			C				Not Reported
	Lansoprazole			C				Not Reported
	Amlodipine Odan			C				Not Reported
	Fosamac			C				Not Reported
	Fosamac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15739036	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-990422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Teva-Mycophenolate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Mycophenolate Sodium			S	Unknown			Teva

	Prednisone		S	Oral	Actavis
	Cellcept		S	Unknown	Not Reported
	Imuran		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15755064	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-990843		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S				Teva
	Mycophenolate Mofetil			S				Teva
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15792301	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201901-000018		62 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus	Plaquenil 200 Mg Tablet			S	Oral			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15833907	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1003339		50 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Nail Disorder; Nail Pigmentation	Hydroxychloroquine			S		400 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15918090	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-007791			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Migraine; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Penicillin /00000901/			S	Unknown	Unk		Not Reported
	Entocort			S	Unknown	Unk		Not Reported
	Sulfa /00302001/			S	Unknown	Unk		Not Reported
	Gentamycin /00047101/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15945998	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011286		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Hypersensitivity; Drug	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral	15 Mg, Qwk		Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Q12h		Not Reported
	Prednisone	S	Oral	15 Mg, Qd		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Celebrex	C	Unknown			Not Reported
	Gold	C	Unknown			Not Reported
	Morphine	C	Unknown			Not Reported
	Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15953478	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	200 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported

					Remicade		S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Xeljanz		C	Unknown	Unk	Not Reported
					Sulfasalazine		C	Unknown	Unk	Not Reported
					Wellbutrin		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	15977906	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16048332	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid	Leflunomide			S	Unknown	Unk		Sanofi
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

Nodule; Sleep Disorder Due To General Medical Condition, Insomnia Type; Synovitis; White Blood Cell Count Decreased	Plaquenil	S	Unknown	Unk	Sanofi
	Benzylpenicillin	S		Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Penicillin [Penicillin Nos]	S	Unknown	Unk	Not Reported
	Pregabalin	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16345487	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028345			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster;	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Vancomycin Hydrochloride			S	Unknown	Unk		Aurobindo
	Ceftazidime			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	500.0 Milligram, Two Times A Day		Not Reported
	Mycophenolate Mofetil			S	Unknown	500.0 Milligram, Two Times A Day		Not Reported
	Plaquenil			S	Unknown	200.0 Milligram, Two Times A Day		Not Reported
	Plaquenil			S	Unknown	200.0 Milligram, Two Times A Day		Not Reported
	Prednisone			S	Unknown	7.5 Milligram		Not Reported
	Prednisone			S	Unknown	10.0 Milligram, Daily		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000.0 Milligram		Not Reported

Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Paracetamol	C	Oral	650.0 Milligram	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Apo Amlo	C	Unknown	Unk	Not Reported
	Apo-K	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	50.0 Milligram	Not Reported
	Epoetin Alfa	C	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	10.0 Milligram	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Insulin Lispro	C	Unknown	Unk, 3 Times A Day	Not Reported
	Januvia	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Pantoloc	C	Unknown	40.0 Milligram, Daily	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Risedronate	C	Unknown	35.0 Milligram, Every Week	Not Reported
	Slow-K	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Ventolin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16404378	NON-EXPEDITED			US-PFIZER INC-2019145252		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg/Ml, Weekly		Unknown
	Enbrel			S				Unknown

	Methotrexate Sodium	S	Gradually Increasing Dose	Unknown
	Methotrexate Sodium	S		Unknown
	Norco	S	Unk	Not Reported
	Norco	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	400 Mg, Daily	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Tylenol No. 4	S	Unk	Not Reported
	Tylenol No. 4	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16459283	EXPEDITED (15-DAY)		HO, LT, OT	US-MEDAC PHARMA, INC.-2069418		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure; Hypercalcaemia; Lymphoproliferative Disorder	Methotrexate			S				Medac
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16543774	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063574		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Naproxen	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2 Every 1 Day		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16649876	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			C				Not Reported
	Gold			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16649877	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001727		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Burning Sensation; Injection Site Pain; Rheumatoid Arthritis	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650243	NON-EXPEDITED		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03138		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiomyopathy	Hydroxychloroquine			S	Unknown	6 Milligram/Kilogram (Prolonged Treatment)			Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650244	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2019-03457		48 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Field Defect	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650251	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03065		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyschromatopsia; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650252	NON-EXPEDITED		OT	IT-LUPIN PHARMACEUTICALS INC.-2019-03276		4 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Hydroxychloroquine			S	Unknown	100 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	Unk (Restarted)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650253	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2019-03774		58 YR	Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650254	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-03103		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650255	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2019-03459		64 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Hyperpigmentation	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650256	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2019-03458		55 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650257	NON-EXPEDITED		HO, OT	CA-LUPIN PHARMACEUTICALS INC.-2019-03154		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd (4.1 Mg/Kg)		Lupin
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Mycophenolic Acid			C	Unknown	720 Milligram, Qd		Not Reported
	Cyclosporine			C	Unknown	250 Milligram, Qd		Not Reported
	Atorvastatin			C	Unknown	10 Milligram, Qd		Not Reported

	Amlodipine			C	Unknown	5 Milligram, Qd				Not Reported
	Metoprolol			C	Unknown	25 Milligram, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650258	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2019-04093		11 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eyelid Rash; Photosensitivity Reaction	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Tacrolimus			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650261	NON-EXPEDITED		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2019-02537		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650262	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2019-03423		44 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Vision Blurred	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650263	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2019-02977		58 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oral Pigmentation	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650264	NON-EXPEDITED			IL-LUPIN PHARMACEUTICALS INC.-2019-03460		41 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650340	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-04428			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Duloxetine			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650355	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR134431			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Myalgia	Benlysta Solution For Injection			S	Subcutaneous	Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Acthar Gel			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650409	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-042836			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract	Pregabalin Capsules			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Pregabalin Capsules			S	Oral	2 Dosage Form, Once A Day		Not Reported

Infection; Pain In Extremity; Parkinson'S Disease; Peripheral Swelling; Therapeutic Product Effect Incomplete	Risedronate	S	Oral	1 Dosage Form, Once A Day	Aurobindo
	Risedronate	S	Unknown	1 Dosage Form, Once A Day	Aurobindo
	Risedronate	S	Unknown	400 Milligram, Once A Day	Aurobindo
	Arava	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Milligram, Every Week	Not Reported
	Plaquenil	S	Oral	400 Milligram, Two Times A Day	Not Reported
	Plaquenil	S	Oral	200 Milligram, Two Times A Day	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Plaquenil	S	Oral	200 Milligram, Two Times A Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Every Week	Not Reported
	Arava	S	Unknown	20 Milligram, Once A Day	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Two Times A Day	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650487	EXPEDITED (15-DAY)		HO	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pneumonia	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported

		Sulfasalazine			S	Unknown					Not Reported
		Methotrexate			S	Unknown					Not Reported
		Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650509	EXPEDITED (15-DAY)		OT	AU-ACCORD-149003			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Chronic Spontaneous Urticaria; Osteoporosis; Rash Vesicular	Montelukast			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Xolair			S				Not Reported
	Ciclosporin			S				Not Reported
	Prednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650628	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2872142-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650732	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202199		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S				Sanofi
	Arava	S				Sanofi
	Methotrexate	S				Not Reported
	Sulfasalazine	S				Not Reported
	Rituxan	S				Not Reported
	Enbrel	S				Not Reported
	Xeljanz	C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650733	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202131		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Rituximab			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650735	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202940		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Minocycline Hydrochloride			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Xeljanz			S		5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650737	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Myochrysine			S	Parenteral	50 Mg, Qm		Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Bismuth Subsalicylate			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650738	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203481		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C		15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650739	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203479		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder; Unevaluable Event	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Minocycline Hydrochloride			S				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S				Not Reported
	Ustekinumab			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650741	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity;	Hydroxychloroquine Sulfate			S	Unknown	40 Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
	Ascorbic Acid	S		Unk Unk, Qd	Not Reported
	Atenolol	S	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qow	Not Reported
	Methotrexate	S	Oral	25 Unk	Not Reported
	Methotrexate	S	Oral	25 Unk	Not Reported
	Methotrexate	S	Oral	25 Unk	Not Reported
	Ferrous Fumarate	S	Unknown		Not Reported
	Ferrous Fumarate/Folic Acid	S	Unknown	1 Df, Qd	Not Reported
	Folic Acid	S	Unknown	5 Mg, Biw	Not Reported
	Folic Acid	S	Unknown	5 Mg, Biw	Not Reported
	Pantoprazole	S			Not Reported
	Pantoprazole	S		40 Mg, Qd	Not Reported
	Naproxen	S	Oral	1000 Mg, Qd	Not Reported
	Naproxen	S	Oral	500 Mg, Bid	Not Reported
	Naproxen	S	Oral	1000 Mg, Qd	Not Reported
	Naproxen	S	Oral	500 Mg, Bid	Not Reported
	Naproxen	S	Oral	100 Mg, Qd	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Abatacept	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	Unk, Qow	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qw	Not Reported
	Methotrexate Sodium	S	Oral	25.0 Mg, Qw	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Not Reported
	Co Atenolol	S	Unknown	25 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported

Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Hydroxychloroquine	S				Sanofi
	Arava	S				Sanofi
	Celecoxib	S				Not Reported
	Methotrexate	S	Oral			Not Reported
	Actemra	S				Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C		1 Every 24 Hours (S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650746	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Paracetamol			S				Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Actemra			S				Not Reported
	Cimzia			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Methotrexate			C		Unk Unk, Qw		Not Reported
	Synthroid			C				Not Reported

	Meloxicam			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650747	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qow [1 Every 2 Week(S)]		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Orencia			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16650748	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203473		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Surgical Failure	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Mobicox			C		15 Mg, Qd				Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651227	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Pain	Hydroxychloroquine			S		200 Mg, Bid		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	1 Df, Qd		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651228	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Enbrel			S				Not Reported
	Actemra			S		8 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		750 Mg		Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Meloxicam			C					Not Reported
		Sulfasalazine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651229	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202717		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Leflunomide			S	Unknown	5 Mg		Sanofi
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651231	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202759		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration;	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	5 Mg, Unk		Sanofi
	Leflunomide			S	Oral	10 Unk		Sanofi

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Methotrexate		S	Unknown	5 Mg, Unk		Not Reported
	Cimzia		S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel		S	Unknown	50 Mg, Unk		Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia		S	Unknown	750 Mg, Unk		Not Reported
	Remicade		S	Unknown			Not Reported
	Xeljanz		S	Oral	5 Mg, Bid		Not Reported
	Prednisone		C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651232	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Leflunomide			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651233	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203472		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		5 Mg, Qd. 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651234	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203478		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Plaquenil			S		10 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Simponi			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651237	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA204365		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Plaquenil			S		400 Mg, Qd, Therapy Duration- 518.0		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Arava			C				Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651238	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Retinopathy	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Actemra			C				Not Reported
	Humira			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Simponi			C				Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651239	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203005			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported

Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide	S	Unknown			Sanofi
	Methotrexate	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Celebrex	C				Not Reported
	Tramacet	C				Not Reported
	Tramadol	C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651241	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202469		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S		8 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Arava			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cymbalta			C				Not Reported
	Elavil [Amitriptyline Hydrochloride]			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Imitrex [Sumatriptan]			C				Not Reported
	Lyrica			C				Not Reported
	Premarin			C				Not Reported
	Tenormin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651242	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202767		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg		Not Reported
	Rituximab			S		Unk		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Orencia			S				Not Reported
	Orencia			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qw		Not Reported
	Adalimumab			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Qw		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Qw		Not Reported
	Etanercept			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651244	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651246	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202982		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Hydroxychloroquine			S				Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651247	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202999			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil	S		400 Mg	Sanofi
	Leflunomide	S			Sanofi
	Sulfasalazine	S			Not Reported
	Methotrexate	S	Subcutaneous	25 Mg	Not Reported
	Minocycline Hydrochloride	S			Not Reported
	Azathioprine	S		100 Mg	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported
	Hydroxychloroquine	C			Not Reported
	Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651250	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202981		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Arava			S		10 Mg		Sanofi
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651253	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Sulfasalazine			S		500 Mg, Qid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetaminophen			C		500 Mg		Not Reported
	Hydrocortisone Valerate			C				Not Reported
	Hydromorphone			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Lyderm [Fluocinonide]			C				Not Reported
	Naproxen			C		250 Mg, Qd		Not Reported
	Naproxen			C		Unk		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Sodium Aurothiomalate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651254	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203052		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Incorrect Route Of Product Administration; Tuberculin Test Positive; Tuberculosis	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Arava			S		10 Mg, Qd		Sanofi
	Folic Acid			C		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651260	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203398		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Plaquenil	S	Oral	200 Mg, Bid		Sanofi
	Arava	S	Oral	200 Mg, Qd		Sanofi
	Arava	S	Oral	Unk		Sanofi
	Methotrexate	S	Oral	20 Mg, Qw		Not Reported
	Actemra	S				Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651274	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203419		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg		Sanofi
	Plaquenil			S	Oral	400 Mg		Sanofi
	Methotrexate			S	Intramuscular	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Arava			S	Oral	10 Mg		Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Ergocalciferol			C				Not Reported
	Lozide [Gliclazide]			C				Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Metformin			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Asa			C		81 Mg		Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651276	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	600 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Hydroxychloroquine			S	Oral	20 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Arava			S	Oral	20 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw [1 Every 1 Week(S)]		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C		1 Df, Qw [1 Every 1 Week(S)]		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous	Formulation: Solution		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd [2 Every 1 Day(S)]		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd [1 Every 1 Day(S)]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651277	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S		10 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder	Cimzia		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651278	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Rituxan			S				Not Reported
	Actemra			C				Not Reported
	Desoximetasone			C				Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651281	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203470		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Plaquenil			S		400 Mg		Sanofi
	Minocycline Hydrochloride			S		50 Mg		Not Reported
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S		Unk		Not Reported

	Xeljanz	S		5 Ng, Bid		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]	C				Not Reported
	Bcg Vaccine	C	Intravesical			Not Reported
	Amoxil [Amoxicillin]	C				Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651285	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203482		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Plaquenil			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651286	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202747			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

	Orencia	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Tocilizumab	S				Not Reported
	Xeljanz	S				Not Reported
	Cimzia	C	Subcutaneous			Not Reported
	Prednisone	C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651289	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203477		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Anakinra			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2 Every 1 Week		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651290	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203055			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Intravenous (not otherwise specified)				Not Reported
	Celebrex			C					Not Reported
	Lyrica			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651291	EXPEDITED (15-DAY)		OT	CA-SA-2017SA134372			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Benzylpenicillin			S	Unknown	Unk Unk,Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			C	Unknown	Unk Unk,Unk		Not Reported
	Paracetamol			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651293	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203394			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Plaquenil			S		200 Mg, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Prednisone			S		6 Mg, Qd		Not Reported
	Pregabalin			S		150 Mg, Qd		Not Reported

	Sulfasalazine	S		Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S		Unk		Not Reported
	Imuran [Azathioprine Sodium]	S		Unk		Not Reported
	Trazodone	S		25 Mg, Qd		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651297	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202976		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Solution		Not Reported
	Hydroxychloroquine			S				Sanofi
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16651302	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis;	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi

Therapeutic Response Decreased	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Methotrexate	C		20 Mg, Qw		Not Reported
	Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652209	NON-EXPEDITED			US-PFIZER INC-2019326411		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S		Unk		Not Reported
	Hydroxychloroquine Sulphate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652283	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Plaquenil			S		200 Mg, Bid		Sanofi
	Sulfasalazine			S		1 G, Bid		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S				Not Reported
	Cimzia			S				Not Reported
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652289	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204186			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Oral			Sanofi
	Plaquenil			S	Oral			Sanofi
	Plaquenil			S	Oral	2 Df, Qd		Sanofi
	Leflunomide			S	Oral			Sanofi
	Actonel			C		3.5 Mg		Not Reported
	Calcium Ascorbate			C	Oral	500 Mg, Qd		Not Reported
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported
	Methotrexate			C	Oral	25 Mg, Qw		Not Reported
	Prednisone			C	Oral	2 Df, Qd		Not Reported
	Prednisone			C	Oral	3 Df, Qd		Not Reported
	Prednisone			C	Oral	4 Df, Qd		Not Reported
	Prednisone			C	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			C	Oral	1000 Mg, Bid		Not Reported
	Vitamin D3			C	Oral			Not Reported
	Xeljanz			C		1 Df, Qd		Not Reported
	Xeljanz			C		1 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652290	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204084		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S		5 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S		5 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Enbrel			S		50 Unk		Not Reported

	Enbrel	S		50 Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		750 Mg	Not Reported
	Orencia	S		750 Mg	Not Reported
	Remicade	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	C		50 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652291	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported

	Diphenhydramine	C	Unknown	Not Reported
	Dyclonine Hydrochloride	C	Unknown	Not Reported
	Enablex [Darifenacin Hydrobromide]	C		Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Restasis	C		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C		Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16652293	EXPEDITED (15-DAY)		DS	CA-SA-2019SA204179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Baclofen			S				Not Reported
	Duloxetine Hydrochloride			S				Not Reported
	Pregabalin			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Celebrex			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653095	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084334		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653168	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1084330		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Mycophenolate Mofetil	S	Unknown			Teva
	Actemra	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Celebrex	C	Unknown			Not Reported
	Humira	C	Subcutaneous			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	7 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16653184	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084327		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity;	Methotrexate			S	Unknown			Barr

Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil	S	Unknown	Teva
	Mycophenolate Mofetil	S	Unknown	Teva
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16654409	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1085540		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Spironolactone			S	Oral	25 Mg		Actavis
	Ramipril			S	Oral	5 Mg		Actavis
	Lansoprazole			S	Oral	15 Mg		Teva
	Doxycycline			S	Oral	200 Mg		Actavis

	Bisoprolol (Fumarate Acide De)		S	Oral	5 Mg	Teva
	Plaquenil 200 Mg, Comprime Pellicule		S	Oral	3 Dosage Form	Not Reported
	Tardyferon 80 Mg, Comprime Enrobe		S	Oral	2 Dosage Form	Not Reported
	Coumadine		S	Oral	5 Mg And 6 Mg 1 Day Out Of 2	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jul-2019	16654522	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown	For Months;		Not Reported
	Imuran			S	Unknown	3-4/12		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Folic Acid			C				Not Reported
	Pariet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	10614679	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1496772		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis;	Actemra			S	Intravenous (not otherwise specified)	Started Summer 2013, Had 3 Doses In Total		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown	2009 Or 2012 Start, Stopped Fall 2014. Later		Not Reported

Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting				Re-Started It Again.		
	Celebrex	S	Unknown	Re-Started When Had A Rheumatoid Arthritis Flare		Not Reported
	Celebrex	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	6 Months		Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Stopped As Did Not Do Anything		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Dilaudid	C	Unknown	As Needed, Started 2009 Approximately		Not Reported
	Dilaudid	C	Unknown	As Required		Not Reported
	Lyrica	C	Oral	2 Capsules Morning, 1 At Night, 2010 Start Approx.		Not Reported
	Hydromorph Contin	C	Unknown			Not Reported
	Hydromorph Contin	C	Unknown	Sustained Release		Not Reported
	Furosemide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	12287019	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016047205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

							otherwise specified)			
			Plaquenil			S	Unknown	Unk		Not Reported
			Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
			Xeljanz			C	Unknown	Unk		Not Reported
			Apo-Hydroxyquine			S	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	12297942	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016226407			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Enbrel			S	Subcutaneous	1 Df, Qwk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	12676638	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2012049633		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Enbrel	S	Subcutaneous	1 Dosage Form, Qwk	Amgen
	Enbrel	S	Intravenous (not otherwise specified)	Unk Unk, Qwk	Amgen
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Intra-arterial	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Intra-articular	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	13166259	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005004		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate /00113802/		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Desoximetasone		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	14431871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-118970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Disorder; Off Label Use; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported
	Desvenlafaxine Succinate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported

	Xeljanz			C	Unknown				Not Reported
	Arava			C	Unknown				Not Reported
	Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	15294428	EXPEDITED (15-DAY)		DS, OT	CA-CELGENEUS-CAN-20180803437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	15626277	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3285		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Contraindicated Product Administered; Drug Ineffective; Haematochezia; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Amlodipine Besilate	S	Oral		Not Reported
	Amlodipine Besilate	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Amlodipine	S	Oral		Not Reported
	Apo-Amlodipine	S	Oral		Not Reported
	Asacol	S	Oral		Not Reported
	Depo-Medrol	C	Intramuscular	80mg/Ml As Needed	Not Reported
	Depo-Medrol	C	Intramuscular	40mg/Ml As Needed	Not Reported
	Depo-Medrol	C	Intramuscular	120mg/Ml, As Needed	Not Reported
	Norvasc	C	Oral	Strength: 5 Mg	Not Reported
	Norvasc	C	Oral	Strength: 5 Mg	Not Reported
	Folic Acid	C	Unknown	5 Days Per Week	Not Reported
	Ferrous Gluconate	C	Oral	300 Mg (35 Mg Iron)	Not Reported
	Glucosamine W/Minerals Nos/Vitamins Nos	C	Oral	62.5 Mg/50 Mg/25 Mg/100 Mcg Particles/Crystals In Oral Tablet Daily	Not Reported
	Vitamin D3	C	Oral		Not Reported
	Tylenol	C	Oral	Strength: 500 Mg, As Needed	Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Atacand Plus	C	Oral	Strength: 16/12.5 Mg	Not Reported
	Cholecalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16231022	EXPEDITED (15-DAY)		OT	FR-CELLTRION INC.-2019FR020577			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Dependence; Drug Ineffective; Product Use In Unapproved Indication	Rituximab (Unknown)	S	Unknown	Unk		Not Reported
	Cyclophosphamide	S	Unknown	Unk		Not Reported
	Erythropoietin	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone Nos	S	Unknown	1 Mg/Kg/D Tapered		Not Reported
	Ciclosporin	S	Unknown	Unk		Not Reported
	Azathioprine Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16236347	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA111772		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Chronic Kidney Disease; Hypercalcaemia; Intentional Product Misuse; Nephrosclerosis; Off Label Use; Product Selection Error; Pruritus; Renal Failure; Toxicity To Various Agents	Colecalciferol			S		8 Drops, Qd; 500 Iu Per Drop		Not Reported
	Colecalciferol			S		8-12 Drops,1000 Iu, Qd; Daily Dosage Of 8000-12000 Iu		Not Reported
	Indapamide			S		2.5 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Amlodipine			C		10 Mg, Qd		Not Reported
	Perindopril			C		8 Mg, Qd		Not Reported
	Rosuvastatin			C		10 Mg, Qd		Not Reported
	Febuxostat			C		80 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16282330	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer

Abdominal Pain Upper; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Acetylsalicylic Acid (Pain And Fever)	S				Bayer
	Arava	S	Unknown	Unk		Not Reported
	Diclofenac Potassium	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S				Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Motrin Migraine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Tramadol Hydrochloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16290399	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-087678		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Naproxen Sodium (<= 220 Mg)			S	Unknown			Bayer
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Methylprednisolone Acetate			C		40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16470169	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016509		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure	Ciprofloxacin			S	Unknown	Unk		Apotex
	Clindamycin			S	Unknown			Not Reported

Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Enalapril	S	Unknown		Apotex
	Hydrochlorothiazide	S	Unknown		Apotex
	Losartan	S	Unknown	Unk	Apotex
	Hydralazine	S	Unknown		Apotex
	Moxifloxacin	S	Unknown	Unk	Apotex
	Pantoprazole	S	Unknown		Apotex
	Penicillin	S	Unknown	Unk	Apotex
	Metoprolol	S	Unknown		Not Reported
	Cefalexine	S	Unknown	Unk	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Unk	Not Reported
	Pariet	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported
	Cipro /00697201/	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16580198	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852952-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Adverse Reaction; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16627512	EXPEDITED (15-DAY)		HO, LT, OT	SA-PFIZER INC-2019316051		8 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Embolism	Methylprednisolone			S		Unk, Pulse Dose		Pfizer
	Hydroxychloroquine			S		Unk, 1x/Day		Not Reported
	Prednisolone			S	Oral	2 Mg/Kg, 1x/Day		Not Reported
	Prednisolone			S	Oral	Unk, Low Dose		Not Reported
	Prednisolone			S	Oral	10 Mg, Alternate Day		Not Reported
	Prednisolone			S	Oral	20 Mg, Alternate Day		Not Reported
	Azathioprine			S		Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16648646	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019321213		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Spironolactone			S	Oral	25 Milligram, Qd		Pfizer
	Lansoprazole			S	Oral	15 Milligram, Qd		Unknown
	Ramipril			S	Oral	5 Milligram, Qd		Pfizer
	Ramipril			S	Oral	Unk		Pfizer
	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	600 Milligram (3 Dosage Form), Qd		Not Reported
	Tardyferon		S	Oral	160 Milligram(2 Dosage Form), Qd		Not Reported
	Coumadine		S	Oral	5 Mg And 6 Mg 1 Day Out Of 2		Not Reported
	Bisoprolol Fumarate		S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16654591	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-044331			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Spironolactone			S	Oral	25 Milligram, Once A Day		Aurobindo
	Doxycycline			S	Oral	200 Milligram, Once A Day		Not Reported
	Ramipril			S	Oral	5 Milligram, Once A Day		Aurobindo
	Lansoprazole			S	Oral	15 Milligram, Once A Day		Not Reported
	Bisoprolol			S	Oral	5 Milligram, Once A Day		Aurobindo
	Coumadine			S	Oral	5 Mg And 6 Mg 1 Day Out Of 2		Not Reported
	Tardyferon			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Oral	3 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16654759	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084337		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling;	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported

Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655128	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-073651			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655162	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203508			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Ineffective	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Azithromycin			C		250 Mg, Qd		Not Reported
	Methotrexate			C	Oral	25 Mg, Qw		Not Reported
	Morphine			C	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655163	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204095			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Therapeutic Response Decreased; Treatment Failure	Plaquenil			S	Oral	400 Mg, Qd, 1 Every 24 Hour(S)		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd: 1 Every 24 Hour(S)		Sanofi
	Arava			S	Oral	Unk Unk, Unk		Sanofi

Methotrexate	C	25 Mg, Qw: 1 Every 1 Week(S)	Not Reported
Methotrexate	C	22.5 Mg, Qw, 1 Every 1 Week(S)	Not Reported
Sulfasalazine	C	1 G, Qd: 1 Every 24 Hour(S)	Not Reported
Sulfasalazine	C	2 G, Qd, 1 Every 24 Hour(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655164	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204151		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rabeprazole Sodium			C		20 Mg		Not Reported
	Tramadol Hydrochloride			C	Oral	50 Mg		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655165	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Bacitracin			S				Not Reported
	Methotrexate			S				Not Reported
	Neomycin Sulfate			S				Not Reported

	Actemra			S	Subcutaneous				Not Reported
	Polymyxin B Sulfate			S					Not Reported
	Etanercept			S	Subcutaneous				Not Reported
	Prednisone			C	Intramuscular				Not Reported
	Xeljanz			C	Oral	2 Df, Bid, 5mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655166	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA204090		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Nerve Injury; Renal Function Test Abnormal; Tuberculin Test Positive	Plaquenil			S	Oral	400.0 Mg		Sanofi
	Arava			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655167	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	2 Df, Bid,200 Mg		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	200 Mg, Biw, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk, Unk, Solution		Not Reported

			Intramuscular	
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Qm	Not Reported
Xeljanz	S	Unknown	Unk Unk, Unk	Not Reported
Desoximetasone	C	Unknown	Unk Unk, Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk Unk, Unk	Not Reported
Darifenacin	C	Unknown	Unk Unk, Unk	Not Reported
Ativan	C	Unknown	Unk Unk, Unk	Not Reported
Codeine	C	Unknown	Unk Unk, Unk	Not Reported
Anakinra	C	Unknown	Unk Unk, Unk	Not Reported
Dexamethasone	C	Unknown	Unk Unk, Unk	Not Reported
Dilaudid	C	Unknown	Unk Unk, Unk	Not Reported
Diphenhydramine	C	Unknown	Unk Unk, Unk	Not Reported
Furosemide	C	Unknown	Unk Unk, Unk	Not Reported
Hydromorphone	C	Unknown	Unk Unk, Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Unk Unk, Unk,Suspension Intra-Articular	Not Reported
Loperamide	C	Unknown	Unk Unk, Unk	Not Reported
Morphine Sulphate	C	Unknown	Unk Unk, Unk	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk Unk, Unk	Not Reported
Omnaris	C	Unknown	Unk Unk, Unk, Spray Metered Dose	Not Reported
Oxyneo	C	Unknown	Unk Unk, Unk,Tablet-Extended Release	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk Unk, Unk Tablet Enteric Coated	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk Unk, Unk	Not Reported
Restasis	C	Unknown	Unk Unk, Unk, Emulsion	Not Reported
Synthroid	C	Unknown	Unk Unk, Unk	Not Reported
Trimethoprim	C	Unknown	Unk Unk, Unk	Not Reported
Urispas	C	Unknown	Unk Unk, Unk	Not Reported

	Vagifem			C	Unknown	Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655169	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204134			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655179	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202618		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Methotrexate			S		20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S				Sanofi

	Arava	S	Oral	Unk	Sanofi
	Arava	S		Unk	Sanofi
	Cortisone Acetate	S		25 Mg	Not Reported
	Alendronate Sodium	S			Not Reported
	Sulfasalazine	S		500 Mg	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S			Not Reported
	Actemra	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfathalidine	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Salazopyrin	C			Not Reported
	Diclofenac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655548	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204018			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling	Plaquenil			S	Oral	Unk		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi

	Methotrexate			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655647	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-139200		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Aleve			S	Unknown	Unk		Bayer
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Ow		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	4 Mg, Ow		Not Reported
	Methotrexate			S	Intra-articular			Not Reported
	Methotrexate			S	Intra-articular	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655650	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Hepatic Enzyme Increased; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Urticaria	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Calcium Carbonate;Magnesium Carbonate;Magnesium Trisilicate			C				Not Reported
	Prednisone			C		12 Mg		Not Reported
	Prednisone			C		11 Mg		Not Reported
	Prednisone			C		20 Mg		Not Reported

	Prednisone			C		13 Mg			Not Reported
	Prednisone			C		15 Mg			Not Reported
	Prednisone			C		10 Mg			Not Reported
	Prednisone			C		17 Mg			Not Reported
	Prednisone			C		Unk Unk, Qd			Not Reported
	Synthroid			C		130 Ug, Qd			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655654	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		2 Df, Qd		Sanofi
	Methotrexate			S		15 Mg, Qw [1 Every 1 Week(S)]		Not Reported
	Methotrexate			S		20 Mg, Qw [1 Every 1 Week(S)]		Not Reported
	Actemra			S				Not Reported
	Enbrel			S		1 Df, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655831	EXPEDITED (15-DAY)		OT	CA-ROCHE-2366060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16655995	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1071820		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Bisoprolol			S	Oral	5 Milligram, Qd		Not Reported
	Spironolactone			S	Oral	25 Milligram, Qd		Not Reported
	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Ramipril			S	Oral	5 Milligram, Qd		Not Reported
	Lansoprazole			S	Oral	15 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	3 Dosage Form, Qd		Mylan
	Tardyferon			S	Oral	2 Dosage Form, Qd		Mylan
	Coumadine			S	Oral	5 Mg And 6 Mg 1 Day Out Of 2		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656277	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-139201		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration;	Aleve			S	Unknown			Bayer

Infection; Pneumonia; Synovitis	Arava		S	Unknown		Not Reported
	Celebrex		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	Unk Unk, Ow	Not Reported
	Enbrel		S	Intravenous (not otherwise specified)	Unk Unk, Ow	Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Mg	Not Reported
	Methotrexate		S	Intra-arterial		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Prednisone		S	Unknown	5 Mg	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656862	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139203		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown			Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Teva			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

Folic Acid	C		Not Reported
Naproxen	C		Not Reported
Hydroxychloroquine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656983	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202972		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	1 Df, Qd		Sanofi
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Mg, Qd		Sanofi
	Arava			S		1 Df, Qd		Sanofi
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		Unk Unk, Qw		Not Reported
	Enbrel			S		1 Df		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Xeljanz			S	Oral	2 Df, Qd (5 Mg Stength)		Not Reported
	Xeljanz			S		Unk		Not Reported

	Xeljanz	S	2 Df, Qd		Not Reported
	Xeljanz	S	2 Df, Qd (5 Mg Stength)		Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656986	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Celecoxib			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656987	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204317		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S		1 G, Bid		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported

					Orencia		S	125 Mg, Qw		Not Reported
					Orencia		S	125 Mg, Qw		Not Reported
					Humira		S	40 Mg, Unk		Not Reported
					Humira		S	40 Mg, Unk		Not Reported
					Humira		S	40 Mg, Unk		Not Reported
					Folic Acid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16656988	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202955		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Arava			S		1 Df, Qd		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Sulfasalazine			S		1500 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657002	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203009		45 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported

	Tramacet				C					Not Reported
	Tramadol				C		100 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657725	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Aleve			S	Unknown	Unk		Bayer
	Aspirin			S	Unknown	Unk		Bayer
	Apo-Sulfatrim			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfamethoxazole;Trimethoprim			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657813	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139213		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Prednisone Teva	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Hydroxychloroquine Sulfate	C		Unk		Not Reported
	Naproxen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657861	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203507			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	2 Df, Qw		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Vioxx			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657914	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019032052			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Cimzia			S	Subcutaneous	Single Use Prefilled		Not Reported

Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound				Syringe		
	Cetirizine Hydrochloride	S		Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Actemra	S		Unk		Not Reported
	Arava	S		Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Folic Acid	S		Unk		Not Reported
	Fosamax	S		Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Ucb
	Hydroxychloroquine Sulfate	S				Not Reported
	Methotrexate	S		Unk		Ucb
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		Unk		Not Reported
	Prednisone	S		Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657945	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis;	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer
	Naproxen Sodium			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Xeljanz	S		5 Mg, Bid		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657977	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139366		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium (<= 220 Mg)			S				Bayer
	Enbrel			S				Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S				Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657978	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139307		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	12.5 Mg		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657982	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139312		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	400.0 Mg		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	5.0 Mg, Bid		Not Reported
	Folic Acid	C		Unk		Not Reported
	Methotrexate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658003	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139367		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		400 Mg		Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported
	Xeljanz			S		5.0 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658004	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139374		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue;	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Apo-Naproxen	S	Unknown	Unk		Not Reported
	Apo-Prednisone	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658107	EXPEDITED (15-DAY)		OT	PHHY2019US175356		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658280	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139539		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Naproxen Sodium (<= 220 Mg)			S				Bayer
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		400 Mg		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			C				Not Reported

	Orencia	S				Not Reported
	Prednisone	S				Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658282	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-139579		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer
	Acetaminophen			C				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C		Unk		Not Reported
	Ferrous Gluconate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lasix [Furosemide]			C				Not Reported
	Methylprednisolone [Methylprednisolone Acetate]			C		Unk		Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C		Unk		Not Reported
	Oxyneo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658328	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139670		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Folic Acid			C				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C		20 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658457	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139588		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use;	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported

Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S		Unk		Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	C				Not Reported
	Prednisone	S				Not Reported
	Tocilizumab	S				Not Reported
	Xeljanz	S	Oral	5 Mg(2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658787	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085080		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Indomethacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658795	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085089		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Indometacin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16842739	DIRECT	Y				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Intestinal Haemorrhage	Hydroxychloroquine 200 Mg	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	12929734	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091804			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Milligram, Qd		Not Reported
	Atasol /00020001/			C	Unknown			Not Reported
	Baclofen			C	Unknown	10 Milligram, Bid		Not Reported
	Levaquin			C	Unknown	500 Milligram, Qd		Not Reported

	Calcium	C	Unknown	500 Milligram, 1 Every 1 Day	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qwk	Not Reported
	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Estradiol	C	Unknown	0.6 Percent, Tid	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported
	Calcium Gluconate	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Xalatan	C	Unknown	50 Milligram, 1 Every 1 Day	Not Reported
	Xalatan	C	Unknown	5 Milligram, 1 Every 1 Day	Not Reported
	Xalatan	C	Unknown	Unk, 1 Every 1 Day	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	13047484	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016225792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	300 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	14032090	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2012196433		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Enbrel			S	Subcutaneous	Unk , Weekly		Pfizer
	Enbrel			S	Intravenous (not otherwise specified)	Unk , Weekly		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Methotrexate Sodium			S	Intra-articular	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	14516779	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2250003-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; General Physical Condition Abnormal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	15600169	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-			Female	CAN

972925

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	15600182	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-972935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Simponi			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	15600755	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2018-CA-973737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Indometacin			S	Oral	150 Milligram Daily;		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	15635783	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978349			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Azathioprine	S	Unknown			Not Reported
	Sarilumab	S	Subcutaneous			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Magnesium	C				Not Reported
	Metformin	C	Unknown			Not Reported
	Nexium	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	15944870	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013556			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16048890	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059122			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Prednisone			C						Not Reported
	Sulfasalazine			C			Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16098613	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1026017		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Leflunomide			S	Unknown			Barr
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16415191	NON-EXPEDITED			US-PFIZER INC-2019241669		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported
	Belladonna			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Tavist			S		Unk		Not Reported

	Codeine	S	Unk	Not Reported
	Benadryl	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Tylenol	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported
	Thimerosal	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16556644	EXPEDITED (15-DAY)		OT	PHHY2019DE153000		26 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaplastic Large Cell Lymphoma T- And Null-Cell Types; Product Use In Unapproved Indication	Azathioprine			S	Unknown	5 Mg, Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	150 Mg, Qd		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16627367	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190725259		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Fosamax			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Methotrexate			S	Subcutaneous					Not Reported
	Methotrexate			S	Subcutaneous					Not Reported
	Methotrexate			S						Not Reported
	Methotrexate			S						Not Reported
	Myochrysine			S	Intramuscular					Not Reported
	Orencia			S	Unknown					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Cyclosporine			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659189	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2872324-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Knee	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis	Arava	S	Oral	Not Reported
	Arava	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tramacet	S	Unknown	Not Reported
	Tramadol + Acetaminofen	S	Oral	Not Reported
	Metformin	C	Unknown	Not Reported
	Lorazepam	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Methylprednisolone Acetate	C	Unknown	Not Reported
	Depomedrol	C	Intramuscular	Not Reported
	Lyrica	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Tylenol Arthritis	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659212	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-215231			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antiphospholipid Syndrome;	Methotrexate			S	Unknown	Unk		Sun

Cryoglobulinaemia; Necrosis; Polyarteritis Nodosa; Pyoderma Gangrenosum	Hydroxychloroquine	S	Unknown	Unk		Sun
	Prednisone	S	Unknown	Unk		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659612	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-05489		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659740	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Arava			S		20 Mg		Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659743	EXPEDITED (15-DAY)		OT	CA-SA-2019SA203511			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Arava	S	Oral	10 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate	S	Oral	Unk Unk, Unk		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen	S	Oral	500 Mg, Qd		Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia	S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab	S	Unknown	Unk Unk, Unk		Not Reported
	Vioxx	S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide	C		10 Mg, Unk		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659941	EXPEDITED (15-DAY)		OT	PHHY2019CA177900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Prednisone			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Cimzia			S	Subcutaneous	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16659945	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039232		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Spironolactone			S	Oral			Zydus Pharm
	Ramipril			S	Oral			Zydus Pharm
	Lansoprazole			S	Oral			Zydus Pharm
	Bisoprolol			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tardyferon			S	Oral			Not Reported
	Doxycycline			S	Oral			Not Reported
	Coumadine			S	Oral	5 Mg And 6 Mg 1 Day Out Of 2		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660101	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2583		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cheilitis; Insomnia; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Stomatitis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Fentanyl		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660179	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-073756			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pruritus; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660266	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Interstitial Lung Disease	Plaquenil			S	Unknown	200 Mg, 2 Every 1 Days		Sanofi
	Leflunomide			S	Unknown	10 Mg, Q24d		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660267	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204259		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Leflunomide			S				Sanofi

	Methotrexate	S				Not Reported
	Anakinra	S	Subcutaneous	100 Mg		Not Reported
	Enbrel	S	Subcutaneous	25 Mg, 2 Every 1 Week		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16660514	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-139679		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			C	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone Teva			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661046	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085334		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr

Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661047	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085343		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661070	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661328	NON-EXPEDITED			US-PFIZER INC-2019329581			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661405	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1071102		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Interaction; Infection; Neutropenia; Propionibacterium Infection; Staphylococcal Infection	Methotrexate			S	Oral	Methotrexate Had Been On Hold For 3 Weeks Later		Not Reported
	Prednisone			S	Oral	25 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Oral	2.5 Milligram, Qd		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Mylan
	Diazepam			C	Unknown			Mylan

	Folic Acid	C	Unknown			Mylan
	Ibuprofen	C	Unknown	As Needed		Mylan
	Hydrocodone Bitartrate And Acetaminophen	C	Unknown	As Needed		Mylan
	Omeprazole	C	Unknown			Mylan
	Sulindac	C	Unknown	200 Mg Twice		Mylan
	Acetaminophen	C	Unknown	As Needed		Mylan
	Venlafaxine	C	Unknown			Mylan
	Vancomycin	C	Intravenous (not otherwise specified)			Mylan
	Cefazolin	C	Intravenous (not otherwise specified)			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661468	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661537	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085232		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Methotrexate		S	Unknown	Barr
	Risedronate		S	Unknown	Teva
	Actemra		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16661624	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1071575		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; False Positive Investigation Result	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16662554	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085358		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16662569	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663600	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydrochlorothiazide/Lisinopril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663724	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Abatacept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663727	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085446		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Etanercept			S	Unknown	Not Reported
	Gold Injections			S	Intramuscular	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Imuran			S	Unknown	Not Reported
	Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri			S	Subcutaneous	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituximab Gp2013			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663732	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663811	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086091		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Acetaminophen	C				Not Reported
	Pregabalin	C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663812	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086114		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Methotrexate			C				Not Reported
	Supeudol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663813	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-021887		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In	Metformin Hydrochloride			S	Unknown			Santarus
	Topicort Mild Cream 0.05% (Desoximetasone)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Altace		C		Not Reported
	Asa		C		Not Reported
	Dl-Alpha Tocopherol;Fish Oil		C		Not Reported
	Folic Acid		C		Not Reported
	Methotrexate		C		Not Reported
	Rosuvastatin Calcium		C		Not Reported
	Vitamin D		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16663831	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1072391		52 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ovarian Granulosa Cell Tumour	Methotrexate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	250 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664130	EXPEDITED (15-DAY)		OT	PHHY2019FR178868			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Prednisone			S	Transplacental	Mother Dose 5 Mg		Novartis
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Mother Dose 2 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664214	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1085487		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Leflunomide			S	Unknown			Barr

					Actemra		S	Intravenous (not otherwise specified)	Not Reported
					Humira		S	Subcutaneous	Not Reported
					Orencia		S	Unknown	Not Reported
					Plaquenil		S	Unknown	Not Reported
					Remicade		S	Unknown	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Not Reported
					Methotrexate		C	Unknown	Not Reported
					Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664224	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Drug Ineffective; Joint Stiffness; Joint Swelling; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Indomethacin			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	25 Milligram Daily;		Barr
	Prednisone			S	Oral	50 Milligram Daily;		Actavis
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	25 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold Radioactive Colloidal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Indocid	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Prednisone	S	Oral	3 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Cymbalta	C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664403	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085466		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Hot Flush; Nausea; Rhinorrhoea; Sinus Congestion	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664416	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1085816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Abatacept			S	Unknown			Not Reported

Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Etanercept	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664417	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085928		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Anxiety; Condition Aggravated; Drug Ineffective; Drug Intolerance; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664420	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086165		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	.5 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664424	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085393		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664425	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086220		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Rheumatoid Arthritis	Diclofenac W/Misoprostol			S	Oral	100 Milligram Daily;		Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	133.3333 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Advil			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	16664485	EXPEDITED (15-DAY)		OT	PHHY2019US175838		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neutropenia	Methotrexate Sodium			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate Sodium			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Q24h (For 6 Weeks Postoperatively)		Not Reported
	Prednisone			S	Oral	2.5 Mg, Qd		Novartis
	Prednisone			S				Novartis
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported

	Diazepam	C	Unknown	Unk Unk, Prn		Not Reported
	Ibuprofen	C	Unknown	Unk, Prn		Not Reported
	Folic Acid	C	Unknown	1 Mg, Bid		Not Reported
	Omeprazole	C	Unknown	20 Mg, Qd		Not Reported
	Sulindac	C	Unknown	200 Mg, Bid		Not Reported
	Hydrocodone/Acetaminophen	C	Unknown	Unk		Not Reported
	Venlafaxine	C	Unknown	Unk Unk, Qd		Not Reported
	Cefazolin	C	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported
	Vancomycin	C	Intravenous (not otherwise specified)	1750 Mg, Q12h		Not Reported
	Daptomycin	C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Ertapenem	C	Intravenous (not otherwise specified)	1 G, Q24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	15804322	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S				Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665092	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086068		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665100	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086503		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665101	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086173		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Aspirin /00002701/	C	Unknown			Not Reported
	Cymbalta	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Remicade	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665102	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086069			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665110	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665111	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085821		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Motor Dysfunction; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Calcium Dpantothenate/Ergocalciferol/Nicotinamide/Pyridoxinehydrochlor			C	Unknown			Not Reported

Extremity; Pneumonia; Rash; Sinusitis; Somnolence

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665113	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086587		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665134	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086159		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			C	Unknown			Not Reported
	Hydrochlorothiazide/Lisinopril Dihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665138	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086481		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Supeudol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665139	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086145		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia		S	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665145	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086191		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665152	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086675		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Aspirin		C	Unknown		Not Reported
	Cymbalta		C	Unknown		Not Reported
	Hydromorphone		C	Unknown		Not Reported
	Synthroid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665158	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086197		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported

	Diclofenac			C	Unknown	100 Milligram Daily;			Not Reported
	Methotrexate			C	Unknown				Not Reported
	Voltaren [Diclofenac]			C	Unknown	100 Milligram Daily;			Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665214	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086176		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	480 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
		Simponi			S		Sunconjunctival			Not Reported
		Risedronate			C		Unknown			Not Reported
		Xeljanz			C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665335	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086083		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C				Not Reported
	Zostavax			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665336	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Otezla			S	Unknown					Not Reported
	Simponi			S	Unknown					Not Reported
	Stelara			S	Unknown					Not Reported
	Xeljanz			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665339	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086094		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoarthritis; Synovitis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665342	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086117		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Cutaneous	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr

Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Methotrexate		S	Subcutaneous		Barr
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Anakinra		S	Subcutaneous	100 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Xeljanz		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2019	16665344	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1086157		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Aug-2019	16665791	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139648		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Aleve			S	Unknown	Unk		Bayer
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Ow		Not Reported
	Enbrel			S	Unknown	12.5 Mg, Ow		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Ow		Not Reported
	Kineret			S	Subcutaneous	50 Mg, Qd		Not Reported
	Kineret			S	Unknown	50 Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg (12 Every 2 Week)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250.0 Mg, Q1min		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	250.0 Mg, Qd		Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	15050951	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002129		53 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Macular Fibrosis; Posterior Capsule Opacification	Plaquenil 200 Mg Tablet	S	Oral	200 Mg And 400 Mg Alternativeliy	Concordia
	Plaquenil 200 Mg Tablet	S	Oral	200 Mg And 400 Mg Alternativeliy	Concordia
	Prednisolone	S	Oral		Concordia
	Methotrexate	C			Not Reported
	Foliamin	C			Not Reported
	Esomeprazole Magnesium	C			Not Reported
	Warfarin	C			Not Reported
	Minodronic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	15573002	EXPEDITED (15-DAY)		OT	US-SA-2018SA298977		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis	Kevzara			S	Subcutaneous	200mg/1.14 Ml, Qow		Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16305935	EXPEDITED (15-DAY)		DE, HO, OT	DE-MYLANLABS-2019M1044234		69 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Cardiac Failure; Invasive Lobular Breast Carcinoma; Myocardial Infarction	Methotrexate			S	Unknown	2.5 Milligram, Qw (2.5 Mg, Qwk)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (400 Mg, Qd)		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd (200 Mg, Qd)		Mylan
	Chloroquine			S	Unknown	200 Milligram, Qd (200 Mg, Qd)		Mylan
	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Mylan

	Acetylsalicylic Acid			C	Unknown	Unk			Mylan
	Carvedilol			C	Unknown	Unk			Mylan
	Valsartan			C	Unknown	Unk			Mylan
	Quensyl			C	Unknown	Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16425708	NON-EXPEDITED			US-PFIZER INC-2019252465		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16638566	EXPEDITED (15-DAY)		HO, OT	FR-BAUSCH-BL-2019-020885		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Doxycycline			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Ramipril			S	Oral	Dosage Increased		Not Reported
	Spironolactone			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tardyferon			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Coumadine			S	Oral	5 Mg And 6 Mg		Not Reported
	Bisoprolol			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16657664	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2872151-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16665951	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001747		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Asthenia; Bone Marrow Failure; Chills; Cough; Decreased Appetite;	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S	Unknown	3 Months Prior To		Not Reported

Decreased Appetite; Fatigue; Hypercalcaemia; Lymphadenopathy; Lymphoproliferative Disorder; Off Label Use; Pancytopenia; Pyrexia; Splenomegaly; Weight Decreased							Admission			
	Methotrexate			S	Unknown					Not Reported
	Methotrexate			S						Not Reported
	Mycophenolate Mofetil			S	Unknown					Not Reported
	Mycophenolate Mofetil			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16665953	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201904-000945		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthritis; Joint Stiffness; Urticaria	Plaquenil			S	Unknown			Concordia
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666140	NON-EXPEDITED			US-APPCO PHARMA LLC-2072740		45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscle Contractions Involuntary; Muscular Weakness; Paraesthesia	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Levothyroxine			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666299	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2872314-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Aclasta	S	Intravenous (not otherwise specified)		Not Reported
	Tramadol + Acetaminofen	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Tramacet	S	Unknown		Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Tylenol Arthritis Pain	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Lorazepam	C	Unknown		Not Reported
	Depomedrol	C	Intramuscular	Form Of Administration - Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666397	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04839		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666399	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04867		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666517	EXPEDITED (15-DAY)		DE	DE-SAMSUNG BIOEPIS-SB-2019-21366			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Etanercept			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666590	EXPEDITED (15-DAY)		OT	CA-SA-2019SA204282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response	Plaquenil			S		400 Mg, Qd		Sanofi
	Sulfasalazine			S		2 G, Qd		Not Reported
	Leflunomide			S	Other	20 Mg, Qd		Sanofi
	Actemra			S	Subcutaneous	Unk		Not Reported

Decreased	Enbrel		S			Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown	20 Mg, Qw	Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666611	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol #3			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666644	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086138		47 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		C			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
05-Aug-2019	16666645	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086558		52 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Unknown			Barr		
	Leflunomide			S	Oral			Barr		
	Methotrexate			S	Unknown			Barr		
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Enbrel			S	Subcutaneous			Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported		
	Orencia			S	Unknown			Not Reported		
	Orencia			S	Unknown			Not Reported		
	Remicade			S	Intravenous (not otherwise specified)			Not Reported		
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported		
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
05-Aug-2019	16666647	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085868		12 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		

Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide	S	Oral	Barr
	Methotrexate	S	Subcutaneous	Barr
	Adalimumab	S	Subcutaneous	Not Reported
	Etanercept	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666681	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04868		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666683	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04870		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666685	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04869		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666688	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04871		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666788	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-04872		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666982	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Plaquenil			S					Sanofi
	Hydroxychloroquine			S					Sanofi
	Hydroxychloroquine Sulfate			S					Sanofi
	Leflunomide			S					Sanofi
	Methotrexate			S					Not Reported
	Actemra			S					Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous	40 Mg			Not Reported
	Orencia			S					Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16666986	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210811		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Plaquenil			S				Sanofi
	Hydroxychloroquine			S				Not Reported
	Arava			S				Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Rosuvastatin			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667199	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-139354		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Arthritis; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Naproxen Sodium (<= 220 Mg)	S		Unk	Bayer
	Actemra	S	Intravenous (not otherwise specified)	280 Mg(1 Every 2 Weeks)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Anakinra	S		50 Mg	Not Reported
	Anakinra	S	Subdermal	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 G(1 Every 1 Day)	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Naproxen	S	Oral	3 Mg(2 Every 1 Day)	Not Reported
	Apo-Naproxen	S		5 Unk(2 Every 1 Day)	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S	Subcutaneous	25 Unk (2 Every 1 Weeks)	Not Reported
	Enbrel	S	Subcutaneous	12.5 Unk(1 Every 1 Weeks)	Not Reported
	Folic Acid	C			Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	5 Mg(1 Every 1 Day)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg(1 Every 2 Weeks)	Not Reported
	Methotrexate	S	Subcutaneous	15 Unk(1 Every 1 Weeks)	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg	Not Reported
	Orencia	S	Intravenous (not	250 Unk(1 Every 1 Week0	Not Reported

		otherwise specified)		
Orencia	S		250 Unk(1 Every 1 Week)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Unk(1 Every 1 Week0	Not Reported
Prednisone	S	Oral	5 Mg(2 Every 1 Day)	Not Reported
Prednisone	S	Oral	3 Mg(2 Every 1 Day)	Not Reported
Prednisone	S		Unk	Not Reported
Prednisone	S	Oral	1.3 Mg	Not Reported
Sulfasalazine	S	Oral	250 Mg (1 Every 1 Day)	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg(1 Every 2 Weeks)	Not Reported
Triamcinolone	S			Not Reported
Triamcinolone Acetonide	S		Unk	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667216	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BAYER-2019-139642		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia;	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Naproxen Sodium (<= 220 Mg)			S				Bayer
	Abatacept			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Actemra			S		Unk Unk, Biw		Not Reported
	Actemra			S		Unk Df		Not Reported
	Apo-Naproxen			S				Not Reported
	Apo-Naproxen			S	Oral	5 Mg, Bid		Not Reported
	Apo-Naproxen			S		3 Unk		Not Reported
	Apo Triamcinolone Aq			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Ow		Not Reported

Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Mg, Biw	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Ow	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Biw	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg, Ow	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral	5 Mg, Qd	Not Reported
	Hydroxychloroquine	S			Not Reported
	Immune Globulin, Intravenous	C	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S		1 Df, 9.0 Month(S)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg 5.0 Month(S)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg Every 6 Weeks	Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Kineret	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q1mon	Not Reported
	Orencia	S	Nasal	250 Mg, Ow	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S			Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S			Not Reported
	Triamcinolone	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667347	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-139871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Aleve			S	Unknown	Unk		Bayer
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Depo-Medrol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667354	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019327586		70 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Salazopyrina			S	Oral	500 Mg, Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, Daily		Pfizer
	Dolquine			S	Oral	200 Mg, Daily		Not Reported
	Lantus			C	Subcutaneous	22 Iu, Daily		Not Reported
	Osvical D			C	Oral			Not Reported
	Soludronate Semanal			C	Oral	70 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667446	EXPEDITED (15-DAY)		HO	CA-BAYER-2019-140029		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Naproxen Sodium (<= 220 Mg)			S		Unk		Bayer
	Actemra			S		Unk		Not Reported

Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S		1 Every 12 Hour (S) (5.0 Milligram)		Not Reported
	Apo-Naproxen	S				Not Reported
	Enbrel	S				Not Reported
	Folic Acid	C		Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Humira	S				Not Reported
	Hydroxychloroquine	S		400.0 Mg		Not Reported
	Leflunomide	C				Not Reported
	Methotrexate	S				Not Reported
	Methotrexate	S				Not Reported
	Orencia	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine	C				Not Reported
	Prednisone Acetate	S				Not Reported
	Xeljanz	S	Oral	1 Every 12 Hour (S) (5.0 Milligram)		Not Reported
	Xeljanz	S	Oral	2 Every 12 Hour (S) (5.0 Milligram)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667543	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil			S		400 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S				Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported

	Hydroxychloroquine Sulfate			C						Not Reported
	Leflunomide			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16667545	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210809		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Diclofenac Sodium			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Methotrexate			S	Oral	25 Mg (Solution)		Not Reported
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution For		Not Reported

						Subcutaneous)				
	Xeljanz			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16668080	EXPEDITED (15-DAY)		OT	CA-SA-2019SA201473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Hepatotoxicity	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16668394	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2019US030764		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unknown Freq. (Solution Subcutaneous)		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unknown Freq.		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unknown Freq. (Solution Subcutaneous)		Not Reported
	Hydroxyquinoline Sulfate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Unknown Freq. (Solution)		Not Reported
	Neoral			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

	Rapamune	S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk, Unknown Freq. (Powder For Solution Intravenous)		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Imuran /00001501/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16669507	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Plaquinil, Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16669782	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA208812		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine			S	Oral			Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw (1df Qw)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw (1df Qw)		Not Reported
	Sulfasalazine			S				Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S		50 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Xeljanz			C				Not Reported
	Valtrex			C	Oral	2 Df, Qd (1000 Mg)		Not Reported
	Rosuvastatin Calcium			C	Oral	Unk Unk, Qd		Not Reported

	Naproxen	C	Oral	2 Df, Qd (500 Mg)	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	2 Df, Qd (500 Mg)	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Aug-2019	16669836	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019332622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness	Methotrexate Sodium			S	Unknown			Pfizer
	Gold			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Motrin [Ibuprofen]			S				Not Reported
	Aleve			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	14785355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107848			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S				Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

	Imuran [Azathioprine]	S	Unknown		Not Reported
	Imuran [Azathioprine]	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S			Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	14921458	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			S	Intracardiac	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	15089236	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002196		44 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Vitreous Detachment	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Onetram			C				Not Reported
	Nexium			C				Not Reported
	Prorenal			C				Not Reported
	Seroquel			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Cefalexin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	15114144	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201807-002265		24 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Exposure During Pregnancy; Glaucoma	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Colchicine			C				Not Reported

		Heparin Calcium			C					Not Reported
		Miya Bm			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	15419642	EXPEDITED (15-DAY)		OT	CA-SA-2017SA086384		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate Sodium			S	Oral	35 Mg,Qw		Not Reported
	Risedronate Sodium			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Subcutaneous	17.5 Mg,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg, Qcy		Sanofi
	Plaquenil			S	Oral	300 Mg,Qd		Sanofi
	Plaquenil			S	Oral	300 Mg, Qd		Sanofi
	Remicade			S	Intravenous (not otherwise specified)	35 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G,Qcy		Not Reported
	Actonel			S		35 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Leflunomide			S	Oral	20 Mg, Qcy		Sanofi
	Leflunomide			S	Oral	20 Mg, Qh		Sanofi
	Arava			S	Oral			Sanofi

	Cimzia	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Risedronic Acid	S		35 Mg, Qw	Not Reported
	Hydroxychloroquine	S	Unknown		Sanofi
	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Sanofi
	Simponi	S			Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Xeljanz	C			Not Reported
	Risedronate	C			Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	15922942	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA030536		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain;	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Oral	25 Mg, Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Topicort			S	Subcutaneous	Unk		Sanofi
	Arava			S	Oral	20 Mg, Unk		Sanofi
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	25 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Methotrexate			S	Oral	1 G, Bid		Not Reported

Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Sanofi
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Subcutaneous	1 G, Q12h	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Paracetamol	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Sanofi
	Sarilumab	S	Unknown	Unk	Sanofi
	Hydrocortisone Acetate	S	Unknown	Unk	Sanofi
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk		Not Reported
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Stelara	S	Unknown	Unk		Not Reported
	Leflunomide	C				Not Reported
	Salazopyrin	C				Not Reported
	Atasol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16054264	EXPEDITED (15-DAY)		HO	DE-ABBVIE-19K-062-2668618-00		67 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foot Deformity	Humira			S	Subcutaneous			Not Reported
	Chloroquine Phosphate\Hydroxychloroquine Sulfate\Quinacrine Hydrochloride			S	Unknown			Not Reported
	Chloroquine Phosphate\Hydroxychloroquine Sulfate\Quinacrine Hydrochloride			S	Unknown	Between 2012 And 2013		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16081543	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023040		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Doxycycline Hyclate			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline			S	Unknown			Actavis

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown	23 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	25 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	24 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
	Tylenol 8 Hr Arthritis	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16479452	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-457		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure; Hypercalcaemia; Lymphoproliferative Disorder; Off Label Use	Methotrexate			S	Unknown			Westward
	Methotrexate			S				Westward
	Hydroxychloroquine			S	Unknown			Westward
	Mycophenolate Mofetil			S	Unknown			Westward

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16533198	NON-EXPEDITED			US-PFIZER INC-2019283369		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Feeling Abnormal	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Methotrexate Sodium			S				Pfizer

	Humira	S	Unk		Not Reported
	Humira	S			Not Reported
	Plaquenil	S	Unk		Not Reported
	Plaquenil	S			Not Reported
	Arava	C	Unk		Not Reported
	Prednisone	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16623470	EXPEDITED (15-DAY)		OT	US-SA-2019SA196907		59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Off Label Use	Mycophenolate Mofetil			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Sanofi
	Dupilumab			S		Unk		Sanofi
	Azathioprine			S	Oral			Not Reported
	Prednisone			C				Not Reported
	Cyclosporine			C	Oral			Not Reported
	Thalidomide			C	Oral			Not Reported
	Tacrolimus			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16649758	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2872126-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16651300	EXPEDITED (15-DAY)		OT	CA-SA-2019SA201463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Prednisone			S	Oral	Unk Unk, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	Unk Unk, Qd		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk Unk, Qw		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Zoloft			C				Not Reported
	Levofloxacin			C				Not Reported
	Lyrica			C				Not Reported
	Acyclovir [Aciclovir]			C		Unk		Not Reported
	Amitriptyline			C	Oral	25 Mg, Qd		Not Reported
	Constella			C	Oral	145 Mg, Qd		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Oral	Unk Unk, Qd, Prn		Not Reported
	Aerius [Ebastine]			C	Oral	Unk Unk, Prn		Not Reported
	Zopiclone			C	Oral	Half To 1 Tablet Prn		Not Reported
	Zomig			C	Oral	Unk Unk, Prn		Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671788	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1087139			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Drug Ineffective; Respiratory Tract Infection	Methotrexate	S	Unknown			Barr
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Pneumococcal Conjugate Vaccine	S	Unknown			Not Reported
	Pneumococcal Polysaccharide Vaccines	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671796	NON-EXPEDITED		OT	US-TEVA-2019-US-1087231		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia	Methotrexate			S	Oral	7.5 Mg Weekly		Barr
	Plaquenil			S	Oral	400 Milligram Daily; 200 Mg Twice Daily		Not Reported
	Prednisone			C	Oral			Not Reported
	Folate			C	Oral			Not Reported
	Hydrocortisone Butyrate			C	Topical	Applied On Affected Areas Of The Face		Not Reported
	Triamcinolone Acetonide			C	Topical	Applied To Affected Skin And Trunk		Not Reported
	Fluocinonide Acetonide			C	Topical	Applied On Scalp		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671862	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported

	Orencia			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671863	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211511		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Enbrel			S				Not Reported
	Etanercept			S				Not Reported
	Remicade			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671866	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211523		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Plaquenil			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Orencia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported

Xeljanz	C	Oral	5 G, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671893	EXPEDITED (15-DAY)		OT	CA-SA-2019SA212273		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Risedronate Sodium			S		35 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Leflunomide			S		1 Df, Qd		Sanofi
	Hydroxychloroquine			S		1 Df, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671924	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086592		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671935	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1086742			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671944	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1087069		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S		20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	C		2 Gram Daily;		Not Reported
	Wellbutrin	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16671957	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2647			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672025	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1086090		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)	.2857 Mg/Kg Daily; 8 Mg/Kg 1 Every 4 Weeks		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade			S	Oral	3 Mg/Kg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672486	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085349		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672500	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086200		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr

	Methotrexate		S	Subcutaneous	Barr
	Orencia		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Etanercept		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Tofacitinib		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672583	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085340		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672640	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210655		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Meloxicam			C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672650	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211008		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S		8 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672651	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210489		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Intentional Product Misuse; Musculoskeletal Disorder; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil	S				Sanofi
	Leflunomide	S				Sanofi
	Sulfasalazine	S				Not Reported
	Enbrel	S		1 Df, Qw		Not Reported
	Enbrel	S		1 Df, Qow		Not Reported
	Enbrel	S		1 Df, Qw		Not Reported
	Methotrexate	C				Not Reported
	Naprosyn E	C		2 Df, Qd		Not Reported
	Prednisone	C		7.5 Mg, Qd		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672657	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672658	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		1 Df, Qd (400 Mg)		Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported

Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide	S		20 Mg, Qd	Sanofi
	Arava	S	Oral	20 Mg, Qd	Sanofi
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Sanofi
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira	S			Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Actemra	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tylenol [Paracetamol]	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672660	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA211386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S		200 Mg		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab	S		Unk		Not Reported
	Arava	C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Mg, Bid		Not Reported
	Prednisone	C		Unk		Not Reported
	Simponi	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16672665	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Hydroxychloroquine			S		Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Cosentyx			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16673502	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211176		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Arthroplasty; Arthralgia; Drug Ineffective; Hip Arthroplasty; Knee Arthroplasty; Pain In Extremity; Peripheral Swelling; Psoriasis	Plaquenil			S				Sanofi
	Sodium Aurothiomalate			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S				Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16673503	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210715		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Apo-Prednisone			S		5 Mg		Not Reported
	Leflunomide			S				Sanofi
	Plaquenil			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S		1 G, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16673506	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211541			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16673508	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine			S		300 Mg		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16673709	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019334533		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674095	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086106		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Estrace			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Oral			Not Reported
	Cymbalta			C	Unknown	120 Milligram Daily;		Not Reported
	Altace			C				Not Reported
	Altace			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Oral	40 Milligram Daily;		Not Reported
	Atorvastatin Calcium			C	Oral			Not Reported

	Gabapentin		C	Unknown		Not Reported
	Gabapentin		C	Oral		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Hydrochlorothiazide		C	Oral		Not Reported
	Tapentadol		C	Unknown		Not Reported
	Tramacet		C	Unknown		Not Reported
	Tramadol Hydrochloride		C	Oral		Not Reported
	Hydromorphone Hydrochloride		C			Not Reported
	Mupirocin Calcium Dihydrate		C	Topical		Not Reported
	Prednisone		C	Oral		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Oral	15 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674410	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085355			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674411	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085346		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674421	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085367			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methylprednisolone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Synovitis	Arava	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Rituxan	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674442	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1086133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674443	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086192		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674444	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085820		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; X-Ray Abnormal	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674501	NON-EXPEDITED			US-TEVA-2019-US-1087212		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Live Birth; Maternal Exposure During Pregnancy	Cefuroxime			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674523	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S		50 Mg		Not Reported
	Plaquenil			S		400 Mg		Sanofi
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			C				Not Reported
	Amoxil [Amoxicillin]			C				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Bcg			C	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C				Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674533	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086589			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy;	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr

Rheumatoid Factor Positive	Enbrel			S	Subcutaneous		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674536	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1086689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Oral	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674556	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211546		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Therapeutic Product Effect Decreased	Plaquenil	S	Unknown			Sanofi
	Arava	S	Oral	20 Mg, Qd		Sanofi
	Actemra	S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Meloxicam	C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674564	EXPEDITED (15-DAY)		CA, OT	CA-PFIZER INC-2012007043		28 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Cleavage Syndrome; Exposure During Pregnancy	Methotrexate Sodium			S	Transplacental	15 Mg, Weekly		Unknown
	Hydroxychloroquine			S	Transplacental	400 Mg, Daily		Not Reported
	Folic Acid			C	Transplacental	5 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674640	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086855		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674641	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086879		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Latent Tuberculosis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C		5 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Oral	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Oral	400 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674689	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2019-CA-1086897		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	5.7143 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674700	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyneuropathy	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate			C	Unknown				Not Reported
	Methotrexate			C	Unknown				Not Reported
	Orencia			C	Unknown				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674701	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086692		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674702	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086680		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir	C	Unknown		Not Reported
	Tenofovir Disoproxil	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674703	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086059		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

	Desoximetasone	S	Oral			Not Reported
	Desoximetasone	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Oral	200 Milligram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674726	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674747	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Plaquenil		S	Oral	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Gold		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674749	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086677		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674769	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086602		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Apo-Hydroxyquine			S	Unknown			Not Reported

Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Not Reported
	Etanercept			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Rituximab Gp2013			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Xeljanz			C		Not Reported
	Actemra			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16674921	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2019-US-1087263		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Interaction; Infection; Neutropenia; Propionibacterium Infection; Staphylococcal Infection	Methotrexate			S	Oral	Methotrexate Had Been On Hold For 3 Weeks Later		Barr
	Prednisone			S	Oral			Actavis
	Hydroxychloroquine			S	Oral			Teva
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Diazepam			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Ibuprofen			C	Unknown	As Needed		Not Reported
	Hydrocodone-Acetaminophen			C	Unknown	As Needed		Not Reported
	Omeprazole			C	Unknown			Not Reported
	Sulindac			C	Unknown	200 Mg Twice		Not Reported
	Acetaminophen			C	Unknown	As Needed		Not Reported
	Venlafaxine			C	Unknown			Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)			Not Reported

	Cefazolin			C	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675365	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086063		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Prednisone			C	Oral	50 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675366	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Leflunomide	S	Oral	20 Milligram Daily;		Barr
	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	C				Not Reported
	Wellbutrin	C	Oral			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675367	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086050		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre- Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Baclofen	C	Unknown			Not Reported
	Calcium	C	Unknown	500 Milligram Daily;		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Estradiol	C	Unknown	1.8 Percent Daily;		Not Reported
	Estrogel	C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide	C	Unknown	40 Milligram Daily;		Not Reported
	Gravol	C	Unknown			Not Reported
	Levaquin	C	Unknown			Not Reported
	Morphine	C	Unknown			Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan	C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan	C	Ophthalmic	50 Microgram Daily;		Not Reported
	Zingiber Officinale	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675368	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086554		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Desoximetasone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675385	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086590		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2367326		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675584	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086547			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675590	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086635		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Pantoprazole Sodium			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumurate			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumurate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zoplicone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675592	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086657		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Leflunomide	S	Oral	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675608	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086552			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675609	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086551		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675616	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086514		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arrhythmia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sarilumab			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675617	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086515			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Arthrotec			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Mefenamic Acid			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675618	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086561		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported

			Gabapentin			C	Oral				Not Reported
			Nitroglycerin			C					Not Reported
			Rosuvastatin Calcium			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Aug-2019	16675621	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016300		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Fatigue; Nausea; Nodule; Prostate Cancer; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aspirin/00002701/			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Iron			C				Not Reported
	Aspirin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	12911487	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091512		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Back Pain; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Inability; Glaucoma; Hand Deformity; Hepatic	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Enzyme Increased; Hypersensitivity; Hypertension; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Pneumonia; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, 2 Every 1 Week	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Calcium	C	Unknown	500 Mg, Qd	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Tiaprofenic Acid	C	Unknown	300 Milligram, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Estrogel	C	Unknown	0.6 Percent, Tid	Not Reported
	Estrogel	C	Unknown	Unk, Qd	Not Reported
	Furosemide	C	Unknown	40 Mg, Qd	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
	Valsartan	C	Unknown	320 Mg, Qd	Not Reported
	Xalatan	C	Unknown	50 Mg, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Aspirin /00002701/	C	Unknown	81 Milligram, Qd	Not Reported
	Estradiol	C	Unknown	Unk Unk, Tid	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15711405	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2587088-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15796563	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995681		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

Vitamin D /00107901/	C	Unknown	4000 Iu (International Unit) Daily;	Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
Ergocalciferol	C	Unknown	4000 Iu (International Unit) Daily;	Not Reported
Ergocalciferol	C		4000 Iu (International Unit) Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15931083	EXPEDITED (15-DAY)		HO, LT, OT	NL-BAUSCH-BL-2019-003596		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Drug Ineffective; Lupus Nephritis; Myocarditis; Renal Tubular Necrosis; Respiratory Failure	Prednisolone			S	Unknown			Bausch And Lomb
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15932700	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655933-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Surgical Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

					Plaquenil		S	Unknown		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Mobicox		C	Unknown		Not Reported
					Remicade		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15935524	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657198-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Infection; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15941786	EXPEDITED (15-DAY)		HO	CA-ABBVIE-19K-028-2658866-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	15998003	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2676309-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16022960	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-021390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16262841	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2764855-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16528545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2013175727		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Constipation; Eye Disorder; Herpes Zoster; Nasopharyngitis; Pain; Pulmonary Fibrosis; Upper	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer

Respiratory Tract Infection	Enbrel	S	Subcutaneous	50 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Fentanyl	C		Unk, Patch	Not Reported
	Tylenol W/Codeine No. 3	C		Unk	Not Reported
	Lipitor	C		Unk	Not Reported
	Irbesartan	C		300 Mg, 1 Tablet Per Day	Not Reported
	Irbesartan	C		300 Mg, Unk	Not Reported
	Asa	C		81 Mg, Unk	Not Reported
	Amlodipine	C		5 Mg, Q	Not Reported
	Dexilant	C		60 Mg, Qd	Not Reported
	Vitamin B Complex	C		Unk	Not Reported
	Cranberry	C		Unk	Not Reported
	Senokot	C		Unk	Not Reported
	Pantoprazole	C		40 Mg, Qd	Not Reported
	Atorvastatin	C		10 Mg, Qd	Not Reported
	Duragesic	C		Unk	Not Reported
	Tears Naturale	C	Ophthalmic	Unk	Not Reported
	Eurofer	C		300 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C		Unk	Not Reported
	Acetaminophen W/Codeine Phosphate	C			Not Reported
	Duragesic Mat	C	Unknown		Not Reported
	Calcium D-Pantothenate	C		Unk	Not Reported
	Nicotinamide	C		Unk	Not Reported
	Pyridoxine Hydrochloride/Riboflavin/Thiamine Hydrochloride	C		Unk	Not Reported
	Dextran 70/Hypromellose	C	Ophthalmic	Unk	Not Reported
	Methotrexate Sodium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16657848	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019032032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine Hydrochloride]			S		Unk		Not Reported
	Tocilizumab			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Ucb
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Ucb
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16669953	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-073641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Triamcinolone Acetonide		S	Unknown	Unk	Bristol Myers Squibb
	Actemra		S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Enbrel		S	Subcutaneous	12.5 Milligram	Not Reported
	Enbrel		S	Subcutaneous	25 Milligram	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	5 Milligram, Qd	Not Reported
	Immune Globulin, Intravenous		S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab		S	Unknown		Not Reported
	Kineret		S	Subcutaneous	50 Milligram, Qd	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram/Sq. Meter, Qd	Not Reported
	Naproxen		S	Unknown	Unk	Not Reported
	Prednisone		S	Oral	5 Milligram, Bid	Not Reported
	Prednisone		S	Oral	3 Milligram, Bid	Not Reported
	Sulfasalazine		S	Oral	250 Milligram, Qd	Not Reported
	Infliximab		S	Unknown	5 Milligram	Not Reported
	Infliximab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16675883	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-216487		60 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Bisoprolol			S	Oral	5 Milligram, Daily		Sun
	Lansoprazole			S	Oral	15 Milligram, Daily		Sun
	Ramipril			S	Oral	5 Milligram, Daily		Ranbaxy
	Spironolactone			S	Oral	25 Milligram, Daily		Sun

	Plaquenil 200 Mg, Comprime Pellicule	S	Oral	3 Dosage Form, Daily	Not Reported
	Tardyferon 80 Mg, Comprime Enrobe	S	Oral	2 Dosage Form, Daily	Not Reported
	Doxycycline	S	Oral	200 Milligram, Daily	Not Reported
	Coumadine	S	Oral	5 Mg Et 6 Mg 1 Jour Sur 2 ()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676001	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Hepatotoxicity	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676096	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2877291-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Hearing Aid User; Joint Swelling; Mobility Decreased; Pain; Pruritus; Therapeutic Product Effect Decreased; Urticaria	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2367325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tylenol [Paracetamol]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676405	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086741		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Depo-Medrol	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Oral	1 Gram Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676426	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086771		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Anakinra			S	Subcutaneous			Not Reported

	Apo-Azathioprine	S	Oral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Kineret	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676467	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2877135-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Not Reported
	Actemra			S	Unknown					Not Reported
	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676497	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676517	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrochlorothiazide			S	Unknown			Ivax
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676739	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA210500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Cosentyx			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	520 Mg		Not Reported
	Otezla			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676740	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Plaquenil			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Naproxen			C		500 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676741	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA210667		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Leflunomide			S		1 Df, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			S	Oral	25 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Indomethacin [Indometacin]			S				Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			C	Oral	30 Mg, Qd		Not Reported
	Folic Acid			C	Oral	Unk Unk, Qw		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676768	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211485		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported

	Cimzia			S	Subcutaneous				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676769	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210855		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Shoulder Operation; Swelling; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676770	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Abatacept			S				Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S				Not Reported

	Gold	S				Not Reported
	Rituximab	S		Unk		Not Reported
	Amitriptyline	C				Not Reported
	Clindamycin	C				Not Reported
	Cefazolin	C				Not Reported
	Prednisone	C		10 Mg		Not Reported
	Tylenol [Paracetamol]	C				Not Reported
	Xeljanz	C	Oral	5 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676771	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210793		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Hydromorphone			S	Oral	12 Mg, Qd		Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			S	Oral			Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676773	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211013			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Folic Acid	C	Oral	2.5 Mg, Qd	Not Reported
	Methotrexate	C	Oral	10 Mg, Qw	Not Reported
	Methotrexate	C	Oral	15 Mg, Qw	Not Reported
	Pantoprazole	C			Not Reported
	Pantoprazole Magnesium	C	Oral	40 Mg, Qd	Not Reported
	Tenofovir Disoproxil	C			Not Reported
	Tenofovir Disoproxil Fumarate	C		300 Mg	Not Reported
	Xeljanz	C			Not Reported
	Zopiclone	C		7.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676774	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Plaquenil			S				Sanofi
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituxan			S		500 Mg		Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676813	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208769		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Unevaluable Event	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C		500 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16676823	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Liver Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Diclofenac Sodium			S				Not Reported
	Pantoprazole Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677188	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086931			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Plaquenil		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677440	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086129		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil/00002202/			C	Unknown			Not Reported

	Elavil/00002202/	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex/01044801/	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677629	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211395		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine			S		100 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16677636	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210777		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood	Hydroxychloroquine			S				Sanofi
	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi

Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Unevaluable Event; Weight Increased	Methotrexate	S			Not Reported
	Naproxen	S			Not Reported
	Sulfasalazine	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	624 Mg, Q4w	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	680 Mg, Q4w	Not Reported
	Anakinra	S			Not Reported
	Etanercept	S			Not Reported
	Infliximab	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	624 Mg, Q4w	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	680 Mg, Q4w	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine Hydrochloride	C	Oral		Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Naprosyn [Naproxen]	C			Not Reported
	Oxycontin	C			Not Reported
	Oxyneo	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16678223	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA210697		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate	S		400 Mg	Sanofi
	Actemra	S			Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Sanofi
	Naproxen	S			Not Reported
	Prednisone	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	C			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	C			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16678681	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210533		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia	Hydroxychloroquine			S	Unknown			Sanofi
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Qw		Not Reported
	Arava			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

	Prednisone			C	Oral	5 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16678685	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210958		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Hot Flush; Nausea; Rhinorrhoea; Sinus Congestion	Plaquenil			S		200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16678752	EXPEDITED (15-DAY)		OT	TW-BAUSCH-BL-2019-021884			Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Uveitis	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	Dose Gradually Declined Over 1 Year		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679185	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086883		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities;	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679255	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1087329		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Fatigue; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; No Adverse Event; Overwork; Peripheral Swelling; Poor Quality Sleep; Temperature Intolerance; Therapeutic Product Effect Incomplete; Vomiting	Hydromorphone			S	Oral	12 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S	Oral			Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679256	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086874		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679258	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086885		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic	Leflunomide			S	Unknown			Barr

Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679379	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086655		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Ineffective; Hepatic Enzyme Increased	Leflunomide			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Actemra			C	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Varenicline Tartrate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679579	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1088057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab Gp2013			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone (Mah Unknown)			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679599	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1088415		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram Daily;		Barr
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

					Anakinra	S	Subcutaneous	100 Milligram Daily;	Not Reported
					Enbrel	S	Subcutaneous		Not Reported
					Humira	S	Subcutaneous		Not Reported
					Hydroxychloroquine	S	Unknown	200 Milligram Daily;	Not Reported
					Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679900	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086678		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16679986	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086641			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Diclofenac Sodium/Misoprostol			S	Unknown			Actavis
	Diclofenac Sodium/Misoprostol			S	Unknown	100 Milligram Daily;		Actavis
	Diclofenac Sodium/Misoprostol			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Simponi		S	Unknown		Not Reported
	Arthrotec		C		100 Milligram Daily;	Not Reported
	Gold		C			Not Reported
	Imuran		C			Not Reported
	Vitamin D3		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680265	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086970			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Pencillin G			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pregabalin			C				Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680286	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086979			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Methotrexate		S	Unknown	Barr
	Leflunomide		S	Oral	Teva
	Penicillin G		S	Unknown	Not Reported
	Aspirin		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Oral	Not Reported
	Pregabalin		C	Unknown	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680292	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1087102			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Leflunomide			S	Oral			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Penicillin G			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Pregabalin			C				Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2019	16680306	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086976		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral	1.4286 Milligram Daily;	Barr
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram Daily;	Not Reported
	Folic Acid	C	Oral	2.5 Milligram Daily;	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
	Zopiclone	C	Unknown	7.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	13167152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016260289		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug Ineffective; Drug Intolerance; Retinopathy	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Plaquenil /00072603/			S		200 Mg, 2x/Day		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Arava			S		10 Mg, Daily		Not Reported
	Arthrotec			S		50 Mg/200ug, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	14282167	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2017527846		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epiglottitis; Infection; Swelling	Tofacitinib Citrate			S	Oral	10 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported
	Nitrofurantoin			C	Unknown	50 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	14371446	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Drug Intolerance; Glaucoma; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Osteoarthritis; Pain; Rheumatoid Arthritis; Sinusitis; Therapeutic Product Effect Decreased; Treatment Failure; Vertigo	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Unk, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Cortisone			S	Unknown	Unk		Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown	7.5 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	15875858	EXPEDITED (15-DAY)		HO	PHHY2019DE014240			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Non-Cardiac Chest Pain	Erelzi			S	Subcutaneous	50 Mg, Qmo		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qmo		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qmo		Novartis
	Methotrexate			S	Unknown	7.5 Mg, Qmo		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16271237	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2015-022272		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Topicort			S	Cutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral	Dosage Form Unspecified		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Apo Hydroxyquine	S	Subcutaneous		Not Reported
	Fosamax	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	As Needed	Not Reported
	Humira	S	Subcutaneous	Pre-Filled Syringe Solution Subcutaneous	Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe Solution Subcutaneous	Not Reported
	Methotrexate Sodium	S	Oral	Permanently Withdrawn	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 365 (Unspecified)	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Duration 365 (Unspecified)	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Topicort	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone	S	Unknown	Prn	Not Reported
	Sulfathalidine	S	Unknown		Not Reported

	Cimzia	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16655160	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202952		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Treatment Failure	Hydroxychloroquine			S	Oral			Sanofi
	Hydroxychloroquine			S	Subcutaneous	Unk		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Tablet		Not Reported
	Methotrexate			S	Unknown	Unk, Solution		Not Reported
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16671752	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA210753		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Cosentyx			S				Not Reported
	Enbrel			S				Not Reported
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Naprosyn E			C				Not Reported
	Sulfasalazine			C		500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16680882	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2680		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681028	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086773		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Diclofenac Sodium/Misoprostol			S	Unknown	100 Milligram Daily;		Actavis

Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Leflunomide	S	Unknown		Barr
	Leflunomide	S	Unknown		Barr
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown	100 Milligram Daily;	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Imuran [Azathioprine]	C	Unknown		Not Reported
	Vitamin D [Colecalciferol]	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681029	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C		500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681049	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr

	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C				Not Reported
	Xeljanz	C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681486	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211006		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Plaquenil			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Arava			S				Sanofi
	Xeljanz			S	Oral	2.5 Mg, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Actemra			S	Unknown				Not Reported
	Enbrel			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681489	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210548			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Clarithromycin			S				Not Reported
	Ciprofloxacin Salt Not Specified			S				Not Reported
	Clindamycin, Salt Not Specified			S				Not Reported
	Codeine			S				Not Reported
	Enalapril Maleate			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Isoniazid			S				Not Reported
	Methotrexate			S	Subcutaneous	10.0 Mg, Qw		Not Reported
	Levofloxacin			S				Not Reported
	Rabeprazole Sodium			S				Not Reported
	Cefalexin			S				Not Reported
	Losartan Potassium			S				Not Reported
	Moxifloxacin Hydrochloride			S				Not Reported
	Enbrel			S				Not Reported
	Fosamax			S				Not Reported
	Penicillin [Penicillin Nos]			S				Not Reported
	Pantoprazole Magnesium			S				Not Reported
	Lopresor [Metoprolol Succinate]			S				Not Reported
	Celebrex			S				Not Reported
	Cipro [Ciprofloxacin Hydrochloride]			C				Not Reported
	Esomeprazole			C				Not Reported
	Gold			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Iron Sucrose			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681763	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681764	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Pregabalin			C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681834	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210699		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Methotrexate	S	Oral	10 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	162 Mg	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681837	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211009		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	300 Mg, Qd		Sanofi
	Risedronate Sodium			S	Unknown	35 Mg, Qw		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qh		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Enbrel	S	Subcutaneous	50 Mg		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681840	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S				Sanofi
	Plaquenil			S				Sanofi
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16681859	EXPEDITED (15-DAY)		OT	CA-SA-2019SA212189		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Methotrexate			S				Not Reported
	Risedronic Acid			S		35 Mg, Qw		Not Reported
	Hydroxychloroquine Sulfate			S		1 Df, Qd		Sanofi
	Leflunomide			S		1 Df, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	1 Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682214	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210744		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Mg		Not Reported

Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Anakinra		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682215	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210983		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid [2 Every 1 Day(S)]		Sanofi
	Prednisone			S	Oral	5 Mg, Qd [1 Every 1 Day(S)]		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid [2 Every 1 Day(S)]		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw [1 Every 1 Week(S)]		Not Reported
	Arava			S	Unknown	20 Mg, Qd [1 Every 1 Day(S)]		Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Solution		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682216	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211527		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood	Plaquenil			S				Sanofi
	Amlodipine Besilate			S	Oral	5 Mg, Qd		Not Reported

Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate	S	Oral	Unk	Not Reported
	Asacol	S		800 Mg, Tid	Sanofi
	Gliclazide	S			Not Reported
	Gliclazide	S			Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Leflunomide	S			Sanofi
	Amlodipine Besilate	S	Oral	Unk Unk, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Orencia	S			Not Reported
	Acetaminophen	C	Oral	650 Mg	Not Reported
	Amlodipine Besilate	C			Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Crestor	C			Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Diphenhydramine	C	Oral	50 Mg	Not Reported
	Ebastine	C			Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Tylenol [Paracetamol]	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682231	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086774		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086764		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Prednisone			C	Unknown	12 Milligram Daily;		Not Reported
	Prednisolone			C	Unknown			Not Reported

	Penicillamine	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682481	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019338612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Methotrexate Sodium			S	Unknown	15 Mg, Weekly (1 Every 1 Week)		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Folate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 2x/Day		Not Reported
	Prednisone			S	Unknown	Weekly (1 Every 1 Week)		Not Reported
	Prevacid			C		Unk		Not Reported
	Actonel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2369616		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration-730		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682773	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086786		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Gold			C				Not Reported
	Imuran			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16682838	EXPEDITED (15-DAY)		OT	PHHY2019US179546		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maculopathy; Retinal Injury	Hydroxychloroquine		S	Unknown		Novartis
	Chloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16683237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086830		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16683284	EXPEDITED (15-DAY)		OT	CA-SAOL THERAPEUTICS-2019SAO00311		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid	Winrho Sdf			S				Saol Therapeutics
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, 2x/Week		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	15 Mg, 1x/Week		Not Reported
	Sulfasalazine			S	Oral			Not Reported

Arthritis; Therapy Non-Responder; Treatment Failure	Tofacitinib		S	Subcutaneous	5 Mg, 2x/Week	Not Reported
	Celebrex		C	Oral	400 Mg	Not Reported
	Ibuprofen		C			Not Reported
	Lipitor		C	Oral	10 Mg, 1x/Week	Not Reported
	Prednisone		C			Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16683285	EXPEDITED (15-DAY)		HO, OT	CA-SAOL THERAPEUTICS-2019SAO00307		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Varicella Zoster Immune Globulin			S	Intramuscular			Saol Therapeutics
	Actemra			S				Not Reported
	Arava			S		20 Mg, 1x/Day; 1 Every 24 Hours		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Isoniazid			S				Not Reported
	Methotrexate			S	Subcutaneous	Unk, 1x/Week		Not Reported
	Myochrysine			S	Intramuscular	50.0 Mg, 1x/Week		Not Reported
	Plaquenil			S	Oral	200.0 Mg, 1x/Day; 1 Every 24 Hours		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Remicade			S		200.0 Mg		Not Reported
	Sulfasalazine			S	Oral	2000.0 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16683286	EXPEDITED (15-DAY)		HO, OT	CA-SAOL THERAPEUTICS-2019SAO00308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal;	Rho D Immune Globulin			S				Saol Therapeutics

Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Therapy Non-Responder; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride	S				Not Reported
	Boric Acid	S				Not Reported
	Disodium Edetate	S				Not Reported
	Enbrel	S	Subcutaneous	50 Mg, 1x/Week		Not Reported
	Humira	S	Subcutaneous	40 Mg; 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine	S				Not Reported
	Phenylephrine Hydrochloride	S				Not Reported
	Sodium Borate	S				Not Reported
	Tofacitinib	S				Not Reported
	Celebrex	C				Not Reported
	Ibuprofen	C				Not Reported
	Lipitor	C				Not Reported
	Methotrexate	C	Oral	15 Mg, 1x/Week		Not Reported
	Prednisone	C				Not Reported
	Sulfasalazine	C	Oral			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16683785	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2882264-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16683857	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684016	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086843		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Stress	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

			Sulfasalazine		S	Unknown				Not Reported
			Marijuana		C	Unknown				Not Reported
			Celebrex		C	Unknown				Not Reported
			Ergocalciferol		C	Unknown				Not Reported
			Risedronate		C	Unknown				Not Reported
			Wellbutrin		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684023	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086789		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Aug-2019	16684769	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Drug Dependence; Drug Ineffective; Fall; Fatigue; Headache; Incorrect Route Of Product Administration; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Infliximab			S	Oral			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown	Unknown		Not Reported
	Dexamethasone			C	Unknown	Unknown		Not Reported
	Gabapentin			C	Unknown	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	12328981	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054202		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Enzyme Increased	Enbrel		S	Subcutaneous	Unk	Amgen
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Cimzia		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	5 Milligram	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Apo-Prednisone		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	12540829	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016087584		87 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Disease Recurrence; Drug Ineffective; Heart Rate Increased; Joint Arthroplasty; Macular Degeneration; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Aspirin			C	Unknown	81 Milligram, Qd		Not Reported
	Tylenol			C	Oral	Unk, Qd		Not Reported
	Arava			C	Oral	10 Milligram, Bid		Not Reported
	Lucentis			C		Unk Unk, Qmo		Not Reported

	Acetylsalicylic Acid			C		Unk			Not Reported
	Tylenol Arthritis Pain			C	Oral	3 Dosage Form, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	12764900	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076339		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Pain; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	3 Dosage Form		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	12775137	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-014207			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; Off Label Use; Respiratory Arrest; Visual Impairment	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Celebrex			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported

					Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic	Not Reported
					Sulfasalazine	S	Oral	1 G, Bid	Not Reported
					Arava	S	Unknown		Not Reported
					Celecoxib	S	Oral		Not Reported
					Etanercept	S	Subcutaneous	50 Milligram, Qwk	Not Reported
					Prednisone	S	Unknown		Not Reported
					Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	12945677	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016157990		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, Q8wk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

					Xeljanz		S	Unknown	Unk	Not Reported
					Apo-Leflunomide		S	Unknown	Unk	Not Reported
					Infliximab		S	Intravenous (not otherwise specified)	400 Mg, Unk	Not Reported
					Rituxan		C	Unknown	Unk	Not Reported
					Prednisone		C	Unknown	Unk	Not Reported
					Naproxen		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	14921136	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056462		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15319529	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003037		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Missed; Exposure During Pregnancy	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prograf			C				Not Reported
	Predonine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15325105	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201808-003068			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Neoral			C				Not Reported
	Cellcept			C				Not Reported
	Nexium 1-2-3			C				Not Reported
	E Keppra			C				Not Reported
	Baktar			C				Not Reported
	Singulair			C				Not Reported
	Bonalon			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15707100	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-18K-028-2585732-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Anakinra	S	Unknown			Not Reported
	Anakinra	S				Not Reported
	Arava	S	Unknown			Not Reported
	Arava	S				Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Ilaris	S	Unknown	Single-Use Vial		Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S				Not Reported
	Sodium Aurothiomalate	S	Intramuscular			Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15760997	NON-EXPEDITED			US-PFIZER INC-2018522388		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Doxycycline Hyclate			S		Unk		Pfizer
	Fluconazole			S		Unk		Pfizer

	Methotrexate Sodium	S	Unk	Pfizer
	Cyclosporin	S	Unk	Not Reported
	Isotretinoin	S	Unk	Not Reported
	Hydroxychloroquine	S	Unk	Not Reported
	Niacinamide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15940310	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-19K-028-2658630-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade			S					Not Reported
	Rituxan			S	Unknown				Not Reported
	Rituxan			S					Not Reported
	Sodium Aurothiomalate			S	Intramuscular				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	15941775	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-19K-028-2658994-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Single Use Vial		Not Reported
	Ilaris			S	Subcutaneous	Single Use Vial		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16110332	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201903-000763		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Kevzara			S	Subcutaneous	200 Mg/1.14ml, Delivered Via Sarilumab Prefilled Syringe		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16360953	EXPEDITED (15-DAY)		HO, LT, OT	MX-UCBSA-2019021970		19 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Altered State Of Consciousness; Asthenia; Dizziness; Drug Interaction; Impulsive Behaviour; Irritability; Major Depression; Nausea; Suicidal Ideation; Suicide Attempt	Keppra	S	Unknown Dose	Not Reported
	Hydroxychloroquine	S	Unknown Dose	Not Reported
	Lamotrigine	S	Unknown Dose	Not Reported
	Lamotrigine	S		Not Reported
	Phenobarbital	S	Unknown Dose	Not Reported
	Prednisone	S	Unknown Dose	Not Reported
	Valproate Magnesium	S	Unknown Dose	Not Reported
	Valproate Magnesium	S		Not Reported
	Warfarin	S	Unknown Dose	Not Reported
	Azathioprine	C	Unknown Dose	Not Reported
	Calcium	C	Unknown Dose	Not Reported
	Vitamin D	C	Unknown Dose	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16671743	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA210567		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Plaquenil			S				Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		10 Mg		Not Reported

		Prednisone			C					Not Reported
		Prednisone			C		5 Mg, Qd			Not Reported
		Prednisone			C					Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685410	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209004			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685413	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208867			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685418	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210630		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Fatigue; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Poor Quality Sleep; Temperature Intolerance; Therapeutic Product Effect Incomplete; Vomiting	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Hydromorphone			S	Oral	12.0 Mg, Qd		Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685420	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Eye Disorder;	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi

Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S	Unknown	Unk Unk, Unk	Sanofi
	Sulfasalazine	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Golimumab	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Orencia	S	Unknown	Unk Unk, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Prednisone	C	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685426	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S		2.5 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	25 Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Infliximab			S		25 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16685427	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA210798		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S				Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686491	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	600 Mg, Qw		Sanofi
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Folic Acid			C	Unknown	1 Df, Qw		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C	Unknown	Unk Unk, Unk		Not Reported

Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz	C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686598	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-07274		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypertensive Crisis; Posterior Reversible Encephalopathy Syndrome	Mycophenolate Mofetil			S	Oral	1500 Milligram, Bid		Alkem
	Azathioprine			S	Oral	25 Milligram, Od		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			S	Oral	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686698	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209094		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Pregabalin			S	Oral	Unk Unk, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Gold			S		Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Cellcept [Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported

	Hydrochloride]								
	Enbrel			S	Unknown	Unk Unk, Unk			Not Reported
	Orencia			S	Unknown	Unk Unk, Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk			Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686957	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1088773		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Joint Swelling; Pain In Extremity; Weight Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Dexilant			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16686959	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089078			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687388	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1087620		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Hydromorphone			S	Oral	12 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Percocet			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	2 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687482	EXPEDITED (15-DAY)		LT	CA-PFIZER INC-2019340990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective;	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

Therapeutic Response Decreased	Actemra	S	Unk		Not Reported
	Adalimumab	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported
	Rituximab	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687955	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086681		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687956	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208777		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis	Leflunomide	S	Unknown	20 Mg		Sanofi
	Methotrexate	S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg		Sanofi
	Sulfasalazine	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	200 Mg		Not Reported
	Enbrel	S	Unknown	50 Mg		Not Reported
	Varenicline Tartrate	S	Oral	1 Df, Qw		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Oxycodone Hydrochloride	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Unknown			Not Reported
	Valtrex	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687959	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210731		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Rosuvastatin Calcium			S	Oral	5 Mg, Bid		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported

Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Skin Ulcer; Swelling; Treatment Failure	Sodium Aurothiomalate	S	Intramuscular			Not Reported
	Actemra	S	Unknown			Not Reported
	Apo-Azathioprine	S				Not Reported
	Azathioprine	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Cephalexine	C	Unknown	500 Mg, Qid		Not Reported
	Methotrexate	C				Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687971	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S				Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported

Cimzia	S			Not Reported
Diclofenac Sodium And Misoprostol	S		50 Mg, Bid	Not Reported
Diclofenac Sodium And Misoprostol	S		Unk	Not Reported
Diclofenac Sodium And Misoprostol	S		Unk	Not Reported
Enbrel	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Actemra	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Rituxan	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Simponi	S	Subcutaneous	Solution	Not Reported
Simponi	S			Not Reported
Arthrotec	C		50 Mg, Bid	Not Reported
Vitamin D3	C			Not Reported
Imuran [Azathioprine]	C			Not Reported
Gold	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687979	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210538		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Drug Ineffective; Fatigue; Nausea; Nodule; Prostate Cancer; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Aspirine			C	Unknown	81.0 Mg, Unk		Not Reported
	Iron			C	Unknown	Unk Unk, Unk		Not Reported
	Meloxicam			C	Unknown	Unk Unk, Unk		Not Reported

	Meloxicam			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16687986	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Synovitis	Plaquenil			S		400 Mg, Qd		Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Methotrexate			S		20 Mg, Q4w		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16688138	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16688785	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019338998		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16688856	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16688888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2368265		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Swelling; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Therapy Duration-2 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration- 3 Years		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	Therapy Duration-275		Not Reported

	Xeljanz	C	Oral	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16689253	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2019340995			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Methotrexate Sodium			S	Oral	Unk Unk, Weekly		Pfizer
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk Unk, 4x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16689325	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1087599		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Fatigue; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Poor Quality	Hydromorphone			S	Oral	12 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Sleep; Temperature Intolerance; Therapeutic Product Effect Incomplete; Vomiting	Plaquenil	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16689347	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA210592			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Celecoxib			S				Not Reported
	Methotrexate			S		1 Ml, Qw		Not Reported
	Prednisone			S		7 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S		Unk		Not Reported
	Gold			S				Not Reported
	Anakinra			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16689864	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1088771		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram Daily;		Not Reported
	Prednisone			C	Unknown	15 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16690071	EXPEDITED (15-DAY)		OT	PHHY2019CA183761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Myfortic			S	Unknown	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Mmf			S	Unknown	1 G, Bid		Not Reported
	Prednisone			S	Unknown	Up To 70mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16690151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089085		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2019	16690152	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089193		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	12717327	EXPEDITED (15-DAY)		DS, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00007830			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Plaquenil Tablet	S	Oral	Concordia
	Plaquenil Tablet	S	Oral	Concordia
	Hydroxychloroquine	S	Oral	Concordia
	Hydroxychloroquine	S	Oral	Concordia
	Hydroxychloroquine Tablet	S	Subcutaneous	Concordia
	Hydroxychloroquine	S	Oral	Concordia
	Arava	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Unknown	Not Reported

Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Actemra	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cortisone	S	Oral	Not Reported
Cortisone	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Golimumab	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Atasol	C			Not Reported
	Leflunomide	C	Oral		Not Reported
	Salazopyrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	12913805	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092864		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	12930178	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091856		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Qwk	Bristol Myers Squibb
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Bristol Myers Squibb
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Apo-Methotrexate	S	Subcutaneous		Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Naprosyn /00256201/	S	Unknown	500 Mg, Bid	Not Reported
	Prednisone	S	Unknown	2.5 Mg, Qwk	Not Reported
	Prednisone	S	Unknown	20 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown	5 Mg, Unk	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Lovastatin	C	Unknown		Not Reported
	Metoprolol	C	Unknown	50 Mg, Unk	Not Reported
	Naproxen Sodium	C	Unknown	1000 Mg, Qd	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	12931989	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Orencia	S	Unknown	750 Milligram, Q2wk		Bristol Myers Squibb
	Methotrexate	S	Unknown	20 Mg, Qwk		Not Reported
	Arava	S	Oral	Unk		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	13168075	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005403		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Off Label Use; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	13852789	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070079		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone	Orencia			S	Intravenous (not	750 Mg, Qmo		Bristol Myers Squibb

Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Off Label Use; Rheumatoid Factor Positive			otherwise specified)			
	Arava	S	Unknown	20 Mg, Unk		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk, 233 Days		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine	S	Unknown	2 G, Unk, 151 Days		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram(Therapy Duration 7 Years)		Not Reported
	Leflunomide	S	Unknown	20 Milligram(599 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	14633475	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019597			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	14917304	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093137		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Apo-Warfarin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	14921811	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044402		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Finger Deformity; Gait Disturbance; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	16111918	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Ergocalciferol			C	Unknown	2000 Iu, Unk		Not Reported
	Folinic Acid			C	Unknown	Unk		Not Reported

Perindopril Erbumine	C	Oral	4 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	16690461	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1088784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	16690466	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089105		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Feeling Hot; Gait Inability; Immunisation Reaction; Loss Of Personal Independence In Daily Activities; Ocular Vascular Disorder; Off Label Use; Ophthalmic Vein Thrombosis; Pain; Pain In Extremity; Pyrexia; Therapeutic Response Decreased; Thrombosis; Vaccination Complication	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Cymbalta			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Zostavax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Aug-2019	16690470	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089077		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone Acetate			C	Unknown	5 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported

	Desoximetasone			C	Unknown					Not Reported
	Desoximetasone			C	Unknown	5 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2019	11835910	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015133027		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Condition Aggravated; Drug Hypersensitivity; Joint Destruction; Joint Range Of Motion Decreased; Joint Swelling; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2019	13571368	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201705-003053		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased;	Plaquenil Tablet			S	Oral			Concordia
	Plaquenil Tablet			S	Oral			Concordia
	Hydroxychloroquine			S	Unknown	Every 24 Hours		Concordia
	Hydroxychloroquine			S	Unknown	Daily Dose : Unknown		Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S	Unknown	Daily Dose: Unknown		Concordia
	Hydroxychloroquine			S	Unknown			Concordia
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown	Daily Dose: Unknown		Not Reported

Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra	S	Subcutaneous	Daily Dose: Unknown	Not Reported
	Enbrel	S	Unknown	Daily Dose : Unknown	Not Reported
	Enbrel	S	Subcutaneous	Daily Dose: Unknown	Not Reported
	Humira	S	Subcutaneous	Daily Dose: Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Risedronate Sodium	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Daily Dose: 1 G,Qcy	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Apo Risedronate	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Oral	Daily Dose: Unknown	Not Reported
	Cimzia	S	Subcutaneous	Daily Dose : Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Daily Dose: Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Daily Dose: Unknown	Not Reported
	Risedronic Acid	S	Unknown		Not Reported
	Simponi	S	Unknown	Daily Dose: Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine	C			Not Reported
	Risedronate	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2019	13989299	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201709-005376			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective	Hydroxychloroquine Tablet			S	Unknown			Concordia
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2019	14289811	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-109948		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Abatacept			S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q2wk, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk, Cyclical		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Not Reported

	Prednisone		C	Unknown	50 Mg, Qd			Not Reported
	Apo-Leflunomide		S	Oral	10 Mg, Unk			Not Reported
	Apo-Leflunomide		S	Unknown	5 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Aug-2019	14611134	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201803-000916		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; General Physical Condition Abnormal	Plaquenil			S	Unknown			Concordia
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	12316986	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016053975		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	12460764	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016075271		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen

Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Simponi	S	Subcutaneous	50 Milligram, Q3wk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q3wk	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Arthrotec	S	Oral	50 Milligram, Bid	Not Reported
	Arthrotec	S	Unknown	100 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	200 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Diclofenac Sodium/Misoprostol	S	Oral	50 Milligram, Bid	Not Reported
	Tylenol	C	Unknown	650 Milligram, Bid	Not Reported
	Tylenol	C	Unknown	1300 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	650 Milligram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Advil	C	Oral	200 Milligram If Needed	Not Reported
	Advil	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Oral	200 Milligram	Not Reported
	Acetaminophen	C	Unknown	650 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	12531046	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016330540		87 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Disease Recurrence; Drug Ineffective; Heart Rate Increased; Macular Degeneration	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Arthrotec			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly: 4 Tablets Orally (2.5mg) Once Weekly On Wednesdays		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			C	Oral	10 Mg, 2x/Day		Not Reported
	Tylenol [Paracetamol]			C	Oral	3 Tablets, Qd		Not Reported
	Lucentis			C		Unk Unk, Qmo		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	81 Milligram, Qd		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Tylenol Arthritis Pain			C	Oral	3 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	12913333	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092042		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Mobility	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported

Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
	Celebrex	C	Oral	200 Mg, Unk		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	13179031	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0383		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug Intolerance; Retinopathy; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Oral	50 Mg/200ug		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	13846402	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070131		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk, 1 Every Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	0.8 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported

Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	10 Milligram, 1 Every 2 Days	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown	50 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Aurothiomalate De Sodium	S	Unknown		Not Reported
	Aurothiomalate De Sodium	S	Unknown		Not Reported
	Rituximab;Urelumab	C	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	14214127	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2017489360		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epiglottitis	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, Daily		Not Reported
	Nitrofurantoin			C	Oral	50 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	14369414	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-120164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15274420	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-181398		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hyperinsulinaemic Hypoglycaemia; Presyncope	Hydroxychloroquine		S	Unknown	200 Mg, Bid		Sun
	Prednisone		C	Unknown	20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15384104	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082855		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Butterfly Rash; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Pneumococcal Vaccine			C	Unknown	Unk		Not Reported
	Tetanus Vaccine			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15470422	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-014635			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Glucose Fluctuation; Diarrhoea; Malabsorption; Nausea; Osteoarthritis; Retching; Systemic Lupus Erythematosus; Vomiting; Weight Decreased	Xyrem	S	Oral	2.5 G, Bid	Jazz
	Xyrem	S	Oral	Dose Adjustment	Jazz
	Xyrem	S	Oral	6 G, First Dose	Jazz
	Xyrem	S	Oral	6.5g, Second Dose	Jazz
	Pilocarpine	S		Unknown	Not Reported
	Promethazine	S			Not Reported
	Hydroxychloroquine Phosphate	S			Not Reported
	Xifaxan	C		Unk	Not Reported
	Vitamin D3	C		Unk	Not Reported
	Linzess	C		Unk	Not Reported
	Zanaflex	C		Unk	Not Reported
	Cyclobenzaprine	C		Unk	Not Reported
	Zolpidem Tartrate	C		Unk	Not Reported
	Adderall	C		Unk	Not Reported
	Advair Hfa	C		Unk	Not Reported
	Allegra Allergy	C		Unk	Not Reported
	Metoprolol Tartrate	C		Unk	Not Reported
	Metoclopramide	C		Unk	Not Reported
	Rizatriptan	C		Unk	Not Reported
	Theophylline	C		Unk	Not Reported
	Biotin	C		Unk	Not Reported
	Cymbalta	C		Unk	Not Reported
	Maxalt Mlt	C		Unk	Not Reported
	Prevacid	C		Unk	Not Reported
	Requip	C		Unk	Not Reported
	Singulair	C		Unk	Not Reported
	Cyanocobalamin	C		Unk	Not Reported
	Xarelto	C		Unk	Not Reported
	Xopenex	C		Unk	Not Reported
	Zinc Gluconate	C		Unk	Not Reported

					Zyrtec	C	Unk		Not Reported
					Advair	C	Unk		Not Reported
					Ambien	C	Unk		Not Reported
					Morphine Sulf	C	Unk		Not Reported
					Tramadol Hcl	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15583131	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2540068-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete; Visual Impairment; X-Ray Abnormal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15629303	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557369-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15632465	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Off Label Use; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15634984	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105508			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthritis; Drug Ineffective; Fatigue; Joint Effusion; Off Label Use; Pain; Polyarthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15635671	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105914		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Fatigue; Off Label Use; Pain; Polyarthritis; Respiratory Failure; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk, 5.0 Years		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Mefenamic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, 2 Every 1 Day		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	1000 Milligram, Tid		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15698625	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2015-0585		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Plaquenil	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Elavil	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Diclo	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Nifedipine	S	Unknown	Not Reported
Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Misoprostol	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Orencia				S	Unknown			Not Reported
Orencia				S	Subcutaneous			Not Reported
Apo-Azathioprine				S	Unknown			Not Reported
Apo-Leflunomide				S	Unknown			Not Reported
Actemra				S	Unknown			Not Reported
Arava				S	Unknown			Not Reported
Etanercept				S	Unknown			Not Reported
Apo-Naproxen				S	Unknown			Not Reported
Apo Celecoxib				S	Unknown			Not Reported
Apo Pregabalin				S	Unknown			Not Reported
Amitriptyline Hydrochloride W/Perphenazine				S	Unknown			Not Reported
Winpred				S	Unknown			Not Reported
Tofacitinib				C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15948108	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	15962088	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016521103		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated	Enbrel			S	Unknown	Unk		Pfizer

Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Synovitis	Infliximab		S	Intravenous (not otherwise specified)	400 Mg, Unk	Not Reported
	Methotrexate Sodium		S	Subcutaneous	15 Mg, 1 Every 1 Week	Unknown
	Methylprednisolone		S	Unknown	80 Mg, Unk	Pfizer
	Sulfasalazine		S	Unknown	Unk	Pfizer
	Xeljanz		S	Unknown	Unk	Pfizer
	Arava		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	400 Mg, 1 Every 8 Weeks	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Certolizumab Pegol		S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16222504	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP012093			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Fatigue; Glaucoma; Headache; Lacrimation Increased; Photophobia; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Oral	65 Mg, Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	520 Mg, Unk		Not Reported

	Dilaudid	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Alendronate Sodium W/Colecalciferol	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Hydrocortisone	C	Unknown	Unk	Not Reported
	Hyzaar	C	Unknown	Unk	Not Reported
	Orencia	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16388184	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-051037		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
	Actemra	S	Unknown			Not Reported
	Naproxen	S	Unknown			Not Reported
	Prednisone Acetate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16544232	NON-EXPEDITED			US-PFIZER INC-2019291914		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective	Methotrexate Sodium			S		Unk, Weekly		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		5 Mg, Unk		Not Reported
	Folic Acid			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16600689	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068165			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

	Celebrex			C	Unknown	Unk				Not Reported
	Leflunomide			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16650301	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-073759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16677417	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019336929		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematochezia	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Prednisone			S		5-40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16688774	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019338623		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate Sodium			S	Unknown	25 Mg, Weekly (1 Every 1		Pfizer

				Week)	
	Humira	S	Subcutaneous	200 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Atrovent	C		Unk	Not Reported
	Benzotropine	C		Unk	Not Reported
	Chlordiazepoxide	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Methoprazine	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Methotrexate	C		25 Mg, 1 Every 1 Week	Not Reported
	Risedronate Sodium	C		Unk	Not Reported
	Salbutamol	C		Unk	Not Reported
	Trifluoperazine [Trifluoperazine Hydrochloride]	C		Unk	Not Reported
	Zoplicone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16690997	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2881763-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691180	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA216819		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate	S		200 Mg	Sanofi
	Methotrexate	S		25 Mg, Qw	Not Reported
	Methotrexate	S		20 Mg, Qw	Not Reported
	Leflunomide	S		20 Mg	Sanofi
	Actemra	S	Intravenous (not otherwise specified)	8 Mg	Not Reported
	Etanercept	S		50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691209	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Sanofi
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691235	NON-EXPEDITED			US-APOTEX-2019AP019030			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Noncompliance	Clarithromycin			S	Oral	1500 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Not Reported
	Amitriptyline			S	Unknown	20 Mg, Q.H.S.		Not Reported
	Atovaquone			C	Unknown	250 Mg, Unk		Not Reported
	Proguanil			C	Oral	100 Mg, Bid		Not Reported
	Amoxicillin			C	Unknown	Unk		Not Reported
	Metronidazole			C	Oral	500 Mg, Bid, For Two Consecutive Days Per Week		Not Reported
	Atovaquone/Proguanil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691240	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208331			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691241	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208333		50 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Sleep Disorder; Treatment Noncompliance	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691401	EXPEDITED (15-DAY)		OT	US-ZYDUS-039534		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Drug Interaction; Neutropenia; Propionibacterium Infection; Staphylococcal Infection	Hydroxychloroquine			S	Oral			Zydus Pharm
	Methotrexate			S	Unknown			Zydus Pharm
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Diazepam			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

	Hydrocodone Bitartrate/Paracetamol	C	Unknown		Not Reported
	Omeprazole	C	Unknown		Not Reported
	Sulindac/Sulindac Sodium	C	Unknown		Not Reported
	Paracetamol	C	Unknown		Not Reported
	Venlafaxine	C	Unknown		Not Reported
	Methotrexate	S	Oral		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691441	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089211		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Methotrexate			S	Subcutaneous			Barr
	Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691442	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089175		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	S	Unknown	7 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691574	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210550		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691587	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported

	Polymyxin B Sulfate		S	Unknown		Not Reported
	Actemra		S	Subcutaneous		Not Reported
	Prednisone		C	Intramuscular		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691592	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089171		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691593	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089267		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

Peripheral Swelling; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	2000 Milligram Daily;	Not Reported
	Apo-Prednisone		S	Rectal	5 Milligram Daily;	Not Reported
	Arava		S	Unknown		Not Reported
	Humira		S	Subcutaneous	20 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691993	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Folate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692041	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2882164-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pneumonia	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692072	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Plaquenil			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk, Unk		Sanofi
	Methotrexate			S		Unk, Unk		Not Reported
	Sulfasalazine			S		Unk, Unk		Not Reported
	Leflunomide			S		Unk, Unk		Sanofi
	Actemra			S		640 Mg, Unk		Not Reported
	Ciclosporin			S		Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran [Azathioprine Sodium]			S		Unk, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692237	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR142835		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose	Wellbutrin Xl			S	Oral	Unk		Glaxosmithkline
	Digoxin			S	Oral	Unk		Glaxosmithkline
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Opsumit			S	Oral	Unk		Not Reported
	Glipizide			S	Oral	Unk		Not Reported

	Remodulin			C	Intravenous (not otherwise specified)	Unk				Not Reported
	Eliquis			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692522	NON-EXPEDITED			US-PFIZER INC-2019339687		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Sulfasalazine			S		1500 Mg, 2x/Day		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly (Split Dosing)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692552	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019341333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692556	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019341334		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Methotrexate Sodium			S	Unknown	Unk		Pfizer

	Sulfasalazine		S	Unknown	Unk		Pfizer
	Actemra		S	Unknown	Unk		Not Reported
	Adalimumab		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported
	Leflunomide		S	Unknown	Unk		Not Reported
	Rituximab		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692557	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019340879		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692701	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210549		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid (2 Every 1 Day)		Sanofi
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk Unk, Unk		Not Reported
	Arthrotec	C		Unk Unk, Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Gold	C	Unknown	Unk Unk, Unk		Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692769	EXPEDITED (15-DAY)		OT	CA-SA-2019SA220512		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Desoximetasone			S	Oral			Sanofi
	Arava			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, 2 In 1 Day		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi

	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Sanofi
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Diclofenac	C		Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693236	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA210527		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye;	Plaquenil			S	Unknown	400.0 Mg, Qd		Sanofi
	Plaquenil			S				Sanofi
	Arava			S	Oral	20.0 Mg, Qd		Sanofi
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Gabapentin			S	Oral	100.0 Mg, Bid		Not Reported
	Methotrexate			S	Subcutaneous	1.0 Df, Qw		Not Reported
	Myochrysine			S	Intramuscular	50.0 Mg, Q3w		Not Reported
	Nortriptyline Hydrochloride			S				Not Reported

Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure; Unevaluable Event; Unevaluable Event	Oxycodone Hydrochloride	S			Not Reported
	Sulfasalazine	S	Oral	500.0 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	500.0 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S		400.0 Mg, Qd	Sanofi
	Apo-Gabapentin	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488.0 Mg, Qd	Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Subcutaneous	50.0 Mg, Qw	Not Reported
	Fentanyl Matrix	S		Patch	Not Reported
	Orencia	S	Subcutaneous	1.0 Df, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1.0 Df, Qw	Not Reported
	Biotin	C			Not Reported
	Calcium	C			Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Esomeprazole	C			Not Reported
	Fentanyl	C			Not Reported
	Ferrous Gluconate	C			Not Reported
	Fish Oil	C			Not Reported
	Genteal [Hypromellose]	C		Solution Opthalmic	Not Reported
	Lomotil [Loperamide Hydrochloride]	C			Not Reported
	Lomotil [Loperamide Hydrochloride]	C			Not Reported
	Loperamide	C			Not Reported
	Nasonex	C		Spray, Metered Dose	Not Reported
	Nexium [Esomeprazole Sodium]	C			Not Reported
	Nortriptyline	C			Not Reported
	Omega-3 [Salmo Salar Oil]	C			Not Reported
	Omega 3-6-9 [Fish Oil]	C			Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Oxycodone And Acetaminophen	C		Unk	Not Reported
	Oxycodone And Acetaminophen	C		Unk	Not Reported
	Pantoprazole	C			Not Reported

	Prednisone	C		Not Reported
	Pyridoxine	C		Not Reported
	Sodium	C		Not Reported
	Thiamine Hcl	C		Not Reported
	Trazodone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol [Paracetamol]	C		Not Reported
	Vitamin A [Retinol]	C		Not Reported
	Vitamin B3	C		Not Reported
	Vitamin B12 [Vitamin B12 Nos]	C		Not Reported
	Vitamin D [Vitamin D Nos]	C		Not Reported
	Vitamin D3	C		Not Reported
	Vitamin E [Tocopherol]	C		Not Reported
	Xeljanz	C		Not Reported
	Acetaminophen	C		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C		Not Reported
	Vitamin C [Ascorbic Acid]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693241	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208570		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Arava			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		1 Df, Qd		Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Xeljanz	S	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693459	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2882710-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			C	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693497	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089235		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown	400 Milligram Daily;		Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Unknown	Tablet (Extended Release)		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019344896		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Septic Shock; Synovitis; Urinary Tract Infection	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Abatacept			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Salicylates Nos			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077005		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid	Abatacept			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram, Qcycle		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qcycle		Not Reported

Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693528	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Bactrim			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693592	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019342801		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Methotrexate Sodium	S	Unknown	Unk, 1x/Day		Pfizer
	Sulfasalazine	S	Oral	1000 Mg, 2 Every 1 Day(S)		Pfizer
	Arava	S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693667	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089153			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported
	Plantago Ovata			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Vaginal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693669	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089169		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693693	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089925		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Oral Infection; Therapeutic Product Effect Decreased; Tooth Abscess	Methotrexate			S	Oral			Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693694	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Methylprednisolone			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rituxan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693738	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1089404			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Unknown	Not Reported
	Humira			S	Unknown	Not Reported
	Hydroxychloroquine /00072603/			S	Oral	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Rituxan			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693744	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1089372			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693746	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Methotrexate	S	Unknown			Barr
	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Naproxen	C	Unknown			Not Reported
	Actonel	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693768	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077044		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported

	Neoral	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
	Rituxan	S	Endocervical		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693824	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA208330		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort;	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Qw		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Perindopril Erbumine			C	Oral	8 Mg, Qd		Not Reported
	Gabapentin			C	Oral	400 Mg, Bid		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Oral	Unk		Not Reported

Nasopharyngitis; Nausea; Night Sweats; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Celebrex	C		Unk		Not Reported
	Desoximetasone	C		Unk		Not Reported
	Ergocalciferol	C		Unk		Not Reported
	Fentanyl	C	Unknown	1 Df, Unk		Not Reported
	Metformin;Sitagliptin	C	Oral	2 Df, Qd		Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd		Not Reported
	Ranitidine	C	Oral	150 Mg, Qd		Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid		Not Reported
	Synthroid	C	Oral	1 Df, Qd		Not Reported
	Tylenol [Paracetamol]	C		Unk		Not Reported
	Vitamin B 12	C	Oral	1 Df, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd		Not Reported
	Zostavax	C	Unknown	Unk		Not Reported
	Varilrix	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694104	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE-IL2019EME140081			Unknown	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Condition Aggravated; Diplopia; Magnetic Resonance Imaging Brain Abnormal	Benlysta			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Imuran			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694232	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089194		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate		S	Unknown	Barr
	Actemra		S	Subcutaneous	Not Reported
	Actemra		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Cellcept		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Lyrica		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694356	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089087			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694385	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077040			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Bid		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694398	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694415	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089243		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Rituximab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694416	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089269		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694445	EXPEDITED (15-DAY)		DE	PHHY2019DE185052			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Novartis
	Etanercept			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694467	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1089354		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Morphine	C				Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694468	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089346		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Sulfasalazine			S	Oral					Not Reported
	Meloxicam			C	Oral					Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694511	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089333		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694624	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089166		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling;	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Pain; Pain In Extremity; Peripheral Swelling; Swelling	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Tramadol Hydrochloride		C	Oral		Not Reported
	Xeljanz		C	Oral	100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16694658	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089344		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16695051	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2882106-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol Arthritis			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16891558	DIRECT		LT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Caffeine Increased	Hydroxychloroquine Sulfate 200mg Tablets, Usp			S	Oral	Quantity:200 Mg Milligram(S);	5 MTH	Not Reported
	Tylenol			C				Not Reported
	Ibyprophen			C				Not Reported
	Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	10187077	EXPEDITED (15-DAY)		OT	CA-ROCHE-1301050		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Arthralgia; Back Pain; Blood Pressure Fluctuation; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Chest Pain; Cough; Depression; Device Breakage; Dry Throat; Erythema; Fatigue; Fatigue; Feeling Hot; Gastritis; Headache; Heart Rate Decreased; Heart Rate Decreased; Hot Flush; Infection; Infusion Related Reaction; Infusion Related Reaction; Intentional Product Use Issue; Labyrinthitis; Migraine; Musculoskeletal Chest Pain;	Rituxan			S	Intravenous (not otherwise specified)	Recent Dose On 06/Jul/2015 Last Rituximab Infusion 15/Feb/2016 Previous Rituxan Infusion: 12/Jun/201		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Atorvastatin			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Dexilant			C				Not Reported
	Acebutolol			C	Unknown	Mylan		Not Reported
	Clopidogrel			C				Not Reported
	Oxycodone			C	Unknown	Every Evening		Not Reported
	Tylenol [Paracetamol]			C	Oral			Not Reported
	Solu-Medrol			C	Intravenous (not otherwise specified)			Not Reported
	Xalatan			C				Not Reported

Nasopharyngitis; Neuralgia; Off Label Use; Oxygen Saturation Decreased; Pain In Extremity; Pharyngitis; Prostatic Disorder; Pruritus; Rash; Rash Erythematous; Rheumatoid Arthritis; Thermal Burn; Throat Tightness; Tooth Fracture; Tooth Infection; Vision Blurred; Weight Decreased	Azarga	C				Not Reported
	Statex [Morphine Sulfate]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	13105897	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016239656		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	14280645	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201712-006602		37 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Epiglottitis; Infection; Oropharyngeal Pain; Oropharyngeal	Hydroxychloroquine			S	Oral			Concordia
	Tofacitinib Citrate			S	Oral			Not Reported

Swelling; Swelling	Tofacitinib Citrate	S	Oral		Not Reported
	Nitrofurantoin	C			Not Reported
	Nitrofurantoin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	14925171	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044235		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wheezing	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	50 Milligram		Not Reported
	Folic Acid			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported

Rheumatoid Arthritis	Methotrexate		S	Subcutaneous		Barr
	Risedronate		S	Unknown		Teva
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown	300 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Actonel		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16098187	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1026103			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16264542	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2764807-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition	Humira			S	Subcutaneous			Not Reported

Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Acetaminophen	S	Oral		Not Reported
	Oxycodone Hydrochloride	S	Oral		Not Reported
	Oxycodone Terephthalate	S	Oral		Not Reported
	Hydromorphone	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16478641	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15314		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Gastric Haemorrhage; Gastrointestinal Haemorrhage; Headache; Hepatic Enzyme Increased; Influenza Like Illness; Infusion Related Reaction; Joint Swelling; Malaise; Musculoskeletal Disorder; Nausea; Rheumatoid Nodule; Substance-Induced Psychotic Disorder; Urinary Tract Infection; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil			C	Unknown	Unknown		Not Reported

	Xeljanz			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695099	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001855		37 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Exposure During Pregnancy; Intrauterine Infection; Premature Delivery	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prednisolone			S	Unknown			Not Reported
	Metronidazole			S	Oral			Not Reported
	Ciprofloxacin Hydrochloride			S	Oral			Not Reported
	Cefmetazole Sodium			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	E Keppra			C				Not Reported
	Predonine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695332	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211408		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Amoxicillin And Clavunate Potassium			C				Not Reported

	Amoxil [Amoxicillin]			C						Not Reported
	Bcg Vaccine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695353	EXPEDITED (15-DAY)		OT	CA-SA-2019SA222582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Unevaluable Event; Vomiting	Leflunomide			S		Qd, 10-20mg		Sanofi
	Sulfasalazine			S		1 G, Bid		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Baricitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695814	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210566		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Levofloxacin			S				Not Reported
	Clarithromycin			S				Not Reported
	Celecoxib			S				Not Reported
	Ciprofloxacin Salt Not Specified			S				Not Reported
	Clindamycin, Salt Not Specified			S				Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Hydralazine Hydrochloride			S		Unk		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydrochlorothiazide			S				Not Reported
	Metoprolol Tartrate			S				Not Reported
	Moxifloxacin Hydrochloride			S				Not Reported
	Rabeprazole Sodium			S				Not Reported
	Cefalexin			S				Not Reported
	Enalapril			S				Not Reported

	Enbrel	S	Unk	Not Reported
	Losartan	S		Not Reported
	Orencia	S		Not Reported
	Pantoprazole Magnesium	S		Not Reported
	Penicillin G [Benzylpenicillin]	S		Not Reported
	Prednisone	C	8.5 Mg, Qd	Not Reported
	Iron Sucrose	C		Not Reported
	Hydroxychloroquine	C		Not Reported
	Gold	C		Not Reported
	Esomeprazole	C		Not Reported
	Cipro [Ciprofloxacin]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695902	EXPEDITED (15-DAY)		LT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2793			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16695904	EXPEDITED (15-DAY)		LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported

Product Effect Decreased; Visual Impairment	Sulfasalazine		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Indometacin		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16696687	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR141241			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Decreased Appetite; Fatigue; Musculoskeletal Stiffness; Road Traffic Accident; Weight Decreased	Benlysta Powder For Infusion			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Aspirin			C	Oral	1 Df, Qd		Glaxosmithkline
	Tylenol Arthritis Pain Prolonged-Release Tablet			C	Oral	2 Df, Tid		Not Reported
	Biotin Capsule			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Tablet			C	Oral	1 Df, Bid		Not Reported
	Amlodipine Tablet			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16696894	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA208281		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hypertension; Osteoarthritis; Pneumonia;	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi

Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Naproxen	C	Unknown	500 Mg, Qd	Not Reported
	Nifedipine	C	Unknown		Not Reported
	Palafer	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Toloxin [Digoxin]	C	Unknown	Unk	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported

	Zinc Citrate			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16696898	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210554		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16697402	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089912		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

Rheumatoid Arthritis; Synovitis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16697536	EXPEDITED (15-DAY)		HO, OT	PHHY2019TR182875		13 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Osteonecrosis; Product Use In Unapproved Indication; Swelling	Methylprednisolone			S	Oral	48 Mg, Qd (5.3 G Cumulative Dose)		Novartis
	Methylprednisolone			S	Oral	8 Mg, Qd (5.3 G Cumulative Dose)		Novartis
	Cyclophosphamide			S	Intravenous (not otherwise specified)	4 Ug/L, Qmo		Not Reported
	Cyclophosphamide			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Risperidone			S	Unknown	Unk		Not Reported
	Risperidone			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16697810	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019342797		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698324	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885038-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased; Bronchitis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Vitamin D			C	Oral			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C				Not Reported
	Hydromorphone			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Calcium Carbonate			C	Oral			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown	(Extended Release)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698329	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis;	Methotrexate			S	Unknown			Barr

Systemic Lupus Erythematosus	Enbrel		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698332	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089487		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Oral			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	750 Milligram 1 Every 1 Weeks		Not Reported
	Rituxan			S	Unknown	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698370	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089933		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Back Pain; Drug Intolerance; Eye Disorder; Impaired Healing; Localised	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported

Infection; Mobility Decreased; Musculoskeletal Disorder; Pain; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hepatitis A Vaccineinact/Hepatitis B Surface Antigen(Recombinant)	C			Not Reported
	Hepatitis B Vaccine Hbsag	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698394	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1091338		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability; Herpes Zoster; Hiatus Hernia; Insomnia; Muscle Spasms; Pain In Extremity; Rheumatoid Arthritis; Sarcoidosis; Skin Cancer; Sleep Disorder Due To General Medical Condition, Insomnia Type	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Plaquenil			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698448	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1090934		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Sulfasalazine			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698449	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1091372		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability; Herpes Zoster; Hiatus Hernia; Insomnia; Muscle Spasms; Rheumatoid Arthritis; Sarcoidosis; Skin Cancer	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698451	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089676		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral	25 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Penicillin G			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	3 Gram Daily;		Not Reported
	Calcium	C				Not Reported
	Hydroxychloroquine	C				Not Reported
	Plaquenil	C	Unknown			Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
	Tylenol	C	Unknown			Not Reported
	Vitamin D	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698474	EXPEDITED (15-DAY)		OT	GB-FRESENIUS KABI-FK201908905			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin (Manufacturer Unknown)			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown	Unk		Not Reported
	Diclofenac Sodium/Misoprostol			S	Intracardiac	Unk		Not Reported
	Pethidine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	400 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Pethidine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Adalimumab		S	Subcutaneous	400 Milligram, Unk	Not Reported
	Pregabalin		S	Unknown	Unk	Not Reported
	Erythromycin		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Celecoxib		S	Oral	200 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698656	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-022653		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution For Subcutaneous		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698736	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1075784		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Ranitidine			S	Oral	300 Milligram, Qd		Not Reported
	Zolpidem			S	Oral	10 Milligram, Qd		Not Reported
	Lactulose			S	Oral	1 Dosage Form, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	400 Milligram		Mylan
	Dulcolax /00064401/			S	Oral	5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16698790	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089913		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699240	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089489		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699335	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699338	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089936			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699356	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089905			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Unknown				Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699393	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089968		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Gastric Disorder; Interstitial Lung Disease; Lung Disorder; Pneumonitis; Polyarthritis; Rheumatoid Arthritis; Treatment Failure; Unevaluable Event	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	3 Gram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16699745	EXPEDITED (15-DAY)		OT	AR-TEVA-2019-AR-1090779		28 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity	Hydroxychloroquine			S	Unknown			Teva
	Methylprednisolone			C	Unknown	1 Mg/Kg Daily;		Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown	Pulse Therapy After Lupus Flare With Renal Involvement And Thrombotic Microangiopathy		Not Reported
	Prednisone			C	Unknown	1 Mg/Kg Daily;		Not Reported

	Prednisone	C	Unknown	Taper	Not Reported
	Prednisone	C	Unknown	60 Milligram Daily;	Not Reported
	Cyclophosphamide	C	Unknown	6g	Not Reported
	Cyclophosphamide	C	Unknown		Not Reported
	Mycophenolate	C	Unknown		Not Reported
	Alpha-Methyldopa	C	Unknown	1500 Milligram Daily;	Not Reported
	Amlodipine	C	Unknown	10 Milligram Daily;	Not Reported
	Trimethoprim/Sulfamethoxazole	C	Unknown	Trimethoprim/Sulfamethoxazole (160/800 Mg) 1 Tablet Monday, Wednesday And Friday	Not Reported
	Calcium Carbonate	C	Unknown	1250 Milligram Daily;	Not Reported
	Erythropoietin	C	Unknown		Not Reported
	Rituximab	C	Unknown	71.4286 Milligram Daily; Scheduled For 3 Weeks	Not Reported
	Eculizumab	C	Unknown		Not Reported
	Eculizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Aug-2019	16702434	DIRECT		OT			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate Increased	Generic Hydroxychloroquine Sulfate 200			S	Oral	Other Strength:Not Listed;Quantity:2 Tablet(S);		Sandoz
	Vitamin D (Ergocalcifero 50000 Caps)			C				Not Reported
	Progesterone Micronized			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Femring			C				Not Reported
	Women Gummy Multi-Vitamin			C				Not Reported
	Calcium Carbonate Gummies			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	11832595	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015438353		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Condition Aggravated; Drug Hypersensitivity; Joint Destruction; Joint Range Of Motion Decreased; Joint Swelling; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	12461709	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016288429		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Intramuscular	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Intramuscular	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	2 G, Qd (1 Every 24 Hours)		Pfizer
	Arthrotec			S	Oral	50 Mg, Bid (2 Every One Day)		Pfizer
	Arthrotec			S	Unknown	100 Mg, 1x/Day		Pfizer
	Plaquenil			S	Unknown	400 Mg, Qd (1 Every 24 Hour)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic Every Two Weeks, Q2wk		Not Reported

	Humira	S	Subcutaneous	40 Mg, Cyclic (Cyclical)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Every 3 Weeks	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Every 3 Weeks (Q3wk)	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	200 Mg, Unk	Not Reported
	Gold (198 Au)	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Oral	50 Mg, 2x/Day	Not Reported
	Advil	C	Oral	200 Mg, As Needed (Once A Day If Needed)	Not Reported
	Tylenol	C	Unknown	650 Mg, Bid (2 Every 1 Days)	Not Reported
	Tylenol	C	Unknown	1300 Mg, Daily	Not Reported
	Tylenol	C	Unknown	650 Mg, Unk	Not Reported
	Mefenamic Acid	C	Oral	200 Mg, Unk	Not Reported
	Acetaminophen	C	Unknown	650 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	12890986	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013207		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug	Apo-Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Apo-Fentanyl Matrix			S	Unknown	Unk		Aveva
	Celecoxib			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Fentanyl			S	Unknown	Unk		Apotex

Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Sulfasalazin	S	Oral	2.5 G, Qd	Not Reported
	Sulfasalazin	S	Oral	500 Mg, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q.3w	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T., 1 Every 1 Month	Not Reported
	Arava	S	Oral	20 Mg, Qd, 1 Every 1 Day	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk, 1.0 Dosage, As Required	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported
	Esomeprazole Magnesium	C	Unknown	400 Iu, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported

Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	400 Unk, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1200 Mg, Bid, 2 Every 1 Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	15629225	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558756-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	15854355	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633529-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

					Simponi		S	Subcutaneous		Not Reported
					Celebrex		C	Unknown		Not Reported
					Gold		C	Unknown		Not Reported
					Morphine		C	Unknown		Not Reported
					Tofacitinib		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16093433	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0584		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Myfortic			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16360160	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2798726-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16649875	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201907-001724		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Arthritis Infective; Drug Interaction; Neutropenia; Osteomyelitis Acute; Propionibacterium Infection; Staphylococcal Infection	Hydroxychloroquine			S	Oral			Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Restart		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G For 6 Weeks Post Operatively		Not Reported
	Ceftriaxone			S				Not Reported
	Ceftriaxone			S				Not Reported

					Prednisone	S	Oral		Not Reported
					Prednisone	S			Not Reported
					Diazepam	C			Not Reported
					Folic Acid	C			Not Reported
					Ibuprofen	C			Not Reported
					Hydrocodone/Acetaminophen	C			Not Reported
					Omeprazole	C			Not Reported
					Sulindac	C			Not Reported
					Acetaminophen	C			Not Reported
					Venlafaxine	C			Not Reported
					Cefazolin	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16675800	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001773		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gait Disturbance; Myocardial Infarction; Pain; Swelling; Therapeutic Response Decreased	Plaquenil			S	Unknown			Concordia
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16680846	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001809		35 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Foetal Death	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Prograf			C				Not Reported

		Persantin			C						Not Reported
		Prednisolone			C						Not Reported
		Edirol			C						Not Reported
		Edirol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700185	EXPEDITED (15-DAY)		OT	NZ-ABBVIE-19P-118-2882566-00		20 YR	Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Drug Ineffective; Drug-Induced Liver Injury; Groin Abscess; Headache; Meningitis Aseptic; Nausea; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			C		20 Mg/D		Not Reported
	Vitamin D			C		1.25 Mg/Month		Not Reported
	Omeprazole			C		20mg/D		Not Reported
	Fluoxetine			C		40mg/D		Not Reported
	Humulin Insulin			C		108 U / D		Not Reported
	Amitriptyline			C		10mg Nocte		Not Reported
	Asacol			C		6 Tabs Per Day		Not Reported
	Sumatriptan			C		As Required According To Dosing Schedule		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2368270		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700282	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR143039			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Mood Altered	Benlysta			S	Unknown	Unk		Glaxosmithkline
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	112		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700303	EXPEDITED (15-DAY)		OT	US-ZYDUS-016821		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; False Positive Investigation Result; Light Chain Disease; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700374	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Hepatitis	Hydroxychloroquine			S	Oral			Concordia
	Azathioprine			S	Unknown			Not Reported
	Myfortic			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700444	EXPEDITED (15-DAY)		CA, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077181			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breech Presentation; Ebstein'S Anomaly; Exposure Via Breast Milk; Foetal Exposure During Pregnancy	Warfarin Sodium			S	Transplacental	Unk		Bristol Myers Squibb
	Warfarin Sodium			S	Transmammary	Unk		Bristol Myers Squibb
	Belimumab			S	Transplacental	10 Milligram/Kilogram, Qmo		Not Reported
	Belimumab			S	Transmammary	10 Milligram/Kilogram, Qmo		Not Reported
	Prednisone			S	Transplacental	2.5 Milligram, Qd		Not Reported
	Prednisone			S	Transmammary	2.5 Milligram, Qd		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700820	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2019-CA-1090908		28 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anterior Chamber Cleavage Syndrome; Aphakia; Corneal Opacity; Eye Disorder; Foetal Exposure During Pregnancy	Methotrexate		S	Transplacental	Barr
	Folic Acid		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700822	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089502		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown	300 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			C		81 Milligram Daily;		Not Reported
	Aspirin			C	Unknown			Not Reported
	Aspirin			C		81 Milligram Daily;		Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700838	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Rheumatoid Arthritis; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acidophilus /00079701/			C	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Kenalog /00031902/			C	Unknown			Not Reported
	Lidocaine			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Pantoloc/01263201/			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Triamcinolone			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1090899			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700881	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001872		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Atypical Mycobacterial Infection; Disease Recurrence; Disseminated Mycobacterium Avium Complex Infection; Nephropathy Toxic; Osteomyelitis; Subcutaneous Abscess; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azithromycin			S	Oral			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Amikacin Sulfate			S	Intravenous (not otherwise specified)	Parenteral Amikacin		Not Reported
	Amikacin Sulfate			S		Implantation Of Amikacin Beads		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported
	Linezolid			S	Oral			Not Reported
	Tigecycline			S	Intravenous (not			Not Reported

						otherwise specified)				
		Cefoxitin			S	Intravenous (not otherwise specified)				Not Reported
		Clofazimine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700889	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211284		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Arava			S		Unk		Sanofi
	Morphine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700891	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1090913		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil		S	Unknown	400 Milligram Daily;	Not Reported
	Reactine (Cetirizine)		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700920	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888366-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16700968	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019AMR145361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Benlysta			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Solumedrol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701030	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2829		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701039	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2803		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Methotrexate (Trade Name Unknown)		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701104	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001869			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Plaquenil			S	Oral			Concordia
	Prednisone			S	Oral	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S		Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Zoloft			C				Not Reported
	Levofloxacin			C				Not Reported
	Lyrica			C				Not Reported
	Acyclovir			C				Not Reported
	Amitriptyline			C				Not Reported
	Constella			C				Not Reported
	Reactine [Cetirizine Hydrochloride]			C				Not Reported
	Aerius			C				Not Reported
	Zopiclone			C				Not Reported
	Zomig			C				Not Reported
	Vitamin C			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701112	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA211301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Arava			S				Sanofi

Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Pharyngitis; Vomiting; Weight Decreased	Acetylsalicylic Acid	S			Not Reported
	Sulfamethoxazole/Trimethoprim	S			Not Reported
	Sulfamethoxazole/Trimethoprim	S			Not Reported
	Diclofenac Potassium	S			Not Reported
	Hydroxychloroquine	S			Sanofi
	Naproxen	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701259	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN-001130			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Feeding Disorder; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Metoprolol			S	Unknown	Unk		Ipca
	Prednisolone			S	Unknown	Unk		Not Reported
	Amlodipine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701318	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2800		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Septic Shock; Synovitis; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Salicylates Nos		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701321	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2019-2817		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atrovent			C	Unknown			Not Reported
	Benzotropine			C	Unknown			Not Reported
	Chlordiazepoxide			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methoprazine			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Trifluoperazine			C	Unknown			Not Reported
	Zoplicone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701456	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN-001131			Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Foetal	Hydroxychloroquine			S	Unknown	Unk		Ipca

Exposure During Pregnancy; Foetal Growth Restriction; Hyperbilirubinaemia; Thrombocytopenia	Metoprolol			S	Unknown	Unk		Ipca
	Prednisolone			S	Unknown	Unk		Not Reported
	Amlodipine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701571	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1090911		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Distension; Cellulitis; Constipation; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Ill-Defined Disorder; Mouth Ulceration; Nausea; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Ulcer	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5 Milligram Daily;		Not Reported
	Betaloc			C				Not Reported
	Desoximetasone			C				Not Reported
	Losec			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16701976	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1090821		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability; Herpes Zoster; Hiatus	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported

Hernia; Insomnia; Muscle Spasms; Sarcoidosis; Skin Cancer	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16702713	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092156		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Dermatitis Allergic; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Weeks		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16702714	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092196		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Deformity; Bone Erosion; Condition Aggravated; Drug Ineffective	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Weeks		Barr
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Leucovorin Calcium			C		5 Milligram		Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Sulfasalazine			C	Oral	1 Gram		Not Reported
	Vitamin D [Colecalciferol]			C				Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16702745	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyarthritis	Methotrexate			S	Subcutaneous	25 Milligram 1 Every 1 Weeks		Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16703696	EXPEDITED (15-DAY)		LT	NO-JNJFOC-20190720013		64 YR	Female	NOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Recurrent	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Prednisolon /00016201/			S	Oral			Not Reported
	Prednisolon /00016201/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16703865	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA211151		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		20 Mg, Unk		Sanofi
	Alendronate Sodium			S		70 Mg, Qw		Not Reported
	Alendronic Acid			S		70 Mg, Qw		Not Reported

Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Hydroxychloroquine	S	Unknown		Sanofi
	Codeine	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	12 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Qw	Not Reported
	Methotrexate	S	Unknown	12 Mg, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Enbrel	S	Unknown	25 Mg, Qow	Not Reported
	Humira	S	Unknown	40 Mg, Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	780 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Actemra	S		680 Mg, Q4w	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported
	Tocilizumab	S		360 Mg, Qm	Not Reported
	Tocilizumab	S		680 Mg, Qm	Not Reported
	Xeljanz	C			Not Reported
	Ciclosporin	C		150 Mg, Qd	Not Reported

	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16704205	EXPEDITED (15-DAY)		HO	NL-TEVA-2019-NL-1091073			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Methotrexaat Tablet, 10 Mg (Milligram)			S	Unknown	1 X Per Week 25 Milligram		Barr
	Hydroxychloroquine			S	Unknown	2dd 200 Mg		Teva
	Tramadol Capsule 50mg			C	Unknown	2 X Per Day If Required		Not Reported
	Prednisolon Tablet 5mg			C		Morning 10mg ' Savonds		Not Reported
	Omeprazol			C	Unknown	1 X Per Day 20mg		Not Reported
	Desloratadine Tablet 5mg			C	Unknown	1 X Per Day 5 Milligram		Not Reported
	Dextran 70/Hypromellose Oogdr 1/3mg/Ml			C	Unknown	Use As Necessary		Not Reported
	Hypromellose Oogdruppels 3,2mg/Ml			C	Unknown	Use As Necessary		Not Reported
	Foliumzuur Tablet 5mg			C	Unknown	1dd5		Not Reported
	Carbomeer Ooggel 2mg/G (Carbomeer 980)			C		Use As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16704219	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089921		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer;	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

Staphylococcal Infection; Therapeutic Product Effect Incomplete	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acidophilus /00079701/	C	Unknown	Not Reported
	Aspirin/00002701/	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Deflazacort	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Kenalog /00031902/	C	Unknown	Not Reported
	Lidocaine	C	Unknown	Not Reported
	Metronidazole	C	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Pantoloc /01263201/	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Triamcinolone	C	Unknown	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Aug-2019	16704899	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888359-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Administered; Drug Ineffective; Drug Intolerance; Dry Mouth; Headache; Joint Range Of Motion Decreased; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Asa	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Tylenol	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Nifedipine	C	Unknown	Not Reported
	Lipitor	C	Unknown	Not Reported
	Gliclazide	C	Unknown	Not Reported
	Gabapentin	C		Not Reported
	Folic Acid	C	Unknown	Not Reported
	Domperidone	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	12329958	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055488		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported

	Naprosyn [Naproxen]			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Crestor			C		Unk			Not Reported
	Folic Acid			C		Unk			Not Reported
	Naprelan			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	12547776	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016088428		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Triple			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	12627680	NON-EXPEDITED		OT	CA-AMGEN-CANSL2016099312		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Back Pain; Constipation;	Single Dose Prefilled Autoinjector(Enbrel)			S	Unknown	50 Milligram, Qwk		Amgen

Dactylitis; Diarrhoea; Disability; Dizziness; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Finger Deformity; Hyperaesthesia; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Psoriasis; Reflexes Abnormal; Restlessness; Sacroiliitis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk, Every 10 Days	Amgen
	Enbrel	S	Unknown	50 Mg, Every 9-10 Days	Amgen
	Enbrel	S	Unknown	50 Mg, Every 7 Days	Amgen
	Amitriptyline	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Cymbalta	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Elavil	S	Unknown	Unk	Not Reported
	Elavil	S	Unknown	Unk (Capsule)	Not Reported
	Clonazepam	C		1 Milligram, Prn	Not Reported
	Vit D	C		4000 International Unit, Qd	Not Reported
	Flax Seed Oil	C		Unk	Not Reported
	Omega 3	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported
	D-Alpha Tocopherol	C		Unk	Not Reported
	Tylenol No.2	C		Unk (120 Tabs)	Not Reported
	Ergocalciferol	C		4000 International Unit, Qd	Not Reported
	Flaxseed Oil	C		Unk	Not Reported
	Gabapentin	C		300 Milligram	Not Reported
	Hydromorphone	C		1 Milligram, 1/2 Times A Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	13113136	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0143		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	15973937	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA018099			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Synovitis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Mg, Unk		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Mg, 1 Every 8 Weeks		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, 1 Every 8 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16381300	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2805003-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Form Of Administration-Solution, Single Use Pre-Filled Syringe		Not Reported
	Methotrexate			S	Oral	Form Of Administration-Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Form Of Administration-Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Form Of Administration-Solution		Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16535834	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-018952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid	Diclofenac Sodium Ophthalmic Solution 0.1%			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown				Not Reported
	Cimzia			S	Subcutaneous				Not Reported
	Cortisone Acetate			S	Topical				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Folic Acid			S	Unknown				Not Reported
	Fosamax			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Phthalylsulfathiazole			S	Unknown				Not Reported
	Prednisone			S	Intravenous (not otherwise specified)				Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16633068	EXPEDITED (15-DAY)		HO, OT	GR-BAUSCH-BL-2019-020739		11 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Measles; Off Label Use	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methylprednisolone	S	Intravenous (not otherwise specified)	3 Pulses		Not Reported
	Cyclophosphamide	S	Unknown			Not Reported
	Enoxaparin	C				Not Reported
	Salmeterol	C	Respiratory (inhalation)			Not Reported
	Fluticasone	C	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705133	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2884223-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705378	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888374-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Mupirocin			C	Topical			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Estrace			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Conjugated Estrogens			C	Oral			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported
	Apo-Gabapentin			C	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Cipralex			C	Unknown			Not Reported
	Atorvastatin Calcium			C	Oral			Not Reported
	Altace			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Tramacet			C	Oral			Not Reported
	Taro-Mupirocin			C	Topical			Not Reported

	Tapentadol Hydrochloride			C						Not Reported
	Shark Liver Oil			C	Unknown					Not Reported
	Prednisone			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705620	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0768		87 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Macular Degeneration	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg (4 Tablets)/ On Wednesdays		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			C	Oral			Not Reported
	Tylenol Arthritis			C	Oral			Not Reported
	Lucentis			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705629	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2867		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Simponi			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705631	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2806		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Inappropriate Schedule Of Product Administration; Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Every 1 Days		Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705975	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava			S	Oral	Unk		Sanofi
	Sulfasalazine			S		1 G, Bid		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Folic Acid			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi

	Actemra		S		Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Tofacitinib Citrate		S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705980	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA211217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis;	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Celecoxib			S	Unknown	Unk Unk, Bid		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Hydromorphone Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk Unk, Unk		Not Reported
	Lorazepam			S	Unknown	1 Mg, Qd		Not Reported
	Morphine Salt Not Specified			S	Unknown	Unk Unk, Unk		Not Reported
	Ciclosporin			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported

Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Orencia		S	Unknown	Unk Unk, Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Citalopram		C	Unknown	10 Mg, Qd		Not Reported
	Methotrexate		C	Subcutaneous	25 Mg, Qw		Not Reported
	Pantoloc [Pantoprazole]		C	Unknown	40 Mg, Bid		Not Reported
	Prednisone		C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Aug-2019	16705981	EXPEDITED (15-DAY)		OT	CA-SA-2019SA211180		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Fatigue; Pain; Polyarthritis; Respiratory Failure; Rheumatoid Arthritis; Synovitis; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Mefenamic Acid			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Xeljanz			S		5 Mg, Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		1000 Mg, Tid		Not Reported
	Lyrica			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	12327306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nausea; Vomiting	Enbrel			S	Unknown	Unk			Amgen
	Humira			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	12340057	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055345		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hyperhidrosis; Influenza; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported
	Celebrex			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	12347281	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016244516		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Enbrel			S		50 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Pfizer
	Cimzia			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported

	Naprosyn [Naproxen]	S		Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported
	Prednisone	S		Unk		Not Reported
	Crestor	C		Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Naprelan	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	13053291	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	13055037	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK187738		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Voltarene [Diclofenac Sodium]			S	Oral	Unk		Glaxosmithkline
	Salazopyrine			S	Oral	Unk		Not Reported

	Opdivo			S	Intravenous (not otherwise specified)	1 Df Biw				Not Reported
	Plaquenil			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	13519993	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038587		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	760 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Q4wk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported

Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Unknown	12.5 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q4wk	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Q4wk	Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
	Tocilizumab	S	Unknown	680 Mg, Q4wk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	680 Mg, Qmo	Not Reported
	Actemra	S	Unknown	360 Mg, Qmo	Not Reported
	Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Myochrysine	S	Parenteral	50 Mg, Qmo	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram	Not Reported
	Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
	Alendronate	S	Unknown	70 Milligram, Qwk	Not Reported
	Etanercept	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Etanercept	S	Unknown	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Milligram, Once Every 2 Hours	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
	Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	14188597	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017169116		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Enbrel	S	Subcutaneous	50 Milligram, Qwk		Amgen
	Etanercept	S	Subcutaneous	50 Milligram, Qwk		Amgen
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate Sodium	S	Subcutaneous	22.5 Milligram, Qwk		Not Reported
	Plaquenil	S	Unknown	200 Milligram		Not Reported
	Prednisone	S	Oral	5 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	22.5 Milligram, Qwk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	15298021	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803489		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Reaction; Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocin			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram		Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Salazopyrin			S	Unknown			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Orencia		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	15800901	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616917-00		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	15807040	EXPEDITED (15-DAY)		OT	CA-SA-2019SA005513		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Methotrexate			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Risedronic Acid			S				Not Reported
	Actonel			S	Unknown	35 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Sanofi
	Hydroxychloroquine			S		Unk Unk, Qd		Sanofi
	Risedronate Sodium			S		35 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk			Not Reported
	Hydroxychloroquine			C	Unknown	300 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16130114	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2723334-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16444969	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033573			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea;	Mirtazapine Tablet			S	Unknown	15 Milligram		Aurobindo

Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Plaquenil		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	25 Milligram	Not Reported
	Lyrica		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16539002	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2256		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Constipation; Eye Disorder; Herpes Zoster; Nasopharyngitis; Pain; Pulmonary Fibrosis; Upper Respiratory Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Cranberry			C	Unknown			Not Reported
	Dexilant			C	Unknown			Not Reported
	Duragesic Mat			C	Unknown			Not Reported
	Eurofer			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported

	Lipitor	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Senokot	C	Unknown	Not Reported
	Tears Naturale	C	Unknown	Not Reported
	Tylenol W/Codeine No. 3	C	Unknown	Not Reported
	Vitamin B Complex	C	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Not Reported
	Fentanyl	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Duragesic	C	Unknown	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Calcium D-Pantothenate	C	Unknown	Not Reported
	Nicotinamide	C	Unknown	Not Reported
	Pyridoxine Hydrochloride/Riboflavin/Thiamine Hydrochloride	C	Unknown	Not Reported
	Dextran 70	C	Unknown	Not Reported
	Hypromellose	C	Unknown	Not Reported
	Methotrexate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708500	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888272-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708546	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2073230		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708661	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2889909-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Arava			C				Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Ketorolac			C				Not Reported

		Folic Acid			C					Not Reported
		Advil			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16708919	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Lipitor			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16709777	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093149			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Leflunomide			C		20 Milligram Daily;		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C		3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16710554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2370885		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16710582	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019349350		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate Sodium			S	Unknown	0.6 Ml, Weekly		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16711011	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888911-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
			Hydroxychloroquine		S		Unknown			Not Reported
			Enbrel		S		Subcutaneous			Not Reported
			Cimzia		S		Subcutaneous			Not Reported
			Xeljanz		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16711096	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2888296-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16711822	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20190802522		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-	Otezla			S	Unknown	60 Milligram		Celgene
	Otezla			S	Unknown			Celgene
	Otezla			S	Unknown			Celgene
	Alendronate Sodium			S	Unknown	40 Milligram		Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported

Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Leflunomide	S	Oral		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral		Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Methotrexate	S	Unknown	7.1429 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous drip		Not Reported
	Rituxan	S	Intravenous drip	2000 Milligram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported

Leflunomide	S	Oral			Not Reported
Benadryl	C	Unknown			Not Reported
Colchicine	C	Oral			Not Reported
Dexilant	C	Unknown			Not Reported
Febuxostat	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Gravol	C	Unknown			Not Reported
Mogadon	C	Oral	5 Milligram		Not Reported
Nitrazepam	C	Unknown	5 Milligram		Not Reported
Oxycodone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Uloric	C	Unknown	160 Milligram		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712060	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Blister; Disability; Fatigue; Joint Swelling; Nausea; Product Dose Omission; Quality Of Life Decreased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Skin Discolouration; Visual Impairment; Vomiting	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712328	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2019-023054		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Metronidazole	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Oral			Not Reported
	Arava	S	Unknown	Unknown		Not Reported
	Erythromycin	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Bisoprolol Fumarate	S	Unknown	Unknown		Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Levofloxacin	S	Unknown	Unknown		Not Reported
	Norflox (Norfloxacin)	S	Unknown	Unknown		Not Reported
	Demerol	S	Unknown	Unknown		Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Arthrotec	S	Unknown	Unknown		Not Reported
	Celor	S	Unknown	Unknown		Not Reported
	Celebrex	S	Oral	Unknown		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Lyrica	S	Unknown	Unknown		Not Reported
	Meperidine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712445	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092147		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Lyrica	C	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712446	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092254			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Diarrhoea; Drug Ineffective; Fungal Infection; Hepatotoxicity; Herpes Zoster; Rash; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported
	Apixaban			C	Unknown	10 Milligram Daily;		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoloc[Pantoprazole]			C	Unknown			Not Reported
	Pantoloc[Pantoprazole]			C	Unknown	40 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Teva-Propranolol			C	Unknown			Not Reported
	Teva-Propranolol			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712447	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Pain In Extremity; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712457	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Interstitial Lung Disease; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16712458	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092962			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product	Azathioprine			S	Unknown			Not Reported

Administered; Drug Ineffective; Joint Swelling	Methotrexate	S	Oral	Barr
	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Oral	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	12321556	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054658		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Spinal Disorder; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	15282400	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-181447		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypoglycaemia	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16713028	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1092209		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16713051	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092337		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Drug Ineffective; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Arava	C	Unknown	20 Milligram Daily;		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Xeljanz	C	Oral	11 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Aug-2019	16713164	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093739		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	20 Milligram, 1 Every 1 Week		Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Prednisone			S	Unknown	3 Df		Actavis
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2019	13882319	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201708-004755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder Due To General Medical Condition, Insomnia Type; Synovitis; White Blood Cell Count Decreased	Plaquenil Tablet	S	Oral		Concordia
	Hydroxychloroquine	S	Unknown		Concordia
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Penicillin	S	Unknown		Not Reported
	Acetylsalicylic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Benzylpenicillin	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Pregabalin	C			Not Reported
	Tylenol	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Aug-2019	16178067	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736338-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	13116445	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2017-001069		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Dorzolamide Hydrochloride + Timolol Maleate			S	Ophthalmic			Bausch And Lomb
	Ramipril			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Cosopt			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Levothyroxine			C				Not Reported
	Hydroxychloroquine Phosphate			C				Not Reported
	Tylenol With Codein			C				Not Reported
	Tylenol			C				Not Reported
	Paracetamol/Caffeine/Dihydrocodeine			C				Not Reported

	Caffeine	C		Not Reported
	Methylprednisolone	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Diphenhydramine	C		Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen And Codeine Phosphate	C		Not Reported
	Acetaminophen/Caffeine/ Dihydrocodeine	C		Not Reported
	Acetaminophen /Caffeine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	13174436	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015254758		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Abnormal; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	15795569	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1900590US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Risedronate Sodium - Bp			S	Unknown	35 Mg, Q Week		Allergan
	Methotrexate			S	Subcutaneous	17.5 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Enbrel			S	Unknown	Unk				Not Reported
	Humira			S	Subcutaneous	Unk				Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	15857448	NON-EXPEDITED			US-MYLANLABS-2019M1000410		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	200 Milligram, Bid		Mylan
	Lyrica			C		Unk		Mylan
	Benicar			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	15933701	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655946-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Limb Discomfort; Loss Of Consciousness; Mobility Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Gold	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	15941997	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1774238-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Humira 40mg/0.8ml			S	Subcutaneous	Cyclical		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cortisone			C				Not Reported

	Prednisone	C				Not Reported
	Tylenol Arthritis	C				Not Reported
	Naproxen	C				Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Naprosyn	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16283707	EXPEDITED (15-DAY)		HO, OT	CA-CELGENEUS-CAN-20190409739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Infliximab			S	Intravenous drip	520 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16387848	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP015481			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Ibuprofen			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported

				Orencia	S	Unknown	Unk		Not Reported
				Plaquenil /00072602/	S	Oral	200 Mg, Qd		Not Reported
				Prednisone	C	Unknown	Unk		Not Reported
				Prednisone	C				Not Reported
				Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16407950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2809851-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16548529	EXPEDITED (15-DAY)		OT	PHHY2019ES156461		51 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pericarditis; Pleural Effusion; Pleurisy; Pneumonia; Product Use In Unapproved Indication; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	15 Mg, Qw		Novartis
	Methotrexate			S				Novartis
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S				Not Reported
	Leflunomide			S				Not Reported

	Prednisone		S	Unknown	30 Mg, Qd		Not Reported
	Prednisone		S				Not Reported
	Prednisone		S				Not Reported
	Prednisone		S				Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Q12h		Not Reported
	Aspirin		C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16578321	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852199-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16649158	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1082804		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Cefazolin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Amlodipine			C				Not Reported
	Arava			C	Unknown			Not Reported
	Arava			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16665338	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086086		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C				Not Reported

	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C		12 Milligram Daily;	Not Reported
	Tocilizumab	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16675612	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086060		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16705069	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888307-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Cimzia	S	Unknown	Single-Use Pre-Filled Syringe		Not Reported
	Rituxan	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Celebrex	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16713558	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888896-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity;	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Depomedrol	C	Intra-articular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16713621	EXPEDITED (15-DAY)		CA, OT	US-CIPLA LTD.-2019US05804			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ebstein'S Anomaly; Foetal Exposure During Pregnancy	Warfarin			S	Transplacental	Unk		Invagen
	Low Molecular Weight Heparin			S	Transplacental	Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Belimumab			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714130	EXPEDITED (15-DAY)		OT	CA-SA-2019SA223467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Enbrel			C				Not Reported
	Cimzia			C		Unk		Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714359	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Drug Ineffective; Eye Pruritus; Headache; Hepatitis; Nausea; Unevaluable Event; Vomiting	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Daily Dose:10-20mg Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Baricitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16714677	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016248640		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hyperhidrosis; Influenza; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	22.5 Mg, Qwk		Unknown
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16715817	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019354373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer

Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716329	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716330	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093306			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprosyn			S	Oral	1000 Milligram Daily;		Not Reported

	Orencia	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Vioxx	S	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716331	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093335		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716594	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093863		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lower Respiratory Tract Infection; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Prednisone			C		10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716626	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094240		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	40 Gram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	750 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716627	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093811		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Pain; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Erythematous; Rheumatoid Arthritis	Orencia	S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Venlafaxine Hydrochloride	C				Not Reported
	Plaquenil	C				Not Reported
	Naproxen Sodium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716629	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094356			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716631	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Discomfort; Joint Stiffness; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram, 1 Every 1 Weeks		Barr
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	L-Thyroxine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716640	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	25 Milligram		Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			C	Unknown	400 Milligram		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716641	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093821		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716646	EXPEDITED (15-DAY)		OT	PHHY2019IN188612			Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomegaly; Cardiomyopathy Neonatal;	Metoprolol			S	Transplacental	Maternal Dose: Unk		Not Reported

Foetal Exposure During Pregnancy; Foetal Growth Restriction; Hyperbilirubinaemia Neonatal; Low Birth Weight Baby; Neonatal Hepatomegaly; Neonatal Respiratory Distress; Neonatal Tachycardia; Poor Peripheral Circulation; Premature Baby; Pulmonary Oedema Neonatal; Thrombocytopenia Neonatal	Prednisolone	S	Transplacental	Maternal Dose: Unk	Novartis
	Hydroxychloroquine	S	Transplacental	Maternal Dose: Unk	Not Reported
	Amlodipine	S	Transplacental	Maternal Dose: Unk	Not Reported
	Levothyroxine	S	Transplacental	Maternal Dose: Unk	Not Reported
	Aspirin	S	Transplacental	Maternal Dose: 75mg/D	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716674	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094355		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	20 Milligram, 4 Every 1 Weeks		Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily; Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716849	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716851	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093807		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716853	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094516			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Fatigue; Pain; Polyarthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716856	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093797		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716860	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1093874		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716862	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093759		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716863	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1094309		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate		S	Oral		Barr
	Actemra		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Arava		C	Unknown		Not Reported
	Orencia		C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716866	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

	Xeljanz			C	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716868	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094313		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716873	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported

		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716892	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amoxicillin Sodium/Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported
	Bacillus Calmette-Guerin Vaccine			C	Intravenous (not otherwise specified)			Not Reported
	Bacillus Calmette-Guerin Vaccine			C	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716944	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092325		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716945	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092340		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717009	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094349			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal;	Methotrexate			S	Oral	20 Milligram Daily;		Barr

Dermatitis Allergic; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Prednisone	C		5 Milligram Daily;	Not Reported
	Celebrex	C		200 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717086	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092319		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717089	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1092339		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Synovitis; Therapeutic Product Effect Incomplete; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717149	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1093742		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Condition Aggravated; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Surgery; Venous Operation; Visual Impairment	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown	8 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Methotrexate			S	Unknown			Barr

Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous		Not Reported
	Apo-Leflunomide			S	Unknown		Not Reported
	Enbrel			S	Subcutaneous		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Orencia			S	Unknown		Not Reported
	Plaquenil			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717153	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093755			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717369	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093827		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated	Methotrexate			S	Oral			Barr

Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Arava		C	Unknown		Not Reported
	Lyrica		C	Oral		Not Reported
	Prednisone		C	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717411	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717468	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717498	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093391		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717499	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093816			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717537	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093416		71 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Nausea; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl			C				Not Reported
	Ergocalciferol			C				Not Reported
	Leucovorin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717538	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Leucovorin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717539	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093427			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717616	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093455		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717722	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093898		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717899	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1093064		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Etanercept		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717921	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Nausea; Retinal Disorder; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulpate			C	Unknown			Not Reported
	Isoniazid/Pyridoxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717928	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1093373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Disorder; Malaise; Therapeutic Product Effect Decreased	Methotrexate		S	Unknown	Barr
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Rituxan		C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717982	EXPEDITED (15-DAY)		OT	PHHY2019IN188610			Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brow Presentation; Enchondromatosis; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Musculoskeletal Stiffness; Premature Baby; Rhinoplasty	Metoprolol			S	Transplacental	Unk		Not Reported
	Prednisolon			S	Transplacental	Unk		Novartis
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Amlodipine			S	Transplacental	Unk		Not Reported
	Levothyroxine			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	12337495	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055245		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Musculoskeletal Pain; Vulvovaginal Rash	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	12914296	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Off Label Use; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1.2 Milliliter, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	12914309	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091711		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qwk		Not Reported

Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qwk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qwk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Oral	5 Mg, Qd	Not Reported
	Immune Globulin Iv	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immune Globulin Iv	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Triamcinolone Hexacetonide	S	Other	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Naproxen	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported

			Tocilizumab		S	Unknown	280 Milligram			Not Reported
			Triamcinolone Acetonide		S	Unknown				Not Reported
			Hydroxychloroquine Sulfate		S	Oral	5 Milligram/Kilogram, Qd			Not Reported
			Apo-Prednisone		S	Oral	5 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	13153200	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005842		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	5 Milligram, Qd		Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg, Prn		Not Reported
	Dexamethasone			C	Unknown	5 Mg, Qd		Not Reported
	Prednisone Acetate			C	Unknown	5 Mg, Qd		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk, Prn		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	13158932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005744		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Oral	25.0 Milligram, 1 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25.0 Milligram, 1 Every 1 Day		Not Reported
	Arava			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	10 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Prednisone			C	Oral	5 Milligram, Qd		Not Reported
	Prednisone			C	Oral	50 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	14137928	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15684670	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016241428		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Spinal Disorder; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk Unk, Qwk		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15859165	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633277-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Gabapentin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16106118	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055250		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported

	Plaquenil	S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil	S	Oral	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate Sodium	S	Oral	Unk		Not Reported
	Methotrexate Sodium	S	Intramuscular	25 Milligram, Qwk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Naprosyn	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16123531	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091229		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methyl Salicylate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16153359	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728652-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Depomedrol			C	Intramuscular			Not Reported
	Prednisone			C				Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16234916	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190406515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Otezla			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Not Reported

	Cosentyx		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Stelara		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown	2 Gram	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Methotrexate		C	Unknown		Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16397168	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP015529		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Ibuprofen			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16445870	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8.0 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16658760	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085056		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise;	Indometacin			S	Unknown			Actavis
	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis

Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Prednisone	S	Oral	3 Milligram Daily;	Actavis
	Prednisone	S	Oral	25 Milligram Daily;	Actavis
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	25 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold Radioactive Colloidal	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Prednisone	S	Oral	3 Milligram Daily;	Not Reported
	Prednisone	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Cimzia	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Gold (198 Au) Colloidal	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported

	Cymbalta	C	Unknown	30 Milligram Daily;		Not Reported
	Folic Acid	C	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16665094	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1086055		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Actemra			C	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16671925	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086052		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Knee Arthroplasty; Mouth Ulceration; Musculoskeletal Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16674122	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	Solution		Barr
	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16695839	EXPEDITED (15-DAY)		HO, OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001860			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage Neonatal; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Hydrocephalus	Plaquenil 200 Mg Tablet			S	Transplacental			Concordia
	Plaquenil 200 Mg Tablet			S	Transplacental			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16698373	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1089975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Imuran			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16700837	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089495		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acidophilus/00079701/	C	Unknown		Not Reported
	Aspirin/00002701/	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Deflazacort	C	Unknown	18 Milligram Daily;	Not Reported
	Dilaudid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown	18 Milligram Daily;	Not Reported
	Januvia	C	Unknown		Not Reported
	Kenalog/00031902/	C	Unknown		Not Reported
	Lidocaine	C	Unknown		Not Reported
	Metronidazole	C	Unknown		Not Reported
	Nitroglycerin	C	Unknown		Not Reported
	Pantoloc/01263201/	C	Unknown	40 Milligram Daily;	Not Reported
	Pregabalin	C	Unknown	200 Milligram Daily;	Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported
	Risedronate	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown	40 Milligram Daily;	Not Reported
	Salbutamol	C	Unknown		Not Reported
	Triamcinolone	C	Unknown		Not Reported
	Tylenol/00020001/	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16710949	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016333883		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Bacitracin			S	Unknown	Unk		Pfizer
	Neomycin Sulfate			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Polymyxin B Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	Unk		Not Reported
	Prednisone			C	Intramuscular	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718480	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217111		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported

	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Unknown	Unk Unk, Unk		Not Reported
	Cefalexin			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718482	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA217148			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718484	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Q4w		Not Reported
	Actemra			S	Unknown	1 Df, Qw		Not Reported
	Ciclosporin			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported

	Humira			S	Subcutaneous	1 Df, Qw			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw			Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk Unk, Unk			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Qw			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718486	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217053		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718507	NON-EXPEDITED			US-TEVA-2018-US-954514		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn	Hydroxychloroquine			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718598	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217218		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Plaquenil			S	Unknown	100 Mg, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718675	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216492		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Arava			S	Unknown	Unk Unk, Unk		Sanofi

Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Nausea; Rash; Therapeutic Product Effect Decreased	Clarithromycin	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk Unk, Unk	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Ciprofloxacin Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Clindamycin Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Codeine	S	Unknown	Unk Unk, Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk Unk, Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Rabeprazole Sodium	S	Unknown	Unk Unk, Unk	Not Reported
	Plaquenil	S	Unknown	Unk Unk, Unk	Sanofi
	Levofloxacin	S	Unknown	Unk Unk, Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk Unk, Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk Unk, Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk Unk, Unk	Not Reported
	Enalapril	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk Unk, Unk	Not Reported
	Penicillin [Penicillin Nos]	S	Unknown	Unk Unk, Unk	Not Reported
	Prednisone	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Gold	C			Not Reported
	Iron Sucrose	C			Not Reported
	Esomeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718813	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1094453		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Methotrexate	S	Unknown			Barr
	Methotrexate	S				Barr
	Actemra	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil /00072602/	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16718834	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892212-00		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Multimorbidity; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719080	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic	Arava			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported

Response Decreased	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Enbrel	S		50 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719184	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216293			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methylprednisolone			S	Unknown	80 Mg		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Qow		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Mg, Q8w		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719213	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2888902-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2889126-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Aortic Aneurysm; Drug Hypersensitivity; Drug Ineffective; Hypertension; Laboratory Test Abnormal; Mitral Valve Prolapse; Nausea	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Codeine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719792	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019356829		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Daily		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Effexor Sr			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hyzaar			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16719989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019354203		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1 Every 2 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720030	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019352858		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Abatacept			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720035	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019352869		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Methotrexate Sodium			S	Unknown	Unk Unk, Weekly		Pfizer
	Leucovorin			S	Unknown	Unk Unk, Weekly		Pfizer
	Actemra			S	Unknown	Unk Unk, Weekly		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	2 Df, 1 Every 2 Day (S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720231	EXPEDITED (15-DAY)		OT	CA-SA-2019SA218711			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric	Arava			S	Oral	20 Mg, Qd(1 To 4-5 Bm Per Day)		Sanofi

Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Plaquenil	S		400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	15 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid (Or 500mg Q Unk1)	Not Reported
	Prednisone	S		25 Mg, Qd	Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported
	Shingrix	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720233	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217087		71 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Nausea; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qow		Not Reported
	Leucovorin [Calcium Folinate]			C	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720235	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217228		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Depression; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Feeling Abnormal; Joint Range Of Motion Decreased; Joint Swelling; Mobility Decreased; Mood Swings; Motor Dysfunction; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Pneumonia; Rash; Sinusitis; Somnolence	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Sulfasalazine			S		1 G, Bid		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Calcium D-Pantothenate			C		1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16720314	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Range Of Motion Decreased; Pain; Synovitis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721256	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pain; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Tofacitinib Citrate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721327	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094455		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	1 Df 1 Every 1 Weeks		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Oral			Not Reported
	Lyrica	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721426	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093286		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C		100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721573	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721650	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093789		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Acetaminophen/Codeine Phosphate			C	Unknown			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported

		Leflunomide			C	Unknown				Not Reported
		Naproxen			C	Unknown				Not Reported
		Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721653	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094365		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Tylenol/00020001/			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Codeine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721656	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721659	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Contraindicated Product	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Retinopathy; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prolia Pre-Filled Syringe.Preservative-Free.	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721661	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093793		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Toradol			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721664	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093817		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisolone			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	5 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown	5 Milligram Daily;		Not Reported
	Tylenol/00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721665	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094164		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Urethral	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721666	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Reactine//Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721667	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1093872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721670	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Humira	S	Subcutaneous			Not Reported
	Lyrica	S	Oral			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721675	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094000		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

					Xeljanz	S	Unknown		Not Reported
					Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
					Leflunomide	C	Unknown		Not Reported
					Gold	C	Unknown		Not Reported
					Bacillus Calmette-Guerin	C	Intravenous (not otherwise specified)		Not Reported
					Bacillus Calmette-Guerin	C	Unknown		Not Reported
					Amoxil	C	Unknown		Not Reported
					Amoxicillin Sodium/Clavulanate Potassium	C	Unknown		Not Reported
					Amoxicillin Sodium/Clavulanate Potassium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721683	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721691	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated	Methotrexate			S	Unknown			Barr

Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Cortisone Acetate		S	Topical	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721695	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094450		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

	Prednisone				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721759	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094183		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721760	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093753		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Xeljanz		S	Oral	100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721764	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093812		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Xeljanz			S	Oral	100 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721765	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721766	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093835		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Methotrexate	S	Unknown		Barr
	Prednisone	S	Unknown		Actavis
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721820	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093876		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721842	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1094330		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Celebrex			C	Unknown	200 Milligram Daily;		Not Reported
	Prednisone			C		5 Milligram Daily;		Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721887	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094518		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cutaneous	Methotrexate			S	Oral			Barr

Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721946	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721947	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094089			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Arthritis; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Treatment Failure	Methotrexate	S	Unknown			Barr
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721948	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093826		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Desoximetasone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721976	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093858		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721978	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094178		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2.5 Milligram Daily;		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721979	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Failure; Wound	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram Daily;	Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil		S	Unknown	400 Milligram Daily;	Not Reported
	Reactine//Cetirizine Hydrochloride		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721982	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094265		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Alendronate Sodium			C	Unknown				Not Reported
	Fosamax			C	Unknown				Not Reported
	Ibuprofen			C	Unknown				Not Reported
	Lisinopril			C	Unknown				Not Reported
	Vitamin D3			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721984	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093861		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Methotrexate			S	Unknown			Barr
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16721988	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094472		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Methotrexate			S	Unknown			Barr

Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Oral		Barr
	Apo-Azathioprine		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Xeljanz		S	Oral	100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722002	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093775		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

					Hydroxychloroquine		S	Unknown			Not Reported
					Orencia		S	Unknown			Not Reported
					Plaquenil		S	Unknown			Not Reported
					Rituxan		S	Intravenous (not otherwise specified)			Not Reported
					Sulfasalazine		S	Unknown			Not Reported
					Sulfasalazine		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722003	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093822		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Asthma; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)			
				Rituxan	S	Intravenous (not otherwise specified)			Not Reported
				Xeljanz	S	Unknown			Not Reported
				Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
				Sulfasalazine	S	Unknown	1 Gram Daily;		Not Reported
				Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722021	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094246		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Anakinra			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722024	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty;	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722026	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093916		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Drug Ineffective; Drug Intolerance; Nausea; Retinitis; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722038	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093782		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722044	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093880		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
	Xeljan	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722103	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1094294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722104	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093792		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Hydrochlorothiazide			S	Unknown			Ivax
	Prednisone			S	Unknown			Actavis
	Apo-Hydro			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722132	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093836			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cortisone Acetate		S	Unknown	Not Reported
	Cortisone Acetate		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil/00072603/		S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
	Reactine//Cetirizine Hydrochloride		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722133	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094522			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Estradiol		C	Unknown		Not Reported
	Estrogel		C	Unknown	1 Dosage Forms Daily;	Not Reported
	Furosemide		C	Unknown	40 Milligram Daily;	Not Reported
	Morphine		C	Unknown		Not Reported
	Potassium Chloride		C	Unknown	1500 Milligram Daily;	Not Reported
	Valsartan		C	Unknown	320 Milligram Daily;	Not Reported
	Xalatan		C	Unknown	50 Microgram Daily;	Not Reported
	Zingiber Officinale		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722217	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094100			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported

	Xeljanz			C	Oral	20 Milligram Daily;			Not Reported
	Xeljanz			C		10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722334	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093377		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Celebrex			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722335	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093370		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722338	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1093374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Insomnia; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stress At Work; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722347	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094193		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722349	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2019-CA-1093379		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Fibromyalgia; Gait Disturbance; Hypertension; Hypertrophic Cardiomyopathy; Hypoacusis; Joint Swelling; Mobility Decreased; Pain; Pain In Extremity; Sleep Disorder Due To General Medical Condition, Insomnia Type; Temperature Intolerance; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722639	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892228-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

Colchicine	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Mercaptopurine	C	Unknown		Not Reported
Tenoxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722674	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2452291-00		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Finger Deformity; Headache; Macular Degeneration; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Synovitis; Wrist Deformity	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Asacol			C	Unknown			Not Reported
	Sulfasalazine			C	Endocervical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	16722688	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001879			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Methotrexate			S	Oral			Not Reported

	Methotrexate			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	12769954	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Rituxan			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

	Hydroxychloroquine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	14186780	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170122		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Chloroquine			S	Unknown	250 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	250 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	14195502	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491606		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Enbrel			S	Unknown	20 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Sulfasalazine			S	Unknown	1 G, Bid		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	250 Mg, Qd		Not Reported
	Apo-Leflunomide			S		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15400059	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Reactine [Cetirizine Hydrochloride]			S	Unknown				Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Certolizumab Pegol			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15698627	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3590		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Impairment; Spinal Disorder; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15722481	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202740		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Otezla			S	Oral			Celgene
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Methotrexate			C	Unknown					Not Reported
	Arava			C	Unknown					Not Reported
	Leflunomide			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16044413	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Hypersensitivity; Drug Ineffective	Methotrexate			S	Oral			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	200 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	5 Milligram Daily;		Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16081399	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012915			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Acetazolamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S				Not Reported

				Hydroxychloroquine Sulphate		S	Unknown	Unk		Not Reported
				Remicade		S	Intravenous (not otherwise specified)	1 Dosage Form (Every Month)		Not Reported
				Remicade		S				Not Reported
				Leflunomide		S	Unknown	Unk		Not Reported
				Leflunomide		S				Not Reported
				Methotrexate		S	Unknown	Unk		Not Reported
				Methotrexate		S				Not Reported
				Ferric Hydroxide Polymaltose Complex		S	Unknown	Unk		Not Reported
				Remicade		S	Intravenous (not otherwise specified)	1 Dosage Form (Every Month)		Not Reported
				Remicade		S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16206273	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019776			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Clavulin			S	Intracardiac	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported
	Orencia			S	Intracardiac	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram, Two Times A Day		Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram		Not Reported

	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	200 Milligram, Two Times A Day	Not Reported
	Plaquenil	C	Unknown	200 Milligram	Not Reported
	Prednisone	C	Unknown	7.5 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	705 Milligram, Daily	Not Reported
	Tridural	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16388794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-051033		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hcl / Pseudoephedrine Hcl			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported

Methotrexate	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Apo Prednison	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Folic Acid	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16674093	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086126		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Leflunomide	S	Unknown		Barr
	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Leflunomide	S	Oral		Barr
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Oral	12.5 Milligram Daily; Solution	Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous	12.5 Milligram Daily;	Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Oral	12.5 Milligram Daily;	Barr
	Methotrexate	S	Unknown	2.8571 Milligram Daily;	Barr
	Methotrexate	S	Unknown	2.8571 Milligram Daily;	Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16691457	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1090514		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; False Positive Investigation Result	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16722950	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001881			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hemiparaesthesia; Hyperaesthesia; Neuropathy Peripheral	Hydroxychloroquine			S		200 Mg, 100 (66993-057-02)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16722951	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001880			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lipodystrophy Acquired; Lupus Nephritis; Proteinuria; Retinal Degeneration; Toxicity To Various Agents	Plaquenil			S	Unknown			Concordia
	Strensiq			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723230	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0956		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723235	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001882			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Plaquenil			S	Unknown	Drug Discontinued		Concordia
	Plaquenil			S	Unknown	Dose Decreased		Concordia
	Humira			S	Subcutaneous	Drug Discontinued		Not Reported
	Humira			S	Subcutaneous	Dose Increased		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723319	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093810		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Methotrexate			S	Oral			Barr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate		S	Subcutaneous	Barr
	Enbrel		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Benadryl		C	Unknown	Not Reported
	Naproxen Sodium		C	Unknown	Not Reported
	Plaquenil		C	Unknown	Not Reported
	Venlafaxine		C	Unknown	Not Reported
	Cetirizine Hydrochloride		C	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723320	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093788		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723441	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094359		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Fatigue; Pain; Polyarthritis; Respiratory Failure; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown	3000 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723453	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557368-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Discomfort; Drug Ineffective; Erythema; Joint Swelling; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723499	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633521-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Discomfort; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16723558	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093777		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16724125	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-053921			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease;	Ciprofloxacin			S	Unknown	Unk		Aurobindo

Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine	S	Unknown	Unk	Not Reported
	Clavulin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram, Two Times A Day	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16724299	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015288217		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypoaesthesia; Paraesthesia	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Plaquenil			S	Oral	200 Mg, Twice Daily		Not Reported
	Modafinil			C	Oral	200 Mg, Once Daily		Not Reported
	Cymbalta			C		60 Mg, Daily		Not Reported
	Cymbalta			C				Not Reported
	Amitriptyline			C		500 Mg, Daily At Night (Hs)		Not Reported
	Amitriptyline			C				Not Reported
	Vimovo			C		500 Mg, Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16724518	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019357075		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Malaise; Osteomyelitis; Pneumonia	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725655	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1095221			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725656	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate			S	Unknown			Barr

Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone		S	Unknown	Actavis
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Reactine//Cetirizine Hydrochloride		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725659	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093732		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)	
	Plaquenil		S	Oral	Not Reported
	Naprosyn/00256201/		C	Unknown	Not Reported
	Ramipril		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Metformin		C	Unknown	Not Reported
	Lozide/00340101/		C	Unknown	Not Reported
	Lantus		C	Subcutaneous	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Asa		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725667	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095246		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Risedronate			C				Not Reported
	Indometacin			C	Unknown	50 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16725703	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2895578-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pain; Pulmonary Thrombosis	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

Enbrel	S	Unknown	Not Reported
Enbrel	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Anakinra	S	Unknown	Not Reported
Anakinra	S		Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S		Not Reported
Oxycodone	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S		Not Reported
Marijuana	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S		Not Reported

	Orencia			S	Unknown				Not Reported
	Orencia			S					Not Reported
	Ilaris			S	Unknown				Not Reported
	Ilaris			S					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S					Not Reported
	Lyrica			C					Not Reported
	Kineret			C					Not Reported
	Rituximab W/Urelumab			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726016	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095196			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726018	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095239			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;			Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726019	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094876			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726057	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095748		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726058	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Nausea; Retinal Toxicity; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			C				Not Reported
	Prednisone			C	Unknown	6 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726126	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Ativan			C				Not Reported
	Darifenacin			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Furosemide			C				Not Reported
	Loperamide			C				Not Reported

	Norflex			C						Not Reported
	Omnaris			C						Not Reported
	Pantoprazole			C						Not Reported
	Synthroid			C						Not Reported
	Vagifem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726206	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094210			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Swelling; Urticaria	Methotrexate			S	Intramuscular			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arthrotec			S	Oral	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Mefenamic Acid			C				Not Reported
	Tylenol			C		1300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726208	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine//Cetirizine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726254	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094666			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Orencia		S	Subcutaneous		Not Reported
					Reactine [Cetirizine]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726279	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094816		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726409	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726410	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093882		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported

	Sulfasalazine			S	Unknown	2000 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726411	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094252			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726412	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093918		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

		Plaquenil			S	Unknown				Not Reported
		Plaquenil			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726423	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093937		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726436	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Stress	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown	200 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Domperidone	C	Unknown	10 Milligram Daily;		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726524	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094507		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Soft Tissue Swelling; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported

Darifenacin	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog /00031902/	C	Intra-articular	Not Reported
Loperamide	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726596	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095218			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

Disorder	Arava			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported
	Rituxan			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726644	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095242		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726695	EXPEDITED (15-DAY)		OT	PHHY2019CA192699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

			Azathioprine		S	Unknown	Unk			Not Reported
			Anakinra		S	Unknown	Unk Unk, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726796	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1094667		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	16726816	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	9029204	NON-EXPEDITED		OT	CA-AMGEN-CANSP2013004594		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Injection Site Erythema; Injection Site Infection; Injection Site Pain; Injection Site Reaction; Injection Site Recall Reaction; Injection Site Swelling; Injection Site Warmth; Laboratory Test Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Mtx			S	Unknown	12.5-25 Mg, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			C		Unk		Not Reported
	Hyzaar			C		Unk		Not Reported
	Effexor			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	12353014	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016247212		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Musculoskeletal Pain; Vulvovaginal Rash	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	12491777	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016078118		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Tofacitinib			S	Unknown	5 Milligram, Bid		Not Reported
	Tofacitinib			S	Subcutaneous	5 Milligram, Bid		Not Reported
	Tofacitinib			S	Unknown	10 Milligram, Bid		Not Reported
	Tofacitinib			S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	567 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	8.0 Mg/Kg, Qmo		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported

Rho D Immune Globulin	S	Unknown	Unk	Not Reported
Benzalkonium Chloride	S	Unknown	Unk	Not Reported
Boric Acid	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Disodium Edetate	S	Unknown	Unk	Not Reported
Phenylephrine Hcl	S	Unknown	Unk	Not Reported
Sodium Borate	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram, Kg, Qmo, 5 Years	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, Bid	Not Reported
Tofacitinib Citrate	S	Subcutaneous	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Arava	S	Unknown	20 Milligram	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr	S	Unknown	Unk	Not Reported
Ibuprofen	C	Oral	400 Milligramdaily, If	Not Reported

						Needed			
	Ibuprofen			C	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported
	Xeljanz			C	Unknown	Unk			Not Reported
	Lipitor			C	Oral	10 Milligram, Qd			Not Reported
	Lipitor			C	Unknown	Unk			Not Reported
	Celebrex			C	Unknown	Unk			Not Reported
	Celebrex			C	Oral	400 Milligram			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	13183111	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2816		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	13519392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038157		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15355332	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201809-003180		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Rash	Plaquenil 200 Mg Tablet			S	Oral	200 Mg Daily And 400 Mg Daily, Alternately		Concordia
	Plaquenil 200 Mg Tablet			S	Oral	200 Mg Daily And 400 Mg Daily, Alternately		Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Prednisolone			S	Oral			Concordia
	Edirol			C				Not Reported
	Edirol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15668984	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-980782		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Methotrexate			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15699045	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2582115-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Domperidone			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15929031	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007531		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Surgical Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mobicox			C		15 Milligram Daily;		Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16068343	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-19K-028-2702970-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16071519	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe Solution Subcutaneous		Not Reported

	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Azathioprine		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Plaquenil		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Imuran		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16086084	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1911621US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate Sodium - Bp			S	Oral	35 Mg, Q Week		Allergan
	Risedronate Sodium - Bp			S	Oral	Unk		Allergan
	Actonel Dr			S	Oral	35 Mg, Q Week		Allergan
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Plaquenil			S	Oral	300 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Anakinra			S	Subcutaneous	100 Unk		Not Reported

	Arava	S	Oral			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Gold For Rheumatoid Arthritis	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	S	Oral	10 Mg, 5 Mg,2 In 1 D		Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16103293	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-19K-028-2713266-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial		Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported

	Anakinra	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16237677	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-076823		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Cipro			S	Unknown	Unk		Bayer
	Azathioprine			S	Unknown	Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Ow		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Bid		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	7.5 Mg, Qd		Not Reported
	Tridural			C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			C				Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16548670	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1072555		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Skin Ulcer; Swelling; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Rosuvastatin			S	Unknown			Actavis
	Rosuvastatin Calcium			S	Unknown			Actavis
	Rosuvastatin Calcium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

	Sulfasalazine	S	Unknown			Not Reported
	Cephalexin	C	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;		Not Reported
	Coversyl	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16617646	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20190717471		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported
	Ciclosporin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16638085	EXPEDITED (15-DAY)		OT	PHHY2019FR170403		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Prednisone			S	Oral	25 Mg, Qd		Novartis
	Kardegic			S	Oral	75 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd (200 Mg Matin Et Soir)		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd (200 Mg Matin Et Soir)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16674135	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1086137		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Diabetes Mellitus; Wound Infection				otherwise specified)		
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
	Naprosyn /00256201/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16689757	NON-EXPEDITED			US-PFIZER INC-2019339961			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Joint Lock	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16727745	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001887			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Plaquenil			S	Unknown			Concordia
	Arava			S	Oral	(1 To 4-5 Bm Per Day)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	(Or 500mg Qunk1)		Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Shingrix			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16727761	EXPEDITED (15-DAY)		OT	NZ-CONCORDIA PHARMACEUTICALS INC.-GSH201908-		20 YR	Female	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Adalimumab			C				Not Reported
	Adalimumab			C				Not Reported
	Prednisone			C				Not Reported
	Vitamin D			C				Not Reported
	Omeprazole			C				Not Reported
	Fluoxetine			C				Not Reported
	Humulin			C				Not Reported
	Amitriptyline			C				Not Reported
	Asacol			C				Not Reported
	Sumatriptan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16727933	EXPEDITED (15-DAY)		DE	DE-ROCHE-2377022			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728014	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054075			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

					Enbrel	S	Unknown	Unk	Not Reported
					Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
					Methotrexate	S	Unknown	Unk	Not Reported
					Misoprostol	S	Unknown	Unk	Not Reported
					Naproxen	S	Unknown	Unk	Not Reported
					Prednisone	S	Unknown	Unk	Not Reported
					Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728019	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054088			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Misoprostol			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728026	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896124-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Abnormal; Condition Aggravated; Drug Ineffective; End Stage Renal Disease; Proteinuria	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Infliximab	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728096	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-053955			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Clindamycin			S	Unknown	Unk		Aurobindo
	Losartan			S	Unknown	Unk		Aurobindo
	Cephalexin			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Celebrex			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hctz			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported

	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G	S	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Once A Day	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728280	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095543		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthritis Bacterial; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Gastric Disorder; Mobility Decreased; Nerve Injury; Pain; Post Procedural Complication; Procedural Complication; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095488		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous			Not Reported
	Arava	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;		Not Reported
	Morphine Sulfate Injection 1mg/Ml	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Morphine	C				Not Reported
	Plaquenil	C				Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728346	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2932		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728712	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094839		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported

Decreased	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Arava	C	Unknown			Not Reported
	Humira	C	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown	2 Gram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728716	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079075		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728727	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094136		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C				Not Reported
	Infliximab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728737	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1094462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16728745	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1093784		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown	Solution		Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	125 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729218	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079067			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729362	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095073		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hangover; Ill-Defined Disorder; Malaise; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729785	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896210-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16730710	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Contraindicated Product Administered; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sinusitis; Treatment Failure; Vertigo	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731057	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095153			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein	Methotrexate			S	Oral			Barr

Increased; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Methotrexate	S	Subcutaneous		Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731061	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019034750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Thyroid Disorder	Cimzia			S	Subcutaneous			Ucb
	Arava			S		10 Milligram, Once Daily (Qd)		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731082	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096382		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Other			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731093	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096401		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731095	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1095842		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731098	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Leukopenia; Retinopathy	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731099	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Methotrexate	S	Subcutaneous			Barr
	Prednisone	S	Oral			Actavis
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731102	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731250	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096434		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
		Varicella Zoster Vaccine Live			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731890	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095249			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Spinal Compression Fracture	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731926	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095368			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731928	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095307			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Hepatic Enzyme Abnormal; Rheumatoid Arthritis	Methotrexate	S	Unknown		Barr
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Celebrex	C			Not Reported
	Plaquenil	C			Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731932	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096165		79 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Blood Pressure Systolic Increased; Condition Aggravated; Hypoaesthesia	Methotrexate			S	Oral			Barr
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Tylenol Arthritis Pain 8h			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731943	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096259		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731944	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096197		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Esomeprazole			C	Unknown	40 Milligram Daily;		Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Nexium			C	Unknown			Not Reported
	Suphedrine Pe			C	Unknown	10 Milligram Daily;		Not Reported
	Trazodone			C	Unknown	200 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported
	Tylenol			C	Unknown	3000 Milligram Daily;		Not Reported
	Valsartan			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Wellbutrin Xl			C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731951	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096246			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732020	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095224		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732027	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095306		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732057	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732061	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095384		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732063	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1095869		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732070	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095244		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported
	Plaquenil			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732087	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732090	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1095955		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr

Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate		S	Subcutaneous		Barr
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Actemra		C	Subcutaneous		Not Reported
	Arava		C		20 Milligram Daily;	Not Reported
	Hydroxychloroquine		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732095	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1095846		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

						otherwise specified)				
		Plaquenil			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732146	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096239			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown	15 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16732149	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1096170		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Contraindicated Product Administered; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	12350661	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016056846		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Hypoaesthesia; Migraine; Nausea; Pharyngeal Oedema; Rheumatoid Factor Positive; Swelling Face; Synovitis; Uveitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Arthrotec			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	12500845	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-045096		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Calcium			C	Unknown	500 Milligram, Qd		Not Reported
	Dorzolamide			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qd		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	1 Dosage Form		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Jamp K20			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Xalatan			C	Unknown	50 Mg, Qd		Not Reported
	Gravol Ginger Nighttime			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

	Xeljanz	C	Unknown			Not Reported
	Zingiber Officinale	C	Oral	500 Milligram		Not Reported
	Estradiol	C	Unknown			Not Reported
	Dorzolamide Hcl/Timolol Maleate	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	12705278	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-041312		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Viral Infection	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	12766798	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076609		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

	Enbrel		S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate		S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Plaquenil		S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil		S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Phosphate		S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram, Qd	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Naprosyn [Naproxen]		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	12769886	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076654		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram Every 1 Week		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Every 1 Week		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cyclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times Every 1 Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	50 Unk Every 1 Week		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every 1 Week		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Gold	S	Intramuscular	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	20.0 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Meloxicam	C	Oral	7.5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	12913913	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	200 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Milligram, Bid		Not Reported

Remicade	S	Unknown	300 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Benadryl /00000402/	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Cortisone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Enablex /01760401/	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lasix /00032601/	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Norflex /00018303/	C	Unknown	Unk	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc /01263204/	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported

	Vagifem	C	Unknown	Unk		Not Reported
	Anakinra	C	Unknown	Unk		Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Diphenhydramine	C	Unknown	Unk		Not Reported
	Darifenacin	C	Unknown	Unk		Not Reported
	Furosemide	C	Unknown	Unk		Not Reported
	Morphine Sulfate	C	Unknown	Unk		Not Reported
	Pantoprazole Sodium	C	Unknown	Unk		Not Reported
	Dyclonine Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	13107848	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-073911		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Incomplete	Abatacept			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Abatacept			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Abatacept			S	Intravenous (not otherwise specified)	Unk Unk, Qmo		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Mtx /00113801/			C	Unknown	Unk		Not Reported

	Teva Telmisartan	C	Unknown	Unk	Not Reported
	Simvastatin	C	Unknown	Unk	Not Reported
	Risedronate	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Pro-Bisoprolol	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Vit D	C	Unknown	Unk	Not Reported
	Statex /00036302/	C	Unknown	Unk	Not Reported
	Paroxetine	C	Unknown	Unk	Not Reported
	Asa	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Alprazolam	C	Unknown	Unk	Not Reported
	Amlodipine	C	Oral	5 Milligram, Qd	Not Reported
	Pantoprazole	C	Intracardiac	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Telmisartan	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	13153192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005886		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Cyclobenzaprine	C	Unknown	10 Milligram		Not Reported
	Desoximetasone	C	Unknown	5 Milligram, Qd		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Prednisolone Acetate	C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	14482710	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-850765		38 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Normal Newborn; Pregnancy On Oral Contraceptive; Product Use Issue	Methotrexate			S	Unknown			Barr
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	14648692	EXPEDITED (15-DAY)		OT	CA-GLENMARK PHARMACEUTICALS-2018GMK033327			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Disorder; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck	Gabapentin			S	Unknown	Unk		Glenmark
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Od		Not Reported
	Folic Acid			S	Unknown	1 Df, Bid		Not Reported
	Folic Acid			S	Unknown	1 Df, 2 Every 1 Week		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Od		Not Reported

Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	25 Mg, Qw		Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid		Not Reported
	Prednisone	S	Unknown	5 Mg, Od		Not Reported
	Actemra	C	Unknown	Unk		Not Reported
	Golden Seal /01446501/	C	Unknown	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Remicade	C	Unknown	Formulation: Powder For Solution Intravenous		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	15707728	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-986081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Teva
	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	15858704	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016087083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer

Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel	S	Unknown	Unk	Pfizer
	Tofacitinib Citrate	S	Unknown	5 Mg, 2x/Day	Pfizer
	Tofacitinib Citrate	S	Unknown	10 Mg, 2x/Day	Pfizer
	Tofacitinib Citrate	S	Unknown	5 Mg, 2x/Week	Pfizer
	Tofacitinib Citrate	S	Subcutaneous	5 Mg, 2x/Day	Pfizer
	Methotrexate Sodium	S	Subcutaneous	High Dose, Unk	Unknown
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Sulfasalazine	S	Oral	Unk	Pfizer
	Sulfasalazine	S	Oral	Unk	Pfizer
	Phenylephrine Hcl	S	Unknown	Unk	Unknown
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rho D Immune Globulin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	567 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic (Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Benzalkonium Chloride	S	Unknown	Unk	Not Reported
	Boric Acid	S	Unknown	Unk	Not Reported
	Disodium Edetate	S	Unknown	Unk	Not Reported
	Sodium Borate	S	Unknown	Unk	Not Reported
	Benzalkonium Chloride W/Diphenhydra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported

	Arava	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16478700	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-16267			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16622976	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-041416			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm;	Mirtazapine Tablet			S	Unknown	15 Milligram		Aurobindo

Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	Unk	Not Reported
	Lyrica		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	25 Milligram	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16701324	EXPEDITED (15-DAY)			CA-ABBVIE-19K-028-2875962-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Pamidronate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Dilaudid			C				Not Reported
	Tenoxicam			C				Not Reported
	6-Mercaptopurine Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16716948	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1093734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16732678	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095412		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16732748	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054455			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Meloxicam			S	Oral	7.5 Milligram, Once A Day		Aurobindo
	Pantoprazole			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Cosentyx			S	Oral	300 Milligram, 1 Every 1 Month(S)		Not Reported
	Diclofenac			S	Oral	Unk, 3 Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Calcium Folinate			S	Oral	5 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	4 Dosage Form, Every Week		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Diltiazem Hydrochloride			C	Oral	240 Milligram		Not Reported
	Fluticasone Propionate			C		Unk		Not Reported
	Mar-Pantoprazole			C	Unknown	Unk		Not Reported
	Mometasone Furoate			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Salbutamol Sulfate			C		Unk		Not Reported
	Tramadol Hydrochloride			C	Oral	Unk, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16732753	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054488			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16732789	EXPEDITED (15-DAY)		OT	JP-CONCORDIA PHARMACEUTICALS INC.-GSH201906-001618		61 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acquired Pigmented Retinopathy; Retinal Disorder; Retinal Pigment Epitheliopathy; Visual Acuity Reduced	Plaquenil 200 Mg Tablet	S	Oral			Concordia
	Plaquenil 200 Mg Tablet	S	Oral	200 Mg Once A Day And 400 Mg Once A Day, Alternately		Concordia
	Plaquenil 200 Mg Tablet	S	Oral	200 Mg Once A Day And 400 Mg Once A Day, Alternately		Concordia
	Prednisolone	C				Not Reported
	Adalat Crono	C				Not Reported
	Crestor	C				Not Reported
	Nexium 1-2-3	C				Not Reported
	Prograf	C				Not Reported
	Azilva	C				Not Reported
	Infree S	C				Not Reported
	Azulfidine En	C				Not Reported
	Carvedilol	C				Not Reported
	Cilostazol	C				Not Reported
	Cardenalin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733110	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-046			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733251	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095546		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Humira			S	Subcutaneous	Not Reported
	Plaquenil			S	Oral	Not Reported
	Macrobid			C		Not Reported
	Tylenol			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733753	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733754	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095673		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Hip Arthroplasty; Hypertension; Loss Of	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Pain; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733755	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095308		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733767	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095661		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue;	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported

Injection Site Reaction; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Apo-Prednisone	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Remicade	S	Unknown			Not Reported
	Arava	C				Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16733810	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734671	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1096264		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported
	Thiamine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734673	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-055702			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis;	Ramipril			S	Unknown	Unk Unk, Once A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Ophthalmic	Unk		Not Reported

Sciatica	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Levothyroxine	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	400 Milligram, Once A Day	Not Reported
	Tylenol No.2	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734682	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096698		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734722	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097441		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16734735	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097471			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Pneumococcal Vaccine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735111	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019360937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise;	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown

Pleurisy; Pneumonia	Actemra	S	Unk		Not Reported
	Arava	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735121	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019360763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Vision Blurred	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 1x/Day		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735588	EXPEDITED (15-DAY)		HO	PHHY2019FR193639		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure	Ciclosporin			S	Oral	200 Mg, Unk		Novartis
	Cellcept			S	Oral	Unk		Not Reported
	Belimumab			S	Subcutaneous	200 Mg, Unk		Not Reported
	Dexamethasone			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported
	Cortancyl			S	Oral	15 Mg, Unk		Not Reported
	Amlor			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Mycostatine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735928	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735929	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate Tab 25mg			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Pseudoephedrine Hcl			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735933	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Ineffective; Fear Of Injection; Rheumatoid Arthritis; Stress	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown	200 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16735934	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous	Solution Subcutaneous			Not Reported
	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736081	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096413		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736084	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096414		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736895	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096654			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Diarrhoea; Drug Ineffective; Fungal Infection; Hepatotoxicity; Herpes Zoster; Rash; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptylene			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported
	Atorvastatin			C				Not Reported
	Novo Pranol			C	Unknown			Not Reported
	Pantoloc[Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736896	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Simponi	S	Subcutaneous		Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Celebrex	C			Not Reported
					Lyrica	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736901	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096904			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736903	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097127		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral			Actavis
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S		10 Milligram Daily;		Not Reported
	Celebrex			C				Not Reported

	Ergocalciferol			C						Not Reported
	Folic Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736904	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096812			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16736981	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Weeks		Barr
	Actemra			S	Intravenous (not			Not Reported

Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete			otherwise specified)		
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram Daily;	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Humira	S	Unknown	400 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Weeks	Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 1 Month	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Methotrexate	S	Vaginal	25 Milligram	Not Reported
	Methotrexate	S			Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Ativan	C	Unknown	1 Gram	Not Reported
	Ativan	C	Unknown	1 Milligram Daily;	Not Reported
	Benadryl	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported

Darifenacin	C	Unknown		Not Reported
Desoximetasone	C	Oral		Not Reported
Dilaudid	C	Unknown	16 Milligram Daily;	Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Dyclone	C	Unknown		Not Reported
Enablex	C	Unknown		Not Reported
Furosemide	C	Unknown	1200 Milligram Daily;	Not Reported
Furosemide	C	Unknown	40 Milligram	Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog	C	Intra-articular		Not Reported
Kineret	C	Unknown		Not Reported
Loperamide	C	Unknown	2 Dosage Forms Daily;	Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Orphenadrine	C	Unknown	2 Dosage Forms Daily;	Not Reported
Pantoloc	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported
Restasis	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737140	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2019150766		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Marrow Failure	Belimumab	S	Subcutaneous	200 Mg, Unk		Glaxosmithkline
	Ciclosporin	S	Oral	200 Mg, Unk		Glaxosmithkline
	Cellcept	S	Oral	Unk		Not Reported
	Cortancyl	S	Oral	15 Mg, Unk		Not Reported
	Plaquenil	S	Oral	400 Mg, Unk		Not Reported
	Dexamethasone	S	Oral	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Glaxosmithkline
	Lorazepam	C	Unknown	Unk		Glaxosmithkline
	Pantoprazole	C	Unknown	Unk		Glaxosmithkline
	Mycostatine	C	Unknown	Unk		Glaxosmithkline
	Amlor	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737205	EXPEDITED (15-DAY)		OT	AU-SHIRE-AU201923097			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Morphoea; Product Use In Unapproved Indication	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	1 Gram Per Kilogram, 1x A Month		Shire
	Methotrexate			S	Unknown	15 Milligram/Sq. Meter, 1x/Week		Not Reported
	Methylprednisolone			S	Unknown	30 Milligram/Kilogram, 1x A Month		Not Reported
	Mycophenolate Mofetil			S	Unknown	300 Milligram, 2x/Day:Bid		Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisolone			S	Unknown	1 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 3x A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737211	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016253044		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Hypoaesthesia; Migraine; Nausea; Pharyngeal Oedema; Rheumatoid Factor Positive; Swelling Face; Synovitis; Uveitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Arthrotec			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737270	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1095848			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)		
	Plaquenil		S	Other		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate		S	Parenteral		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Citalopram Hydrobromide		C	Unknown		Not Reported
	Ketoprofen		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Omeprazole		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Oral	5 Milligram Daily;	Not Reported
	Rosuvastatin Calcium		C	Unknown		Not Reported
	Rosuvastatin Calcium		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737445	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Interstitial Lung Disease; Nausea	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Arava			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737452	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096286		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Malaise; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis Noninfective	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Estradiol			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	L-Thyroxine			C				Not Reported
	Tylenol Arthritis Pain 8h			C	Unknown			Not Reported
	Ergocalciferol/Nicotinamide/Riboflavin/Thiamine Hydrochloride/Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737478	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	16737517	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096509			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	13519915	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038598		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood	Orencia			S	Intravenous (not	750 Milligram, Qmo		Bristol Myers Squibb

Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Incorrect Route Of Product Administration; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure			otherwise specified)		
	Orencia	S	Vaginal	750 Milligram, Qmo	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Qmo	Not Reported
	Sulfasalazine	S	Oral	2.5 Mg, Qd	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Apo Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50.0 Mg, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50.0 Mg, Q3wk	Not Reported
	Myochrysine	S	Intramuscular	60 Milligram, Q3wk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Xeljanz	S	Endocervical		Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Vitamin B-1	S	Unknown		Not Reported
	Fentanyl Matrix	S	Unknown		Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Nortriptyline Hydrochloride	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	S	Unknown	Unk	Not Reported
	Omega 3 [Fish Oil;Tocopherol]	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride;Paracetamol	C	Unknown	1 Df, Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Qmo	Not Reported
	Actonel	C	Unknown	36 Mg, Qwk	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported

Esomeprazole Magnesium Trihydrate	C	Unknown	400.0 Iu, Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported
Tylenol [Paracetamol]	C	Oral	1000 Mg, Qd	Not Reported
Retinol	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, 2 Every 1 Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Ascorbic Acid	C	Unknown		Not Reported
Biotin	C	Unknown		Not Reported
Docosahexanoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Mg, Bid	Not Reported
Ferrous Fumarate	C	Unknown		Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown		Not Reported
Retinol Palmitate	C	Unknown		Not Reported
Riboflavin	C	Unknown		Not Reported
Sodium Ascorbate	C	Unknown		Not Reported
Thiamine Hydrochloride	C	Unknown		Not Reported
Thiamine Mononitrate	C	Unknown		Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported

	D-Alpha Tocopherol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Vitamin-E [Tocopheryl Acetate]	C	Unknown		Not Reported
	Vitamin B-6	C	Unknown		Not Reported
	Cholecalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Oxycocet	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Oxycodone And Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	14629676	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038174		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Septra			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Neotrin [Ammonium Chloride;Guaifenesin;Sulfameth			C	Unknown	Unk		Not Reported

oxazole;Trimethoprim]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	14921235	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044362		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	14923039	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Off Label Use; Rash; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	15400040	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2019	15703047	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2580829-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Arthropathy; Deafness; Decreased Appetite; Dizziness; Drug	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported

Hypersensitivity; Ear Infection; Feeding Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous				Not Reported
	Gold			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Motrin			S	Unknown				Not Reported
	Naprosyn			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Tramadol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Aug-2019	16480280	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-16022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Imuran			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

			Plaquenil		S	Unknown	Unknown			Not Reported
			Plaquenil		S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	12558642	NON-EXPEDITED		OT	US-AMGEN-USASP2016088427		82 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Asthenia; Cardiac Disorder; Iron Deficiency Anaemia; Mitral Valve Disease; Rhinorrhoea; Sjogren'S Syndrome; Suicidal Behaviour; Therapeutic Product Effect Decreased; Viral Infection	Single Dose Prefilled Syringe(Enbrel)			S	Unknown	Unk		Amgen
	Xeljanz Xr			S	Oral	11 Milligram, Qd		Not Reported
	Xeljanz Xr			S	Oral	11 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sotalol			C		40 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	13052817	EXPEDITED (15-DAY)		HO, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201612-006498		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Plaquenil			S	Oral			Concordia
	Voltarene (Diclofenac Sodium)			S	Oral			Not Reported
	Opdivo			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	13158922	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005391			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Anakinra			C	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	13182508	NON-EXPEDITED			US-PFIZER INC-2017045198		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Estradiol			S		Unk		Pfizer
	Vioxx			S		Unk		Not Reported
	Restasis			S		Unk		Not Reported
	Duragesic [Fentanyl]			S		Unk		Not Reported
	Refresh Tears			S		Unk		Not Reported
	Systane (Polyethylene Glycol			S		Unk		Not Reported

400\Propylene Glycol)			
Lasix [Furosemide]	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
Calcium	S	Unk	Not Reported
Trazodone	S	Unk	Not Reported
Celexa [Celecoxib]	S	Unk	Not Reported
Prilosec [Omeprazole]	S	Unk	Not Reported
Humira	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	13852876	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069854		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actonel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Sulfasalazine	S	Oral	500 Milligram		Not Reported
	Cyclobenzaprine	C	Unknown	10 Milligram		Not Reported
	Desoximetasone	C	Unknown	5 Milligram		Not Reported
	Desoximetasone	C	Unknown	5 Milligram, Qd		Not Reported
	Prednisone Acetate	C	Unknown	5 Milligram, Qd		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	15266484	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018318379		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S		500 Mg, 2x/Day		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, Monthly		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, 2x/Week (2 Every 1 Week)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Days		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	15605977	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-102350		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Gait	Orencia			S	Unknown			Bristol Myers Squibb

Disturbance; Multiple System Atrophy; Off Label Use; Rheumatoid Arthritis	Remicade	S	Oral	3 Milligram/Kilogram, Qcycle		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	Unk, Qwk		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Q4wk		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz	S	Intravenous (not otherwise specified)	5 Milligram, Qod		Not Reported
	Methotrexate	S	Oral	Unk Unk, Qwk		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	15631891	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105424		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Intracavernous	Unk		Not Reported

Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil /00072602/	S	Oral	400.0 Mg, Qd	Not Reported
Prednisone	S	Unknown		Not Reported
Reactine /00884302/	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Actemra	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	15967087	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2019063768			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Non-Cardiac Chest Pain	No Subject Drug			S		No Dose Given		Not Reported

					Methotrexate Sodium		S	Unknown	7.5 Mg, Monthly	Pfizer
					Methotrexate Sodium		S		7.5 Mg, Unk	Pfizer
					Methotrexate Sodium		S		15 Mg, Unk	Pfizer
					Methotrexate Sodium		S		15 Mg, Unk	Pfizer
					Methotrexate Sodium		S		20 Mg, Unk	Pfizer
					Methotrexate Sodium		S		5 Mg, Unk	Pfizer
					Methotrexate Sodium		S		7.5 Mg, Unk	Pfizer
					Erelzi [Etanercept Szzs]		S	Subcutaneous	50 Mg, Qmo	Not Reported
					Erelzi [Etanercept Szzs]		S	Subcutaneous	50 Mg, Qmo	Not Reported
					Erelzi [Etanercept Szzs]		S	Subcutaneous	50 Mg, Qmo	Not Reported
					Leflunomide		S	Unknown	10 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	15978358	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013840			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported

	Ibuprofen			C	Unknown					Not Reported
	Prednisone			C	Unknown	20 Mg, Unk				Not Reported
	Morphine			C	Unknown					Not Reported
	Acetaminophen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16169405	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019145977		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Nasopharyngitis; Oropharyngeal Pain; Rheumatoid Arthritis; Rhinorrhoea; Throat Irritation	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S	Oral	200 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	300 Mg, 1x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16274691	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2767506-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Dysphonia; Erythema; Macular Degeneration	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16411462	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056060		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb

Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Bristol Myers Squibb
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Bristol Myers Squibb
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Q2mo	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown	Unk	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Intra-articular	Unk	Bristol Myers Squibb
	Orencia	S	Intravenous drip	250 Milligram, Qmo	Bristol Myers Squibb
	Orencia	S	Unknown		Bristol Myers Squibb
	Orencia	S		250 Milligram, Qmo	Not Reported
	Orencia	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Bid	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown	50 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5.0 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported

Enbrel	S	Subcutaneous	25 Milligram	Not Reported
Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Human Immunoglbulin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Human Immunoglbulin	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Human Immunoglbulin	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk, Q6wk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, 5 Months	Not Reported
Infliximab	S	Unknown	5 Milligram	Not Reported
Infliximab	S	Unknown	3 Milligram/Kilogram, Q6wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	50 Milligram, Bid	Not Reported

	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	3.0 Milligram, Bid	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk, Cyclica	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Triamcinolone Hexacetonide	S	Other		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Oral	5 Milligram, Qd	Not Reported
	Apo-Naproxen	S	Oral	3 Milligram, Qd	Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Etanercept	S	Subcutaneous	12.5 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Kineret	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16541722	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Unknown	20 Milligram, Qd		Not Reported

Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Hydroxychloroquine	S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram		Not Reported
	Prednisone	S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine	S	Unknown	1000 Gram, Bid		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16591358	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013412		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Celecoxib			S	Unknown	Unk		Apotex
	Celecoxib			S				Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	7 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	11 Ml, 1 Every 1 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Mg, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16591559	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP018196		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Celecoxib			S	Unknown	200 Mg, Bid		Apotex
	Lorazepam			S	Unknown	1 Mg, Qd		Not Reported
	Cyclosporine			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Citalopram			C	Unknown	10 Mg, Qd		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Pantoloc /01263201/			C	Unknown	40 Mg, Bid		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16638924	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1081884		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva

Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Naproxen Sodium	S	Unknown			Teva
	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16738576	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096553		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16738645	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2962		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16738653	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2019-2974		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16738656	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2946			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Carpal Tunnel Syndrome; Drug Ineffective; Fall; Fear Of Injection; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16738836	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2970		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Effexor Sr			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739069	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability	Plaquenil			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Imuran			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739474	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Hypersensitivity; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			C	Oral	10 Milligram Daily;		Not Reported
	Gold			C				Not Reported
	Morphine			C				Not Reported
	Celebrex			C				Not Reported
	Prednisone			C	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739475	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-23772		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported

Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Certolizumab Pegol	S	Subcutaneous			Not Reported
	Ciclosporin	S	Unknown	Unknown		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Gold	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Pregabalin	S	Unknown	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Simponi	S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739584	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096576		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739741	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3008		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Musculoskeletal Pain; Vulvovaginal Rash	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739832	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739833	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097244		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Methotrexate			S	Unknown			Barr
	Nystatin			S	Unknown			Teva
	Nystatin			S				Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739834	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096757		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Hypertension; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Desoximetasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739906	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-080318			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16739999	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3004		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clostridium Difficile Infection; Diarrhoea; Drug Intolerance; Malaise; Osteomyelitis; Pneumonia	Methotrexate (Trade Name Unknown)		S	Oral	Not Reported
	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16740000	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3014			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16740442	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019362765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741409	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741482	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019361126		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Methotrexate Sodium			S	Unknown	Unk Unk, 1 Every 1 Week(S)		Pfizer
	Hydroxychloroquine			S	Unknown	Unk Unk, 1 Every 1 Day(S)		Not Reported
	Leflunomide			S	Unknown	Unk Unk, 1 Every 1 Day(S)		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741742	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096405		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Disorder; Nervous System Disorder; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gadolinium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741744	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1096378		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Stent Placement; Terminal State; Thrombosis	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Ilaris Single-Use Vial		C	Subcutaneous	Not Reported
	Plaquenil		C		Not Reported
	Rituximab		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741746	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1098064		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Mouth; Dupuytren'S Contracture; Limb Injury; Osteoarthritis	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741748	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown	640 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	200 Milligram		Not Reported

	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741753	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096389		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			C				Not Reported
	Alprazolam			C				Not Reported
	Amlodipine			C				Not Reported
	Asa			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Celebrex			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported

	Metformin			C						Not Reported
	Methotrexate			C						Not Reported
	Pantoprazole			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741756	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096486		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Methotrexate			S	Unknown	40 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1 Gram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		165 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741757	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1096330		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate			S	Oral			Barr

Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Arava		C	Oral		Not Reported
	Orencia		C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741801	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1097542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Imuran			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741802	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096776		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Folic Acid			C	Oral	5 Milligram Daily;		Not Reported
	Hydroxychloroquine			C	Oral	400 Milligram Daily;		Not Reported
	Leflunomide			C	Oral	20 Milligram Daily;		Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Orencia			C	Oral	400 Milligram Daily;		Not Reported
	Tofacitinib Citrate			C				Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741803	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097539		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741804	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097545			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported

	Leflunomide			C	Unknown					Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741805	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097546		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16741830	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1097550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Unknown					Not Reported
	Tocilizumab			S	Unknown					Not Reported
	Azathioprine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742046	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096749		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C		15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742084	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096907		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration;	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Toe Amputation	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Folic Acid	C			Not Reported
	Prednisone	C		10 Milligram Daily;	Not Reported
	Restasis	C			Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742099	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1097890		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cystitis; Diarrhoea; Feeding Disorder; Gait Disturbance; Hepatic Enzyme Increased; Hypertension; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Urinary Tract Infection; Weight Decreased; Wound	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz Xr			S	Oral	11 Milligram Daily;		Not Reported
	Xeljanz Xr			S	Oral	11 Milligram Daily;		Not Reported
	Arava			C				Not Reported
	Azathioprine			C				Not Reported
	Humira			C				Not Reported
	Lactobacillus Acidophilus			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Vitamin D [Colecalciferol]			C				Not Reported
	Voltaren [Diclofenac Diethylamine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1098018			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Cough; Gait Disturbance; Pain; Rheumatoid Arthritis; White Blood Cell Count Decreased	Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742159	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
		Simponi			S		Subcutaneous			Not Reported
		Sulfasalazine			S		Unknown			Not Reported
		Topicort			S		Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742160	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1096747		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			C	Unknown			Not Reported
	Thiamine Hydrochloride			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742161	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097129		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Anaphylactic Reaction; Drug Ineffective; Infection	Methotrexate		S	Unknown		Barr
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Lipitor		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742162	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1097279			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Imuran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742833	EXPEDITED (15-DAY)		HO, OT	GB-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001109		63 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Antinuclear Antibody Positive; C-Reactive Protein Increased; Cheilitis; Dermatitis Allergic; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Erythema; Hypertension; Hyponatraemia; Leukocytosis; Oral Discomfort; Palpable Purpura; Periorbital Oedema; Pyrexia; Rash; Rash; Rash; Scab; Skin Discolouration; Swelling Of Eyelid	Hydroxychloroquine	S	Unknown		Concordia
	Naproxen	C			Not Reported
	Co-Codamol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	10740173	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014333721		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Oropharyngeal Pain; Rheumatoid Arthritis; Rhinorrhoea; Stress; Throat Irritation	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Folic Acid			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	300 Mg, 1x/Day		Not Reported
	Arava			S	Oral	200 Mg, 1x/Day		Not Reported
	Prednisone			C		5 Mg, Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	14263210	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP022159		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Levofloxacin	S	Unknown	Unk	Apotex
	Norfloxacin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Erythro-Base	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Celecoxib	S	Oral	200 Mg, Qd	Apotex
	Ceclor	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	15017085	EXPEDITED (15-DAY)		HO, LT, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201806-002049		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Bronchopleural Fistula; Chest Discomfort;	Hydroxychloroquine			S	Unknown			Concordia
	Prednisolone			S				Concordia

Dyspnoea; Hypoxia; Palpitations; Pleurisy; Pneumothorax; Pneumothorax; Pulmonary Fibrosis; Pulmonary Hypertension; Respiratory Failure; Subcutaneous Emphysema; Tachycardia; Tachypnoea; Toxicity To Various Agents	Prednisone	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16552297	NON-EXPEDITED			US-PFIZER INC-2019287311			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Jaundice	Skelaxin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16572422	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP018023		44 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; No Adverse Event; Respiratory Arrest; Visual Impairment	Celecoxib			S	Oral	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclical		Not Reported
	Sulfasalazine			S	Oral	1 G, Q.12h		Not Reported

		Prednisone			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16591416	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP017538			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	2 Mg, Qd		Not Reported
	Prednisone			C	Unknown	2 Mg, 1 Every 24 Hours		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16593954	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP018215		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Celecoxib	S	Unknown	Unk		Apotex
	Azathioprine	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Neoral	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16658759	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1085097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Indometacin			S	Oral	150 Milligram Daily;		Not Reported
	Indometacin			S	Oral	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Indomethacin [Indometacin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16733722	EXPEDITED (15-DAY)		HO, LT, OT	HK-SA-2019SA234673		12 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Interstitial Lung Disease; Pulmonary Fibrosis	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Leflunomide			S				Sanofi
	Etanercept			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16742935	EXPEDITED (15-DAY)		OT	CA-SA-2019SA080335			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Hydroxychloroquine			S		300 Mg, Qd		Sanofi
	Plaquenil			S		Unk		Sanofi
	Levothyroxine Sodium			S	Oral	0.075 Ug, Qd		Not Reported
	Sulfasalazine			S		1000 Mg, Qd		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Azathioprine			C		50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16744093	EXPEDITED (15-DAY)		HO	CA-SA-2017SA049083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Fall; Gait Disturbance; Mobility Decreased; Peripheral	Plaquenil			S	Unknown	200 Mg,Bid		Sanofi
	Avara			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Oral	200 Mg,Qd		Sanofi
	Lovenox			S		Unk		Sanofi
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

Swelling; Therapeutic Response Decreased	Xeljanz		C	Oral	5 Mg,Bid		Not Reported
	Xeljanz		C	Oral	5 Mg,Bid		Not Reported
	Xeljanz		C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16744544	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019363096		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Hydroxyzine			C		Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Plaquenil Sulfate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16745325	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/19/0113728		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Kidney Transplant Rejection	Tacrolimus			S		3.5-8 Ng/Ml		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Telmisartan			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16745349	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-18-071			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Hypersensitivity	Methotrexate			S	Oral			Hikma

	Methotrexate		S	Oral	Hikma
	Hydroxychloroquine		S	Unknown	Hikma
	Sulfasalazine		C	Unknown	Not Reported
	Arava		C	Unknown	Not Reported
	Enbrel		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16745409	NON-EXPEDITED			US-PFIZER INC-2019365045		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Dolobid			S		Unk		Not Reported
	Evoxac			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16745628	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097475			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mobility Decreased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16745757	NON-EXPEDITED			US-SA-2018SA297971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gastrointestinal Disorder	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747445	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1096181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown	17.5 Milligram 1 Every 1 Weeks,		Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravnous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported
	Thiamine Hydrochloride			C	Unknown			Not Reported

	Thiamine Hydrochloride				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747897	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1098776		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Diverticulitis; Drug Ineffective; Malaise; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747908	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1098782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Polyarthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Cortisone Acetate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747975	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096540		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	Barr
	Minocycline Hydrochloride	S	Unknown	Actavis
	Apo-Azathioprine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747991	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1096500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16747999	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-024022		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure	Dexamethasone			S	Oral			Valeant
	Cellcept			S	Oral			Not Reported
	Cortancyl			S	Oral	Dose Increased		Not Reported
	Cortancyl			S	Oral	Dose Increased		Not Reported
	Plaquenil			S	Oral			Not Reported
	Belimumab			S	Subcutaneous			Not Reported
	Ciclosporine			S	Oral			Not Reported
	Amlor			C				Not Reported
	Paracetamol			C				Not Reported
	Lorazepam			C				Not Reported
	Pantoprazole			C				Not Reported
	Mycostatine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16748032	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1097342		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough;	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Secretion Discharge; Sputum Discoloured; Thrombosis	Plaquenil		S	Unknown	Not Reported
	Warfarin Sodium		S	Unknown	Not Reported
	Warfarin Sodium		S	Unknown	Not Reported
	Warfarin Sodium		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16748033	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097346		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Meloxicam			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Rabeprazole			S	Unknown			Teva
	Desoximetasone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16935294	DIRECT	N				61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Plaquenil Tab 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	11195055	EXPEDITED (15-DAY)		HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-037283		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Pneumonia; Sepsis; Splenomegaly; Systemic Lupus Erythematosus; Urinary Tract Infection	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Quensyl			S	Unknown	200 Milligram, Bid		Not Reported
	Pantozol /01263204/			C	Unknown	Unk, Qd		Not Reported
	Tilidine Hydrochloride			C	Unknown	Unk, Qd		Not Reported
	Amlodipin /00972401/			C	Unknown	2.5 Milligram		Not Reported
	Decortin H			C	Unknown	40 Milligram		Not Reported
	Vigantoletten			C	Unknown	1000 International Unit		Not Reported
	Delix /00885601/			C	Unknown	2.5 Milligram		Not Reported
	Cellcept /01275102/			C	Unknown	Unk		Not Reported
	Torem /01036501/			C	Unknown	5 Milligram		Not Reported
	Clexane			C	Subcutaneous	0.4 Milliliter		Not Reported
	Prednisolon /00016201/			C	Unknown	75 Milligram		Not Reported
	Ibuprofen			C	Unknown	600 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	15853478	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634392-00		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Responder; Treatment Failure	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	15877717	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0502		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	High Dose		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclic		Not Reported

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Phenylephrine Hcl	S	Unknown		Not Reported
Benzalkonium Chloride	S	Unknown		Not Reported
Boric Acid	S	Unknown		Not Reported
Disodium Edetate	S	Unknown		Not Reported
Sodium Borate	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Tofacitinib Citrate	S	Subcutaneous		Not Reported
Tofacitinib Citrate	S	Unknown	2x/Week	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Ibuprofen	C	Unknown		Not Reported
Lipitor	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16160518	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2732377-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Humira		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16167056	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2733030-00		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16174045	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736313-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness;	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Hydroxychloroquine Actavis	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16290466	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121650		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S		400 Mg, Unk		Sanofi
	Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Leflunomide			C	Unknown	Unk, Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			C		400 Mg, Unk		Not Reported
	Amoxil [Amoxicillin]			C	Unknown	Unk Unk, Unk		Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16293516	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121677		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16293520	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121576		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Sensitivity To Weather Change	Arava			S	Unknown	10 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Oral	25 Mg		Not Reported
	Plaquenil			S		400 Mg, Bid		Sanofi
	Enbrel			S	Unknown	50 Mg, Qm		Not Reported
	Celebrex			C	Oral	200 Mg, Bid		Not Reported
	Methotrexate			C		50 Mg, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16738036	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2019SK195615		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy;	Ciclosporin			S	Unknown			Novartis

Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Jc Virus Infection; Mental Impairment; Pneumonia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Methotrexate		S	Unknown			Not Reported
	Mycophenolate Mofetil		S	Unknown			Not Reported
	Azathioprine		S	Unknown			Not Reported
	Prednisone		S	Unknown			Not Reported
	Hydroxychloroquine		S	Unknown			Not Reported
	Belimumab		S	Unknown	Unk		Not Reported
	Cyclophosphamide		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16748321	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201908-001896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Hydroxychloroquine			S	Unknown			Concordia
	Plaquenil			S	Unknown			Concordia
	Levothyroxine Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16748540	EXPEDITED (15-DAY)		OT	IL-ALKEM LABORATORIES LIMITED-IL-ALKEM-2019-05570		45 YR	Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Treatment Failure	Colchicine			S	Unknown	2 Milligram, Qd		Alkem
	Azathioprine			S	Unknown	2 Milligram/Kilogram, Qd		Not Reported
	Prednisone			S	Unknown	40 Milligram, Qd		Not Reported

		Hydroxychloroquine			S	Unknown	Unk			Not Reported
		Methotrexate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16748674	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097763		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16748811	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3038		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anaemia; Angioedema; Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Bone Erosion; Diarrhoea; Drug Intolerance; Dyspnoea; Feeling Drunk; Gastrointestinal Disorder;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hepatic Enzyme Abnormal; Hypoaesthesia; Migraine; Nausea; Pharyngeal Oedema; Rheumatoid Factor Positive; Swelling Face; Synovitis; Uveitis	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16749528	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019363523		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Adalimumab			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16749618	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019365540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S	Unknown	15 Mg, 1 Every 1 Week(S)		Pfizer
	Arava			S		20 Mg, 1 Every 1 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg, 1 Every 1 Day(S)		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16750354	NON-EXPEDITED			US-PFIZER INC-2019367637			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer

		Sulfasalazine			S		Unk			Pfizer
		Plaquenil [Hydroxychloroquine Sulfate]			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16750366	NON-EXPEDITED			US-PFIZER INC-2019368106		78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Skin Burning Sensation	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16751142	EXPEDITED (15-DAY)		DS	CA-ROCHE-2381901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Statex [Morphine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16751629	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16752067	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097372		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Esomeprazole	C	Unknown	40 Milligram Daily;	Not Reported
	Lumigan Rc	C	Ophthalmic		Not Reported
	Nexium/01479302	C	Unknown	40 Milligram Daily;	Not Reported
	Sulfasalazine	C	Unknown	2000 Milligram Daily;	Not Reported
	Suphedrine/00005601	C	Unknown	10 Milligram Daily;	Not Reported
	Trazodone	C	Unknown	200 Milligram Daily;	Not Reported
	Tylenol/00020001/	C			Not Reported
	Tylenol Extra Strength	C			Not Reported
	Valsartan	C			Not Reported
	Wellbutrin	C	Unknown	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16752195	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097387		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2019	16752304	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Ineffective;	Methotrexate			S	Oral			Barr

Hypersensitivity; Mobility Decreased; Mouth Ulceration; Spinal Stenosis; Urinary Tract Infection	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	C			Not Reported
	Morphine	C			Not Reported
	Prednisone	C	Oral	15 Milligram Daily;	Not Reported
	Tofacitinib	C	Oral	10 Milligram Daily;	Not Reported
	Gold	C	Unknown		Not Reported
	Morphine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	11754253	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015121229		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Dyspnoea; Hypersensitivity; Mobility Decreased; Neutropenia; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Up To 20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	800 Milligram/ Four Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	12913272	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-044383		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Off Label Use; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Tetanus Vaccine			C	Unknown			Not Reported
	Haemophilus Influenzae			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram		Not Reported
	Pneumococcal Vaccine Conj 7v (Crm197)			C	Unknown	Unk		Not Reported
	Pneumococcal Vaccine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	13851357	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070741			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate /00113802/			S	Unknown	17.5 Mg, Qwk		Not Reported

	Plaquenil /00072602/	S	Oral		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Hydrochloride B1	C	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Acetaminophen W/Oxycodone	C	Unknown		Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Percocet /00446701/	C	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16164910	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2733232-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Arava	C	Not Reported
	Calcium Carbonate	C	Not Reported
	Cymbalta	C	Not Reported
	Elavil	C	Not Reported
	Hydrochlorothiazide	C	Not Reported
	Imitrex	C	Not Reported
	Lyrica	C	Not Reported
	Premarin	C	Not Reported
	Tenormin	C	Not Reported
	Xeljanz	C	Not Reported
	Sumatriptan Succinate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16170438	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2732340-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16628685	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1079580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Ciclosporin			S	Unknown			Ivax
	Lorazepam			S	Unknown	1 Milligram Daily;		Actavis
	Morphine			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Citalopram			C	Unknown	10 Milligram Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Pantoloc/01263201/			C	Unknown	80 Milligram Daily;		Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16702258	NON-EXPEDITED			US-PFIZER INC-2019344521			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Celebrex	S	Unk	Pfizer
	Neurontin	S	Unk	Pfizer
	Procardia	S	Unk	Pfizer
	Wellbutrin Sr	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
	Salagen	S	Unk	Not Reported
	Ferrex	S	Unk	Not Reported
	Flexeril [Cefixime]	S	Unk	Not Reported
	Seroquel	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753306	EXPEDITED (15-DAY)		OT	CA-ROCHE-2386026		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753331	EXPEDITED (15-DAY)		OT	CA-ROCHE-2386399		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753419	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097924		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Arthroplasty; Arthralgia; Drug Ineffective; Hip Arthroplasty; Knee Arthroplasty; Pain In Extremity; Peripheral Swelling; Psoriasis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753449	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000012			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Fatigue; Headache; Mood Altered; Nausea; Product Dose Omission; Pruritus; Rash; Rash; Rash; Systemic Lupus Erythematosus; Temperature Intolerance; Varicose Vein	Hydroxychloroquine	S	Unknown	Unk		Concordia
	Teriflunomide	S	Oral	14 Mg, Qd		Not Reported
	Teriflunomide	S	Oral	14 Mg, Qd		Not Reported
	Teriflunomide	S	Oral	14 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2384248		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous	Therapy Duration-1.0 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2382555		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Rash; Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Plaquenil [Hydroxychloroquine			C				Not Reported

	Sulfate] Actemra				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16753850	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-001210			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Haemolytic Uraemic Syndrome; Thrombotic Microangiopathy	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Lisinopril			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16754842	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1079991		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Mycobacterial Infection; Osteomyelitis Bacterial; Pyrexia; Subcutaneous Abscess; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Oral			Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Linezolid			S	Oral			Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)			Mylan
	Clofazimine			S	Unknown			Mylan

	Amikacin			S	Intravenous (not otherwise specified)				Mylan
	Amikacin			S	Unknown	Amikacin Containing Spacer			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16755100	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1080477			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diabetes Insipidus; Drug Interaction; Therapeutic Product Effect Decreased	Desmopressin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16755240	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2019-105263			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peripheral Swelling; Product Dose Omission	Prednisone			S	Unknown	Unk Unknown, Unknown		Vintage
	Plaquenil /00072603/			S	Unknown	Unk Unknown, Unknown		Not Reported
	Levothyroxine			C	Unknown	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16755370	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2018-043426			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Swelling	Prednisone			S	Oral	5 Mg, Bid		Vintage
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Plaquenil /00072602/			S	Oral	1.5 Df, Daily		Not Reported
	Methotrexate			S	Oral	2.5 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16755479	EXPEDITED (15-DAY)		OT	PHHY2019US197419		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Mycobacterial Infection; Osteomyelitis; Product Use In Unapproved Indication; Subcutaneous Abscess	Hydroxychloroquine			S	Unknown			Novartis
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16755847	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000017			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Retinal Fovea Disorder; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2019	16756308	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019365543		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hernia; Nausea	Methotrexate Sodium			S	Subcutaneous	1 Mg, 1 Every 1 Week(S)		Unknown
	Sulfasalazine			S		1 G, 2 Every 1 Day(S)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	12345283	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055351			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Larynx Irritation; Nausea; Rheumatoid Arthritis; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Zostavax			S	Unknown	Unk		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	12912770	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091798		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Pantoprazole			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	14171507	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-087457			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Off Label Use; Rash; Rheumatoid Arthritis; Treatment Failure	Abatacept			S	Subcutaneous	125 Mg/Ml, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	1 Df, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	1 Df, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk, Qd		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	14453315	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018CA006030		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling	Ilaris			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S				Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Xeljanz	S	Oral	1 Df, Q12h	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	14495808	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007083		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Off Label Use; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin D /07503901/			C	Unknown	4000 International Unit, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Ergocalciferol			C	Unknown	4000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	14752157	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2018146052		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lipitor			S	Unknown	20 Mg, Daily		Pfizer
	Atorvastatin Calcium			S	Unknown	Unk		Pfizer
	Levofloxacin			S	Unknown	Unk (Dnk)		Pfizer
	Amoxicillin			S	Unknown	Unk		Pfizer
	Infliximab			S	Unknown	250 Mg, Unk (Infusion)		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Doxycyclin /00055701/			S	Unknown	50 Milligram		Not Reported
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	4 Dosage Form, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Oral	4 Dosage Form, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	25 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	24 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	23 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Tylenol Arthritis			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

	Methotrexate			C	Unknown	25 Milligram				Not Reported
	Methotrexate			C	Oral	4 Dosage Form, Qwk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15400071	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083701			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15400476	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Doxycycline			S	Unknown	50 Milligram		Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram		Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Etanercept	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	25 Milligram		Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
	Xeljanz	C	Unknown	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15635832	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105857		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Celecoxib			S	Unknown	Unk Mg (Titer), Q12h		Not Reported
	Dilaudid			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine			S	Unknown				Not Reported
	Lorazepam			S	Unknown	1.0 Mg, Qd			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk			Not Reported
	Citalopram			C	Unknown	10 Mg, Qd			Not Reported
	Pantoloc /01263201/			C	Unknown	40 Mg, Unk			Not Reported
	Prednisone			C	Unknown	10 Mg, Qd			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15673994	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2573626-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15675678	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573363-00		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15679032	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573391-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate	Humira			S	Subcutaneous			Not Reported
	Apo Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Abnormal; Rheumatoid Arthritis	Palafer Cf			S	Unknown	Not Reported
	Pantoprazole Sodium			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Celebrex			C	Oral	Not Reported
	Prednisone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15683086	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2575137-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15947364	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011979			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatotoxicity; Off Label Use; Rash; Treatment Failure	Orencia			S	Subcutaneous	1 Df, Qwk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	1 Dosage Form		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15965226	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014264		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	15978553	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013865		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Orencia	S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Enbrel	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Advil /00044201/	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Ketorolac	C	Unknown			Not Reported
	Actemra	C	Subcutaneous	162 Milligram, Qwk		Not Reported
	Naproxen	C	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown	200 Mg, Qd		Not Reported
	Arava	C	Unknown	20 Mg, Qwk		Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16177713	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1360		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nasopharyngitis; Oropharyngeal Pain; Rheumatoid Arthritis; Rhinorrhoea; Stress;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Throat Irritation	Arava			S	Oral	Not Reported
	Arava			S	Oral	Not Reported
	Plaquenil			S	Oral	Not Reported
	Xeljanz			S	Unknown	Not Reported
	Folic Acid			S	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16195720	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741762-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rabeprazole Sodium			C				Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16226780	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110697		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Haemorrhage; Headache; Hepatic Enzyme Increased; Influenza Like Illness; Infusion Related	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S				Not Reported

Reaction; Malaise; Nausea; Urinary Tract Infection; Vomiting	Etanercept	S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg/Kg, Q6w		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		2 Df, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		400 Mg		Not Reported
	Xeljanz	C		2 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16228158	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP012003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Acetaminophen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	12.5 Mg, Q.O.D.		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Indomethacin /00003801/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexaat /00113801/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Statex /00036302/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16293525	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Unk		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16381798	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005424		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like Illness; Insomnia; Nasopharyngitis; Off Label Use; Pain In Jaw	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Bristol Myers Squibb
	Calcium Folinate			S	Oral	5 Milligram, Daily		Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	12.5 Milligram, Qwk		Not Reported
	Prednisone			S	Oral	5 Milligram, Daily		Not Reported
	Leflunomide			S	Oral	20 Milligram, Daily		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Vitamin B12 /00056201/			C	Oral	1 Dosage Form, Daily		Not Reported

Acetaminophen W/Oxycodone	C	Oral			Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Desoximetasone	C	Unknown	Unk		Not Reported
Fentanyl	C	Unknown	1 Dosage Form		Not Reported
Gabapentin	C	Oral	400 Milligram, Bid		Not Reported
Metformin;Sitagliptin	C	Oral	Unk, Bid		Not Reported
Perindopril Erbumine	C	Oral	8 Milligram, Qd		Not Reported
Rabeprazole	C	Oral	180 Milligram, Qd		Not Reported
Ranitidine	C	Oral	150 Milligram, Qd		Not Reported
Rosuvastatin Calcium	C	Oral	5 Milligram, Bid		Not Reported
Synthroid	C	Oral	1 Dosage Form, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Zopiclone	C	Oral	7.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16382249	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-107627		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Skin Reaction; Synovitis; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16754110	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016250123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Larynx Irritation; Nausea; Rheumatoid Arthritis; Weight Decreased	Enbrel			S	Unknown	Unk	Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk	Unknown
	Methotrexate Sodium			S	Oral		Pfizer
	Humira			S	Subcutaneous	Unk	Not Reported
	Plaquenil			S	Unknown	Unk	Not Reported
	Zostavax			S	Unknown	Unk	Not Reported
	Rituxan			C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16757926	EXPEDITED (15-DAY)		HO	FR-SA-2019SA231768		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Squamous Cell Carcinoma Of The Oral Cavity	Arava			S	Oral	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	1 Df, Qw		Sanofi
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q15d (Every Week Before / 01/2015)		Not Reported
	Humira			S	Subcutaneous	1 Df, Qw		Not Reported
	Metoject			S	Subcutaneous	1 Df, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16757942	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126544		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder;	Plaquenil			S	Unknown	400 Mg,Qd		Sanofi
	Sulfasalazine			S	Unknown	1 G,Bid		Not Reported
	Leflunomide			S				Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported

Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Unknown	Unk Unk,Unk			Not Reported
	Rituxan			S					Not Reported
	Rituximab			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16758518	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16758534	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3085		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16758539	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		40 YR	Male	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16758631	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3091		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Unevaluable Event	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxyzine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16759098	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201908-001870			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Drug	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia

Ineffective; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Methotrexate	S	Subcutaneous	15 Mg		Not Reported
	Leflunomide	S	Unknown	10-20 Mg, Qd		Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid		Not Reported
	Baricitinib	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16759690	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019366585		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Squamous Cell Carcinoma Of The Oral Cavity	Enbrel			S	Subcutaneous	50 Mg, Unk (Every 15 Days) (Every Week Before 01/2015)		Pfizer
	Novatrex			S	Oral	1 Df, Weekly		Pfizer
	Humira			S	Subcutaneous	1 Df, Weekly		Not Reported
	Plaquenil			S	Oral	1 Df, Weekly		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Metoject			S	Subcutaneous	1 Df, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16759716	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201908-001869			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Prednisone			S	Oral	Unk Unk, Qd		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Weekly		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Zoloft			C		Unk		Not Reported
	Levofloxacin			C		Unk		Not Reported

	Lyrica	C	Unk	Not Reported
	Acyclovir	C	Unk	Not Reported
	Amitriptyline	C	Unk	Not Reported
	Constella	C	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unk	Not Reported
	Aerius	C	Unk	Not Reported
	Zopiclone	C	7.5 Mg, Unk	Not Reported
	Zomig	C	Unk	Not Reported
	Vitamin C	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16760382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2389675			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16760775	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201908-001742			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Burning Sensation; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	1 In 2 Weeks, Duration : At Least 2 Years		Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16760779	EXPEDITED (15-DAY)		OT	CA-ROCHE-2384241		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Actemra			C	Unknown	Therapy Duration-7.0 Month(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2019	16761529	EXPEDITED (15-DAY)		DE, HO	PHHY2019US201980		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypotension; Intentional Overdose; Metabolic Acidosis; Mydriasis; Pulmonary Oedema; Pupil Fixed; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	200 Mg, Unk (Approx 60 Tablets)		Novartis
	Naproxen			S	Oral	750 Mg, Unk (Several)		Not Reported
	Ibuprofen			S	Oral	200 Mg, Unk (Unknown Quantity)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	14917666	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007162		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Off Label Use; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	5.0 Mg, Unk	Not Reported
	Aspirin /00002701/	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16231757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-037508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Prednisone			S	Oral	50 Milligram		Not Reported
	Apo-Prednisone			S	Oral	30 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate		S	Oral	15 Milligram, Qwk	Not Reported
	Plaquenil /00072602/		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate		S	Parenteral		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Citalopram Hydrobromide		C	Unknown		Not Reported
	Ketoprofen		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Omeprazole		C	Unknown		Not Reported
	Prednisone		C	Oral	5 Milligram	Not Reported
	Rosuvastatin Calcium		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16234394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-037149		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Prednisone	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid	Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16287074	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-042109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not	8 Milligram		Not Reported

						otherwise specified)			
		Sulfasalazine			S	Oral	1 Gram		Not Reported
		Simponi			C	Subcutaneous			Not Reported
		Xeljanz			C	Unknown			Not Reported
		Prednisone			C	Unknown	5 Milligram		Not Reported
		Prednisone			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762235	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-082224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown	20 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762240	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-082164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762243	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-082284			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Aug-2019	16762247	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-082260		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	12973343	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091580		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
	Aspirin /00002701/	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	13519919	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038134		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

	Prednisone			C	Unknown	10 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	14922263	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044090		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
	Diamicron			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported

	Depo-Medrol	C	Intra-articular			Not Reported
	Diphenhydramine	C	Oral	50 Milligram		Not Reported
	Ebastine	C	Unknown			Not Reported
	Ferrous Gluconate	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Tylenol [Paracetamol]	C	Unknown			Not Reported
	Vitamin D3	C	Unknown			Not Reported
	Acetaminophen	C	Oral	650 Milligram		Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16673885	NON-EXPEDITED			US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-006			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Codeine			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Hikma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16712983	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-078990		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Opdivo			S	Intravenous (not otherwise specified)	1 Df Biw		Bristol Myers Squibb
	Voltarene [Diclofenac Sodium]			S	Oral	Unk		Not Reported
	Salazopyrine			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16733671	NON-EXPEDITED		OT	HK-AMGEN-HKGNI2019133956		12 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pulmonary Fibrosis	Etanercept			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16741502	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019360986		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16763088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Swelling	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16763122	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3159		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Skin; Fatigue; Pyrexia; Rash; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2019	16763774	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA202358		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	11279105	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2015071199		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	12684404	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016109231		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Multiple	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen

Sclerosis; Paraesthesia; Rheumatoid Arthritis	Celebrex	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	13123418	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1843560-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rocuronium			S	Unknown			Not Reported

	Apo-Hydroxyquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Sulfa	S	Unknown			Not Reported
	Penicillin	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Solution		Not Reported
	Rocuronium Bromide	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	13981287	NON-EXPEDITED			US-PFIZER INC-2017397232		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil /00072602/			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	14351657	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268455		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported

Work Ability; Pain; Treatment Failure	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Orencia	S		Unk Unk,Unk		Not Reported
	Simponi	S	Unknown	Unk Unk,Unk		Not Reported
	Abatacept	S		Unk Unk,Unk		Not Reported
	Methotrexate	C	Subcutaneous	Unk Unk,Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk Unk,Unk		Not Reported
	Arava	C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	15702741	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580894-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported

	Gold		C	Unknown	Not Reported
	Azathioprine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	15922154	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2652807-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			C				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	15941599	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658389-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
			Rituxan			S	Intravenous (not otherwise specified)			Not Reported
			Simponi			S	Subcutaneous			Not Reported
			Sulfasalazine			S	Unknown			Not Reported
			Hydroxychloroquine Sulfate			S	Unknown			Not Reported
			Mycophenolate Mofetil			S	Unknown			Not Reported
			Piroxicam			C				Not Reported
			Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16163883	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2733467-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16223236	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Drug Ineffective; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis;	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

Synovitis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16226585	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Enbrel			S		Unk		Not Reported
	Infliximab			S		Unk		Not Reported
	Orencia			S				Not Reported
	Morphine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16231134	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110726		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Gastrointestinal Disorder; Hyperhidrosis; Hypersensitivity; Inappropriate Schedule Of Product Administration; Nausea; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15-20mg, Qw		Not Reported
	Flagyl			S				Sanofi
	Estradiol			S	Transdermal	1 Df, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Acetaminophen;Codeine			C	Oral			Not Reported
	Cipralex [Escitalopram Oxalate]			C	Oral	20 Mg		Not Reported
	Gabapentin			C	Oral	30 Mg, Qd		Not Reported

	Pantoloc [Pantoprazole]			C	Oral	40 Mg, Qd			Not Reported
	Sulfasalazine			C					Not Reported
	Leucovorin Calcium			C	Oral	5 Mg, Qw			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16231995	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S				Not Reported
	Prednisone			C		10 Mg		Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16291206	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported

	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituxan			S	Unknown	500 Mg, Unk		Not Reported
	Oxycodone			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16293521	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121759		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Rheumatoid Arthritis	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S		Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Oral	Unk Unk, Unk		Not Reported
	Actemra			S		Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C		Unk Unk, Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16293541	EXPEDITED (15-DAY)		DS	CA-SA-2019SA121628			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Disability; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy;	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Leucovorin [Calcium Folinate]	S	Oral	5 Mg, Qw		Not Reported
	Arava	C	Unknown			Not Reported
	Calcium Citrate;Magnesium Citrate	C	Unknown			Not Reported
	Citalopram Hydrobromide	C	Unknown	10 Mg		Not Reported
	Clobetasol Propionate	C	Topical			Not Reported
	Escitalopram Oxalate	C	Unknown			Not Reported
	Naproxen	C	Oral	250 Mg		Not Reported
	Pantoprazole Magnesium	C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16297537	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA121563		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Decreased; Bursitis; Dry Mouth; Epicondylitis; Fibromyalgia; Foot Fracture; Gamma-Glutamyltransferase Increased; Gastric Infection; Gastric Ulcer; Inappropriate Schedule Of Product Administration; Intestinal Obstruction; Joint Swelling; Kidney Enlargement; Malaise; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Product Prescribing Error; Psoriatic Arthropathy; Sjogren'S Syndrome; Tendonitis	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Cosentyx			S	Subcutaneous	300 Mg, Qm		Not Reported
	Cosentyx			S	Subcutaneous	450 Mg		Not Reported
	Diclofenac			C		Unk		Not Reported
	Cimzia			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Ibuprofen			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil			C				Not Reported
	Prednisone			C		Unk		Not Reported
	Simponi			C	Intracardiac			Not Reported
	Leflunomide			C	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16495285	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019272827		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Indometacin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16542688	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling; Treatment Failure	Azathioprine	S	Unknown	Unk		Apotex
	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Leflunomide	S	Unknown	Unk		Apotex
	Methotrexate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S				Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Adalimumab	S	Subcutaneous	Unk		Not Reported
	Abatacept	S	Unknown	Unk		Not Reported
	Cefazolin	C	Unknown	Unk		Not Reported
	Clindamycin	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	10 Mg, Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5.0 Mg, Unk (1 Every 2 Days)		Not Reported
	Xeljanz	C				Not Reported
	Adalimumab	C	Unknown	Unk		Not Reported
	Amitriptyline	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16673126	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015077149		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Toxicity To Various Agents	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
	Sulfasalazine	C	Oral	Unk Unk, 3x/Day		Not Reported
	Tylenol [Paracetamol]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16733250	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1095498		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abscess; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Hepatic Fibrosis; Infection; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Oral			Actavis
	Prednisone			S	Oral	12.5 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Diclofenac			S	Unknown	100 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Vioxx			S	Unknown	2.5 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown			Not Reported

	Humira	C	Unknown			Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram Daily;		Not Reported
	Mobicox	C	Unknown	15 Milligram Daily;		Not Reported
	Myochrysine	C	Intramuscular			Not Reported
	Naproxen	C				Not Reported
	Plaquenil	C				Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Vioxx	C	Unknown	25 Milligram Daily;		Not Reported
	Voltaren [Diclofenac]	C	Unknown	100 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Methotrexat	C				Not Reported
	Prednisone	C	Oral	12.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16764784	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2908029-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tramadol			C				Not Reported
	Celebrex			C	Unknown			Not Reported
	Acetaminofen Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16765357	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Larynx Irritation; Nausea; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Zostavax	S	Unknown	Not Reported
	Rituxan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16765677	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000048			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16766009	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-05683		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	Titration		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16766849	NON-EXPEDITED			US-PFIZER INC-2019376026		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported

	Hydroxychloroquine			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16767657	EXPEDITED (15-DAY)		HO, OT	FR-SA-2019SA244385		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash; Systemic Lupus Erythematosus	Plaquenil			S	Oral			Sanofi
	Rabeprazole Sodium			S	Oral			Not Reported
	Indapamide			S	Oral	1 Df, Qod		Sanofi
	Kenzen [Candesartan Cilexetil]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2019	16768246	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA203252		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	12161994	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016028388		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown				Not Reported
	Methotrexate Sodium	S	Unknown	Unk			Not Reported
	Sulfasalazine	S	Unknown	Unk			Not Reported
	Prednisone	S	Unknown	Unk			Not Reported
	Zopiclone	S	Unknown	Unk			Not Reported
	Hydromorphone	S	Unknown	Unk			Not Reported
	Remicade	C		Unk			Not Reported
	Methotrexate	C		Unk, Qwk			Not Reported
	Cymbalta	C		Unk			Not Reported
	Folic Acid	C		Unk			Not Reported
	Actemra	C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	12449156	EXPEDITED (15-DAY)		HO	FR-ELI_LILLY_AND_COMPANY-FR201606000237			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Erythema; Off Label Use	Cymbalta			S	Oral	Unk, Unknown		Eli Lilly And Co
	Octagam			S	Intravenous (not otherwise specified)	Unk, Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk, Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk, Unknown		Not Reported
	Levothyrox			C	Unknown	Unk, Unknown		Not Reported
	Lercan			C	Unknown	Unk, Unknown		Not Reported
	Cardensiel			C	Unknown	Unk, Unknown		Not Reported
	Folic Acid			C	Unknown	Unk, Unknown		Not Reported
	Kaleorid			C	Unknown	Unk, Unknown		Not Reported
	Esidrex			C	Unknown	Unk, Unknown		Not Reported
	Lamaline /00764901/			C	Unknown	Unk, Unknown		Not Reported

	Elisor			C	Unknown	Unk, Unknown				Not Reported
	Rivotril			C	Unknown	Unk, Unknown				Not Reported
	Nicardisur			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	12850287	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP012926		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	2000 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral			Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Other	Unk		Not Reported
	Abatacept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, (1 Every 2 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 G, Unknown		Not Reported
	Humira			S	Subcutaneous	40 Mg, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

					Actemra		S	Unknown	Unk	Not Reported
					Orencia		S	Subcutaneous	750 Mg, Q.Wk.	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Sulfasalazine		S	Unknown	Unk	Not Reported
					Arava		S	Unknown	Unk	Not Reported
					Xeljanz		S	Oral	5 Mg, Q.O.Wk.	Not Reported
					Tofacitinib		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	13152951	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1848651-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	13957994	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017733		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Bone Disorder;	Mycophenolate			S	Unknown	Unk		Apotex

C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Cyclosporine	S	Unknown	Unk	Apotex
	Cellcept /01275102/	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	500 Mg, Q.M.T.	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Penicillamine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Week	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Q.Wk.	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Doxycycline	C	Unknown	Unk	Not Reported
	Elavil /00002202/	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Tobramycin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	13982243	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083368		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	50 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qd		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Estradiol			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	Unk, Qd		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported

Xalatan	C	Ophthalmic	50 Milligram, Qd		Not Reported
Zingiber Officinale	C	Oral	500 Milligram		Not Reported
Gravol Ginger Nighttime	C	Unknown			Not Reported
Tofacitinib Citrate	C	Oral	5 Mg, Bid		Not Reported
Acetaminophen	C	Unknown			Not Reported
Baclofen	C	Unknown	10 Milligram, Bid		Not Reported
Gravol	C	Unknown			Not Reported
Levaquin	C	Unknown	50 Milligram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Calcium	C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	14921997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15622795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556001-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Syncope	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	C		Not Reported
	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15680527	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575120-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Celebrex			C				Not Reported
	Ergocalciferol			C				Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

	Vitamin D			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15717264	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587930-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Toe Amputation	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15923150	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653452-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Caffeine	C	Unknown			Not Reported
	Codeine Phosphate	C	Unknown			Not Reported
	Meprobamate	C	Unknown			Not Reported
	Dorzolamide Hydrochloride	C	Ophthalmic			Not Reported
	Timolol Maleate	C	Ophthalmic			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Levothyroxine	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Ramipril	C	Unknown	1.0 Dosage Forms		Not Reported
	Plaquenil	C	Unknown			Not Reported
	Tylenol	C				Not Reported
	Dihydrocodeine	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15929179	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653495-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15932513	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656069-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15935371	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656922-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Folic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C		Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15935402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657029-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15935603	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656865-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported
	Prevacid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15940431	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658286-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

							otherwise specified)			
			Rituxan			S	Intravenous (not otherwise specified)			Not Reported
			Simponi			S	Subcutaneous			Not Reported
			Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	15941774	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2659018-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16178501	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736379-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Mouth	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Ulceration; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Cimzia	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16193092	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741781-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16232164	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110764		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Hydroxychloroquine			S				Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Tablet		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Meloxicam			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	160 Mg, Qw		Not Reported
	Actemra			S	Unknown	160 Mg, Qw		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg		Not Reported
	Diclofenac			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16543922	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017643		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex
	Rosuvastatin			S	Unknown			Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Cephalexin /00145501/			C	Unknown	500 Mg, Qid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16770096	EXPEDITED (15-DAY)		OT	CA-SA-2019SA239667			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Arava			S		Unk		Sanofi
	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Humira			S		Unk Unk, Qw		Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16770811	NON-EXPEDITED		HO	FR-AMGEN-FRASP2019140825		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Squamous Cell Carcinoma Of The Oral Cavity	Enbrel			S	Subcutaneous	50 Mg, Unk (Every 15 Days) (Every Week Before 01/2015)		Amgen
	Novatrex [Methotrexate]			S	Oral	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Dosage Form, Qwk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Metoject			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16771050	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268735			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Arabloc			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qd		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown	1 G,Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16771917	EXPEDITED (15-DAY)		OT	NZ-ADVANZ PHARMA-201908000149			Unknown	NZL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown	200 Mg, Qd		Concordia
	Adalimumab	C		Unk		Not Reported
	Adalimumab	C				Not Reported
	Prednisone	C		Unk		Not Reported
	Vitamin D	C		Unk		Not Reported
	Omeprazole	C		Unk		Not Reported
	Fluoxetine	C		Unk		Not Reported
	Humulin	C		Unk		Not Reported
	Amitriptyline	C				Not Reported
	Asacol	C				Not Reported
	Sumatriptan	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16772134	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019372191			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil S			S		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2019	16772606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2909488-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain;	Humira			S	Subcutaneous			Not Reported
	Calcium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported

Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Asa	S	Unknown			Not Reported
	Fosinopril	S	Unknown			Not Reported
	Alendronate	S	Unknown			Not Reported
	Tylenol	S	Unknown	Prn Frequency		Not Reported
	Tylenol	S	Unknown	600 (No Unit)		Not Reported
	Vitamin D	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	12284961	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016048021		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	12691419	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016403962		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	25 Mg, Cyclic(Twice A Week)		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer

	Methotrexate Sodium			S	Unknown	Unk			Pfizer
	Humira			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	15701751	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-986077		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Wrist Surgery	Meloxicam			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16261960	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019180568		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16443253	NON-EXPEDITED		DS	CA-AMGEN-CANSP2016028782		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Inflammation; Nausea; Synovitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	30 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Unknown	20 Milligram, Unk		Not Reported
	Xeljanz			C	Oral	Unk		Not Reported
	Arava			C		10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16478871	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170705		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Drug Hypersensitivity; Drug Ineffective; Hepatitis	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Folic Acid			C		1 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16674530	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1086105			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Doxycycline	S	Unknown	200 Milligram Daily;	Actavis
	Actemra	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Acetaminophenw/Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Celebrex	C	Oral	400 Milligram Daily;	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported

	Methotrexate			C	Unknown	25 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown	25 Milligram Daily;		Not Reported
	Synthroid			C	Unknown			Not Reported
	Tylenol W/Codeine No.3			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16675379	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086597			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown			Actavis
	Doxycycline Hyclate			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline			S	Unknown			Actavis
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16680779	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0976		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Toxicity To Various Agents; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16774636	EXPEDITED (15-DAY)		HO	CA-ADVANZ PHARMA-201908000033			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Fall; Gait Disturbance; Mobility Decreased; Peripheral Swelling; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Avara			S	Unknown	Unk Dosing Details		Not Reported
	Arava			S	Oral	200 Mg, Qd		Not Reported
	Lovenox			S	Unknown	Unk		Not Reported
	Enoxaparin			S		Unk (Enoxaparin Pre-Filled Syringe)		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16774834	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001315			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Sensitivity To Weather Change	Hydroxychloroquine	S	Unknown	400 Mg, Bid		Concordia
	Arava	S	Unknown	10 Mg, Qd		Not Reported
	Sodium Aurothiomalate	S	Oral	25 Mg, Every 4 Weeks		Not Reported
	Enbrel	C		Unk		Not Reported
	Methotrexate	C		Unk		Not Reported
	Celebrex	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16774875	EXPEDITED (15-DAY)		OT	HK-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218915			Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Sulfasalazine			S	Unknown	Unk		Sun
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16775141	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-201908000154			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Drug Intolerance; Erythema; Eye Operation; Feeling Abnormal; Pain; Skin Swelling; Swelling; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Paracetamol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Addera			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Esomex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16775407	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3212			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16775550	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016270111		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil			S		400 Mg, Daily		Not Reported
	Plaquenil			S		200 Mg, Daily		Not Reported
	Plaquenil			S		400 Mg, Daily		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16777721	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1102482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown			Actavis
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab Gp2013			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2019	16778001	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2019-025007		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown			Not Reported
	Topicort			S	Cutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Cortisone			S	Topical			Not Reported

Desoximetasone	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Oral		Not Reported
Sulfathalidine	S	Oral		Not Reported

	Tofacitinib		S	Unknown	Not Reported
	Tofacitinib Citrate		S	Unknown	Not Reported
	Atasol		C	Unknown	Not Reported
	Salazopyrin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	12736972	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-073069		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Oral	400 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Q4wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Apo Folic			S	Unknown	Unk		Not Reported
	Apo-Ramipril			S	Unknown	Unk Unk, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Ophthalmic	Unk Unk, Bid		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Ophthalmic	2 Dosage Form, Qd		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Levothyroxine			S	Unknown	Unk Unk, Qd		Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Cosopt	S	Unknown	Unk Unk, Bid	Not Reported
Altace	S	Unknown	1 Dosage Form, Qd	Not Reported
Tylenol [Paracetamol]	S	Unknown	Unk	Not Reported
Ramipril	S	Unknown	1 Dosage Form, Qd	Not Reported
Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Levothyroxine Sodium	S	Unknown	Unk, One Every Day	Not Reported
Acetaminophen	S	Oral	1000 Milligram	Not Reported
Plaquenil /00072602/	S	Unknown	400 Milligram, Qd	Not Reported
Acetaminophen, Caffeine And Dihydrocodeine Bi	C	Unknown	Unk Unk, Prn	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk Unk, Prn	Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Acetaminophen\Caffeine\Codeine Phosphate	C	Unknown	Unk, Prn	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Levothyroxine	C	Unknown	Unk Unk, Qd	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Meprobamate	C	Unknown		Not Reported
Phosphate [Phosphoric Acid Sodium]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	14372312	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018001862		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Ill-Defined Disorder; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Ulcer	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Qd		Not Reported
	Cortisone			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Betaloc			C		Unk		Not Reported
	Losec			C		Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	14496013	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007268		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease;	Orencia			S	Unknown	1000 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

Malaise; Mass; Nodule; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Mg, Qwk	Not Reported
	Methotrexate	S	Oral	17.5 Milligram, Qwk	Not Reported
	Novo-Rythro	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Wellbutrin	S	Unknown	300 Milligram, Qd	Not Reported
	Rituxan	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Celebrex	C	Unknown	200 Milligram, Bid	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	4000 International Unit, Qd	Not Reported
	Cannabis Sativa	C	Unknown	Unk	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Risedronate	C	Unknown	Unk	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Bupropion	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	14785795	EXPEDITED (15-DAY)		OT	CA-ROCHE-2109114		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Prerenal Failure; Renal Disorder; Treatment Failure	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	14949226	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2018-015284		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Bausch And Lomb
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported

	Cefaclor			S	Unknown	Not Reported
	Erythromycin			S	Unknown	Not Reported
	Celebrex			S	Oral	Not Reported
	Lyrica			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Levofloxacin Hemihydrate			S	Unknown	Not Reported
	Arthrotec			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Pethidine Hydrochloride			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	15622780	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557530-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			C		Solution		Not Reported
	Prednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16142580	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027232		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling;	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Non-Hodgkin'S Lymphoma; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Unevaluable Event	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram	Not Reported
	Plaquenil /00072602/	S	Oral	200 Milligram, Bid	Not Reported
	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown	50 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Humira	S	Subcutaneous	400 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	100 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown	100 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Nanogram, Bid	Not Reported
	Arava	S	Oral	20 Milligram, Qwk	Not Reported
	Adalimumab	C	Unknown		Not Reported
	Amoxicillin And Clavulanate Potassium	C	Unknown		Not Reported
	Amoxil /00249601/	C	Unknown		Not Reported
	Arava	C	Oral	20 Milligram, Qwk	Not Reported
	Bcg	C	Intravenous (not otherwise specified)		Not Reported
	Gold	C	Unknown		Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Amoxicillin Trihydrate	C	Unknown		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown		Not Reported

	Hydroxychloroquine Sulfate	C	Oral	400 Milligram		Not Reported
	Hydroxychloroquine	C	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine	C	Unknown	100 Milligram		Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Bcg	C	Intravesical	Unk		Not Reported
	Amoxicillin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16387439	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-051014		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Glumetza			S	Unknown	500 Milligram, Bid		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicorte			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Remicade			S	Unknown			Not Reported

	Lyrica	C	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Codeine	C	Unknown		Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Altace	C	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Tocopherol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16521587	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2189		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tongue	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ulceration; Tooth Infection; Treatment Failure	Rituxan		S	Unknown	Not Reported
	Adalimumab		S	Subcutaneous	Not Reported
	Plaquenil S		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tramadol		C	Unknown	Not Reported
	Indometacin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16533576	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-019020		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Topicort (Desoximetasone)			S	Cutaneous			Not Reported
	Topicort (Desoximetasone)			S	Other			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Failure; Wound	Fosamax	S	Oral		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	365.0 (Unspecified Therapy Duration)	Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	365.0 (Unspecified	Not Reported

				Therapy Duration)	
	Sulfathalidine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Atasol	C			Not Reported
	Salazopyrin	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16721726	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1077495		82 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dizziness; Lymphopenia; Rash; Rash Erythematous; Skin Plaque; Subacute Cutaneous Lupus Erythematosus	Simvastatin			S	Oral	Unk		Not Reported
	Pravastatin			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Milligram, Bid (200 Mg, Bid)		Mylan
	Acetylsalicylic Acid			C		Unk		Mylan
	Lansoprazole			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16778824	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP008207		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Exposure During Pregnancy; Headache; Off Label Use; Vision Blurred	Prednisolone			S	Unknown	15 Mg/Day		Not Reported
	Prednisolone			S	Unknown	60 Mg/Day		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Strides
	Betamethasone			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Methyldopa			S	Unknown	Unk		Not Reported

					Magnesium		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Hcq		S	Unknown	Unk	Not Reported
					Aspirin /00002701/		S	Unknown	Unk	Not Reported
					Lisinopril		S	Unknown	Unk	Not Reported
					Epoprostenol		S	Unknown	2 Ng/Kg/Min	Not Reported
					Enoxaparin		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16779782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-084386		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Hepatotoxicity; Off Label Use	Orencia			S	Unknown	1000 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16780433	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2019M1082856		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Cardiac Arrest; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Approximately 60 Tablets Of 200 Mg		Not Reported
	Naproxen			C	Oral	Several Amount Of 750mg Naproxen		Mylan
	Ibuprofen			C	Oral	Unknown Quantity Of 200 Mg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16780508	NON-EXPEDITED			US-AMNEAL			Unknown	USA

PHARMACEUTICALS-
2019AGH00053

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Weight Decreased	Hydroxychloroquine Sulfate			S	Oral	1 Tablets, 2x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16780565	EXPEDITED (15-DAY)		HO, OT	RO-MYLANLABS-2019M1082918		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Rheumatoid Arthritis; Treatment Noncompliance; Vascular Stent Thrombosis	Clopidogrel			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	150 Milligram, Qd		Not Reported
	Diclofenac			S	Unknown	(150 Mg/Day) During Periods Of Severe Joint Pain150 Milligram, Qd		Not Reported
	Diclofenac			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	5 Milligram, Qw		Not Reported
	Methotrexate			S	Unknown	30 Milligram, Qw		Not Reported
	Methotrexate			S		5 Milligram		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	3 Gram, Qd		Mylan
	Sulfasalazine			S	Unknown	1 Gram		Mylan
	Sulfasalazine			S	Unknown	1 Gram, Qd		Mylan
	Diclofenac /00372302/			C		Unk		Mylan
	Diclofenac /00372302/			C				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16781888	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA206477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Gold Sodium Thiomalate			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfametoxazol/Trimetoprim			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Mortin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Topical	Unk		Not Reported
	Apo Asa			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16782057	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017044735		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling;	Enbrel			S	Unknown	Unk		Amgen

Oral Infection; Therapeutic Product Effect Decreased; Tooth Abscess	Simponi		S	Unknown	Unk		Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram		Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid		Not Reported
	Mobicox		S	Unknown	Unk		Not Reported
	Celebrex		S	Unknown	Unk		Not Reported
	Methotrexate		S	Oral	17.5 Milligram, Qwk		Not Reported
	Leflunomide		C	Unknown	20 Milligram		Not Reported
	Meloxicam		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Sep-2019	16782273	EXPEDITED (15-DAY)		HO	NL-MYLANLABS-2019M1083399		26 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Petechiae; Systemic Lupus Erythematosus; Urticaria	Mycophenolate Mofetil			S	Unknown	500 Milligram, Bid		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2019	16216656	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-020662			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Ramipril			S	Unknown	Unk, Once A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Every 4 Weeks		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Cosopt			S	Unknown	Unk Unk, Two Times A Day		Not Reported

Cosopt	S	Ophthalmic	Unk Unk, Two Times A Day	Not Reported
Cosopt	S	Ophthalmic	2 Dosage Form, Once A Day	Not Reported
Cosopt	S	Ophthalmic	2 Dosage Form, Two Times A Day	Not Reported
Cosopt	S	Ophthalmic	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Once A Day	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Levothyroxine	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Levothyroxine	S	Unknown	Unk Unk, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Prednisone	S	Unknown	Unk, Once A Day	Not Reported
Remicade	S	Unknown	Unk Unk, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Altace	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported

Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once A Day	Not Reported
Levothyroxine Sodium	S	Unknown	Unk, Once A Day	Not Reported
Codeine Phosphate	S	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1000 Milligram	Not Reported
Dorzolamide Hydrochloride;Timolol Maleate	C	Unknown	Unk. Two Times A Day	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Once A Day	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
Acetaminophen;Caffeine;Dihydrocodeine	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Once A Day	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Tylenol With Codein [Caffeine;Codeine Phosphate;Paracetamol]	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Meprobamate	C	Unknown	Unk	Not Reported
Phosphoric Acid Sodium	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Once A Day	Not Reported
Timolol Maleate	C	Unknown	2 Dosage Form, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2019	16783256	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Freq: Unk X 1 Days		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2019	16783771	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-058249			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril			S	Unknown	1 Dosage Form, Daily		Aurobindo
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Once In Every 4 Weeks		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Altace			S	Unknown	1 Dosage Form, Daily		Not Reported
	Apo Prednison			S	Unknown	7 Milligram, Daily		Not Reported
	Apo Ramipril			S	Unknown	Unk, Daily		Not Reported
	Codeine			S	Unknown	Unk		Not Reported

Codeine	S	Unknown	Unk	Not Reported
Cosopt	S	Unknown	Unk, Two Times A Day	Not Reported
Dorzolamide Hcl And Timolol Maleate	S	Ophthalmic	Unk, Two Times A Day	Not Reported
Dorzolamide Hcl And Timolol Maleate	S	Unknown	Unk, Two Times A Day	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Daily	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Daily	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Daily	Not Reported
Levothyroxine	S	Unknown	Unk, Daily	Not Reported
Levothyroxine	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Once In Every Week	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	7 Milligram, Daily	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Daily	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Dorzolamide Hcl And Timolol Maleate	S	Unknown	Unk, Two Times A Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Acetaminophen;Caffeine;Dihydrocodeine	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	400 Milligram, Daily	Not Reported

Acetaminophen	C	Unknown	Unk		Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk		Not Reported
Caffeine;Codeine Phosphate;Paracetamol	C	Unknown	Unk		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Every Week		Not Reported
Methylprednisolone	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	10425697	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014066465		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Contraindicated Product Administered; Drug Ineffective; Hospitalisation; Meningitis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	11008496	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015032030		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Gastrointestinal Disorder; Hypersensitivity; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

		Methotrexate			S	Oral	25 Mg, Qwk			Not Reported
		Leflunomide			S	Oral	10 Milligram, Qd			Not Reported
		Methotrexate Sodium			S	Oral	25 Mg, Qwk			Not Reported
		Simponi			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	11089916	EXPEDITED (15-DAY)		OT	CA-ROCHE-1431697		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Blood Pressure Increased; Blood Pressure Systolic Increased; Cataract; Decreased Appetite; Dizziness; Dyspepsia; Heart Rate Decreased; Nausea; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)	Frequency: Day 1 And Day 15 Last Dose: 07/Jul/2014 And 29/May/2015 Last Rituximab Infusion Was Recei		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol [Paracetamol]			C	Oral			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Oral			Not Reported
	Solu-Medrol			C	Intravenous (not otherwise specified)			Not Reported
	Lipitor			C	Unknown	Stopped Taking Over A Year Ago Nos		Not Reported
	Cymbalta			C				Not Reported
	Prednisone			C				Not Reported
	Irbesartan			C				Not Reported
	Vitamin D3			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Atorvastatin			C				Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	11130879	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015049563		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Dizziness; Drug Ineffective; Eye Disorder; Headache; Inflammation; Joint Swelling; Ligament Sprain; Nausea; Orthosis User; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	11374404	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014100327		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Gram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Bid		Not Reported
	Orencia			S	Subcutaneous	750 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Other	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil S			S	Unknown	2000 Milligram		Not Reported

	Imuran	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	50 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	Unk, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Q2wk	Not Reported
	Xeljanz	C	Oral	5 Megabecquerel, Bid	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Tofacitinib	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	12702049	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1483		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoaesthesia; Multiple Sclerosis; Paraesthesia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	15935684	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-198493		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Haemophilus Infection; Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			S	Unknown	Unk		Mutual
	Prednisone			S	Unknown	Unk		Mutual
	Prednisone			S	Unknown	Gradually Weaned From 60 To 20 Mg, Daily		Mutual
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S				Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Trimethoprim-Sulfamethoxazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16226782	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S		Therapy Duration: 366.0		Not Reported
	Methotrexate			S	Oral	10 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Orencia			S		Therapy Duration: 365.0		Not Reported

	Sulfasalazine	S				Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16451762	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2016141914		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Inflammation; Nausea; Synovitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	30 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral	Unk		Not Reported
	Arava			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16534354	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK121160		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough;	Wellbutrin			S	Unknown	Unk		Glaxosmithkline
	Erythromycin			S	Subcutaneous	Unk		Glaxosmithkline

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Nodule; Rheumatoid Arthritis; Stress	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	22.5 Mg, We (1 In 1 Wk)		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Glaxosmithkline
	Risedronate	C	Unknown	Unk		Not Reported
	Marijuana	C	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16647628	NON-EXPEDITED			US-PFIZER INC-2019325587		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Pain	Ibuprofen			S		800 Mg Twice A Day (Sometimes)		Pfizer
	Ibuprofen			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Prednisone			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16698956	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016051296		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Ineffective; Finger Deformity; Gait Disturbance; Knee Arthroplasty; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk		Amgen
	Enbrel	S				Amgen
	Arava	S	Unknown	Unk		Not Reported
	Arava	S				Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Humira	S				Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S				Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16783894	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2018SP010306			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Tacrolimus			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16783925	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP010304			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Azathioprine			S	Transplacental	Unk		Not Reported

	Prednisolone			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Strides
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16784485	EXPEDITED (15-DAY)		OT	CA-SA-2019SA249370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral	Unk, Unk		Sanofi
	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk Unk, Unk		Sanofi
	Prednisone			S	Oral	Unk Unk, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Ointment		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Fosamax			S	Oral	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk Unk, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Simponi	S	Subcutaneous	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16784672	NON-EXPEDITED		OT	US-APPCO PHARMA LLC-2074173			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16784840	EXPEDITED (15-DAY)		OT	CA-ROCHE-2396493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Intravenous (not otherwise specified)					Not Reported
	Phthalylsulfathiazole			S	Unknown					Not Reported
	Prednisone			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16784985	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-219614		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Nodule	Methotrexate			S	Unknown	20 Milligram, Weekly		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Daily		Sun
	Prednisone			S	Unknown	5 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16785005	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-219608		38 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Sun
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16785092	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000126			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Haemorrhage	Hydroxychloroquine			S				Concordia
	Dupixent			S	Subcutaneous	300 Mg, Every Orher		Not Reported

Week

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786021	EXPEDITED (15-DAY)		LT	CA-PFIZER INC-2019386922			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Chills; Fatigue; Hyperthermia; Hypoxia	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Acetaminophen			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Acebutolol			C		Unk		Not Reported
	Bromazepam			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Fosinopril			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786303	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE045915		28 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Pneumonia; Sepsis; Splenomegaly; Systemic Lupus Erythematosus; Urinary Tract Infection	Methotrexate			S	Unknown	20 Mg, Qd		Novartis
	Quensyl			S	Unknown	200 Mg, Bid (400 Mg Qd)		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Qw		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Qw		Not Reported
	Folsan			C	Unknown	5 Mg, Tid (15 Mg Qd)		Not Reported
	Prednisolone			C	Unknown	10 Mg, Qd		Not Reported
	Ciprofloxacin			C	Unknown	500 Mg, Bid (100 Mg Qd)		Not Reported
	Pantozol			C	Unknown	40 Mg, Qd		Not Reported
	Piperacillin / Tazobactam			C	Unknown	1 Df, Tid (3ug/Litre)		Not Reported
	Voltaren Resinat			C	Unknown	75 Mg, Bid (150 Mg Qd)		Not Reported

	Prednisolon			C	Unknown	10 Mg, Unk			Not Reported
	Prednisolon			C	Unknown	75 Mg, Unk			Not Reported
	Tilidine Hydrochloride			C	Unknown	Unk, Qd			Not Reported
	Cellcept			C	Unknown	Unk			Not Reported
	Decortin H			C	Unknown	40 Mg, Unk			Not Reported
	Torem			C	Unknown	5 Mg, Unk			Not Reported
	Ibuprofen			C	Unknown	600 Mg, Qd			Not Reported
	Amlodipin			C	Unknown	2.5 Mg, Unk			Not Reported
	Vigantoletten			C	Unknown	1000 Iu, Unk			Not Reported
	Clexane			C	Subcutaneous	0.4 Ml, Unk			Not Reported
	Delix			C	Unknown	2.5 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786573	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1082866		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone			S	Oral			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786797	EXPEDITED (15-DAY)		OT	CA-ROCHE-2397899		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Orencia			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16786970	NON-EXPEDITED			US-SA-2019SA243493			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Erythema; Nausea; Nightmare; Pruritus; Skin Papilloma; Swelling	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787574	EXPEDITED (15-DAY)		DE	US-AMNEAL PHARMACEUTICALS-2019-AMRX-01796		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S	Oral	Approximately 60 Tablets Of 200 Milligram		Amneal
	Naproxen			C	Oral	Several 750 Mg Tablets		Amneal
	Ibuprofen			C	Oral	Unk		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787765	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083467		44 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone			S	Unknown	15 Milligram, Qd (15 Mg/D)		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

	Erythropoietin			S	Unknown	Unk				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787766	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083469		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	1 Milligram/Kilogram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787769	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083458		32 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisone			S	Unknown	40 Mg/D		Not Reported
	Prednisone			S	Unknown	10 Mg/D		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787771	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083464		22 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Prednisone			S	Unknown	Unk (10 Mg/D)		Not Reported
	Prednisone			S	Unknown	1 Milligram/Kilogram, Qd (1mg/Kg/D)		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Erythropoietin			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787773	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083474		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Variable	Prednisone			S	Unknown	2 Milligram/Kilogram, Qd (2mg/Kg/D)		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787835	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083483		33 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk, Qd,1 Mg/Kd/Day		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan
	Erythropoietin			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Erythropoietin			S	Intravenous (not otherwise specified)	Unk		Mylan
	Ciclosporin			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787836	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083491		24 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Variable	Prednisone		S	Unknown	2.5 Milligram, Qd	Not Reported
	Prednisone		S	Unknown	120 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Mylan
	Rituximab		S	Unknown	Unk	Mylan
	Ciclosporin		S	Unknown	Unk	Mylan
	Erythropoietin		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787837	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083496		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Prednisone			S	Unknown	70 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Erythropoietin			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787838	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083510		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	80mg/D		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk, Q3d		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787839	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083503		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	1 G / 3 D		Not Reported
	Cyclophosphamid			S	Unknown	Unk		Mylan
	Cyclosporine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Sep-2019	16787842	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1083488		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Therapeutic Product Effect Variable	Prednisone			S	Unknown	1 Milligram/Kilogram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	10600374	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014090485		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Apo Rabeprazole			C	Unknown	20 Milligram			Not Reported
	Tramadol Hcl			C	Oral	50 Milligram			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid			Not Reported
	Rabeprazole Sodium			C	Unknown	20 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	13057868	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016596720		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	13063303	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2773		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Swelling; Rheumatoid Factor Positive	Plaquenil			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	13216598	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Cortisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intra-arterial	Injection Im Iv Iar Int Ivr 25mg/Ml; Solution Intra Arterial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration- 11.0 Month(S)		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine	S	Oral	Therapy Duration: 365.0		Not Reported
	Fosamax	S	Oral			Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Sulfathalidine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Desoximetasone	S	Oral			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Xeljanz	C				Not Reported
	Tofacitinib Citrate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	13306161	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-019550			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral	11 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sotalol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	13595189	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941650		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Gold	S	Intramuscular	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	13814262	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112513		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk Unk, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	30 Milligram, Qd		Not Reported
	Methacin			C		50 Milligram		Not Reported

	Risedronate			C	Unknown	35 Milligram, Qwk			Not Reported
	Indometacin			C	Unknown	50 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	15764548	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1129		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Nausea; Synovitis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16110767	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044129		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Hepatotoxicity;	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported

Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure	Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	200 Milligram, Bid	Not Reported
	Sulfasalazine		S	Unknown	750 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram, Bid	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Hydrochlorothiazide;Lisinopril Dihydrate		C	Unknown	Unk	Not Reported
	Rituxan		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz Xr		C	Oral	5 Milligram, Bid	Not Reported
	Rituximab		C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16535670	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK120453		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Wellbutrin			S	Unknown	Unk		Glaxosmithkline
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk (1 In 2 Wk)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Z(1 In 2 Wk)		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1d		Not Reported
	Methotrexate			S	Unknown	20 Mg, We ,(1 In 1 Wk)		Not Reported
	Methotrexate			S	Unknown	15 Mg, We (1 In 1 Wk)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Z(1 In 6 Wk)		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk (Extended Release)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16706032	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016235833		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16788402	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-MAPI_00011450			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Erythema	Hydroxychloroquine			S	Oral	Unk		Concordia
	Octagam			S	Intravenous (not otherwise specified)	60 Mg, Qd		Not Reported
	Octagam			S	Intravenous (not otherwise specified)	60 Mg, Bid		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported

	Levothyrox	C	Not Reported
	Lercan	C	Not Reported
	Cardensiel	C	Not Reported
	Folic Acid	C	Not Reported
	Kaleorid	C	Not Reported
	Esidrex	C	Not Reported
	Lamaline (Atropa Belladonna Extract\Caffeine\Papaver Somniferum Tincture\Paracetamol)	C	Not Reported
	Elisor	C	Not Reported
	Rivotril	C	Not Reported
	Nicardipine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16788504	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-040409		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Mycobacterial Infection; Osteomyelitis; Skin Infection; Subcutaneous Abscess	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Mycophenolic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16788740	EXPEDITED (15-DAY)		HO	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-220243		62 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colonic Abscess; Diverticulum Intestinal	Methotrexate			S	Unknown	Unk		Sun
	Medrol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16788742	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201908000229			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown	Unk, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16788777	EXPEDITED (15-DAY)		OT	CA-ROCHE-2395032		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration 195.0 Day(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration 365.0		Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration 640.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration 6.0 Year(S)		Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C				Not Reported
	Lozide [Indapamide]			C				Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

	Ramipril			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16790165	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2019-05766		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypokalaemia; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine Sulfate Tablets			S	Unknown	Approximately 60 Tablets		Lupin
	Naproxen			S	Unknown	Unk, Sevral		Not Reported
	Ibuprofen			S	Unknown	Unk, Unknown Quantity		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16790257	EXPEDITED (15-DAY)		HO	PHHY2019US207773		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiotoxicity; Electrocardiogram Qt Prolonged; Toxicity To Various Agents; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16790649	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019384591		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Pain; Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, 1 Every 1 Week		Pfizer
	Celebrex			S		Unk		Pfizer
	Folic Acid			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Unknown Frequency		Not Reported
	Plaquenil [Hydroxychloroquine			S		400 Mg, 1 Every 1 Day		Not Reported

Sulfate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16791825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2395040			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	240 Days		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	158 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Oxycodone Hydrochloride			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16792104	EXPEDITED (15-DAY)		OT	PHHY2019TW208498			Male	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Uveitis	Ciclosporin			S	Unknown			Novartis
	Prednisolone			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16792169	NON-EXPEDITED			US-TEVA-2019-US-1106307		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash Erythematous; Rash Pruritic	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2019	16795486	DIRECT		OT			43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anger; Condition Aggravated; Depression; Diarrhoea; Dry Mouth; Fatigue; Feeding Disorder; Headache; Irritability; Malaise; Migraine; Sleep Disorder; Social Avoidant Behaviour; Urticaria	Hydroxychloroquine			S	Oral	Quantity:90 Tablet(S);		Sun
	Losatan			C				Not Reported
	Valcyclovir			C				Not Reported
	Singular			C				Not Reported
	Multivit			C				Not Reported
	Magnesium Injection			C				Not Reported
	B12			C				Not Reported
	Zyrtec			C				Not Reported
	Duloxetine			C				Not Reported
	Dexilant			C				Not Reported
	Probiotics			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	10653621	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014097710		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Apo-Prednisone	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	11108701	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015045489		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk (1 Every 2 Week)		Amgen
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, (1 Every 1 Week)		Not Reported
	Methotrexate			S	Unknown	15 Milligram , (1 Every 1 Week)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qwk (1 Every		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

			1 Week)	
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Imuran	S	Unknown	Unk	Not Reported
Gold	S	Intramuscular	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid (2 Every 1 Day)	Not Reported
Anakinra	S	Unknown	Unk Milligram	Not Reported
Anakinra	S	Subcutaneous	100 Milligram, Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram (1 Every 6 Weeks)	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Kineret	S	Subcutaneous	100 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram (1 Every 2 Weeks)	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	11242484	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015065908		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	25 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Myochrysine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	11688884	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015114325		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis;	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Therapeutic Response Decreased	Simponi		S	Subcutaneous	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Celebrex		C		Unk	Not Reported
	Cimzia		C	Subcutaneous	Unk	Not Reported
	Folic Acid		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	12320466	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054551			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	772 Milligram, Qmo		Not Reported
	Apo Hydroxychloroquine			S	Oral	400 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram (1 Every 9 Months)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported

	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	12336617	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054485		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Oral	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Kineret	S	Unknown	100 Milligram	Not Reported
Plaquenil	S	Unknown	100 Milligram	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C	Unknown	9 Milligram, Unk	Not Reported
Prednisone	C	Unknown	20 Milligram, Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	12701291	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016034866		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	40 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	40 Milligram/Kilogram		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported

Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Simponi	S	Subcutaneous	50 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate Sodium	S	Unknown	250 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Prevacid	C	Unknown	30 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	13315449	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-1896317-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Arthralgia; Asthenia; Cardiac Disorder; Drug Ineffective; Dry Eye; Dry Mouth; Emotional Distress; Erythema; Fatigue; Iron Deficiency Anaemia; Mitral	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Valve Disease; Nasopharyngitis; Rhinorrhoea; Suicidal Behaviour; Therapeutic Product Effect Decreased; Viral Infection	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported
	Cimzia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sotalol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	13947753	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017135184		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	13963798	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017821		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst;	Fentanyl			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Gabapentin			S	Oral	100 Mg, 1 Every 2 Weeks		Apotex
	Apo-Gabapentin			S	Unknown			Apotex
	Celecoxib			S	Unknown			Apotex

Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Celecoxib	S			Apotex
	Nortriptyline	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, 1 Every 4 Weeks	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk, 1 Every One Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 4 Weeks	Not Reported
	Orencia	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 2 Weeks	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	488 Mg, Q.M.T.	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Genteal /00445101/	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk, Bid	Not Reported

Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Q.H.	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Trazodone	C	Oral	50 Mg, Q.H.	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Fentanyl	C	Unknown		Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1 Every 2 Weeks	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown		Not Reported
Calcium	C	Unknown		Not Reported
Docosahexaenoic Acid W/Eicosapentae/07931301/	C	Unknown	1200 Mg, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Loperamide /00384302/	C	Unknown	25 Mg, Unk	Not Reported
Nicotinamide	C	Unknown		Not Reported
Pantoprazole	C	Unknown	400 Mg, Qd	Not Reported
Pantoprazole	C	Unknown	40 Mg, Qd	Not Reported
Pyridoxine	C	Unknown		Not Reported
Sodium	C	Unknown		Not Reported
Thiamine Hydrochloride	C	Unknown		Not Reported
Vitamin A /00056001/	C	Unknown		Not Reported
Vitamin B12 /00056201/	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported

	Xeljanz	C	Oral	5 Mg, Unk		Not Reported
	Vitamin D /00107901/	C	Unknown			Not Reported
	Nortriptyline	C	Unknown	Unk		Not Reported
	Omega 3 /01333901/	C	Unknown	Unk		Not Reported
	Omega 3 6 9 /01334101/	C	Unknown	Unk		Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk		Not Reported
	Oxycodone And Acetaminophen	C	Unknown	Unk		Not Reported
	Trazodone /00447702/	C	Unknown	Unk		Not Reported
	Vitamin B3	C	Unknown	Unk		Not Reported
	Vitamin E /00110501/	C	Unknown	Unk		Not Reported
	Lomotil /00034001/	C	Unknown	2.5 Mg, Qd		Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06852001/	C	Unknown	Unk, 1 Every 2 Weeks		Not Reported
	Fentanyl	S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	14069154	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017151637		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	5 Mg, Qwk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk Unk, As Necessary		Not Reported

	Prednisone			C		Unk				Not Reported
	Xeljanz			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	14633458	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	14689297	EXPEDITED (15-DAY)		OT	PHHY2018CA051657		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	15583501	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015053061		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Voltaren			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	15592659	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014351856		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	56 Mg, Weekly		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Unknown

Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate Sodium	S	Other	Unk	Unknown
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk	Unknown
	Methotrexate Sodium	S	Parenteral	Unk	Unknown
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Parenteral	Unk	Pfizer
	Methotrexate Sodium	S	Other	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Gram, Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qwk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Imuran	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	2000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Twice A Day	Not Reported
	Xeljanz	C	Oral	50 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	Unk, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Q2wk	Not Reported
	Xeljanz	C	Oral	5 Mbq, 2x/Day	Not Reported

	Tofacitinib			C		Unk				Not Reported
	Prednisone			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16088836	EXPEDITED (15-DAY)		OT	PHHY2019CA056570		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk Unk, Qw		Not Reported
	Morphine			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16104327	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019007338		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Apo-Hydro			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

		Humira			S	Subcutaneous	40 Milligram, Unk			Not Reported
		Humira			S	Subcutaneous	20 Milligram, Unk			Not Reported
		Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16115535	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044223			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16120417	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported

Renal Impairment; Skin Cancer	Hydroxychloroquine		S		Unk	Concordia
	Fabrazyme		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Fabrazyme		S		Unk	Not Reported
	Fabrazyme		S	Intravenous (not otherwise specified)	110 Units, Frequency Q2	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16793273	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201908000129			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16793277	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000109			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hip Arthroplasty; Hypertension; Impaired Work Ability; Pain; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Unk		Concordia
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Methotrexate			C				Not Reported
	Plaquenil			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794013	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3301		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Frequency Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794015	EXPEDITED (15-DAY)		LT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Chills; Fatigue; Hyperthermia; Hypoxia	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Acebutolol			C	Unknown			Not Reported
	Bromazepam			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Fosinopril			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794202	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201908000131			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Psoriatic Arthropathy	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794244	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019162653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Acetylsalicylic Acid			S	Unknown	Unk		Glaxosmithkline
	Gold Sodium Thiomalate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfametoxazol + Trimetoprim			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Mortin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Topical	Unk		Not Reported
	Apo Asa			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid/Clopidogrel Bisulfate			S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794248	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000086			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure; Therapeutic Response Decreased; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Arabloc			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16794261	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201908000238			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Haemorrhage	Hydroxychloroquine			S	Unknown			Concordia
	Naproxen			S	Unknown	500 Mg, Bid		Not Reported
	Methotrexate			C				Not Reported
	Inflectra			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Celebrex			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Tylenol Arthritis			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795350	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019384721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Decreased; Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate Sodium	S	Unk		Pfizer
	Sulfasalazine	S	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk		Not Reported
	Aleve	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795355	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019384704		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome;	Methotrexate Sodium			S		Unk		Pfizer
	Belimumab			S	Intravenous (not otherwise specified)	810 Mg, Unk		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	810 Mg, Unk		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	820 Mg, Unk		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S		Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Fentanyl/Fentanyl Citrate			S		9.0 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisone Acetate			S		50.0 Mg, Unk		Not Reported
	Prednisone Acetate			S		50.0 Mg, Unk		Not Reported
	Prednisone Acetate			S		50.0 Mg, Unk		Not Reported
	Gravol			C		Unk		Not Reported
	Neurontin			C		Unk		Not Reported
	Neurontin			C		Unk		Not Reported
	Neurontin			C	Oral	400.0 Mg, 1x/Day		Not Reported

Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795357	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019384724		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
	Chloroquine Diphosphate			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795369	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019387181		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oedema Peripheral; Pain	Methotrexate Sodium			S		25 Mg, Weekly (1 Every 1 Week)		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Folic Acid			S		Unk		Not Reported
	Plaquenil Sulfate			S		200 Mg, 2x/Day (2 Every 1 Day)		Not Reported

	Prednisone			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795492	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019387668			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Tylenol Arthritis Pain			C		Unk		Not Reported
	Desoximetasone			C		20 Mg, 1 Every 1 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16795978	EXPEDITED (15-DAY)		LT, OT	PH-AMNEAL PHARMACEUTICALS-2019-AMRX-01850		47 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dissection; Aortitis Salmonella; Arteriosclerosis; Salmonellosis	Azathioprine			S	Unknown	Unk		Amneal
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Daily		Amneal
	Prednisone			S	Oral	10 Milligram, Daily		Not Reported
	Prednisone			S	Unknown	1 Milligram/Kilogram, Daily		Not Reported
	Mycophenolate Mofetil			C	Unknown	500 Milligram, Bid		Not Reported
	Atorvastatin			C	Unknown	40 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796141	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190905052			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Tylenol			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Oral			Not Reported
	Teva-Dorzotimol			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796767	EXPEDITED (15-DAY)		HO, OT	PHHY2019US207682		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Syncope	Hydroxychloroquine			S	Unknown	5 Mg/Kg, Unk		Novartis
	Prednisone			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 G, Iv (Miv)		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Miv		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16796803	EXPEDITED (15-DAY)		OT	PHHY2019CA208169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous drip	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Subcutaneous	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16797061	EXPEDITED (15-DAY)		OT	PHHY2019TN210743		38 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Product Use In Unapproved Indication; Retinal Toxicity; Visual Impairment	Hydroxychloroquine			S	Unknown	500 Mg, Qd (7.6 Mg/Kg/Day)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2019	16797065	EXPEDITED (15-DAY)		OT	PHHY2019AR210721			Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	12141116	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016024996		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported

Decreased; Therapeutic Product Effect Incomplete; Viral Infection	Plaquenil	S	Oral	400 Mg, Qd		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate	S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Qwk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Cymbalta	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	12389606	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014304680		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rabeprazole Sodium			C	Unknown	20 Milligram		Not Reported
	Tramadol Hydrochloride			C	Oral	50 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

	Xeljanz			C	Unknown	5 Milligram, Bid				Not Reported
	Apo Rabeprazole			C	Unknown	20 Milligram				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	12494444	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016078553		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Rituxan			S	Unknown	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk Unk, Cyclical		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Simponi		S	Unknown	Unk		Not Reported
	Methotrexate Sodium		S	Oral	20 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk		Not Reported
	Meloxicam		C	Oral	7.5 Milligram, As Necessary		Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid		Not Reported
	Prednisolone		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	12578002	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016092405		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Cephalexin			C	Unknown	500 Mg, (4 Every 1 Day)		Not Reported

Cephalexin Monohydrate	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	12606343	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016097054		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	150 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	13230256	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017016379		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	500 Milligram, Qwk		Amgen
	Plaquenil			S	Oral	400 Milligram, Unk		Not Reported

Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Adalimumab	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	35 Milligram, Qd	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	13353218	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017040987		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	300 Milligram, Qmo		Not Reported
	Cosentyx			S	Unknown	300 Milligram, Qmo		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Q3wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	600 Milligram, Q6wk		Not Reported
	Infliximab			S	Unknown	600 Milligram		Not Reported
	Folic Acid			C		5 Milligram, Qd		Not Reported
	Naproxen			C		Unk Unk, As Necessary		Not Reported
	Plaquenil			C		300 Mg, Qd		Not Reported
	Folinic Acid			C		Unk		Not Reported
	Acetaminophen And Codeine			C		325 Milligram		Not Reported
	Acetaminophen And Codeine			C	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			C		Unk		Not Reported

	Aspirin	C		Unk	Not Reported
	Baclofen	C		Unk	Not Reported
	Betahistine Hydrochloride	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Clonidine Hydrochloride	C		Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Hydrochlorothiazide	C		Unk	Not Reported
	Losartan	C		Unk	Not Reported
	Metoprolol Tartrate	C		Unk	Not Reported
	Mometasone Furoate	C		Unk	Not Reported
	Tylenol With Codeine	C		Unk	Not Reported
	Caffeine	C		Unk	Not Reported
	Clonidine	C		Unk	Not Reported
	Fluticasone Propionate	C		Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	13558520	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017071644		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram Qd (For 10 Weeks)		Not Reported

	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Doxycyclin	S	Unknown	50 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	4 Df, Qwk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Doxycycline	S	Unknown	50 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Milligram (15 Mg For Over 66 Years And 10 Mg Qwk)	Not Reported
	Methotrexate	C	Oral	4.0 Dosage Forms, Qwk	Not Reported
	Methotrexate	C	Unknown	25 Milligram	Not Reported
	Prednisone	C		10 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	25 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	23 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	24 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk, As Required	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	13916469	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127852			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

					Hydroxychloroquine		S	Unknown	200 Milligram, Bid		Not Reported
					Methotrexate		S	Oral	175 Milligram, Qwk		Not Reported
					Sulfasalazine		S	Unknown	Unk		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported
					Hydroxychloroquine Sulfate		S	Oral	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	14181590	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170158		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	14206973	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017173282		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk (7.5 Mg To 22.5 Mg)	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Q2wk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Remicaide	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Pregabalin	C	Unknown	100 Milligram, Bid	Not Reported
	Pregabalin	C	Unknown	Unk	Not Reported
	Pregabalin	C	Unknown	Unk	Not Reported
	Deflazacort	C	Unknown	6 Milligram, Tid	Not Reported
	Deflazacort	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk (One To Two Tabs Every Four To Six Hours)	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown	4 Milligram, Q4h	Not Reported
	Dilaudid	C	Unknown	4 Milligram 6 Every One Day	Not Reported
	Dilaudid	C		4 Milligram	Not Reported
	Dilaudid	C		Unk	Not Reported
	Risedronate	C	Unknown	150 Mg, Qmo	Not Reported
	Risedronate	C	Unknown	Unk	Not Reported
	Salbutamol	C	Unknown	Unk	Not Reported
	Nitroglycerin	C	Unknown	Unk	Not Reported

Crestor	C	Unknown	40 Mg, Qd	Not Reported
Hydromorph	C	Unknown	9 Milligram, Bid	Not Reported
Januvia	C	Unknown	Unk	Not Reported
Pantoloc	C		40 Milligram, Qd	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Acidophilus	C	Unknown	Unk	Not Reported
Aspirin	C	Unknown	Unk	Not Reported
Triamcinolone	C	Unknown	1 Ml, Unk	Not Reported
Triamcinolone	C	Unknown	Unk	Not Reported
Lidocaine	C		1 Milliliter	Not Reported
Lidocaine	C	Unknown	Unk	Not Reported
Lidocaine	C	Topical	Unk	Not Reported
Kenalog	C	Unknown	40 Mg, Unk	Not Reported
Kenalog	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	Unk	Not Reported
Rosuvastatin Calcium	C	Unknown	40 Mg, Qd	Not Reported
Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	C	Unknown	9 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Unknown	4 Milligram 6 Every One Day	Not Reported
Hydromorphone Hydrochloride	C		Unk	Not Reported
Calcium Gluconate	C		Unk	Not Reported
Lactobacillus Acidophilus	C		Unk	Not Reported
Metronidazole	C		Unk	Not Reported
Risedronate Sodium	C		Unk	Not Reported
Rosuvastatin	C		Unk	Not Reported

Salicylic Acid	C	Unk		Not Reported
Triamcinolone Acetonide	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	14307540	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017188256		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Adalimumab			S	Unknown	40 Milligram, Q2wk		Not Reported
	Adalimumab			S	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	14773054	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018052058		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported

	Simponi		S	Subcutaneous	Unk			Not Reported
	Arava		C	Unknown	Unk			Not Reported
	Leflunomide		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	15202783	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016168075		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Polyneuropathy; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			C		Unk		Not Reported
	Atorvastatin			C	Oral	40 Milligram, Qd		Not Reported
	Methotrexate			C	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	15214457	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015364117		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Enbrel			S		Unk Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported

	Cimzia			C		Unk			Not Reported
	Folic Acid			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	15395194	NON-EXPEDITED			US-PFIZER INC-2018373069		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Condition Aggravated; Headache; Impaired Healing; Nasopharyngitis; Pain; Rhinorrhoea; Scar; Sensitivity To Weather Change	Xeljanz			S	Oral	5 Mg, 2x/Day (1 Tablet) 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Imitrex			C		Unk		Not Reported
	Lisinopril			C		Unk		Not Reported
	Simvastatin			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported
	Benadryl			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Naprosyn [Naproxen Sodium]			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	15583102	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018153729		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Decreased	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	15684023	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018170856		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

	Methotrexate		S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Advil		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Ketorolac		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine Phosphate		C	Unknown	Unk	Not Reported
	Leflunomide		C	Unknown	20 Milligram, Qwk	Not Reported
	Advil [Ibuprofen]		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	15851574	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019007571			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Prednisone			C		10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16104483	NON-EXPEDITED		OT	CA-AMGEN-CANSP2013048937		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Single Dose Prefilled Syringe(Enbrel)			S	Unknown	50 Milligram		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16106939	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019043734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk				Not Reported
	Xeljanz			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16118246	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019130244		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	750 Milligram, Qd		Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Hydrochlorothiazide/Lisinopril Dihydrate			C	Unknown	Unk		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz Xr			C	Oral	5 Milligram, Bid		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16123432	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer

	Methotrexate Sodium		S	Subcutaneous	25 Milligram, Qwk	Pfizer
	Xeljanz		S	Unknown	5 Milligram, Bid	Pfizer
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16124916	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019133855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16211375	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020250			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Milligram		Aurobindo
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Actemra			S	Subcutaneous	Unk, Every Week		Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 24 Hours		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Mobicox			S	Oral	7.5 Milligram, Once A Day		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16758145	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3090			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cartilage Injury; Depression; Dizziness; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Palpitations; Panic Attack; Renal Function Test Abnormal; Tremor	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Diclofenac Sodium			C	Unknown			Not Reported
	Diclofenac Sodium			C				Not Reported
	Xeljanz			C	Unknown			Not Reported
	Diclofenac			C	Oral			Not Reported
	Diclofenac			C				Not Reported

	Tamsulosin Hydrochloride			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16770860	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1102373		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Disorder; Mycobacterial Infection; Nausea; Pyrexia; Renal Injury; Toxicity To Various Agents; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Amikacin			S	Intravenous (not otherwise specified)			Teva
	Amikacin			S	Unknown	Amikacin Containing Spacer		Teva
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported
	Tigecycline			S				Not Reported
	Clofazimine			S	Unknown			Not Reported
	Clofazimine			S				Not Reported
	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported
	Cefoxitin			S				Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported
	Linezolid			S	Oral			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16782274	EXPEDITED (15-DAY)		DE	NL-MYLANLABS-2019M1083426		67 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Neoplasm Malignant;	Prednisolone			S	Unknown	Unk		Not Reported

Product Use In Unapproved Indication	Methotrexate	S	Unknown	Unk			Mylan
	Plaquenil /00072602/	S	Unknown	Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16797602	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16797604	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3325		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Eye Laser Surgery; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Fentanyl Citrate			S	Unknown			Not Reported

Infection; Knee Operation; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Impairment; Weight Decreased	Plaquenil	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Neurontin	C	Unknown		Not Reported
	Neurontin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16798073	EXPEDITED (15-DAY)		DE, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-219564		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Sun
	Ibuprofen			S	Unknown	Unk		Sun
	Naproxen			S	Unknown	Unk (750mg)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16799031	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201908000267			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Chest Pain; Congestive Cardiomyopathy; Cough; Dyspnoea; Pleural Effusion; Sinus Tachycardia; Systolic Dysfunction; Toxicity To Various Agents	Hydroxychloroquine	S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine	S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16799495	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019393155		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, 1 Every 2 Weeks		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16799759	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019388704		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Anakinra			S		Unk		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S		10 Mg, 1x/Day		Not Reported
	Arava			S		10 Mg, 1x/Day		Not Reported
	Plaquenil Sulfate			S		200 Mg, 2x/Day		Not Reported

Decreased	Meloxicam			C	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16801416	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2922224-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Biotin W/Calcium Pantothenate/Nicot			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity;	Actemra			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous		Not Reported
	Enbrel			S	Unknown		Not Reported
	Xeljanz			S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown		Not Reported
	Orencia			S	Unknown		Not Reported
	Sarilumab			S	Unknown		Not Reported
	Premarin			C	Unknown		Not Reported
	Neurontin			C	Unknown		Not Reported
	Folic Acid			C	Unknown		Not Reported
	Hydrodiuril			C	Unknown		Not Reported
	Atacand			C	Unknown		Not Reported
	Tylenol [Paracetamol]			C	Unknown		Not Reported
	Kevzara			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802499	EXPEDITED (15-DAY)		OT	CA-ROCHE-2397745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Not Specified		Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Specified		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Topicort [Desoximetasone]	S	Oral			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Sep-2019	16802519	NON-EXPEDITED			PHEH2019US037016			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Intercepted Medication Error	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	11198503	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015012893		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram (3/C G2)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported

Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C		20 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	C		200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported
	Prednisone	C		10 Milligram, Bid	Not Reported
	Tocilizumab	C		Unk	Not Reported
	Gold	C			Not Reported
	Lyrica	C		75 Milligram, Qd	Not Reported
	Trazodone	C		50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	11379353	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015082402		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid (500mg 2 Tabs)		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Prednisone	S	Unknown	5 Milligram, Qd	Not Reported
Prednisone	S	Unknown	5 Milligram, Qd	Not Reported
Prednisone	S	Unknown	5 Milligram (1 Every 24 Hours)	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram (1 Every 24 Hours)	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Inflectra	S	Intravenous (not otherwise specified)	300 Mg, Q 0, 2, 6 Weeks Then Every 8 Weeks For 12 Months	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Mg, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	S	Intravenous (not	300 Mg, Qd	Not Reported

			otherwise specified)		
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Pantoloc	C	Unknown	80 Mg, (Od) (40 Mg 2 Tabs)	Not Reported
	Pantoloc	C	Unknown	5 Mg, Qd	Not Reported
	Pantoloc	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	80 Mg, Qd	Not Reported
	Pantoprazole Sodium	C		Unk	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	12304663	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015009517		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Unk			Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk			Not Reported
					Arava		C		Unk			Not Reported
					Humira		C		Unk			Not Reported
					Orencia		C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	12330730	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2016054257		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	12543359	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016082789		75 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Skin Cancer; Squamous Cell Carcinoma; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	Up To 25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Celexa			C		40 Milligram, Qd		Not Reported
	Citalopram Hydrobromide			C	Unknown	40 Milligram		Not Reported
	Citalopram Hydrobromide			C	Unknown	1 Dosage Form, Qwk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	150 Milligram (3 Every 1 Day)		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qwk		Not Reported
	Methotrexate			S	Oral	Unk Unk, Qwk		Not Reported
	Neoral			S	Unknown	125 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	12669180	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016106895		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Single Dose Prefilled Autoinjector(Enbrel)			S	Subcutaneous	50 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Unk		Amgen
	Apo-Amlodipine			S	Oral	5.0 Milligram, Unk		Not Reported
	Apo-Amlodipine			S	Oral	5.0 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Norvasc			S	Oral	5 Milligram, Qd		Not Reported
	Norvasc			S	Oral	5 Milligram, Die		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Asacol			S	Oral	800 Milligram, Tid		Not Reported
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	5 Milligram, Cyclical		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Unknown	40 Milligram, Unk		Not Reported
	Depo-Medrol			C	Unknown	80 Milligram, Unk		Not Reported
	Depo-Medrol			C	Intramuscular	120 Milligram, As Necessary		Not Reported
	Depo-Medrol			C	Intra-articular	Unk		Not Reported

	Ferrous Gluconate	C	Oral	300 Milligram, Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Omega Allergenic Extracts	C		Unk Unk, Qd	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
	Vitamin D3	C		1000 International Unit, Qd	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	500 Milligram, As Necessary	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram Every Other Day	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Oral	16-12.5 Milligram, Qd	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Cholecalciferol	C		Unk Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13805306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016034387		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

	Apo-Hydroxyquine		S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz		S	Oral	5 Milligram, Qd	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz		S	Oral	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	20 Milligram, Qwk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Advil		C	Unknown	Unk	Not Reported
	Ketorolac		C	Unknown	Unk Unk, As Necessary	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13819745	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112611			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported

	Apo-Minocycline	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	400 Milligram		Not Reported
	Amoxil	C	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Unk		Not Reported
	Hydroxychloroquine Sulfate	C		Unk		Not Reported
	Leflunomide	C		Unk		Not Reported
	Clavulanate Potassium	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13875919	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2490		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Plaquenil S	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13926382	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017129788		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Response	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, 4 Every 1 Day		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Decreased	Actemra	S	Subcutaneous	Unk		Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil	S	Unknown	400 Milligram, 4 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Leflunomide	C	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13940792	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2013221889		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Enbrel			S	Unknown	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	13988802	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017138778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Other	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Celebrex		C	Unknown	Unk	Not Reported
	Leflunomide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	14551814	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022301		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Vitamin D			C	Unknown	4000 Iu(International Unit), Qd		Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Ergocalciferol	C		4000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15056653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Winpred	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15108655	NON-EXPEDITED		HO, OT	US-AMGEN-USASP2018090376		36 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Multiple Sclerosis; Off Label Use; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Unevaluable Event	Enbrel			S	Unknown	Unk Unk, Qwk (One Shot Per Week)		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15208510	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016551489		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Polyneuropathy; Synovitis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported

	Atorvastatin			C	Oral	40 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15208760	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016078449		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	1.2 Milliliter, Qwk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15294000	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018113034			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Gait Disturbance; Hip Surgery; Knee Arthroplasty; Osteoarthritis; Rheumatoid Arthritis; Sciatica; Unevaluable Event	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15428600	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016087558		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15554506	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018148904		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased;	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Actemra		S	Subcutaneous	162 Milligram	Not Reported
	Methotrexate		S	Oral	10 Milligram, Qd	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15575454	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017386080		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Ovarian Disorder; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15592337	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018456837		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15622705	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557477-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15630592	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine /00884302/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

	Topicort /00028604/			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Topicort [Desoximetasone]			S	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15681543	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014340463		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Single		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15740714	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015222530		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Enbrel		S	Unknown	50 Milligram, Qwk	Pfizer
	Methotrexate Sodium		S	Oral	25 Mg, Weekly (Taken For X-Years)	Pfizer
	Methotrexate Sodium		S		25 Mg, Weekly	Pfizer
	Sulfasalazine		S	Unknown	Unk	Pfizer
	Actemra		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	25 G, Weekly	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Myochrysine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15864418	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019030451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

					Orencia		S	Unknown	Unk	Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
					Rituximab		S	Unknown	Unk	Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Unknown	300 Milligram, Qd	Not Reported
					Prednisone		C		10 Milligram, Qd	Not Reported
					Simponi		C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15930707	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2655661-00		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Pneumonia; Rash; Somnolence; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Acetaminophen W/Codeine Phosphate	C		Not Reported
	Celebrex	C	Oral	Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	15935525	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657077-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
					Simponi	S	Subcutaneous			Not Reported
					Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16115563	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044686		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rosuvastatin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16123648	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019131841		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Gold		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil Sulfate		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rosuvastatin		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16126279	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0874		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydrochlorothiazide/Lisinopril Dihydrate			C	Unknown			Not Reported
	Rituxan			C	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16133290	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16172752	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019053872		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Failure	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]	S	Unknown	Unk		Not Reported
	Plaquenil	C	Unknown	200 Milligram, Bid		Not Reported
	Prednisone	C	Unknown	7.5 Milligram, Qd		Not Reported
	Tridural	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16803450	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-001370			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	60 Df, Single		Ipca
	Ibuprofen 200 Mg Tablets			S	Oral	200 Mg, Unk		Not Reported
	Naproxen			S	Oral	750 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16803764	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3334		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported

Renal Disorder; Tooth Extraction; Tooth Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804294	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1107590		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Amitriptyline			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Misoprostol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Teva
	Pregabalin			S	Unknown			Teva
	Celecoxib			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804322	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1107618		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Amitriptyline			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Misoprostol			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Teva
	Prednisone			S	Unknown			Actavis

	Pregabalin	S	Unknown			Teva
	Diclofenac Sodium	S	Unknown			Actavis
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804703	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2019M1084924		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Sinus Tachycardia; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16804946	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2019M1085055		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiac Failure Congestive; Electrocardiogram Qt Prolonged; Toxicity To Various Agents; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16805423	EXPEDITED (15-DAY)		OT	PHHY2019CN213076			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Palpitations; Pigmentation Disorder; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16805824	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001126			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	12343178	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016240466			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Intravenous (not	772 Milligram, Qmo		Not Reported

				otherwise specified)		
	Apo Hydroxychloroquine		S	Oral	400 Mg, Qwk	Not Reported
	Myochrysine		S	Intramuscular	Unk, Dose Form: Solution Intramuscular	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 9 Month, Dosage Form: Solution Intravenous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	12727842	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-072673		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Benign Neoplasm; Bladder Operation; Disability; Drug Ineffective; Fatigue; Headache; Influenza Like Illness; Malaise; Off Label Use; Peripheral Swelling; Spinal Pain; Urinary Tract Infection; Vaginal Haematoma	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Qmo		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	2000 Dosage Form		Not Reported
	Leflunomide			C	Unknown			Not Reported

	Vitamin D2	C	Oral	2000 Unit, Qd		Not Reported
	Vitamin B12 /00056201/	C	Sublingual	1000 Mg, Qd		Not Reported
	Multivitamin /00097801/	C	Oral	Unk, Qd		Not Reported
	Prednisone	C	Oral	4 Tab, Qd		Not Reported
	Prednisone	C	Oral	3 Tab, Qd		Not Reported
	Prednisone	C	Oral	2 Tab, Qd		Not Reported
	Prednisone	C	Oral	1 Tab, Qd		Not Reported
	Depo-Medrol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	12769017	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-024540		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported

	Xeljanz			S	Oral	5 Mg, Bid			Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd			Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd			Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Qmo			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Prednisone			C	Unknown	Unk Unk, Prn			Not Reported
	Folic Acid			C	Unknown	Unk Unk, Prn			Not Reported
	Naproxen			C	Unknown	Unk Unk, Prn			Not Reported
	Advil /00044201/			C	Unknown	Unk Unk, Prn			Not Reported
	Ketorolac			C	Unknown	Unk, Prn			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	13167859	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005528		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown	2 Tab, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	13595339	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1939773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac	Actemra			S	Unknown			Not Reported

Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Arava	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	13825062	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017332564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported

	Apo-Azathioprine	S	Unknown	100 Milligram	Not Reported
	Apo-Minocycline	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
	Plaquenil	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
	Amoxil	C	Unknown	Unk	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Unk	Not Reported
	Hydroxychloroquine Sulfate	C		Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Adalimumab	C		Unk	Not Reported
	Bcg Vaccine	C		Unk	Not Reported
	Clavulin [Amoxicillin Trihydrate;Clavulanate Potassium]	C		Unk	Not Reported
	Clavulanate Potassium	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	13828010	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2285		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Apo-Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Methacin	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Indometacin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	14921333	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044582		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Asacol			S	Oral	800 Milligram, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Norvasc			S	Oral	5 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported

	Bisoprolol Fumarate	C	Unknown	Unk		Not Reported
	Depo-Medrol	C	Intra-articular	Unk		Not Reported
	Ferrous Gluconate	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Omega Allergenic Extracts	C	Intradermal	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Zopiclone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	14983910	EXPEDITED (15-DAY)		OT	CA-ROCHE-2135982			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Tylenol Arthritis Extended Relief			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15287673	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1196		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Twice Weekly		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous	Twice Weekly		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15560465	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018441493		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S		50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qwk		Not Reported

	Actemra		S	Subcutaneous	162 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15591015	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017113386		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Palpitations; Stomatitis; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Q Week)		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q3wk		Pfizer
	Infliximab			S	Unknown	600 Milligram, Q6wk		Not Reported
	Infliximab			S	Unknown	600 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Not Reported
	Cosentyx			S	Unknown	300 Mg, Qmo		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Humira	S		Unk	Not Reported
Naproxen	C	Unknown	Unk Unk, As Needed (Prn)	Not Reported
Folic Acid	C	Unknown	5 Milligram, Qd	Not Reported
Plaquenil	C		300 Mg, Qd	Not Reported
Acetaminophen And Codeine	C		325 Milligram	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride	C		Unk	Not Reported
Aspirin	C		Unk	Not Reported
Baclofen	C		Unk	Not Reported
Betahistine Hydrochloride	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Clonidine Hydrochloride	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Gabapentin	C		Unk	Not Reported
Hydrochlorothiazide	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Metoprolol Tartrate	C		Unk	Not Reported
Mometasone Furoate	C		Unk	Not Reported
Tylenol With Codeine	C		Unk	Not Reported
Caffeine	C		Unk	Not Reported
Clonidine	C		Unk	Not Reported
Fluticasone Propionate	C		Unk	Not Reported
Folinic Acid	C		Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15696051	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018501207		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Advil [Ibuprofen]			C	Unknown	Unk		Not Reported
	Advil [Ibuprofen]			C		Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ketorolac			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	20 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15928734	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2507444-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rituxan			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15941043	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658294-00		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Myochrysine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	15978337	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013833		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Unknown				Not Reported
	Tocilizumab			S	Unknown				Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk			Not Reported
	Kineret			S	Unknown	Unk			Not Reported
	Desoximetasone			C	Unknown	Unk			Not Reported
	Methotrexate			C	Unknown	25 Mg, Qwk			Not Reported
	Prednisone			C	Unknown	30 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16115143	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019129717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16138970	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Actemra		S	Intravenous (not otherwise specified)	Not Reported
					Apo-Azathioprine		S	Unknown	Not Reported
					Azathioprine		S	Unknown	Not Reported
					Humira		S	Subcutaneous	Not Reported
					Hydroxychloroquine		S	Unknown	Not Reported
					Hydroxychloroquine Sulfate		S	Subcutaneous	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Not Reported
					Plaquenil		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16779482	EXPEDITED (15-DAY)		OT	US-SA-2019SA248837		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Skin Cancer	Plaquenil			S		Unk, Unk		Sanofi
	Fabrazyme			S	Intravenous (not otherwise specified)	Unk, Unk		Sanofi
	Fabrazyme			S		Unk		Sanofi
	Fabrazyme			S	Intravenous (not otherwise specified)	110 U, Frequency: Q2		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402117		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug	Rituxan			S	Intravenous drip			Not Reported

Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808235	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3351			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Magnesium			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

	Potassium			C	Unknown					Not Reported
	Vitamin D			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808236	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808237	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3369		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oedema Peripheral; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808382	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1108880		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis	Atenolol	S	Unknown	25 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Barr
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Palafer® Cf	S	Unknown		Not Reported
	Pantoloc	S	Unknown	40 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Celebrex	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16808742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402077		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16809136	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402110		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported
	Bcg Vaccine			C	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16810756	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019393007		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Warfarin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16810964	EXPEDITED (15-DAY)		DS, OT	CA-MYLANLABS-2019M1087008		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Vision Loss; Reading Disorder; Retinal Injury; Retinopathy; Toxicity To Various Agents; Visual Field Defect	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Mylan
	Propranolol			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Sep-2019	16811763	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1086401		43 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Abuse; Intentional Product Misuse; Off Label Use; Rebound Effect; Still'S Disease	Prednisone			S		20 Mg, Qd		Not Reported
	Prednisone			S		1 Mg/Kg, Qd		Not Reported

	Sulfasalazine	S	Unk	Mylan
	Hydroxychloroquine Sulfate	S	Unk	Mylan
	Methotrexate	C	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	12528517	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016317758		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Up To 25mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Qwk		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Imuran			S		150 Mg, 3x/Day		Not Reported
	Neoral			S		125 Mg, 2x/Day		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	150 Milligram (3 Every 1 Day)		Not Reported
	Celexa			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported
	Citalopram Hydrobromide			C	Unknown	40 Milligram		Not Reported

Citalopram Hydrobromide	C	Unknown	1 Dosage Form, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	12612327	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2016245221		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Unknown
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported
	Bupropion			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	12700555	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016121517		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly(8 Tablets (Strength 2.5mg) Once Weekly)		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Unknown

Methotrexate Sodium	S	Oral	20 Mg, Weekly		Pfizer
Methotrexate Sodium	S	Oral	20 Mg, Unk		Pfizer
Plaquenil	S	Oral	400 Mg, 1x/Day(Once Daily)		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Actemra	S	Subcutaneous	162 Mg, Weekly		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Apo-Folic Acid	S	Urethral	Unk		Not Reported
Cymbalta	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Methotrexate	C	Oral	20 Mg, Qwk		Not Reported
Methotrexate	C	Unknown	20 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	12702020	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1482		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

Disease; Joint Swelling; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Ilaris	S	Subcutaneous	Single Use Vial	Not Reported
	Ilaris	S	Unknown	Single Use Vial	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Kinaret	S	Unknown	Not Reported
Kinaret	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Marijuana	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Apo-Sulfasalazine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported
Lyrica	C	Unknown	Not Reported
Rituximab	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	12707885	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016163941		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; Contraindicated Product Administered;	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer

Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Methotrexate Sodium	S	Unknown	25 Mg, Weekly	Pfizer
	Plaquenil	S	Oral	200 Mg, 2x/Day	Not Reported
	Arava	S	Oral	10 Mg, Once Daily	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic (Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	50 Mg, Qwk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Monthly	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	4 Mg/Kg, Unk	Not Reported
	Actemra	S	Unknown	40 Mg/Kg, Unk	Not Reported
	Actemra	S	Unknown	40 Mg/Kg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, 1x/Day	Not Reported
	Prednisone	C	Unknown	50 Mg, 1x/Day	Not Reported
	Prevacid	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	C	Oral	50 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	12913741	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092672		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	13263381	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0595		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Sleep Disorder; Swelling	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported
	Apo Rabeprazole	C	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	13822142	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016163871		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Pfizer
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Daily		Not Reported
	Plaquenil			S	Unknown	200 Mg, Daily		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported

	Folic Acid	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Advil	C	Unknown	Unk		Not Reported
	Ketorolac	C	Unknown	Unk Unk, As Necessary		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	13922260	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375037			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	175 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	13923291	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1029		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Anakinra	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Kineret	S	Unknown	Not Reported
Kineret	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported

	Arava	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	14190818	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017044608		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Ineffective; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Oral	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

					Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
					Adalimumab	S		Unk	Not Reported
					Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
					Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
					Xeljanz	C	Unknown	Unk	Not Reported
					Prednisone	C		35 Mg, 1x/Day	Not Reported
					Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	14430682	EXPEDITED (15-DAY)		OT	US-ROCHE-2055401			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Cardiac Disorder; Iron Deficiency Anaemia; Mitral Valve Disease; Rhinorrhoea; Sjogren'S Syndrome; Suicidal Behaviour; Therapeutic Product Effect Decreased; Viral Infection	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			S	Oral	Ongoing:Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Single Dose Prefilled Syringe.		Not Reported
	Sotalol			C	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	14562755	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018075047		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin D			C	Unknown	4000 Iu, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Ergocalciferol			C		4000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	14633561	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019582		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Xeljanz			S	Oral	5 Mg, Bid				Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15223209	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017369040		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Therapeutic Response Decreased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		2 G, 1x/Day		Pfizer
	Sulfasalazine			S		2 G, 4 Every 1 Day		Pfizer
	Sulfasalazine			S	Unknown	2 Gram		Pfizer
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Plaquenil			S		400 Mg, 4 Every 1 Day		Not Reported
	Humira			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Leflunomide			C	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15223217	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016360742			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia;	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	150 Mg, Unk		Pfizer
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Actemra			S		Unk		Not Reported

Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Orencia	S	Unk	Not Reported
	Apo-Hydroxyquine	S	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15230255	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1148			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Off Label Use; Overdose; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Therapeutic Response Decreased; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15238954	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015268790		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered;	Enbrel			S		Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	2 Df, 2x/Day		Pfizer

Influenza Like Illness; Malaise; Nausea	Xeljanz	S	Oral	1 Df, 2x/Day	Pfizer
	Xeljanz	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Unknown
	Sulfasalazine	S		1 G (500mg, 2 Tablets), 2x/Day	Pfizer
	Sulfasalazine	S	Unknown	1 Gram, Bid	Pfizer
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Pfizer
	Inflectra	S	Intravenous (not otherwise specified)	300 Mg, Q 0, 2, 6 Weeks Then Every 8 Weeks For 12 Months	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	300 Mg, Qd	Not Reported
	Infliximab Hospira	S			Not Reported
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram (1 Every 24 Hours)	Not Reported
	Plaquenil	S	Oral	400 Mg, 1x/Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S		20 Mg, Unk	Not Reported
	Prednisone	S		5 Mg, Daily	Not Reported
	Prednisone	S	Unknown	5 Milligram (1 Every 24 Hours)	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Infusions	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C		80 Mg, 1x/Day	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	5 Mg, Qd	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	80 Mg, 1x/Day	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Pantoprazole Sodium Anhydrous	C		Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15291621	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016315535		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Kineret	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk, Solution Subcuatenous		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Anakinra	S	Oral	100 Mg, Unk		Not Reported
	Anakinra	S	Unknown	Unk		Not Reported
	Anakinra	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Methotrexate	C	Oral	25 Mg, Weekly		Not Reported
	Methotrexate	C	Unknown	25 Mg, Weekly		Not Reported
	Prednisone	C	Unknown	30 Mg, 1x/Day		Not Reported
	Methotrexate Sodium	C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15464129	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016330709		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	50 Mg, Weekly		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil			S		400 Mg, Daily		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Orencia			S	Intravenous (not	750 Mg, Unk		Not Reported

Abnormal; Restless Legs Syndrome; Treatment Failure					otherwise specified)			
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15575467	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016303303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Humira			S	Unknown	Unk, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Actemra			S	Subcutaneous	Unk, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

	Rituxan	S	Unknown	1000 Unk, Unk	Not Reported
	Orencia	S	Subcutaneous	125.0 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Meloxicam	C	Oral	7.5 Mg, As Necessary	Not Reported
	Meloxicam	C	Oral	7.5 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisolone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15594037	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015184383		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Voltaren			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15605755	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3232		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15668052	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570500-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15719015	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018156473		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported

	Simponi			S	Subcutaneous	Unk				Not Reported
	Leflunomide			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15854878	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017205722		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Stomatitis	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	4 Df (Pills), Weekly		Pfizer
	Methotrexate Sodium			S	Parenteral	15 Mg, Minimum 8 Weeks Required		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Pfizer
	Leflunomide			S		20 Mg, Daily (For 10 Weeks)		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Abatacept			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Prednisone			C		25 Mg, Daily		Not Reported
	Prednisone			C		24 Mg, Daily		Not Reported
	Prednisone			C		23 Mg, 1x/Day		Not Reported
	Prednisone			C		24 Mg, 1x/Day		Not Reported
	Prednisone			C		25 Mg, 1x/Day		Not Reported
	Tylenol Arthritis			C		Unk Unk, As Needed		Not Reported
	Tylenol Arthritis			C		Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

	Methotrexate		C	Unknown	25 Milligram , Unk (15 Mg For Over 66 Years And 10 Mg Qwk) Unk	Not Reported
	Methotrexate		C	Oral	4.0 Dosage Forms, Qwk	Not Reported
	Methotrexate		C	Unknown	25 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15861167	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA018215			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Palpitations; Stomatitis; Therapeutic Product Effect Incomplete	Infliximab Pfizer (Unknown)			S	Unknown	600 Mg, Q6wk		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	600 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Q Week)		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Q3wk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Not Reported
	Cosentyx			S	Unknown	300 Mg, Qmo		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Naproxen			C		Unk Unk, As Needed (Prn)		Not Reported
	Folic Acid			C	Unknown	5 Milligram, Qd		Not Reported
	Plaquenil			C		300 Mg, Qd		Not Reported

Acetaminophen And Codeine	C		325 Milligram	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride	C		Unk	Not Reported
Aspirin	C		Unk	Not Reported
Baclofen	C		Unk	Not Reported
Betahistine Hydrochloride	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Clonidine Hydrochloride	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Gabapentin	C		Unk	Not Reported
Hydrochlorothiazide	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Metoprolol Tartrate	C		Unk	Not Reported
Mometasone Furoate	C		Unk	Not Reported
Tylenol With Codeine	C		Unk	Not Reported
Caffeine	C		Unk	Not Reported
Clonidine	C		Unk	Not Reported
Fluticasone Propionate	C		Unk	Not Reported
Folinic Acid	C		Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15933276	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655651-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Arava		C	Unknown	Not Reported
	Lyrica		C	Oral	Not Reported
	Prednisone		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported
	Tylenol		C		Not Reported
	Codeine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	15955031	NON-EXPEDITED			US-PFIZER INC-2019062677		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Venlafaxine Hcl			S		Unk		Pfizer
	Vitamin C			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16163487	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019144290		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive	Enbrel			S	Unknown	Unk		Pfizer

Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate Sodium	S	Unknown	20 Mg, Weekly	Pfizer
	Sulfasalazine	S	Unknown	1500 Mg, Unk	Pfizer
	Ciprofloxacin	S	Unknown	Unk	Unknown
	Actemra	S	Unknown	Unk	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Mycophenolate Mof	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Clavulin	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C		200 Mg, 2x/Day	Not Reported
	Prednisone	C	Unknown	7.5 Mg, 1x/Day	Not Reported
	Tridural	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16193533	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037144		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Bisoprolol Fumarate			S	Unknown			Teva
	Celecoxib			S	Oral	200 Milligram Daily;		Teva
	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Methotrexate Sodium			S	Unknown			Barr

	Metronidazole	S	Unknown	Actavis
	Norfloxacin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Actavis
	Arava	S	Unknown	Not Reported
	Ceclor	S	Unknown	Not Reported
	Demerol	S	Unknown	Not Reported
	Erythro Base	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Meperidine Hcl	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Act Diclo-Miso	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16473572	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituximab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16535976	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA022402			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Treatment Failure	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Etanercept			S	Subcutaneous	Unk Unk, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Oral	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Kineret	S	Unknown	100 Mg, Unk	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	100 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	9 Mg, Unk	Not Reported
	Prednisone	C	Unknown	20 Mg, Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16783163	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000125			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

		Hydroxychloroquine			S					Concordia
		Prednisone			S	Unknown	Unk			Not Reported
		Prednisone			S					Not Reported
		Prednisone			S					Not Reported
		Azathioprine			S	Unknown	Unk			Not Reported
		Azathioprine			S					Not Reported
		Azathioprine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16813868	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3412		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16814465	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1109216			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

					Enbrel		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine /00072603/		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Prednisone		C	Unknown	2 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16814466	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1109075			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Prednisone			C		2 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16814804	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-GSH201612-006498			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Oral	Unk		Concordia
	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Not Reported
	Opdivo			S	Intravenous (not otherwise specified)	1 Dosage Form, Biw		Not Reported
	Salazopyrine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16815521	EXPEDITED (15-DAY)		CA, OT	AR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-220778			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16815770	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019166366		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Condition Aggravated; Feeling Abnormal; Influenza; Myalgia; Painful Respiration; Pharyngeal Swelling; Photosensitivity Reaction	Benlysta Solution For Injection In Pre-Filled Pen			S	Subcutaneous	200 Mg/Ml, We		Glaxosmithkline
	Imuran			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Acthar			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16816028	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-4214		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral		Not Reported
	Enbrel			S	Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Adalimumab			S	Unknown		Not Reported
	Adalimumab			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16818634	EXPEDITED (15-DAY)		HO	FR-EISAI MEDICAL RESEARCH-EC-2019-062162		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash; Systemic Lupus Erythematosus	Pariet			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Fludex (Indapamide)			S	Oral			Not Reported
	Kenzen			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16819058	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2019DEP000991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Diclofenac Potassium			S	Unknown	50 Mg, Bid		Assertio Therapeutics
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Indometacin			S	Unknown	50 Mg, Tid		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate			S	Oral	15 Mg, Weekly		Not Reported

	Naproxen Sodium			S	Unknown	500 Mg, Qid				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Sep-2019	16983851	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Adalimumab			S	Subcutaneous	Other Frequency:Other;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	11191401	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015056272		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Interaction; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	50 Milligram, Qwk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Orencia			S	Unknown	250 Milligram		Not Reported
	Orencia			S	Subcutaneous	250 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported

Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Leflunomide	S	Oral	10 Milligram	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	10 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	20 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	2.5 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	300 Milligram	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	2 Milligram	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	12671057	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016388561		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Decreased; Colitis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D Deficiency	Enbrel	S	Subcutaneous	50 Mg, Unk	Unknown
	Enbrel	S	Subcutaneous	50 Mg, Unk	Unknown
	Enbrel	S	Subcutaneous	50 Mg, Unk	Unknown
	Enbrel	S	Subcutaneous	50 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q2wk	Unknown
	Methotrexate Sodium	S	Unknown	25 Mg, Q2wk	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Q2wk	Pfizer
	Amlodipine Besilate	S	Oral	5 Mg, 1x/Day	Pfizer
	Amlodipine Besilate	S	Unknown	Unk	Pfizer
	Plaquenil	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Amlodipine	S	Oral	5.0 Mg, Unk	Not Reported
	Apo-Amlodipine	S	Oral	5.0 Mg, Qd	Not Reported
	Asacol	S	Oral	800 Mg, 3x/Day	Not Reported
	Depo-Medrol	C	Unknown	80 Mg, Unk	Not Reported
	Depo-Medrol	C	Unknown	40 Mg, Unk	Not Reported
	Depo-Medrol	C	Intramuscular	120 Mg, Q Prn	Not Reported
	Norvasc	C	Oral	5 Mg, 1x/Day	Not Reported
	Norvasc	C	Oral	5 Mg, Die	Not Reported
	Folic Acid	C	Oral	5 Mg, 5 Days Per Week	Not Reported
	Folic Acid	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Mg (35 Mg Iron) Oral Tablet	Not Reported
	Glucosamine W/Minerals Nos/Vitamins Nos	C	Oral	1 Df, Daily	Not Reported
	Vitamin D3	C	Oral	1000 Iu Oral Daily	Not Reported
	Tylenol	C	Oral	500 Mg, As Needed	Not Reported

	Bisoprolol Fumarate			C	Oral	2.5 Mg, Alternate Day			Not Reported
	Atacand Plus			C	Oral	16/12.5 Mg, 1x/Day			Not Reported
	Omega Allergenic Extracts			C		Unk Unk, Qd			Not Reported
	Cholecalciferol			C		Unk Unk, 1x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	12705604	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1523		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Pain; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Single		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	12727833	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0643			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug	Methotrexate (Trade Name Unknown)			S	Oral	Upto 25 Mg		Not Reported

Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Celexa	C	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	13063318	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0861		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Red Blood Cell Sedimentation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Unknown	Not Reported
	Teva Mycophenolate	S	Oral	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported

	Leflunomide		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Parenteral		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Prednisone		S	Unknown	Decrease Dose Weekly	Not Reported
	Prednisone		S	Unknown		Not Reported
	Piroxicam		S	Unknown		Not Reported
	Mycophenolate		S	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Morphine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	13246029	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0423		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Advil		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Ketorolac		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	13869104	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2472			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxychloroquine			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	13875434	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2494		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	15305866	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA022013			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab Pfizer (Unknown)	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Kineret	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk, Solution Subcuatenous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Anakinra	S	Oral	100 Mg, Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	25 Mg, Weekly	Not Reported
	Methotrexate	C	Unknown	25 Mg, Weekly	Not Reported
	Prednisone	C	Unknown	30 Mg, 1x/Day	Not Reported
	Methotrexate Sodium	C	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	15544380	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-965067			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection;	Acetaminophen			S	Unknown			Not Reported

Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	15935647	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2656819-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

		Tocilizumab			S	Unknown				Not Reported
		Ciclosporin			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16082150	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06038			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atorvastatin			C	Unknown	Unknown		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoloc			C	Unknown	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported

		Pantoprazole Sodium Anhydrous		C	Unknown	Unknown			Not Reported
		Plaquenil		C	Unknown	Unknown			Not Reported
		Plaquenil		C	Unknown				Not Reported
		Plaquenil		C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16138964	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0914		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16279881	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2015CA017558			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue;	Inflectra			S	Intravenous (not otherwise specified)	300 Mg, Q 0, 2, 6 Weeks Then Every 8 Weeks For		Not Reported

Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea				12 Months	
	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	300 Mg, Qd	Not Reported
	Infliximab Pfizer (Unknown)	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	2 Df, 2x/Day	Not Reported
	Xeljanz	S	Oral	1 Df, 2x/Day	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Sulfasalazine	S		1 G (500mg, 2 Tablets), 2x/Day	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S	Unknown	20 Milligram (1 Every 24 Hours)	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, 1x/Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S		20 Mg, Unk	Not Reported
	Prednisone	S		5 Mg, Daily	Not Reported
	Prednisone	S	Unknown	5 Milligram (1 Every 24 Hours)	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Infusions	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C		80 Mg, 1x/Day	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	5 Mg, Qd	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	80 Mg, 1x/Day	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Pantoprazole Sodium Anhydrous	C		Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16451258	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822497-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Usp		Not Reported
	Kineret	S	Subcutaneous	100 Mg Per Syringe		Not Reported
	Desoximetasone	C				Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Azathioprine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16802731	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019043939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Methotrexate			C	Oral	25 Milligram			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820262	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2889468-00		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Carotid Artery Occlusion; Cataract; Dry Eye; Dyspnoea; Hypotension; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pravastatin			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Acebutolol			C	Unknown			Not Reported
	Iron			C				Not Reported
	Celecoxib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820265	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2928046-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw;	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Ciclosporin		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Penicillamin (Penicillamine)		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Tobramycin		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Doxycycline		C	Unknown	Not Reported
	Amitriptyline Hydrochloride		C		Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820420	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820446	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3409		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16820458	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3478		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Empyema	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Leflunomide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821276	EXPEDITED (15-DAY)		OT	PHHY2019GB213987		55 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Headache; Malignant Melanoma; Malignant Neoplasm Progression; Metastases To Central Nervous System; Metastases To Lung; Product Use In Unapproved Indication	Mycophenolate Mofetil	S	Unknown	Unk		Novartis
	Mycophenolate Mofetil	S				Novartis
	Prednisolone	S	Unknown	Unk		Not Reported
	Prednisolone	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported
	Mepacrine	S	Unknown	Unk		Not Reported
	Thalidomide	S	Unknown	Unk		Not Reported
	Thalidomide	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821504	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019393774			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus;	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Belimumab			S	Unknown	810mg, Unk		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	820mg, Unk		Not Reported
	Belimumab			S	Intravenous (not otherwise specified)	820 Mg, Unk		Not Reported
	Belimumab			S	Unknown	810 Mg, Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Fentanyl Citrate			S	Unknown	9.0 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	50.0 Mg, Unk		Not Reported
	Prednisone			S	Unknown	50.0 Mg, Unk		Not Reported
	Prednisone			S	Unknown	50.0 Mg, Unk		Not Reported
	Gravol			C	Unknown	Unk		Not Reported
	Neurontin			C	Oral	400.0 Mg, 1x/Day		Not Reported
	Neurontin			C	Unknown	Unk		Not Reported

Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Acuity Reduced; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821511	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016488961		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Rash; Skin Reaction	Methotrexate Sodium			S		Unk		Pfizer
	Apo-Hydroxyquine			S		200.0 Mg, 1x/Day		Not Reported
	Gold			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821546	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2016366624		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821685	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109445			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib			S	Unknown	200 Milligram Daily;		Teva
	Citalopram			S	Unknown	20 Milligram Daily;		Not Reported
	Indomethacin[Indometacin]			S	Unknown	150 Milligram Daily;		Not Reported
	Indomethacin[Indometacin]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Temazepam			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Toradol			S	Intramuscular			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lidocaine			C				Not Reported
	Methylprednisolone Acetate			C				Not Reported
	Naproxen			C		1000 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported
	Vitamin D[Colecalciferol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821828	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019397120			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Ineffective; Drug Intolerance; Joint Stiffness; Liver Function Test Increased; Retinal Toxicity; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	7.5 Mg, Weekly		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 1x/Day		Not Reported

Folic Acid	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	500 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821838	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019397287		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Swelling	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	1500 Mg, 2x/Day		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Ramipril			C		Unk		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C		Unk		Not Reported
	Oxycodone Hydrochloride/Oxycodone Terephthalate/Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16821842	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019397046		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Neutropenia; Platelet Count Decreased	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16822466	NON-EXPEDITED			US-PFIZER INC-2019398422		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stomatitis	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine			S		400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823207	EXPEDITED (15-DAY)		DS, HO	CA-SAMSUNG BIOEPIS-SB-2019-27315		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823208	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported
	Rituxan			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823349	EXPEDITED (15-DAY)		OT	CA-SAKK-2019SA185374AA		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic	Sarilumab			S				Sanofi
	Cortisone Acetate			S				Not Reported

Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S			Sanofi
	Diclofenac Sodium	S			Not Reported
	Topicort	S	Cutaneous		Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Prednisone	S		Unk	Not Reported
	Arava	S	Oral	Unk	Sanofi
	Cetirizine Hydrochloride	S			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S			Not Reported
	Desoximetasone	S	Oral		Sanofi
	Alendronate Sodium	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S		1 Df, Qd	Sanofi
	Leflunomide	S	Oral		Sanofi
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Df, Qd	Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Sanofi
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Sanofi
	Paracetamol	S			Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Sanofi
	Folic Acid	S			Not Reported
	Stelara	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Golimumab	S			Not Reported
	Cimzia	S	Subcutaneous	Unk, Qd	Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S				Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Hydroxychloroquine	S	Oral	1 Df, Qd		Not Reported
	Actemra	S				Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Atasol [Paracetamol]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16823453	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Infliximab			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16824388	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109564			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Sep-2019	16824473	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109547		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	12997615	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		77 YR	Female	CAN

PHARMA-TREX2016-2043

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Product Complaint; Pulmonary Fibrosis; Rash; Skin Reaction	Methotrexate (Trade Name Unknown)			S	Oral	Strength : 2.5 Mg		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	13057811	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0494			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported

Plaquenil	S	Unknown			Not Reported
Arava	S	Unknown			Not Reported
Arava	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Simponi	S	Unknown			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Unknown	Dose: 1000 (Units Unknown)		Not Reported
Orencia	S	Subcutaneous			Not Reported
Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Meloxicam	C	Oral	As Necessary		Not Reported
Xeljanz	C	Unknown			Not Reported
Prednisolone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	13406867	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2017142138		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Skin Lesion; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		400 Mg, 5 Days Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	13420223	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1056		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Deafness; Skin Lesion; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Hydroxychloroquine	S	Unknown	5 Days Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	13614101	EXPEDITED (15-DAY)		OT	CA-ROCHE-1942010		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15191678	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18K-163-2426211-00		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Event; Axonal Neuropathy; Axonal Neuropathy; Drug Eruption; Drug Eruption; Hospitalisation; Multiple Sclerosis; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported
	Xeljanz Xr			C				Not Reported
	Methotrexate			C				Not Reported

Product Effect Incomplete	Sulfasalasin	C				Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15334316	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018348157		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Diarrhoea; Drug Ineffective; Eructation; Flatulence; Gastrointestinal Haemorrhage	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S		11 Mg, Daily		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		200 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15620319	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555994-00		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Xeljanz			S	Oral					Not Reported
	Infliximab			S	Unknown					Not Reported
	Plaquenil			S	Unknown					Not Reported
	Cefalexin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15621373	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557332-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15621374	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557312-00		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Rheumatoid Arthritis; Therapeutic Product Effect	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

Incomplete; Wrong Technique In Product Usage Process	Prednisone				S	Oral			Not Reported
	Xeljanz				S	Oral			Not Reported
	Methotrexate				S	Subcutaneous			Not Reported
	Etanercept				S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate				S	Unknown			Not Reported
	Folic Acid				C				Not Reported
	Ergocalciferol				C				Not Reported
	Celebrex				C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15625328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557561-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15625429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557490-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Intolerance; Feeling Abnormal; Injection Site Pain; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen Sodium	C	Unknown	Not Reported
	Plaquenil	C		Not Reported
	Venlafaxine Hydrochloride	C		Not Reported
	Benadryl	C		Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15695394	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015052110		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis;	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk (For Four Months)		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk For 126 Days		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (3/C G2)		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Treatment Failure			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	20 Mg, Daily	Not Reported
	Hydroxychloroquine	C	Unknown	200 Mg, 2x/Day (2 Every 1 Day)	Not Reported
	Hydroxychloroquine Sulfate	C		200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported
	Prednisone	C		10 Milligram, Bid	Not Reported
	Tocilizumab	C		Unk	Not Reported
	Gold	C		Unk	Not Reported
	Lyrica	C		75 Mg, 1x/Day (Qd)	Not Reported
	Trazodone	C		50 Mg, 1x/Day (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15851077	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2019GMK039382			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (1 Every 1 Week)		Not Reported

Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Od	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw (1 Every 1 Week)	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous	Unk, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Od (1 Every 1 Day)	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Od (1 Every 1 Day)	Not Reported
	Sulfasalazine	S			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Od	Not Reported
	Arava	S	Oral	20 Mg, Od	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 2 Week	Not Reported
	Actonel	C	Unknown	36 Mg, Qw (1 Every 1 Week)	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
	Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Od	Not Reported
	Nasonex	C	Unknown	Unk, Bid; Formulation: Spray Metered Dose	Not Reported
	Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported

Nexium /01479302/	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, 1 Every 1 Hour	Not Reported
Prednisone	C	Unknown	5 Mg, Od	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, 1 Every 1 Hour	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown		Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Od	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Loperamide Hydrochloride	C	Unknown	25 Mg, Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	400 Mg, Od	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Od	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported

	Alfa-Tocoferol	C	Unknown	1200 Mg, Bid (2 Every 1 Day)		Not Reported
	Omega 3 /01333901/	C	Unknown	1200 Mg, Bid (2 Every 1 Day)		Not Reported
	Retinol Palmitate	C	Unknown	Unk		Not Reported
	Riboflavin	C	Unknown	Unk		Not Reported
	Sodium Ascorbate	C	Unknown	Unk		Not Reported
	Vit D	C	Unknown	400 Df, Od (1 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15930407	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655633-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate			C	Unknown			Not Reported
	Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	15935343	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656862-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Infection; Localised Infection; Pneumonia; Rheumatoid Arthritis; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown	214.0		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	579.0		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Aspirin			C				Not Reported
	Calcium			C				Not Reported
	Deflazacort			C				Not Reported
	Dilaudid			C				Not Reported
	Ergocalciferol			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Januvia			C				Not Reported
	Kenalog			C	Intra-articular			Not Reported
	Lactobacillus Acidophilus			C				Not Reported
	Lidocaine			C	Topical			Not Reported
	Metronidazole			C				Not Reported
	Nitroglycerin			C				Not Reported
	Pantoloc			C				Not Reported
	Pregabalin			C				Not Reported
	Risedronate			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Salbutamol			C				Not Reported
	Triamcinolone			C				Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16079850	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05911		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported
	Cephalexin			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16182692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1057		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Amoxicillin Sodium/Clavulanate Pottasium			S	Unknown			Not Reported

Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Mycophenolate Mof			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Unknown	Not Reported
	Rituximab			S	Unknown	Not Reported
	Tocilizumab			S	Unknown	Not Reported
	Clavulin			S	Unknown	Not Reported
	Plaquenil			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported
	Tridural			C	Unknown	Not Reported
	Tylenol			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16510258	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-1452824		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Off Label Use; Product Use Issue	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown
	Enbrel			S				Unknown
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Sodium			S	Unknown	Not Reported		Not Reported

	Myfortic	S		Unk	Not Reported
	Cellcept	S		Unk	Not Reported
	Plaquenil	S	Oral	200 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Pantoloc	C	Oral	40 Mg, 1x/Day	Not Reported
	Prednisone	C	Oral	3 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16588728	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2019GMK042190			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Mg, 1 Every 2 Weeks		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw (1 Every 1 Week)		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw (1 Every 1 Week)		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, 1 Every 3 Weeks (Solution Intramuscular)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Od (1 Every 1 Day)		Not Reported
	Sulfasalazine			S	Oral	2.5 G, Od (1 Every 1 Day)		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month (Solution Intravenous)		Not Reported
	Docosahexaenoic Acid W/Eicosapentaenoic Acid			C	Unknown	Unk, 1 Every 2 Weeks		Not Reported

	Nasonex	C	Unknown	Unk, Bid (2 Every 1 Day; Spray, Metered Dose)		Not Reported
	Prednisone	C	Unknown	5 Mg, Od (1 Every 1 Day)		Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Unk		Not Reported
	Tylenol /00020001/	C	Oral	1000 Gbq, Od (1 Every 1 Day)		Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Od (1 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16691022	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2881957-00		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Cephalexin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16700069	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2533800-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Dermatitis Acneiform; Dermatitis Acneiform; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Gastrointestinal Disorder; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Pruritus; Synovitis; Unevaluable Event; Unevaluable Event	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Brenzys			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16713467	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888976-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Stelara			S	Subcutaneous					Not Reported
		Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16797608	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3329		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2 Times Per Week		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825034	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825044	EXPEDITED (15-DAY)		OT	PT-CELLTRION INC.-2019PT024897			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Interstitial Lung Disease	Infliximab (Unknown)			S				Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403607		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported

					Apo-Leflunomide		S	Unknown		Not Reported
					Celebrex		C	Unknown		Not Reported
					Loperamide		C	Unknown		Not Reported
					Methotrexate		C	Unknown		Not Reported
					Pantoprazole		C	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported
					Bifidobacterium Bifidum		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825327	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825380	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3490		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported

			Humira		S	Subcutaneous				Not Reported
			Hydroxychloroquine Sulfate		S	Unknown				Not Reported
			Rituxan		S	Intravenous (not otherwise specified)				Not Reported
			Warfarin		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825952	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1108891		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Atenolol			S		25 Milligram Daily;		Not Reported
	Ferrous Fumarate			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Pantoprazole			S	Unknown	40 Milligram Daily;		Teva
	Pantoprazole Sodium			S		40 Milligram Daily;		Teva
	Naproxen Sodium			S	Oral	1000 Milligram Daily;		Teva
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Ascorbic Acid			S				Not Reported
	Co Atenolol			S	Unknown	20 Milligram Daily;		Not Reported
	Co Atenolol			S	Unknown	25 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S		40 Milligram Daily;		Not Reported

	Naprosyn E			S	Oral	1000 Milligram Daily;	Not Reported
	Naproxen Sodium			S	Oral	100 Milligram Daily;	Not Reported
	Orencia			S	Unknown		Not Reported
	Palafer			S	Unknown		Not Reported
	Palafer Cf			S	Unknown		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;	Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;	Not Reported
	Celebrex			C	Oral	200 Milligram Daily;	Not Reported
	Celecoxib			C			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16825996	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3487			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Eye Laser Surgery; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Belimumab			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Fentanyl Citrate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased; Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Acuity Reduced; Visual Impairment; Weight Decreased	Gravol	C	Unknown		Not Reported
	Neurontin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826080	EXPEDITED (15-DAY)		HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-220923		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiac Failure Acute; Ejection Fraction Abnormal; Electrocardiogram Qt Prolonged; Hyperkalaemia; Toxicity To Various Agents; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826127	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Diclofenac	S	Oral		Actavis
	Meloxicam	S	Oral	7.5 Milligram Daily;	Not Reported
	Methotrexate	S	Subcutaneous	25mg 1every 1week	Barr
	Methotrexate	S	Oral	4dosage Forms 1every 1week	Barr
	Methotrexate	S	Oral	10mg 1every 1week	Barr
	Pantoprazole	S	Oral	1 Dosage Forms Daily;	Teva
	Pantoprazole Magnesium	S	Unknown		Teva
	Cosentyx	S	Oral	300mg 1every 1month	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Leucovorin Calcium	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Synthroid	S	Unknown		Not Reported
	Diltiazem Hydrochloride	C	Oral		Not Reported
	Fluticasone Propionate	C	Unknown	Inhalation	Not Reported
	Mar-Pantoprazole	C	Unknown	Tablet (Delayedrelease)	Not Reported
	Mometasone Furoate	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Salbutamol Sulfate	C		Inhalation	Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826135	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-27139		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported

Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis	Cimzia		S	Subcutaneous	Single Use	Not Reported
	Enbrel		S	Subcutaneous	Unknown	Not Reported
	Humira		S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Oral	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Plaquenil		S	Oral	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan		S	Subcutaneous	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi		S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402126			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Loperamide	C	Oral		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826344	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2018-US-001561			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose; Sinus Tachycardia; Ventricular Tachyarrhythmia	Hydroxychloroquine			S	Oral	36 G, Single		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826425	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019261070		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Infection	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16826484	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019400971			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	4 Df, Daily		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

	Humira			S	Subcutaneous	Unk			Not Reported
	Hydroxychloroquine			S	Oral	2 Df, Daily			Not Reported
	Hydroxychloroquine			S	Unknown	2 Df, Daily			Not Reported
	Prednisone			C	Oral	5.0 Mg, Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16827069	NON-EXPEDITED			US-APPCO PHARMA LLC-2074649		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Valacyclovir			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16827115	EXPEDITED (15-DAY)		HO	PHHY2019PH214460		47 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Lower; Anaemia; Aortic Aneurysm; Aortitis Salmonella; Arteriosclerosis; Asthenia; Diarrhoea; Product Use In Unapproved Indication; Retroperitoneal Haematoma; Urinary Tract Infection	Prednisone			S	Oral	10 Mg, Qd		Novartis
	Prednisone			S	Unknown	1 Mg/Kg, Qd		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Not Reported
	Atorvastatin			S	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16827255	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109170		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown			Barr
	Meloxicam	S	Unknown			Teva
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Mobicox	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Depomedrol	C	Intramuscular	80 Milligram Daily;		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Plaquenil	C	Unknown			Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2019	16827621	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cinchonism; Drug Interaction; Tremor	Plaquenil	Y		S				Not Reported
	Cipro			S				Not Reported
	Avelox			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	12914313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092670			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use	Orencia		S	Intravenous (not otherwise specified)	500 Mg, Q4wk	Bristol Myers Squibb
	Arava		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Qwk	Not Reported
	Humira		S	Subcutaneous	40 Milligram, Qcycle	Not Reported
	Methotrexate		S	Unknown	25 Mg, Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	400 Mg, Qd	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate Sodium		S	Unknown	25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	13153125	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005249		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Milligram, Qd		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

	Adalimumab	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Depo Medrol	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Qd	Not Reported
	Methotrexate	C	Unknown	17.5 Milligram	Not Reported
	Methotrexate	C	Unknown	15 Milligram, Qwk	Not Reported
	Sulfasalazine	C	Oral	1 G, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Unk	Not Reported
	Acetaminophene	C	Unknown		Not Reported
	Tylenol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	13648565	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-087026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Off Label Use; Pneumonia; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Methotrexate Sodium	S	Subcutaneous	25.0 Mg, Qwk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported
	Cortisone	C	Unknown			Not Reported
	Desoximetasone	C	Oral	5.0 Mg, Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	13961772	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20170900868		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Event; Adverse Reaction; Arthralgia; Drug Ineffective; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; Gastric Disorder; General Physical Health Deterioration; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rheumatoid Arthritis; Sleep Disorder	Otezla			S	Oral			Celgene
	Otezla			S				Celgene
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Salazopyrin		S	Unknown		Not Reported
	Simponi		S	Subcutaneous	334.0	Not Reported
	Myochrysine		S	Intramuscular		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Abatacept		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15630894	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105546		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15662579	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570035-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15693001	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018172161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	3 Milligram, Qd	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	50 Milligram, Unk	Not Reported
	Prednisone		S	Oral	3 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15705977	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174089		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Malaise; Respiratory Tract Infection; Rheumatoid Arthritis; Sinus Disorder; Sinus Operation; Sinusitis Noninfective	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Estradiol			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	L-Thyroxine			C		Unk		Not Reported
	Nexium			C				Not Reported
	Tylenol Arthritis Pain			C	Unknown	Unk		Not Reported
	Vitamins			C		Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15726241	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018177481		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Prednisone			C		30 Milligram, Qd		Not Reported
	Prednisone			C		30 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15930942	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655641-00		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Actonel		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	15933235	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656070-00		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actonel			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16081383	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012872		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness;	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Oral	300 Milligram, Once A Day		Not Reported
	Pantoprazole Enteric-Coated Tablet			S	Oral	Unk		Aurobindo
	Meloxicam			S	Unknown	150 Milligram, Once A Day		Not Reported
	Depo-Medrol			S	Intra-articular	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Lyrica			S	Oral	300 Milligram, Once A Day		Not Reported
	Lyrica			S	Oral	150 Milligram, Two Times A Day		Not Reported
	Naproxen			S	Oral	Unk Unk, Once A Day		Not Reported
	Naproxen			S	Oral	500 Milligram, Once A Day		Not Reported
	Naproxen			S	Oral	500 Milligram, Two Times A Day		Not Reported
	Naproxen			S	Oral	250 Milligram, Two Times A Day		Not Reported
	Naproxen			S	Oral	1000 Milligram, Once A Day		Not Reported
	Pantoloc			S	Oral	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Septra			S	Unknown	Unk		Not Reported
	Amitriptyline Pamoate			S	Oral	75 Milligram, 1 Every 1 Day		Not Reported
	Azathioprine			S	Oral	150 Milligram		Not Reported
	Azathioprine			S	Unknown	150 Milligram, Two Times A Day		Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown	Unk		Not Reported

Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Etanercept	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once A Day	Not Reported
	Oxycocet	S	Oral	Unk	Not Reported
	Methylprednisolone Acetate	S	Intra-articular	Unk	Not Reported
	Prednisone	S	Unknown	15 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	150 Milligram, Once A Day	Not Reported
	Ranitidine Hydrochloride	S	Oral	300 Milligram, Once A Day	Not Reported
	Ranitidine Hydrochloride	S	Oral	150 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Day	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once A Day	Not Reported
	Trimethoprim	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	10 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz	S	Oral	2 Milligram, Once A Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Apo Amitriptyline	S	Oral	75 Milligram, Once A Day	Not Reported
	Apo Meloxicam	S	Unknown	150 Milligram, Once A Day	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, Two Times A Day	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, Once A Day	Not Reported
	Apo Naproxen	S	Oral	250 Milligram, Two Times A Day	Not Reported
	Apo Naproxen	S	Oral	1000 Milligram, Once A Day	Not Reported
	Apo Prednison	S	Unknown	15 Milligram, Once A Day	Not Reported
	Apo Ranitidine	S	Oral	300 Milligram, Once A Day	Not Reported

Apo Ranitidine	S	Oral	150 Milligram, Two Times A Day	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium;Naproxen	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Imuran	S	Unknown	150 Milligram	Not Reported
Imuran	S			Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Every Week	Not Reported
Methylprednisol Sodium Succinate	S	Unknown	Unk	Not Reported
Mobicox	S	Unknown	Unk	Not Reported
Ratio-Oxycocet	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
Vimovo	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram, Once A Day	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Two Times A Day	Not Reported
Amitriptyline Hydrochloride	S	Oral	75 Milligram, Once A Day	Not Reported
Apo Ranitidine	S	Unknown	Unk	Not Reported
Apo Alendronate	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Oral	Once A Day	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16212992	NON-EXPEDITED			US-PFIZER INC-2019158206		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Diclofenac Sodium			S		Unk		Pfizer
	Cephalexin [Cefalexin]			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16424233	EXPEDITED (15-DAY)		OT	JP-GLAXOSMITHKLINE-JP2019JPN103475		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Enterocolitis; Herpes Zoster; Influenza; Neuralgia	Belimumab			S	Intravenous drip	10 Mg/Kg, 1d		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 2 Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every 4 Weeks		Glaxosmithkline
	Prednisolone Tablets			S	Oral	5 Mg, 1d		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Oral	Unk		Not Reported
	Nexium Capsule			C		Unk		Not Reported
	Ferrous Sodium Citrate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16438417	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033193			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia;	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Topical	Unk		Not Reported

Pemphigus; Systemic Lupus Erythematosus	Actemra	S		Unk	Not Reported
	Cetirizine Hcl	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Subcutaneous	1 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Topicort	S	Unknown	Unk	Not Reported
	Topicort	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16485233	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2834723-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Humira	S	Subcutaneous	Cyclical		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown	4 Year(S)		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16573391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852936-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Prednisone			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16693406	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018036031		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choroiditis; Drug Ineffective; Eye Infection; Nasopharyngitis; Otorrhoea; Uveitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16723416	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-054280		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema;	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram (1 Every 4 Weeks)		Not Reported
	Actemra			S	Unknown	680 Milligram (1 Every 4 Weeks)		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram (1 Every 2 Weeks)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Humira	S	Subcutaneous	40 Milligram (1 Every 2 Weeks)	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram (1 Every Month)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	760 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Daily	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Two Times A Day	Not Reported

Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram (1 Every 4 Weeks)	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram (1 Every 4 Weeks)	Not Reported
Apremilast	S	Unknown	60 Milligram	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S			Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Ibuprofen	S	Oral	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin	S	Oral	600 Milligram, Once A Day	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	10 Milligram, Daily	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported

	Uloric			C	Unknown	80 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16830260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404645		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16830261	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2931548-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Skin Laceration; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Rosuvastatin Calcium	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Prednisone	C				Not Reported
	Allopurinol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16830267	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2931790-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Unevaluable Event; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tofacitinib			C				Not Reported
	Tofacitinib			C				Not Reported
	Gold			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16830336	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16830471	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-201909000420			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16830901	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201904-001259			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S		Unk		Not Reported
	Cefalexin			S	Unknown	Unk		Not Reported
	Arava			C				Not Reported
	Simponi			C				Not Reported
	Methotrexate			C	Oral	15 Mg, Freq: Unk X 1 Weeks		Not Reported
	Prednisone			C				Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831193	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3504		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Neutropenia; Platelet Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831202	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug	Methotrexate (Trade Name			S	Oral			Not Reported

Ineffective; Drug Intolerance; Joint Stiffness; Liver Function Test Increased; Retinal Toxicity; Rheumatoid Arthritis	Unknown)								
	Methotrexate (Trade Name Unknown)			S	Oral				Not Reported
	Arava			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831203	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3537		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Arthroplasty; Knee Arthroplasty; Mobility Decreased; Pain; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Oxycodone Hydrochloride/Oxycodone Terephthalate/Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2931350-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Chloroquine		S	Oral	Not Reported
	Prednisone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831393	EXPEDITED (15-DAY)		DE, HO, OT	US-ZYDUS-040701		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypokalaemia; Hypotension; Intentional Overdose; Metabolic Acidosis; Mydriasis; Pulmonary Oedema; Pupil Fixed; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Approximately 60 Tablets		Zydus Pharm
	Naproxen			S	Oral	Several 750 Mg Naproxen		Zydus Pharm
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16831645	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16832889	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2407222		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported

					Sodium Aurothiomalate		S	Unknown		Not Reported
					Sodium Aurothiomalate		S			Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16832906	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-27296		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16832951	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus			otherwise specified)	
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16833073	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16833244	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404568			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834143	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Abnormal	Bisoprolol	S	Unknown	Duramed
	Methotrexate	S	Unknown	Barr
	Morphine	S	Unknown	Actavis
	Pantoprazole	S	Unknown	Teva
	Prednisone	S	Unknown	Actavis
	Zopiclone	S	Unknown	Not Reported
	Cefixime	S	Unknown	Not Reported
	Imuran	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rivotril	S	Unknown	Not Reported
	Zantac	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834285	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019405416			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Aleve			S	Oral	500 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834462	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110703		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Cephalexin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Actavis
	Hctz			S	Unknown			Ivax
	Losartan			S	Unknown			Teva
	Methotrexate			S	Subcutaneous	1.4286 Milligram Daily;		Barr
	Metoprolol Tartrate			S	Unknown			Actavis
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Pantoprazole Magnesium			S	Unknown			Teva
	Penicillin G/00072602/			S	Unknown			Teva
	Plaquenil /00072602			S	Unknown			Not Reported
	Pariet			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Hydralazine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Prednisone			C	Unknown	8.5 Milligram Daily;		Not Reported
	Iron Sucrose			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Cipro /00697201/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834826	NON-EXPEDITED			PHEH2019US038965		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16834944	EXPEDITED (15-DAY)		HO	PHHO2019US008469		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Pyrexia	Gsk1120212			S	Oral	2 Mg, Qd		Not Reported
	Gsk2118436			S	Oral	150 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Prn (Every 8 Hours)		Not Reported
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported
	Clonazepam			C	Oral	1 Mg, Bid		Not Reported
	Duloxetine			C	Oral	60 Mg, Qd		Not Reported
	Gabapentin			C	Oral	100 Mg, Qd		Not Reported
	Prochlorperazine			C	Oral	10 Mg, Prn (6 Hours)		Not Reported
	Rosuvastatin			C	Oral	5 Mg, Qd		Not Reported
	Bactrim			C	Oral	1 Tab, Bid		Not Reported
	Synthroid			C	Oral	175 Mg, Qd		Not Reported
	Biotin			C	Oral	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16835206	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2933376-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Sep-2019	16835925	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2933244-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	15854701	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634271-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident;	Humira			S	Subcutaneous			Not Reported

Contraindicated Product Administered; Drug Ineffective; Hypersensitivity	Apo-Leflunomide			S	Oral				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil			S	Oral				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Folic Acid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16836061	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-ABBVIE-19K-028-2933774-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Destruction; Nausea; Rheumatoid Arthritis; Septic Shock; Synovitis	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S				Not Reported
	Kineret			S	Subcutaneous	100 Mg Per Syringe Single-Use, Preservative-Free Pre-Filled Syringes		Not Reported
	Kineret			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Orencia			S	Respiratory (inhalation)			Not Reported
	Orencia			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Triamcinolone Aq			S	Unknown	Spray, Metered Dose		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo Naproxen Ec			S	Oral			Not Reported
	Apo Naproxen			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Sulfasalazine	S		Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S		Not Reported
	Infliximab	S	Unknown	Not Reported
	Infliximab	S		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Abatacept	S	Intravenous drip	Not Reported
	Naproxen	S	Unknown	Not Reported
	Naproxen	S		Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16836154	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-061447			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported

	Remicade	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Two Times A Day		Not Reported
	Xeljanz	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16836256	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1111467		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Methotrexate			C	Unknown	Solution		Not Reported
	Xarelto			C	Unknown	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Sep-2019	16836262	EXPEDITED (15-DAY)		DE	CA-TEVA-2019-CA-1111987		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva
	Metformin			S	Unknown	1000 Milligram Daily;		Not Reported
	Prednisone			S	Unknown			Actavis
	Flovent			S	Unknown			Not Reported

	Lasix			S	Unknown	Not Reported
	Lipitor			S	Unknown	Not Reported
	Losec			S	Unknown	Not Reported
	Nitrazadon			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Salmeterol Xinafoate			S	Unknown	Not Reported
	Tylenol			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	11182943	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015191806		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Interaction; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	2.5 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	2.5 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Celebrex			S	Unknown	50 Mg, Qwk		Pfizer
	Celebrex			S				Pfizer
	Sulfasalazine			S	Unknown	2 G, Qd		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 Mg, Unk		Pfizer
	Arava			S	Unknown	10 Mg, Unk		Not Reported

Arava	S	Unknown	20 Mg, Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S			Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Orencia	S		250 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Unknown	300 Mg, Unk	Not Reported
Plaquenil	S	Unknown	300 Mg, Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Mg, Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Mg, Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	12676287	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016107859			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition	Enbrel			S	Unknown	Unk Unk, 2 Times/Wk		Amgen

Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Unknown	Unk Unk, Q2wk	Amgen
	Anakinra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
	Naprosyn [Naproxen]	S	Unknown	500 Milligram, 2 Times/Wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Vioxx	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	13038924	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016172408		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Celebrex	C		200 Milligram, Bid	Not Reported
	Septra	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	13306413	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017031193		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypertension; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd (1 Every 24 Hours)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Hydromorphone Hydrochloride			C	Unknown	1 Milligram, As Necessary		Not Reported
	Hydromorphone Hydrochloride			C		400 Milligram, Qd (1 Every 24 Hours)		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

	Valsartan	C	Unknown	Unk		Not Reported
	Valsartan	C				Not Reported
	Cortisone	C		Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Hydromorphone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	13915127	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127978		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Vasculitic Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Anakinra			S	Unknown	100 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	12.5 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	12.5 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not	500 Milligram, Qmo		Not Reported

				otherwise specified)		
	Orencia		S	Unknown	500 Milligram, Q4wk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	500 Milligram, Q4wk	Not Reported
	Apo-Hydroxyquine		S	Unknown	200 Milligram, Qd	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram, Qd	Not Reported
	Xeljanz		C	Unknown	5 Milligram, 2 Times/Wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	14633601	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-038682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Q12h		Not Reported
	Xeljanz			S	Unknown	1 Dosage Form		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Qd		Not Reported

Prednisone	S	Unknown	9 Milligram, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Prednisone	S	Unknown	9 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Infliximab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	9 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
Simponi	S	Subcutaneous	Unk, Qmo	Not Reported
Cortisone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	600 Milligram, Tid	Not Reported
Cetirizine Hydrochloride	C	Unknown	10 Milligram, Qd	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	10 Milligram, Qd	Not Reported
Acetaminophen	C	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15482066	EXPEDITED (15-DAY)		HO	PHHO2018US010882		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Pleural Effusion; Pneumonia	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Unk		Not Reported
	Afinitor			S	Oral	10 Mg, Qd		Not Reported
	Naproxen			C	Unknown	500 Mg, Unk		Not Reported
	Elocon			C	Topical	0.1 %, Unk		Not Reported
	Magnesium Oxide			C	Oral	400 Mg, Unk		Not Reported
	Fluticasone			C	Unknown	Unk		Not Reported
	Meloxicam			C	Oral	15 Mg, Unk		Not Reported
	Exemestane			C	Oral	25 Mg, Unk		Not Reported
	Astaxanthin			C	Oral			Not Reported
	Vitamin B Complex			C	Unknown			Not Reported
	Glucosamine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15498701	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-092561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg, Q8wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2wk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q2wk		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

					Xeljanz	S	Unknown	Unk	Not Reported
					Arava	S	Unknown	Unk	Not Reported
					Apo-Leflunomide	S	Unknown	Unk	Not Reported
					Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Unk	Not Reported
					Plaquenil	S	Unknown	Unk	Not Reported
					Etanercept	S	Unknown		Not Reported
					Rituxan	C	Unknown	Unk	Not Reported
					Prednisone	C	Unknown	Unk	Not Reported
					Naproxen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15620302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555161-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Musculoskeletal Stiffness; Pain; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15621117	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556002-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous	Not Reported
	Apo-Leflunomide			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15631937	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555328-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Benadryl			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Plaquenil			C				Not Reported
	Reactine [Cetirizine Hydrochloride]			C				Not Reported
	Venlafaxine			C				Not Reported
	Cetirizine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15635056	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105755		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Off Label Use; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	750 Milligram, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Hydrochlorothiazide W/Lisinopril Dihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Unk, Unk		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz Xr			C	Oral	5 Mg, Unk		Not Reported
	Tylenol Extra Strength			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	15663798	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570166-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16342386	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027456		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Once A Day		Not Reported
	Ascorbic Acid			S	Unknown	Unk, Daily		Not Reported
	Co Atenolol			S	Unknown	25 Milligram, Once A Day		Not Reported
	Co Atenolol			S	Unknown	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Ferrous Fumarate			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Two Times A Day		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Two Weeks		Not Reported
	Methotrexate			S	Oral	25 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	25 Milligram, One In Every 2 Weeks		Not Reported
	Methotrexate			S	Oral	Unk, One Every 2 Weeks		Not Reported

Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Once A Day	Not Reported
Methotrexate	S	Oral	25 Milligram, Once A Day	Not Reported
Methotrexate	S	Oral	20 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	20 Milligram, Once In 2 Weeks	Not Reported
Naprosyn	S	Oral	1000 Milligram, Once A Day	Not Reported
Naprosyn	S	Oral	500 Milligram, Two Times A Day	Not Reported
Naprosyn	S	Oral	500 Milligram, Two Times A Day	Not Reported
Naprosyn	S	Oral	100 Milligram, Once A Day	Not Reported
Naprosyn	S	Oral	10000 Milligram, Daily	Not Reported
Naproxen	S	Oral	100 Milligram, Once A Day	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Palafer Cf	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Palafer Cf	S	Unknown	Unk, Once A Day	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
Folic Acid	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times In A Week	Not Reported
Methotrexate	S	Oral	20 Milligram, Every Week	Not Reported
Naproxen Sodium	S	Oral	1000 Milligram, Once A Day	Not Reported
Sulfasalazine	S	Unknown	1000 Milligram, Two Times	Not Reported

				A Day	
	Sulfasalazine	S	Oral	500 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Atenolol	S	Unknown	25 Milligram, Daily	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Palafer	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Two Times A Day	Not Reported
	Celebrex	C	Oral	220 Milligram, Once A Day	Not Reported
	Celebrex	C	Oral	200 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
	Ferrous Fumarate;Folic Acid	C	Unknown	Unk Unk, Daily	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16350638	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2793223-00		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Ill-Defined Disorder; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Ulcer	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Losec			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Betaloc				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16380088	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2804455-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16504577	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018107712		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Infection	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Lipitor			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16673921	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT178365		73 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Meningitis Bacterial; Mental Status Changes; Psychomotor Hyperactivity; Pyrexia	Hydroxychloroquine	S	Oral	200 Mg, Qd		Novartis
	Azathioprine	S	Unknown	75 Mg, Qd		Not Reported
	Prednisolone	S	Unknown	2.5 Mg, Qd		Not Reported
	Prednisolone	S	Unknown	40 Mg, Qd		Not Reported
	Sinvastatina	C	Unknown	20 Mg, Qd		Not Reported
	Olmesartan	C	Unknown	20 Mg, Qd		Not Reported
	Timolol;Travoprost	C	Ophthalmic	5mg/Ml+0.04mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16779698	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ADVANZ PHARMA-201908000112			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiotoxicity; Hypokalaemia; Hypotension; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Pupil Fixed; Renal Failure; Toxicity To Various Agents; Unresponsive To Stimuli	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Approximately 60 Tablets Of 200 Mg X1		Concordia
	Naproxen			S	Unknown	Several 750 Mg, 1x		Not Reported
	Ibuprofen			S	Unknown	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16812236	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019136319			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported

	Sulfate]						
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Methotrexate Sodium		C	Oral	25 Milligram		Not Reported
	Methotrexate Sodium		C		25 Milligram		Not Reported
	Methotrexate Sodium		C	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2406153		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837375	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
					Sulfasalazine		S	Unknown	Not Reported
					Acetaminophen		C	Unknown	Not Reported
					Hydrocortisone Valerate		C	Unknown	Not Reported
					Hydromorphone		C		Not Reported
					Hydroxychloroquine Sulfate		C	Unknown	Not Reported
					Lyderm [Fluocinonide]		C	Unknown	Not Reported
					Naproxen		C	Unknown	Not Reported
					Naproxen		C	Unknown	Not Reported
					Prednisone		C	Unknown	Not Reported
					Sodium Aurothiomalate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837435	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2933255-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Foa-Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Foa-Solution		Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837551	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2861363-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported
	Baclofen			S	Unknown			Not Reported
	Baclofen			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Tylenol			C				Not Reported
	Hydromorphone			C	Oral			Not Reported
	Folic Acid			C				Not Reported
	Calcium Carbonate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837596	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-163-2933512-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837772	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1111986		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Pantoprazole Magnesium			S	Unknown			Teva
	Cefalexin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Teva
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Actavis
	Hctz			S	Unknown			Ivax
	Losartan			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Metoprolol Tartrate			S	Unknown			Actavis
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.			S	Unknown			Teva
	Plaquenil S			S	Unknown			Not Reported
	Pariet			S	Unknown			Not Reported

	Orencia		S	Unknown		Not Reported
	Levaquin		S	Unknown		Not Reported
	Hydralazine Hydrochloride		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Celebrex		S	Unknown		Not Reported
	Biaxin		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Prednisone		C	Unknown	8.5 Milligram Daily;	Not Reported
	Iron Sucrose		C	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown		Not Reported
	Gold		C	Unknown		Not Reported
	Esomeprazole		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16837803	EXPEDITED (15-DAY)		DE	CA-TEVA-2019-CA-1111990		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva
	Metformin			S	Unknown			Actavis
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec			S	Oral			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported

	Tylenol				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16838608	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16838778	EXPEDITED (15-DAY)		HO	CA-ROCHE-2406120		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16839627	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Lyrica			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

					Remicade		S	Intravenous (not otherwise specified)				Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unknown			Not Reported
					Simponi		S	Subcutaneous	Unknown			Not Reported
					Sulfasalazine		S	Unknown	Unknown			Not Reported
					Piroxicam		C	Unknown	Unknown			Not Reported
					Prednisone		C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16839981	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019403301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Mobility Decreased; Neurological Procedural Complication; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Hydroxychloroquine			S	Oral	Unk, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Arava			C		Unk		Not Reported
	Diclofenac			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16840008	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019404193		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported

	Sodium Aurothiomalate			S	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16840031	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019403196			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S	Unknown	15.0 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500.0 Mg, 2x/Day		Pfizer
	Arava			S	Oral	20.0 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400.0 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16840035	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27193			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Bacitracin			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Neomycin Sulfate			S	Unknown	Unknown		Not Reported
	Polymyxin B Sulfate			S	Unknown	Unknown		Not Reported
	Prednisone			C	Intramuscular	Unknown		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16840641	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019403191			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Incorrect Route Of Product Administration; Off Label Use; Pneumonia	Methotrexate Sodium			S	Subcutaneous	23.0 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	500.0 Mg, 2x/Day		Pfizer
	Leflunomide			S	Unknown	1 Every 2 Days		Not Reported
	Plaquenil S			S	Unknown	400.0 Mg, 1 Every 1 Days		Not Reported
	Xeljanz			C	Oral	5.0 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16840689	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019077850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intramuscular	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Sep-2019	16841676	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019401311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache; Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Rheumatoid Arthritis; Weight Fluctuation	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			C		776 Mg, Unk		Not Reported
	Actemra			C		776 Mg, Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, 1x/Day		Not Reported
	Humira			C	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	750 Mg, Monthly		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	12186274	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016032720		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Arthroplasty; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Hip Arthroplasty; Knee Arthroplasty; Pain In Extremity; Peripheral Swelling; Psoriasis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	12286452	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016047242		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Eye Disorder; Feeling Abnormal; Finger Deformity; Foot Deformity; Gait Disturbance; Gait Inability; Hyperhidrosis; Inflammation; Intervertebral Disc Protrusion; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Osteoarthritis; Osteoporosis; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Spinal Disorder; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vomiting; Wrist Deformity	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Winpred			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown	5 Milligram		Not Reported
	Acetaminophen			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Oxycodone Terephthalate			S	Oral	Unk		Not Reported
	Oxycodone Hydrochloride			S	Oral	Unk		Not Reported
	Hydromorphone			S	Oral	12 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Percocet			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Lax-A-Day			C		Unk		Not Reported
	Monurol			C		Unk		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Fosfomycin Trometamol			C	Unknown	Unk		Not Reported
	Macrogol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	12463903	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016074503		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Crestor			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Oral	5 Mg, Bid		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	12539304	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016087938		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Subcutaneous			Amgen
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Methotrexate			S	Oral	25 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			C		200 Mg, Bid		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	12859765	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016142551		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia	Enbrel		S	Unknown	Unk	Amgen
	Apo-Hydroxyquine		S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	20 Milligram, Qd (More Than 3 Months)	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Pregabalin		C	Oral	50 Milligram, Qd	Not Reported
	Acetaminophen		C		Unk Unk, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	13904392	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2605		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Bronchiectasis; Bursitis Infective; Crying; Ear Disorder; Hepatic Enzyme Increased; Inappropriate Schedule Of Product Administration; Infection; Inflammation; Localised Infection; Lower Respiratory Tract Infection; Nasopharyngitis; Nausea; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin	Methotrexate (Trade Name Unknown)			S	Unknown	7.5 To 22.5 Mg; Varying Over The Years		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Cyclic		Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Unknown	On And Off Over The Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported

Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete; Wheezing; Wrist Fracture	Azathioprine	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Cyclic (Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Deflazacort	C	Unknown		Not Reported
	Pregabalin	C	Unknown		Not Reported
	Pregabalin	C			Not Reported
	Tylenol W/Codeine No. 3	C	Unknown	1-2 Tablets Every 4-6 Hours	Not Reported
	Dilaudid	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Salbutamol	C	Unknown		Not Reported
	Nitroglycerin	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Hydromorph	C	Unknown		Not Reported
	Januvia	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Acidophilus	C	Unknown		Not Reported
	Aspirin	C	Unknown		Not Reported
	Onbrez	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Coversyl	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Kenalog	C	Unknown		Not Reported
	Lidocaine	C	Unknown		Not Reported

	Triamcinolone	C	Unknown		Not Reported
	Calcium Gluconate	C	Unknown		Not Reported
	Lactobacillus Acidophilus	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	14464428	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018010867		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Amgen
	Enbrel			S	Intravenous (not otherwise specified)	15 Milligram		Amgen
	Etanercept			S	Subcutaneous	15 Milligram, Qwk		Amgen
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Milligram, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Infliximab			S	Unknown	200 Milligram, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qwk		Not Reported
	Infliximab			S	Unknown	200 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Complication; White Blood Cell Count Increased	Orencia		S				Not Reported
	Adalimumab		S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Adalimumab		S	Unknown	Unk		Not Reported
	Abatacept		S	Unknown	Unk		Not Reported
	Actemra		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	14818743	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018055111			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Aspirin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Phenoxymethylpenicillin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Penicillin G Potassium			S	Unknown	Unk		Not Reported
	Penicillin G Procaine			S	Unknown	Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15556644	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018149424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	160 Milligram		Not Reported
	Actemra			S	Unknown	162 Dosage Form		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Imuran			C	Unknown	50 Milligram, Qd		Not Reported
	Azathioprine			C	Subcutaneous	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15629364	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558897-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling	Humira	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15654298	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018167420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Enbrel			S	Unknown	Unk		Amgen
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

		Prednisone			C		Unk			Not Reported
		Gabapentin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15680068	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3490		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Contraindicated Product Administered; Drug Interaction; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S		Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Actemra	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15699782	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018502371			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Mg, Qd	Not Reported
	Apo-Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	3 Milligram, Qd	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	50 Milligram, Unk	Not Reported
	Prednisone	S	Unknown	50 Milligram, Unk	Not Reported
	Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15715429	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018510015		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Malaise; Respiratory Tract	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer

Infection; Rheumatoid Arthritis; Sinus Disorder; Sinusitis Noninfective	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Qwk		Pfizer
	Orencia	S	Unknown	125 Mg, Qwk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Estradiol	C		Unk		Not Reported
	Celebrex	C		Unk		Not Reported
	Hydroxychloroquine	C		Unk		Not Reported
	L-Thyroxine	C		Unk		Not Reported
	Nexium	C		Unk		Not Reported
	Tylenol Arthritis Pain	C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	15734642	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018518932		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Methotrexate	C	Oral	25 Mg, Qwk		Not Reported
	Prednisone	C		30 Mg, Qd		Not Reported
	Prednisone	C		30 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16204129	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017087685		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypertension	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, 1 Every 24 Hours		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported
	Hydromorph			C	Unknown	1 Mg, As Needed		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16360169	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-048400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia	S	Unknown	Unk		Bristol Myers Squibb
	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16423706	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2817334-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Contraindicated Product Administered; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16445047	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016526		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200.0 Mg, Bid (2 Every 1 Days)		Apotex
	Mycophenolate Sodium			S	Unknown	Unk		Apotex
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Clavulin /00756801/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20.0 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1500.0 Mg, Bid (2 Every 1 Days)		Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Unknown	7.5 Mg, Qd (1 Every 1 Day)		Not Reported
	Tridural			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	200.0 Mg, Bid (2 Every 1 Days)		Not Reported

	Plaquenil /00072602/			C						Not Reported
	Tylenol /00020001/			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16525102	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019AU151840			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anaphylactic Reaction; Arthritis; Asthma; Blister; Chest Pain; Costochondritis; Cough; Device Issue; Dyspnoea; Fatigue; Feeling Abnormal; Gastric Disorder; Headache; Hypoaesthesia; Injection Site Bruising; Musculoskeletal Stiffness; Nausea; Pain; Photosensitivity Reaction; Pleurisy; Pruritus; Rheumatic Disorder; Skin Exfoliation; Suffocation Feeling; Sunburn; Therapeutic Response Unexpected; Vocal Cord Dysfunction	Xolair			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Novartis
	Methotrexate			S	Oral	Unk		Novartis
	Plaquenil			S	Unknown			Not Reported
	Endep			S	Unknown			Not Reported
	Warfarin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16591782	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP018604		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Fatigue;	Celecoxib			S	Unknown	200 Mg, Bid		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S				Apotex
	Lorazepam			S	Unknown	1 Mg, Q.H.		Not Reported

Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Miliaria; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Incomplete	Lorazepam	S	Unknown	1 Mg, Unk	Not Reported
	Citalopram	S	Unknown	10 Mg, Qd	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	200 Mg, Bid	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Citalopram	C	Unknown	10 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Pantoloc /01263201/	C	Unknown	40 Mg, Bid	Not Reported
	Pantoloc /01263201/	C			Not Reported
	Prednisone	C	Unknown	10 Mg, Unk	Not Reported
	Celebrex	C	Unknown	200 Mg, Unk	Not Reported
	Lorazepam	C	Unknown	1 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16701303	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0300		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choroiditis; Drug Ineffective; Eye Infection; Nasopharyngitis; Otorrhoea; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

		Xeljanz			S	Oral				Not Reported
		Xeljanz			S	Oral				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported
		Humira			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16720491	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2889490-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Form Of Administration-Solution, Single Use Pre-Filled Syringe		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16834365	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2605701-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydro			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16840100	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019401953			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Sepsis	Carboplatin			S	Intravenous (not otherwise specified)	Cyclic (Auc = 6 Intravenously Over 15-30 Min On Day 1) Every 21 Days For A Total Of 6 Cycles		Pfizer
	Paclitaxel			S	Intravenous (not otherwise specified)	200 Mg/M2, Cyclic (Over 3 H On Day 1) Every 21 Days For A Total Of 6 Cycles		Pfizer
	Bevacizumab			S	Intravenous (not otherwise specified)	15 Mg/Kg, Cyclic (Initial Infusion Over 90 Min) On Day 1) Every 21 Days For A Total Of 6 Cycles		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day (Cyclic, On Days 1-21) Every 21 Days For A Total Of 6 Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842370	NON-EXPEDITED		OT	US-TEVA-2018-US-993447		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Hydroxychloroquine			S	Unknown			Teva
	Methimazole			S	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842380	NON-EXPEDITED			US-TEVA-2019-US-1009805			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842393	NON-EXPEDITED		OT	US-TEVA-2019-US-1001443		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	400 Milligram Daily; The Woman Had An Approximate Cumulative Dose Of 2.92 Kg, With A Daily Dose Of 5		Teva
	Hydroxychloroquine			S				Teva
	Levothyroxine			C	Unknown			Not Reported
	Dexlansoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Coenzyme Q10			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842630	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201908000332			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S		Unknown		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842726	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3544		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Blood Pressure Increased; Dermatomyositis; Diarrhoea; Drug Ineffective; Foot Fracture; Migraine; Off Label Use; Pain In Extremity; Poor Venous Access; Post-Traumatic Neck Syndrome; Rhinorrhoea; Road Traffic Accident; Thrombophlebitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Diflucan			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Euro D			C	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfamethoxazole			C	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported
	Zoplicone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16842735	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2019-3522		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Pain; Condition Aggravated; Pyrexia; Synovitis	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843515	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2019-US-1112121		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy; Pleural Effusion; Sinus Tachycardia; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram Daily; For 8 Months		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843656	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-000795			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16843790	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201909000610			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Degeneration	Hydroxychloroquine			S	Oral	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16844382	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3606			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Aleve			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16845008	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019397856		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Condition Aggravated; Pyrexia; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	11595073	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015102627		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Apo-Prednisone	S	Oral	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	30 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qwk	Not Reported
	Methotrexate	S	Intramuscular	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Qmo	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Losec	C	Unknown	Unk	Not Reported
	Celexa	C		Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Citalopram Hydrobromide	C		Unk	Not Reported
	Ketoprofen	C		100 Mg, Bid	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported

	Prednisone		C	Oral	50 Milligram, Qd		Not Reported
	Prednisone		C	Oral	3 Milligram, Qd		Not Reported
	Prednisone		C	Oral	5 Milligram		Not Reported
	Naproxen		C	Unknown			Not Reported
	Omeprazole		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	12322789	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016042342		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; X-Ray Abnormal	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Prednisone		S	Unknown	Unk	Not Reported
					Prednisone		S	Unknown	10 Milligram	Not Reported
					Prednisone		S	Unknown	5 Milligram, Qd	Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Orencia		S	Unknown	Unk	Not Reported
					Orencia		S	Subcutaneous	Unk	Not Reported
					Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
					Desoximetasone		S	Oral	Unk	Not Reported
					Desoximetasone		S	Unknown	Unk	Not Reported
					Pantoprazole		C	Unknown	Unk	Not Reported
					Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	12396508	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016065394		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Off Label Use; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

	Xeljanz	S	Oral	5 Milligram		Not Reported
	Adalimumab	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate	S	Unknown	20 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	200 Milligram		Not Reported
	Haemophilus Influenzae	C	Unknown	Unk		Not Reported
	Prevnar 13	C	Intramuscular	Unk		Not Reported
	Tetanus Vaccine	C	Unknown	Unk		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported
	Hydroxychloroquine	C		200 Milligram		Not Reported
	Pneumococcal Vaccine	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	12564449	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015018521		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contraindicated Product Prescribed; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats;	Single Dose Prefilled Autoinjector(Enbrel)			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Calcite D	C		500 Mg + 1000 Mg Die	Not Reported
	Citalopram	C		Unk	Not Reported
	Domperidone	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	5 Milligram	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Gliclazide	C	Unknown	Unk	Not Reported
	Lipitor	C	Unknown	Unk	Not Reported
	Nifedipine	C	Unknown	Unk	Not Reported
	Pantoloc	C		Unk	Not Reported
	Risedronate	C	Unknown	35 Milligram	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	650 Milligram, Bid	Not Reported
	Risedronate Sodium	C	Unknown	Unk	Not Reported
	Actonel	C		35 Milligram, Qwk	Not Reported
	Calcium Carbonate W/Ergocalciferol	C	Unknown	1500 Milligram, Qd	Not Reported
	Pantoprazole Sodium	C		Unk	Not Reported
	Tramadol Hcl/Acetaminophen	C		Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	12685431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016399474			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk, Unk, 2 Times/Wk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk Unk, Q2wk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer

Intolerance; Incorrect Route Of Product Administration; Insomnia; Rheumatoid Arthritis	Methotrexate Sodium	S	Subcutaneous	Unk	Unknown
	Anakinra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	10 Mg, Qd	Not Reported
	Arava	S	Unknown	10 Mg, 1x/Day	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Mg, Bid	Not Reported
	Naprosyn [Naproxen]	S	Unknown	500 Milligram, 2 Times/Wk	Not Reported
	Orencia	S	Endocervical	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Vioxx	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Leflunomide	C	Unknown	10 Mg, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	13066184	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016294889		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Crestor	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Oral	5 Mg, Bid	Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	13128652	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015105293		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue;	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Arava			S	Oral	Unk Unk, Qwk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported

Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Plaquenil	S	Unknown	400 Milligram	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Certolizumab	S	Unknown	200 Mg, Every 2 Weeks	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Humira	S	Unknown	400 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	400 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Actemra	S	Unknown	640 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	640 Milligram, Qwk	Not Reported
	Actemra	S	Unknown	640 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	Unk, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	300 Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported

Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Cimzia	S	Unknown	200 Milligram, Qwk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Cyclical	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported

	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk Unk, Qd	Not Reported
	Leflunomide		S	Unknown	10 Milligram	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide		S	Unknown	20 Mg, Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Piroxicam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	13519994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038504		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Orencia			S	Subcutaneous	250 Mg, Unk		Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate /00113802/			S	Subcutaneous	20 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Milligram		Not Reported

		Prednisone			S	Unknown				Not Reported
		Leflunomide			S	Oral	10 Mg, Unk			Not Reported
		Rituximab			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	14154998	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017164903		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unk		Not Reported
	Cephalexin			C		500 Mg, Tid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	14159440	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017165072		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Depo Medrol			C	Intra-articular	40 Milligram		Not Reported
	Methylprednisolone Acetate			C		40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	14312157	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016084874		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Ciclosporin	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
Orencia	S	Unknown	75 Milligram, Qmo	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported

	Methotrexate		S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate		S	Oral	20 Milligram	Not Reported
	Methotrexate		S	Oral	20 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	20 Milligram	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz		C		5 Milligram, Qd	Not Reported
	Cimzia		C	Subcutaneous	200 Milligram, Q2wk	Not Reported
	Arava		C	Oral	20 Milligram, Qd	Not Reported
	Risedronate		C	Oral	35 Milligram, Qwk	Not Reported
	Rituxan		C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	14818774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112140		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

			Hydroxychloroquine Sulfate		S	Unknown			Not Reported
			Tylenol [Paracetamol]		C	Unknown			Not Reported
			Mefenamic Acid		C				Not Reported
			Prednisone		C	Oral			Not Reported
			Prednisone		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15015132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2139737		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoporosis; Pain; Pruritus; Rash; Swelling	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15163832	EXPEDITED (15-DAY)		OT	DE-NODEN PHARMA DAC-NOD-2018-000066		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Contraindicated Product Administered; Maternal Exposure During	Aliskiren			S	Unknown	Unk		Noden Pharma
	Ramipril			S	Unknown	20 Mg, Unk		Not Reported

Pregnancy; Premature Delivery; Product Monitoring Error	Nicotine			S	Unknown	Unk	Not Reported
	Torasemide			S	Unknown	Unk	Not Reported
	Simvastatin			S	Unknown	Unk	Not Reported
	Ezetimibe			S	Unknown	Unk	Not Reported
	Metamizole			S	Unknown	Unk	Not Reported
	Tacrolimus			S	Unknown	Unk	Not Reported
	Xarelto			S	Unknown	Unk	Not Reported
	Hydroxychloroquine			S	Unknown	Unk	Not Reported
	Prednisolone			S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk	Not Reported
	Pantoprazole Sandoz			S	Unknown		Not Reported
	Salbutamol			S	Unknown	Unk	Not Reported
	Salbutamol Sulfate			S	Unknown	Unk	Not Reported
	Enoxaparin Sodium			S	Unknown	Unk	Not Reported
	Enoxaparin			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15482187	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018140534		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Shoulder Operation; Swelling; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

	Tramadol			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15621214	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557049-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Coversyl			C	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15738001	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017082749		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	15875870	EXPEDITED (15-DAY)		OT	PHHY2019DE016444		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Restlessness	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Methotrexate			S	Unknown	17.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Benepali			S	Unknown	50 Mg, Qw		Not Reported
	Benepali			S	Unknown	50 Mg, Qw		Not Reported
	Hcq			S	Unknown	200 Mg, Unk		Not Reported
	Hcq			S	Unknown	300 Mg, Qd		Not Reported
	Tocilizumab			S	Unknown	162 Mg, Unk		Not Reported
	Chloroquine			C	Unknown	300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16103712	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016048454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
Nortriptyline	S	Unknown	10 Milligram	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
Actonel	C		36 Milligram, Qwk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Esomeprazole	C		40 Milligram, Bid	Not Reported
Oxycodone Terephthalate	C		Unk	Not Reported
Pantoprazole Magnesium	C		40 Milligram, Qd	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C		Unk	Not Reported
Perphenazine	C		Unk	Not Reported
Prednisone	C		5 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C		50 Milligram, Qd	Not Reported
Tylenol [Paracetamol]	C		1000 Milligram, Qd	Not Reported
Vitamin A	C		Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C		Unk	Not Reported
Xeljanz	C		Unk	Not Reported
D-Alpha Tocopheryl Acetate	C		1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride	C		Unk Unk, Qd	Not Reported
Ergocalciferol	C		400 International Unit, Qwk	Not Reported
Ferrous Gluconate	C		300 Milligram, Qd	Not Reported
Loperamide Hydrochloride	C		2.5 Milligram	Not Reported
Nasonex	C		Unk Unk, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C		40 Milligram, Bid	Not Reported
Trazodone	C		Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Omega-3 Fatty Acids	C		Unk	Not Reported

	Acetaminophen			C						Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C			Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16487645	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016157678		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Psoriasis	Enbrel			S		Unk		Pfizer
	Enbrel			S				Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16751020	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-201908000007			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Haemorrhoidal Haemorrhage; Osteomyelitis; Panniculitis; Renal Impairment; Temporomandibular Joint Syndrome; Transient Ischaemic Attack; Upper Respiratory Tract Inflammation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported
	Lendormin			C		Unk		Not Reported
	Lexotan			C		Unk		Not Reported
	Marvelon 21			C		Unk		Not Reported
	Mohrus			C		Unk		Not Reported
	Calonal			C		Unk		Not Reported

Azulfidine En	C	Unk	Not Reported
Alfarol	C	Unk	Not Reported
Tacrolimus	C	Unk	Not Reported
Loxonin	C	Unk	Not Reported
Loxonin	C	Unk	Not Reported
Alendronate	C	Unk	Not Reported
Mecobalamin Sv Nippon	C	Unk	Not Reported
Losartan K	C	Unk	Not Reported
Tramcet	C	Unk	Not Reported
Lansoprazole	C	Unk	Not Reported
Preminent	C	Unk	Not Reported
Mucosta	C	Unk	Not Reported
Ferromia	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16782275	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1083398		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Polyneuropathy; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16831965	EXPEDITED (15-DAY)		OT	CA-ROCHE-2405659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown	Discontinued: 4-5 Years		Not Reported
	Pneumovax	C	Unknown			Not Reported
	Prevnar 13	C	Unknown			Not Reported
	Shingrix	C	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848048	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Levothyroxine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848058	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27363		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait	Etanercept			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra		S	Unknown	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown			Not Reported
	Arava		S	Unknown			Not Reported
	Certolizumab Pegol		S	Subcutaneous			Not Reported
	Enbrel		S	Unknown	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution		Not Reported
	Methotrexate		S	Subcutaneous			Not Reported
	Methylprednisolone		S	Unknown			Not Reported
	Orencia		S	Unknown	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown			Not Reported
	Remicade		S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine		S	Unknown	Unknown		Not Reported
	Xeljanz		S	Unknown	Unknown		Not Reported
	Naproxen		C	Unknown	Unknown		Not Reported
	Prednisone		C	Unknown	Unknown		Not Reported
	Rituxan		C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848127	EXPEDITED (15-DAY)		OT	PH-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-221530		47 YR	Female	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Aneurysm; Infective Aortitis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual
	Azathioprine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848638	EXPEDITED (15-DAY)		DE, HO, LT	US-APPCO PHARMA LLC-2074871		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Hypotension; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Renal Failure; Toxicity To Various Agents	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Naproxen			S	Oral			Not Reported
	Ibuprofen			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848803	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201905-001472			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Dizziness Postural	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Macitentan			S	Oral	10 Mg,		Not Reported
	Prednisolone			S	Oral	4 Mg, Qd		Not Reported
	Imuran			S	Oral	100 Mg, Qd		Not Reported
	Methylprednisolone			S	Oral	32 Mg, Qd		Not Reported
	Ursodeoxycholic Acid			C		Unk		Not Reported
	Thyradin S			C		Unk		Not Reported
	Rabeprazole Na			C		Unk		Not Reported
	Rabeprazole Na			C				Not Reported
	Daiphen			C		Unk		Not Reported
	Daiphen			C				Not Reported
	Pralia			C		Unk		Not Reported
	Tracleer			C		Unk		Not Reported
	Azilva			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848870	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2939203-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Humira			S	Subcutaneous	Not Reported
	Orencia			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Actemra			S	Subcutaneous	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848977	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3657			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Mobility Decreased; Neurological Procedural Complication; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16848994	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2939262-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic	Humira			S	Subcutaneous			Not Reported

Arthropathy; Rheumatoid Arthritis; Uveitis	Cosentyx		S	Unknown		Not Reported
	Stelara		S	Subcutaneous		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Remicade		S	Intravenous drip	Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S			Not Reported
	Otezla		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849029	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2939168-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bursitis; Drug Ineffective; Enthesopathy; Musculoskeletal Stiffness; Palpitations; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Other			Not Reported
	Metoprolol Tartrate			C	Oral			Not Reported
	Losartan			C	Oral			Not Reported

	Hydroxychloroquine	C	Oral	Not Reported
	Gabapentin	C	Oral	Not Reported
	Flonase	C		Not Reported
	Mometasone Furoate	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Etanercept	C	Subcutaneous	Not Reported
	Esomeprazole Magnesium	C	Oral	Not Reported
	Clonidine Hydrochloride	C	Oral	Not Reported
	Calcium	C	Oral	Not Reported
	Betahistine Hydrochloride	C	Oral	Not Reported
	Baclofen	C	Oral	Not Reported
	Aspirin	C	Oral	Not Reported
	Amitriptyline Hydrochloride	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Phthalylsulfathiazole			S	Unknown				Not Reported
		Prednisone			S	Intravenous (not otherwise specified)				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Arava			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411011		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenou		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2409924			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849905	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2937811-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16849989	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		47 YR	Female	CAN

						PHARMA-TREX2019-3623			

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16850470	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201804-001137		78 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Compression Fracture	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Azulfidine En			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16850495	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain In Extremity; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Arava		S	Oral	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16851358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2408467		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16851594	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1113182		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Weight Decreased	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S				Teva
	Venlafaxine Hydrochloride			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16851824	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-001525			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Ipca
	Paxil			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Vitamin D			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Flomax			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	16851894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2409903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Malaise; Therapeutic Product Ineffective; Wheezing	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Sep-2019	17000174	DIRECT	Y					Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Headache; Malaise; Nausea; Pain; Product Dispensing Error; Pyrexia; Wrong Product Administered	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	11701518	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015327719		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Asthenia;	Enbrel			S	Subcutaneous	Unk		Pfizer

Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Intramuscular	Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3.0 Mg, Qd	Not Reported
	Apo-Prednisone	S		30 Milligram, Qd	Not Reported
	Actemra	S		8 Milligram, Qmo	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Citalopram Hydrobromide	C		Unk	Not Reported
	Celexa	C		Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Ketoprofen	C		100 Mg, 2x/Day	Not Reported
	Losec	C	Unknown	Unk	Not Reported
	Losec	C	Unknown	Unk	Not Reported

Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
Prednisone	C	Oral	50 Mg, Daily		Not Reported
Prednisone	C	Oral	5 Mg, 1x/Day		Not Reported
Prednisone	C	Oral	3 Mg, 1x/Day		Not Reported
Prednisone	C	Oral	50 Mg, 1x/Day		Not Reported
Naprosyn	C	Unknown	Unk		Not Reported
Naprosyn	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Omeprazole	C		Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	12265986	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016209964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Eye Disorder; Feeling Abnormal; Finger Deformity; Foot Deformity; Gait Disturbance; Hyperhidrosis;	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported

Inflammation; Intervertebral Disc Protrusion; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Spinal Disorder; Therapeutic Product Effect Incomplete; Vomiting; Wrist Deformity	Orencia	S	Unknown	125 Mg, Weekly	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	5 Mg, Unk	Not Reported
	Winpred	S	Unknown	5 Mg, Unk	Not Reported
	Acetaminophen	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Oral	Unk	Not Reported
	Oxycodone Hydrochloride	S	Oral	Unk	Not Reported
	Hydromorphone	S	Oral	12 Milligram	Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Lax-A-Day	C		Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Fosfomycin Trometamol	C	Unknown	Unk	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Monurol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	12870157	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016478094		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Leflunomide		S	Oral	20 Mg, Qd, (More Than 3 Months)	Not Reported
	Apo-Hydroxyquine		S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide		S	Unknown	20 Mg, 1x/Day	Not Reported
	Acetaminophen		C		Unk Unk, As Necessary	Not Reported
	Pregabalin		C	Oral	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	13054580	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016267960		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Off Label Use; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly(20 Mg, 1 In 1 Wk)		Pfizer
	Methotrexate Sodium			S		20 Mg, Cyclic(Once Every 2 Weeks)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid) (5 Mg, 2 In 1 D)		Pfizer
	Plaquenil			S	Unknown	200 Mg, Daily		Not Reported
	Plaquenil			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40mg/0. 8ml, 40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Hydroxychloroquine			C		200 Milligrams, Unk		Not Reported
	Tetanus Vaccine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, Unk		Not Reported
	Prevnar 13			C	Intramuscular	Unk		Not Reported

	Haemophilus Influenzae	C	Unk	Not Reported
	Hib Vaccine	C	Unk	Not Reported
	Prevnar	C	Unk	Not Reported
	Pneumococcal Vaccine	C	Unk	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	14166864	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017479551		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Enbrel			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Depo Medrol			C	Intra-articular	40 Mg, Unk		Not Reported
	Methylprednisolone Acetate			C		40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	14829520	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018176680			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Aspirin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Decreased	Leflunomide	S	Unknown	Unk		Not Reported
	Penicillin	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Penicillin G	S	Unknown	Unk		Not Reported
	Phenoxymethylpenicillin	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Penicillin G Procaine	S	Unknown	Unk		Not Reported
	Penicillin G Potassium	S	Unknown	Unk		Not Reported
	Pregabalin	C		Unk		Not Reported
	Tylenol	C		Unk		Not Reported
	Acetaminophen	C		Unk		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15482284	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018034475		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet	Enbrel			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Pfizer
	Enbrel			S	Intravenous (not otherwise specified)	15 Mg, Unk		Pfizer
	Etanercept			S	Subcutaneous	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Weekly		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Weekly		Not Reported
	Infliximab			S	Unknown	200 Mg, Weekly		Not Reported
	Infliximab			S	Unknown	200 Mg, Monthly		Not Reported
	Rituximab			S	Intravenous (not	420 Mg, Unk		Not Reported

Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased				otherwise specified)		
	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S		420 Mg, Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Tocilizumab	S				Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic Q2wk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Orencia	S				Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Qwk		Not Reported
	Adalimumab	S	Unknown	Unk		Not Reported
	Adalimumab	S		40 Mg, Unk		Not Reported
	Abatacept	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15556082	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017475999		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported
	Lidocaine Hcl			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Tocilizumab	S		160 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Imuran	C	Unknown	50 Milligram, Qd		Not Reported
	Azathioprine	C	Subcutaneous	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15575294	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016190824		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting; X-Ray Abnormal	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Sulfate]					
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	10 Milligram		Not Reported
	Prednisone	S	Unknown	5 Milligram, Qd		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
	Desoximetasone	S	Oral	Unk		Not Reported
	Desoximetasone	S	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15694711	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2581584-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Arava			S	Unknown				Not Reported
		Azathioprine			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Arava			C	Unknown				Not Reported
		Azathioprine			C	Unknown				Not Reported
		Hydroxychloroquine Sulfate			C	Unknown				Not Reported
		Plaquenil			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported
		Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15702708	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not			Not Reported

							otherwise specified)			
					Prednisone	S	Intravenous (not otherwise specified)			Not Reported
					Prednisone	S	Oral			Not Reported
					Prednisone	S	Unknown			Not Reported
					Hydroxychloroquine Sulfate	S	Unknown			Not Reported
					Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15721382	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3744		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Malaise; Respiratory Tract Infection; Rheumatoid Arthritis; Sinus Disorder; Sinusitis Noninfective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	L-Thyroxine			C	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Vitamins			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15849143	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019026846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15849297	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2633421-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Plaquenil Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Prednisone Teva		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Naproxen Sodium		C	Unknown	Not Reported
	Folic Acid		C	Subcutaneous	Not Reported
	Plaquenil		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15852192	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633997-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15858692	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016332250		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk, Once Every Two Weeks		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Unknown
	Methotrexate Sodium			S	Subcutaneous	220 Milligram		Unknown
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Xeljanz			S		5 Milligram, Qd		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S		40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported

Orencia	S	Unknown	75 Milligram, Qmo	Not Reported
Leflunomide	S		20 Milligram, Qd	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram, Q2wk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Plaquenil	S	Oral	200 Mg, 2x/Day	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Milligram	Not Reported
Rituxan	C	Intravenous (not	Unk	Not Reported

							otherwise specified)			
			Arava		C		Oral	20 Milligram, Qd		Not Reported
			Risedronate		C		Oral	35 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15924107	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653468-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15932037	EXPEDITED (15-DAY)		DS, HO	CA-ABBVIE-19K-028-2655672-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
					Rituxan	S	Intravenous (not otherwise specified)			Not Reported
					Hydroxychloroquine Sulfate	S	Unknown			Not Reported
					Bupropion	C	Unknown			Not Reported
					Esomeprazole	C	Unknown			Not Reported
					Folic Acid	C	Unknown			Not Reported
					Levothyroxine Sodium	C	Unknown			Not Reported
					Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15932395	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2655632-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15935646	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2657083-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	15997085	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2676523-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16156280	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1034358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown	150 Milligram Daily;		Not Reported

	Prednisone			C	Unknown	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16343876	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019215868		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Fentanyl Citrate			S	Unknown	Unk		Unknown
	Gabapentin			S	Oral	100 Milligram, Bid		Pfizer
	Methotrexate Sodium			S	Subcutaneous	1 Dosage Form, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	1 Dosage Form, Qwk		Unknown
	Sulfasalazine			S	Oral	2.5 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Qd		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Nortriptyline			S	Unknown	10 Milligram		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Orencia			S	Vaginal	750 Milligram, Qmo		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported

Actonel	C	36 Milligram, Qwk	Not Reported
Cholecalciferol	C	Unk	Not Reported
Esomeprazole	C	40 Milligram, Bid	Not Reported
Oxycodone Terephthalate	C	Unk	Not Reported
Pantoprazole Magnesium	C	40 Milligram, Qd	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unk	Not Reported
Perphenazine	C	Unk	Not Reported
Prednisone	C	5 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	50 Milligram, Qd	Not Reported
Tylenol [Paracetamol]	C	1000 Milligram, Qd	Not Reported
Vitamin A Nos	C	Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C	Unk	Not Reported
Xeljanz	C	Unk	Not Reported
Trazodone Hydrochloride	C		Not Reported
D-Alpha Tocopheryl Acetate	C	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unk Unk, Qd	Not Reported
Ergocalciferol	C	400 Iu International Unit(S), Qwk	Not Reported
Ferrous Gluconate	C	300 Milligram, Qd	Not Reported
Loperamide Hydrochloride	C	2.5 Milligram	Not Reported
Esomeprazole Magnesium Trihydrate	C	40 Milligram, Bid	Not Reported
Nasonex	C	Unk Unk, Bid	Not Reported
Trazodone	C	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unk	Not Reported
Loperamide	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16561990	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLABS-2019M1063523		43 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Cardiac Failure; Condition Aggravated; Drug Ineffective; Lupus Myocarditis; Lupus Nephritis; Myocarditis; Off Label Use; Product Dose Omission; Renal Tubular Necrosis; Respiratory Failure; Systemic Lupus Erythematosus; Thrombocytopenia	Prednisolone			S		Unk Unk, Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid, Maintenance Therapy		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Methylprednisolone			S		Unk Unk, Unk		Not Reported
	Methylprednisolone			S		Unk Unk, Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk, Unk		Mylan
	Bortezomib			S	Subcutaneous	1.3 Milligram/Sq. Meter, Q3w (1.3 Mg/M2, Q3w, Days 1, 4, 8 And 11)		Mylan
	Bortezomib			S				Mylan
	Bortezomib			S				Mylan
	Rituximab			S		Unk		Mylan
	Cyclophosphamide			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16658505	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-3166455			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Enbrel			S	Subcutaneous	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Celebrex			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported

	Arava	S	Oral	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Naproxen Sodium	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	5 Mg, Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16820422	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16838571	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2933947-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Humira			S	Subcutaneous	6 Years		Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration-365		Not Reported
	Orencia			S	Unknown	Therapy Duration-365		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2409782		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S),1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solution		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Advil [Ibuprofen]	C	Unknown			Not Reported
Mefenamic Acid	C	Unknown			Not Reported
Prednisone	C	Oral			Not Reported
Prednisone	C	Oral			Not Reported
Tylenol [Paracetamol]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854365	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000715			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Device Issue; Implantable Defibrillator Insertion; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Retinal Detachment; Sinusitis; Wrong Technique In Product Usage Process	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg, 1 In 2 Week		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg, 1 In 2 Week		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854492	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION			Male	CAN

PHARMA-TREX2019-3669

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854549	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201908000347			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Rash	Hydroxychloroquine			S	Unknown			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16854707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16855065	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001672			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16855092	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-000992			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Larynx Irritation; Nausea; Rheumatoid Arthritis; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Rituxan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16855395	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2939258-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response	Humira			S	Subcutaneous			Not Reported

Decreased	Arava	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil	S	Oral	Therapy Duration 677	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16855481	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201909000716			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Carotid Artery Occlusion; Cataract; Dry Eye; Dyspnoea; Hypotension; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Humira 40mg/0.8ml			S	Subcutaneous	Unk		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	, 1 In 2 Wk40 Unk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg, 1 In 2 Wk		Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pravastatin			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Acebutolol			C	Unknown			Not Reported
	Iron			C				Not Reported
	Celecoxib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16856656	EXPEDITED (15-DAY)		DE, HO	PHHY2019US222788		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Clostridium Difficile Infection; Cytomegalovirus Infection; Malaise; Productive Cough; Pseudomonal Bacteraemia; Pulmonary	Prednisone			S	Unknown	Unk, Qd (High Dose)		Novartis
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk, Qd Pulse		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Tuberculosis; Pyrexia	Rituximab			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2019	16856682	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019411544		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Celebrex			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Clindamycin Phosphate			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Unknown
	Enbrel			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Cephalexin Monohydrate			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Hctz			S		Unk		Not Reported
	Hydralazine Hydrochloride			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Losartan			S		Unk		Not Reported
	Metoprolol Tartrate			S		Unk		Not Reported
	Pantoprazole Magnesium			S		Unk		Not Reported
	Pariet			S		Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S		Unk		Not Reported
	Cipro [Ciprofloxacin]			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported

Gold	C	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unk	Not Reported
Iron Sucrose	C	Unk	Not Reported
Prednisone	C	8.5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	11524157	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSL2015034635		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Drug Ineffective; Exposure To Communicable Disease; Hip Arthroplasty; Joint Effusion; Joint Stiffness; Localised Infection; Maternal Exposure During Pregnancy; Musculoskeletal Pain; Osteoarthritis; Surgery	Single Dose Prefilled Autoinjector(Enbrel)			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S				Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Ibuprofen			C		400 Milligram, Four Times Day, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	12598134	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015073765		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Contraindicated Product Prescribed; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion	Enbrel			S		50 Milligram, Qwk		Unknown
	Enbrel			S		50 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	50 Mg, Unk		Unknown
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis			otherwise specified)		
	Plaquenil	S	Oral	5 Mg, Bid	Not Reported
	Asa	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Risedronate	C	Unknown	35 Mg, Weekly On Tuesday	Not Reported
	Calcite D	C		1500 Mg, Daily (500mg + 1000mg Die)	Not Reported
	Lipitor	C	Unknown	Unk	Not Reported
	Pantoloc	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Tylenol	C		650 Milligram, Bid	Not Reported
	Citalopram	C		Unk	Not Reported
	Domperidone	C		Unk	Not Reported
	Folic Acid	C	Unknown	5 Milligram	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Gliclazide	C		Unk	Not Reported
	Nifedipine	C	Unknown	Unk	Not Reported
	Calcium Carbonate W/Ergocalciferol	C	Unknown	1500 Milligram, Qd	Not Reported
	Pantoprazole Sodium	C		Unk	Not Reported
	Actonel	C		35 Milligram, Qwk	Not Reported
	Tramadol Hcl/Acetaminophen	C		Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	13075088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Oral			Not Reported
	Crestor			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15635106	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown	250 Milligram, Qmo		Bristol Myers Squibb
	Triamcinolone			S	Subcutaneous	25 Milligram, Q2wk		Bristol Myers Squibb
	Triamcinolone			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Immunoglobulin Human Normal			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Milligram		Not Reported

Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous	15.0 Mg/M2, Qwk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	1.3 Milligram	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Gamastan	S	Intramuscular	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Immunoglobulin [Immunoglobulins Nos]	S	Unknown		Not Reported

	Triamcinolone Hexacetonide			S	Unknown	Unk			Not Reported
	Folic Acid			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15663552	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2570297-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15753832	EXPEDITED (15-DAY)		HO, OT	PHHY2018DE190352		34 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cholelithiasis; Diffuse Large B-Cell Lymphoma Stage Iv; Metastases To Liver; Off Label Use; Osmotic Demyelination Syndrome; Reactive Gastropathy	Methotrexate	S	Unknown	15 Mg, Qw (Qwk)		Novartis
	Mabthera	S	Unknown	375 Mg, Unk		Not Reported
	Abatacept	S	Subcutaneous	125 Mg, Qw		Not Reported
	Abatacept	S	Subcutaneous	125 Mg, Unk		Not Reported
	Tocilizumab	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine	C	Unknown	2000 Ml/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	15923113	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653533-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16352260	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION			Female	CAN

PHARMA-TREX2019-1549

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16796887	EXPEDITED (15-DAY)		HO, OT	PHHY2019CZ210732		57 YR	Male	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lymphopenia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unknown		Novartis
	Methotrexate			S	Unknown	Unk, Unknown		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unknown		Not Reported
	Azathioprine			S	Unknown	Unk, Unknown		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk, Unknown		Not Reported
	Belimumab			S	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unknown		Not Reported
	Cyclosporin A			S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16859618	EXPEDITED (15-DAY)		OT	CA-ROCHE-2410786		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16859724	EXPEDITED (15-DAY)		DE, OT	JP-ADVANZ PHARMA-201909000654			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Neoral			C				Not Reported
	Bredinin			C				Not Reported
	Predonine			C		10 Mg, Qd		Not Reported
	Prednisolone			C		Unk		Not Reported
	Rabeprazole Na			C				Not Reported
	Rabeprazole Na			C				Not Reported
	Rebamipide			C				Not Reported

	Rebamipide	C		Not Reported
	Gasmotin	C		Not Reported
	Gasmotin	C		Not Reported
	Magmitt	C		Not Reported
	Frandol	C		Not Reported
	Loqoa	C		Not Reported
	Sennoside	C	Unk	Not Reported
	Fexofenadine Hydrochloride	C	Unk	Not Reported
	Kipres	C	Unk	Not Reported
	Astomin	C	Unk	Not Reported
	Bayaspirin	C		Not Reported
	Losartan Potassium	C		Not Reported
	Nicorandil	C		Not Reported
	Pravastatin Na	C		Not Reported
	Pralia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860535	EXPEDITED (15-DAY)		LT, OT	JP-ADVANZ PHARMA-GSH201901-000040			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Azulfidine En			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Nexium			C	Unknown	Unk		Not Reported
	Artist			C	Unknown	Unk		Not Reported
	Feburic			C	Unknown	Unk		Not Reported
	Calfina			C	Unknown	Unk		Not Reported
	Nicorandil			C	Unknown	Unk		Not Reported
	Argamate			C	Unknown	Unk		Not Reported
	Pletaal			C	Unknown	Unk		Not Reported
	Methycobal			C	Unknown	Unk		Not Reported

	Goshajinkigan			C	Unknown	Unk				Not Reported
	Sennoside A+B			C	Unknown	Unk				Not Reported
	Magmitt			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860600	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Tofacitinib			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860841	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1114092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)				
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Topicort			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860868	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1114160		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C		150 Milligram Daily;		Not Reported
	Prednisone			C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860926	EXPEDITED (15-DAY)		OT	CA-SA-2019SA223353			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst	Arava		S	Unknown	20 Mg, Qd	Sanofi
	Methotrexate		S	Unknown	Unk Unk, Unk	Not Reported
	Plaquenil		S	Unknown	Unk Unk, Unk	Sanofi
	Celecoxib		S	Unknown	Unk Unk, Prn	Not Reported
	Enbrel		S	Unknown	Unk, Unk	Not Reported
	Imuran [Azathioprine]		S	Unknown	Unk, Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16861020	EXPEDITED (15-DAY)		OT	CA-SA-2019SA263060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Leflunomide			S	Unknown	20 Mg, Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Hs		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Vitamin D3			C	Oral	1, 000 Unknown (2,000 Unknown)		Not Reported
	Asa Ec			C	Oral	81 Mg, Qd		Not Reported
	Tylenol [Paracetamol]			C	Oral	500 Mg, Prn		Not Reported
	Folic Acid			C	Oral	5 Mg Weekly (2.5 Mg Saturday And 2.5 Mg Sunday)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16861077	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113903			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Ibuprofen		S	Unknown		Actavis
	Leflunomide		S	Oral	20 Milligram Daily;	Barr
	Methotrexate		S	Oral		Barr
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16861772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2410764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862509	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000774			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Hyperhidrosis; Loss Of Consciousness; Nausea	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz			S	Oral	1 Dosage Form, Qd (11 Mg)		Not Reported
	Xeljanz			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862573	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019412573		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Hydromorph Contin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	15621786	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557110-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling;	Humira			S	Subcutaneous			Not Reported

Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Apo Leflunomida			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	15935541	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657057-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
			Acetaminophen		C		Unknown			Not Reported
			Gabapentin		C		Unknown			Not Reported
			Reactine [Cetirizine Hydrochloride]		C					Not Reported
			Dexamethasone		C		Unknown			Not Reported
			Desoximetasone		C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	15935657	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657571-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported

	Leflunomide			C	Unknown					Not Reported
	Tofacitinib Citrate			C	Unknown					Not Reported
	Prednisone			C	Oral					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Sep-2019	15990342	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674795-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2019	16864773	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1114496		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr

Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Ciclosporin	S	Unknown		Ivax
	Apo-Leflunomide	S	Oral		Not Reported
	Apremilast	S	Unknown		Not Reported
	Apremilast	S	Unknown		Not Reported
	Apremilast	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported

	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Not Reported
	Colchicine	C	Oral	Not Reported
	Dexilant	C	Unknown	Not Reported
	Febuxostat	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Unknown	Not Reported
	Oxycodone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Uloric	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2019	16864825	EXPEDITED (15-DAY)		OT	PHHY2019US224312		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Hemiparesis; Hypoaesthesia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Novartis
	Aspirin			C	Unknown	Unk Ukn, Unk		Not Reported
	Montelukast			C	Unknown	Unk Ukn, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Sep-2019	16864846	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness;	Azathioprine			S	Unknown			Not Reported

Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Azithromycin		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Barr
	Metoprolol		S	Unknown		Not Reported
	Naproxen		S	Unknown		Teva
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Humira		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	12590294	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015336939		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Enbrel			S		50 Mg, Weekly (4 Years)		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Every 6 Weeks		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	300 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	300 Mg, Unk		Unknown
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Sulfasalazine	S	Oral	1 Gram	Pfizer
Lyrica	S	Unknown	Unk	Pfizer
Actemra	S	Intravenous (not otherwise specified)	640 Mg, Monthly	Not Reported
Actemra	S	Unknown	640 Mg, Weekly	Not Reported
Actemra	S	Unknown	640 Mg, Unk	Not Reported
Actemra	S	Unknown	640 Mg, Monthly	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram	Not Reported
Arava	S	Oral	Unk, Weekly	Not Reported
Arava	S	Oral	Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Every 2 Weeks	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
Humira	S	Unknown	40 Mg, Qwk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Imuran	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not	300 Milligram , Qwk (2	Not Reported

			otherwise specified)	Years)	
Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qd	Not Reported
Apo-Cyclosporine		S	Oral	Unk	Not Reported
Certolizumab Pegol		S	Unknown	200 Mg, Q2wk	Not Reported
Certolizumab Pegol		S	Unknown	200 Mg, Cyclic, 1 Every Two Week	Not Reported
Rituxan		S	Unknown	Unk	Not Reported
Rituxan		S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Mycophenolate Mofetil		S	Unknown	Unk	Not Reported
Orencia		S	Unknown	Unk	Not Reported
Orencia		S	Subcutaneous	125 Milligram, Qd	Not Reported
Simponi		S	Unknown	Unk	Not Reported
Apo-Azathioprine		S	Unknown	Unk	Not Reported
Apo-Leflunomide		S	Unknown	20 Mg, Unk	Not Reported
Varicella Zoster Vaccine Live		S	Subcutaneous	Unk	Not Reported
Leflunomide		S	Unknown	Unk Unk, Qd	Not Reported
Tocilizumab		S	Unknown	640 Mg, Weekly	Not Reported
Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
Prednisone		C		Unk	Not Reported
Piroxicam		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	12696423	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1479			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Enbrel	S	Unknown	2 Times/Wk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Naprosyn	S	Oral		Not Reported
	Naprosyn	S	Unknown	2 Times/Wk	Not Reported
	Orencia	S	Endocervical		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	12913342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092065		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk, Qmo		Bristol Myers Squibb
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	40 Milligram	Not Reported
Enbrel	S	Subcutaneous	50.0 Milligram, Qwk	Not Reported
Actemra	S	Unknown	50 Milligram, Qwk	Not Reported
Actemra	S	Unknown	4.0 Milligram/Kilogram	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1 Gram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	300 Milligram, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1 Gram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Methotrexate	C	Oral	Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram	Not Reported
Methotrexate	C	Unknown	0.8 Milliliter, Qwk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Tocilizumab	C	Endocervical	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	12913684	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-051750			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Off Label Use; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Arthrotec			S	Oral	50 Milligram, Bid		Not Reported
	Arthrotec			S	Unknown	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qcycle		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q3wk		Not Reported
	Radioactive Gold			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qwk		Not Reported
	Methotrexate			S	Intramuscular	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	200 Milligram		Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q3wk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Oral	50 Milligram, Bid		Not Reported
	Tylenol [Paracetamol]			C	Unknown	650 Milligram, Bid		Not Reported
	Tylenol [Paracetamol]			C	Unknown	1300 Milligram, Qd		Not Reported
	Mefenamic Acid			C	Oral	200 Milligram, Prn		Not Reported
	Acetaminophen			C	Unknown	650 Milligram, Bid		Not Reported
	Advil [Ibuprofen]			C	Oral	200 Milligram, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	12913939	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091688		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Off Label Use; Rheumatoid Arthritis; Synovitis; Underdose; Vomiting	Orencia			S	Subcutaneous	150 Milligram, Qmo		Bristol Myers Squibb
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1 Evey 1 Days		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Rituximab			S	Unknown	1 Gram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram,2 Every 1 Day		Not Reported
	Naprosyn [Naproxen]			C	Unknown	50 Milligram		Not Reported
	Naprosyn [Naproxen]			C	Unknown	500 Milligram,2 Every 1day		Not Reported
	Celebrex			C	Unknown	200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	13492019	EXPEDITED (15-DAY)		OT	PHHY2017GB060287		26 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Novartis

Pregnancy; Otitis Externa; Premature Labour; Staphylococcal Sepsis	Mycophenolate Mofetil	S	Unknown	750 Mg, Bid	Novartis
	Tacrolimus	S	Unknown	2 Mg, Bid	Not Reported
	Tacrolimus	S	Unknown	3 Mg, Bid	Not Reported
	Tacrolimus	S	Unknown	4 Mg, Qd	Not Reported
	Tacrolimus	S	Unknown	3 Mg, Qd	Not Reported
	Azathioprine	S	Unknown	50 Mg, Qd	Not Reported
	Azathioprine	S	Unknown	75 Mg, Qd	Not Reported
	Coal Tar	S	Topical		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg	Not Reported
	Hydroxychloroquine	S			Not Reported
	Prednisolone	S	Oral	30 Mg, Qd	Not Reported
	Prednisolone	S	Oral	30 Mg, Qd	Not Reported
	Prednisolone	S	Oral	20 Mg, Qd	Not Reported
	Prednisolone	S	Oral	30 Mg, Qd	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	500 Mg Per Dose	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	0.4 G/Kg, Qd	Not Reported
	Chlorhexidine	S	Topical		Not Reported
	White Soft Paraffin	S	Topical		Not Reported
	Mupirocin	S	Topical	Unk	Not Reported
	Vancomycin	S	Intravenous (not otherwise specified)		Not Reported
	Insulin	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	13854693	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070294		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthropathy; Crohn'S Disease; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Tuberculin Test Positive; Urinary Tract Infection	Orencia	S	Unknown	750 Milligram	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Unknown	5 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	5 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid (2 Every 1 Day)	Not Reported
	Apo-Leflunomide	S	Unknown	5 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	5 Milligram	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	50 Milligram, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15225624	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2586		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Contraindicated Product Administered; Dermatitis Allergic; Loss Of Personal Independence In Daily Activities; Sleep Disorder	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15314701	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2018CA022130			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Mg, Every 6 Weeks		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S		50 Mg, Weekly (4 Years)		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Decreased	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Mg, Monthly	Not Reported
	Actemra	S	Unknown	640 Mg, Weekly	Not Reported
	Actemra	S	Unknown	640 Mg, Unk	Not Reported
	Actemra	S	Unknown	640 Mg, Monthly	Not Reported
	Actemra	S	Unknown	640 Mg, Weekly	Not Reported
	Arava	S	Oral	Unk, Weekly	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Every 2 Weeks	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Humira	S	Unknown	40 Mg, Qwk	Not Reported
	Humira	S	Unknown	40 Mg, Qwk	Not Reported
	Humira	S	Unknown	40 Mg, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Imuran	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported

Remicade	S	Intravenous (not otherwise specified)	300 Milligram , Qwk (2 Years)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg, Q2wk	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg, Cyclic, 1 Every Two Week	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Qd	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
Tocilizumab	S	Unknown	640 Mg, Weekly	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Piroxicam	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15384166	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082920			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Infection; Joint Swelling; Liver Function	Abatacept			S	Unknown			Bristol Myers Squibb
	Plaquenil /00072602/			S	Unknown			Not Reported

Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Xeljanz Xr	S	Unknown			Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk		Not Reported
	Diphenhydramine	C	Oral	50 Mg, Unk		Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15389414	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 10 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not	1 G, Unk		Not Reported

				otherwise specified)		
	Sarilumab		S	Unknown		Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Adalimumab		S	Unknown	40 Mg, Q2wk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Rabeprazole Sodium		C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15400294	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083850		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15545610	EXPEDITED (15-DAY)		DS, OT	CA-CELLTRION INC.-2018CA023199			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	200 Mg, Weekly		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	200 Mg, Weekly		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	200 Mg, Monthly		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Enbrel			S	Intravenous (not otherwise specified)	15 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg/M2, Weekly		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S		420 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S		Unk		Not Reported

	Adalimumab	S	Subcutaneous	40 Mg, Qwk		Not Reported
	Adalimumab	S	Unknown	Unk		Not Reported
	Adalimumab	S		40 Mg, Unk		Not Reported
	Abatacept	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Etanercept	S	Subcutaneous	15 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15565602	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2017CA015315			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Lidocaine Hcl			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Cephalexin			C		500 Mg Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15676313	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018486815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15712127	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587993-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15744140	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0716		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15756010	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA024792			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

		Desoximetasone			C	Unknown	Unk			Not Reported
		Methotrexate			C	Oral	25 Mg, Qwk			Not Reported
		Prednisone			C		30 Mg, Qd			Not Reported
		Prednisone			C		30 Milligram, Qwk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15776400	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2018-242492		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Contraindicated Product Administered; Disability; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Naproxen Sodium (<=220 Mg)			S	Oral	100 Mg, Qd		Bayer
	Naproxen Sodium (<=220 Mg)			S	Oral	500 Mg, Bid		Bayer
	Adalimumab			S	Subcutaneous			Not Reported
	Folic Acid			S		5 Mg, Bid		Not Reported
	Arava			S		20 Mg, Qd		Not Reported
	Ascorbic Acid			S				Not Reported
	Celebrex			C		200 Mg, Qd		Not Reported
	Co Atenolol			S		25 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Ferrous Fumarate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		40 Mg		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S		20 Mg, Ow		Not Reported
	Methotrexate			S		25 Mg, Ow		Not Reported
	Naprosyn [Naproxen Sodium]			S		1000 Mg, Qd		Not Reported
	Naprosyn [Naproxen Sodium]			S		500 Mg, Bid		Not Reported
	Orencia			S				Not Reported
	Palafer Cf			S				Not Reported
	Abatacept			S				Not Reported
	Actemra			S				Not Reported

	Hydroxychloroquine	S		Not Reported
	Atenolol	S		Not Reported
	Etanercept	S		Not Reported
	Hydroxychloroquin Aristo	S		Not Reported
	Prednisone	S		Not Reported
	Xeljanz	S		Not Reported
	Naprosyn E	S		Not Reported
	Palafer	S		Not Reported
	Pantoloc [Pantoprazole]	S		Not Reported
	Pantoprazole	S		Not Reported
	Sulfasalazine	S		Not Reported
	Celecoxib	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15860956	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-004440			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 Gram, Q6mo		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd		Not Reported

					Etanercept		S	Unknown	50 Milligram, Qwk			Not Reported
					Hydroxychloroquine		S	Unknown	200 Milligram			Not Reported
					Methotrexate		S	Oral	Unk			Not Reported
					Rituximab		S	Intravenous (not otherwise specified)	2 Gram, Q6mo			Not Reported
					Methotrexate		C	Subcutaneous	20 Milligram			Not Reported
					Methotrexate		C	Subcutaneous	25 Milligram, Qwk			Not Reported
					Prednisone		C	Unknown	20 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	15953627	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-011582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16092818	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2653474-00		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Desoximetasone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16119794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020007		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	0.75 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	0.8 Mg/Kg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Endocervical			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16169316	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019148177		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Xeljanz			S	Unknown	Unk, 2x/Day		Pfizer
	Folic Acid			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16300661	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087769		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific	Naproxen Sodium (<= 220 Mg)			S	Unknown	Unk		Bayer
	Actemra			S	Intravenous (not otherwise specified)	280.0 Mg, Ow		Not Reported
	Actemra			S		280.0 Mg, Q2wk		Not Reported
	Anakinra			S	Subcutaneous	50.0 Mg, Qd		Not Reported
	Enbrel			S		12.5 Mg, Ow		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquin Aristo			S	Oral	5.0 Mg		Not Reported
	Intraveous Immune Globulin			S	Intravenous (not otherwise specified)	70.0 Mg		Not Reported

Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)	3.0 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg/M2		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250.0 Mg		Not Reported
	Prednisone	S	Oral	1.3 Milligram		Not Reported
	Sulfasalazine	S	Oral	250.0 Milligram		Not Reported
	Triamcinolone	S	Other	Unk		Not Reported
	Adalimumab	S	Unknown			Not Reported
	Apo-Prednisone	S	Oral	3 Mg, Bid		Not Reported
	Apo-Naproxen	S				Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd		Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16508006	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3979		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Pain In Extremity; Peripheral Swelling; Psoriasis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16781235	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1083199		32 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Iron Deficiency Anaemia; Live Birth; Maternal Exposure During Pregnancy; Premature Rupture Of Membranes; Pyrexia; Tachycardia; Twin Pregnancy	Azathioprine			S		Unk		Not Reported
	Heparin			S		Unk		Not Reported
	Heparin			S		Unk		Not Reported
	Prednisolone			S		5 Milligram, Qd		Mylan
	Cyclophosphamide			S		10.9 Gram		Mylan
	Cyclophosphamide			S		Cumulative Dose		Mylan
	Cyclophosphamide			S		13.9 Gram (Cumulative Dose)		Mylan
	Hcq			S		Unk		Mylan
	Aspirin /00002701/			S		Unk		Mylan
	Belimumab			S		Unk		Mylan
	Folic Acid			S		Unk		Mylan
	Iron			S	Oral	Unk		Mylan
	Ferrum Hausmann /00023505/			S	Oral	Unk		Mylan
	Maltofer /00023548/			S	Oral	Unk		Mylan
	Mycophenolate Mofetil			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16865489	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3771			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported

	Methylprednisolone	S	Unknown	Not Reported
	Pamidronate Disodium	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Bromocriptine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Colchicine	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Mercaptopurine	S	Unknown	Not Reported
	Tenoxicam	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16865947	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113917			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Drug Ineffective; Empyema; Foot Deformity; Hand Deformity; Joint Effusion; Joint Stiffness; Limb Operation; Musculoskeletal Stiffness; Nodule; Pneumonia; Rheumatoid Arthritis; Scar; Toe Operation	Ibuprofen			S	Unknown	400 Mg		Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Urethral	20 Milligram Daily;		Not Reported

	Calcium	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown	2000 Iu (International Unit) Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16865949	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1114414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Alendronate Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not			Not Reported

						otherwise specified)				
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866237	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1114439		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Methotrexate	S	Subcutaneous		Barr
Methotrexate	S	Subcutaneous		Barr
Methotrexate	S	Subcutaneous		Barr
Methotrexate	S	Unknown		Barr
Methotrexate	S	Unknown		Barr
Methotrexate	S	Unknown		Barr
Methotrexate	S	Subcutaneous		Barr
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Orencia	S	Unknown	111.4286 Milligram Daily;	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866618	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1114417		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Ciclosporin	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866625	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2019-06126		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866725	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2019-3787		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Allopurinol	C	Unknown	Not Reported
	Hydromorph Contin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16866866	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-062719		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Dermatitis; Drug Ineffective; Fatigue; Gallbladder Disorder; Groin Pain; Joint Swelling; Miliaria; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete	Celecoxib Capsules			S	Unknown	200 Milligram, Two Times A Day		Aurobindo
	Citalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Citalopram			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lorazepam			S	Unknown	1 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Milligram		Not Reported

	Gold	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Milligram, Once A Day	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Every Week	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Pantoloc	C	Unknown	40 Milligram, Two Times A Week	Not Reported
	Pantoloc	C			Not Reported
	Pantoloc	C			Not Reported
	Pantoloc	C	Unknown	40 Milligram, Two Times A Day	Not Reported
	Pantoloc	C	Unknown	Unk	Not Reported
	Pantoloc	C			Not Reported
	Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16867502	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1090546		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16867559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2412566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16867574	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025875			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Atenolol			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Colchicine			C	Unknown			Not Reported
	Coversyl /00790702/			C	Unknown			Not Reported
	Hctz			C	Unknown			Not Reported
	Leucovorin /00566701/			C	Oral	5 Milligram, Qwk		Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Methotrexate			C	Intramuscular	12.5 Milligram, Qwk		Not Reported
	Ranitidine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868020	EXPEDITED (15-DAY)		OT	CA-ROCHE-2412542			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868289	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019412543		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		2 Df, 1x/Day		Not Reported
	Arava			S	Oral	10 Mg, 1x/Day		Not Reported
	Apo-Naproxen			C		500 Mg, 2x/Day		Not Reported
	Apo-Prednisone			C		5 Mg, Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Ergocalciferol			C	Oral	Unk, 1x/Day		Not Reported
	Folic Acid			C		1 Mg, 1x/Day		Not Reported
	Leucovorin Calcium			C		5 Mg, Weekly		Not Reported
	Pantoprazole			C		40 Mg, 1x/Day		Not Reported
	Tecta			C		1 Df, 1x/Day		Not Reported

	Vitamin C [Ascorbic Acid]			C	Oral	500 Mg, Unk			Not Reported
	Wellbutrin			C		300 Mg, 1x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868639	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019416981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868679	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019414912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1.5 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16868977	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-090935		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Amlodipine			C	Unknown	5 Milligram, Qd		Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Morphine Sulfate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Paroxetine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Simvastatin	C	Unknown	Not Reported
	Statex [Morphine Sulfate]	C	Unknown	Not Reported
	Telmisartan	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Sep-2019	16870211	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA226344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Vitamin C			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Aspirin			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold Radioactive Colloidal			S	Other	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported

	Plaquenil	S	Oral	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	11912599	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-093211		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Xeljanz			S	Oral	50 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Oral	5.0 Milligram, Bid		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Adalimumab		S	Subcutaneous	Unk	Not Reported
	Folic Acid		C	Subcutaneous	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]		C	Unknown	Unk	Not Reported
	Metformin		C	Unknown	2 Dosage Form, Bid	Not Reported
	Insulin		C	Oral	Unk	Not Reported
	Celebrex		C	Unknown	2 Dosage Form, Qd	Not Reported
	Acetaminophen And Codeine		C	Unknown	Unk	Not Reported
	Plaquenil /00072602/		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	2.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	12905519	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Epicondylitis; Eye Disorder; Fatigue; Malaise; Motor Dysfunction; Off Label Use; Pain In Extremity; Pulmonary Mass; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40mg/0.8ml, 40 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	40/0.8 Ml	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Tetanus Vaccine	C	Unknown		Not Reported
	Haemophilus Influenza Type B Vaccine	C	Unknown		Not Reported
	Prevnar 13	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Hib Vaccine	C	Unknown		Not Reported
	Prevnar	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	13057423	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Contraindicated Product Administered; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Eye Disorder; Feeling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Abnormal; Finger Deformity; Foot Deformity; Gait Disturbance; Hyperhidrosis; Intervertebral Disc Protrusion; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Osteoporosis; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Spinal Disorder; Therapeutic Product Effect Incomplete; Vomiting; Wrist Deformity	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Winpred	S	Unknown	Not Reported
	Acetaminophen	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Oral	Not Reported
	Oxycodone Hydrochloride	S	Oral	Not Reported
	Hydromorphone	S	Oral	Not Reported
	Percocet	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Lax-A-Day	C	Unknown	Not Reported
	Fosfomycin Trometamol	C	Unknown	Not Reported
	Macrogol	C	Unknown	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Not Reported
	Monurol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	13070808	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1117		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Asthenia; Contraindicated Product Administered; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Intramuscular	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Losec	C	Unknown	Not Reported
	Celexa	C	Unknown	Not Reported
	Crestor	C	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	14173944	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3423		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Depo Medrol			C	Unknown				Not Reported
		Methylprednisolone Acetate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	14835719	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1296			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Phenoxymethylpenicillin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Penicillin G Procaine			S	Unknown			Not Reported
	Penicillin G Potassium			S	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	15299625	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

		otherwise specified)	
Ciclosporin	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S		Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Hydroxyquine	S		Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Adalimumab	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Humira	S	Unknown	Not Reported

	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	C	Oral	Not Reported
	Plaquenil	C	Subcutaneous	Not Reported
	Plaquenil	C	Subcutaneous	Not Reported
	Arava	C	Oral	Not Reported
	Risedronate	C	Oral	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	15578892	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Decreased	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	15610959	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2842		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Pneumonia; Product Use In Unapproved Indication; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting; X-Ray Abnormal	Enbrel	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	15620153	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555991-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Marijuana			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	15710333	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2585766-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Prednisone		C		Not Reported
	Xeljanz		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	15990259	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2672998-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

		Sulfasalazine			C	Unknown				Not Reported
		Naproxen			C	Unknown				Not Reported
		Leflunomide			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16225724	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA020621			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk (4.0 Years)		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Milligram		Not Reported
	Actemra			S	Unknown	640 Milligram, 1 Every Four Weeks		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk (4.0 Years)		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Sulfate]				
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	200 Milligram, 1 Every Two Week (9 Months)	Not Reported
	Certolizumab Pegol	S	Unknown	200 Milligram, 1 Every Two Week	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk (2.0 Years)	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Piroxicam	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16422056	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019103952		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Voltaren (Diclofenac Sodium)			S				Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S				Glaxosmithkline
	Diclofenac Potassium			S				Glaxosmithkline
	Diclofenac Potassium			S				Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S				Glaxosmithkline

Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac	S			Glaxosmithkline
	Diclofenac	S			Glaxosmithkline
	Vitamin C	S	Unknown	Unk	Glaxosmithkline
	Motrin	S	Unknown	Unk	Glaxosmithkline
	Motrin	S			Glaxosmithkline
	Motrin	S			Glaxosmithkline
	Motrin	S			Glaxosmithkline
	Sulfamethoxazole + Trimethoprim	S	Unknown	Unk	Glaxosmithkline
	Aspirin	S	Oral	Unk	Glaxosmithkline
	Aspirin	S			Glaxosmithkline
	Aspirin	S			Glaxosmithkline
	Aspirin	S			Glaxosmithkline
	Tramadol Hydrochloride	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid Sandoz	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Acetylsalicylic Acid Sandoz	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported

	Humira	S				Not Reported
	Humira	S				Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S				Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S				Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S				Not Reported
	Naprosyn	S	Unknown	Unk		Not Reported
	Naprosyn	S				Not Reported
	Naprosyn	S				Not Reported
	Naprosyn	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16813820	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201906-001612			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vein Occlusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Cellcept			C		Unk		Not Reported
	Prednisolone			C	Oral	Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Magmitt			C		Unk		Not Reported
	Sodium Rabeprazole			C		Unk		Not Reported
	Sodium Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16871601	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-222323		16 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Rash Maculo-Papular; Therapeutic Product Effect Incomplete; Weight Increased	Paracetamol		Y	S	Unknown	Unk		Ohm Lab
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Sun
	Ursodeoxycholic Acid			S	Unknown	100 Milligrams, 1 Pc, Qid		Not Reported
	Cefazolin			C	Unknown	Unk		Not Reported
	Ceftazidime			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	40 Milligram, Bid		Not Reported
	Prednisolone			C	Oral	50 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16871909	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1114578		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling; Malaise; Musculoskeletal Stiffness; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Acetaminophen			S	Oral			Not Reported
	Hydromorphone			S	Oral			Actavis
	Methotrexate			S	Oral			Barr
	Oxycodonehydrochloride			S	Oral			Actavis
	Oxycodone Terephthalate			S	Oral			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2413514			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Nausea	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872279	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000785			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Hydroxychloroquine	S	Oral	400 Mg, Hs		Concordia
	Hydroxychloroquine	S	Unknown	Unk		Concordia
	Leflunomide	S	Unknown	20 Mg		Not Reported
	Methotrexate	S	Oral	25 Mg, Weekly		Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid		Not Reported
	Atorvastatin	S	Oral	40 Mg, Qd		Not Reported
	Vitamin D3	C		Unk		Not Reported
	Asa Ec	C		Unk		Not Reported
	Tylenol	C		Unk		Not Reported
	Folic Acid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872538	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3799			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastric Disorder; Therapeutic Product Effect Decreased; Visual Field Defect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872540	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3817		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Vancomycin			C	Unknown					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872603	EXPEDITED (15-DAY)		OT	CA-ROCHE-2412602		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2412544		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Pantoprazole Magnesium			C	Unknown				Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported
	Zopiclone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872687	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2019M1091542		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown			Not Reported
	Paxil /00830802/			C	Unknown			Mylan
	Aspirin /00002701/			C	Unknown			Mylan
	Vitamin D /07503901/			C	Unknown			Mylan
	Montelukast			C	Unknown			Mylan
	Flomax /01280302/			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872722	EXPEDITED (15-DAY)		DS	CA-ROCHE-2412343		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872794	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019417207		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, 1x/Day		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Levofloxacin			C	Unknown	Unk		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872817	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019418691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			C		15 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872818	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019417192		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Oral	10 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16872945	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019419385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, Once A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Once A Day		Not Reported

	Imuran			S	Unknown	Unk				Not Reported
	Leflunomide			S	Oral	10 Mg, Twice A Week				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873665	EXPEDITED (15-DAY)		OT	CA-ROCHE-2412721		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration- 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration- 9 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration- 15 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			C	Unknown	Therapy Duration-9 Years		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873699	EXPEDITED (15-DAY)		OT	PHHY2019FR226465		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Pericarditis; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873700	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019410488		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Lansoprazole			S	Unknown	Unk		Unknown
	Prednisolone			S	Unknown	Unk		Pfizer
	Ramipril			S	Unknown	Unk		Pfizer
	Exemestane			S	Unknown	Unk		Pfizer
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Metformin Hydrochloride			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
	Dicumarol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16873879	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2946554-00		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Methotrexate	C		Not Reported
	Arava	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Oct-2019	16874201	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019177026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Vitamin C			S	Unknown	Unk		Glaxosmithkline
	Aspirin			S	Oral	Unk		Glaxosmithkline
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold (198 Au) Colloidal			S	Other	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Naproxen			S	Unknown	Unk			Not Reported
	Plaquenil			S	Oral	Unk			Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk			Not Reported
	Tramadol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	13145130	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1000		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported

Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Ciclosporin	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Apo-Cyclosporine	S	Oral	Not Reported

	Certolizumab Pegol	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Cyclic	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cyclosporine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Piroxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	13688270	EXPEDITED (15-DAY)		HO	CA-ROCHE-1953336		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Abnormal; Liver Function Test Increased; Pharyngeal Oedema;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Rash; Swelling; Wheezing	Cimzia			S	Subcutaneous	Not Reported
	Methotrexate Sodium			S	Unknown	Not Reported
	Xeljanz			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	14629140	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031766		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Infliximab			C	Unknown			Not Reported
	Penicillin [Benzylpenicillin]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	15935349	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656800-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Apo Leflunomida	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Digoxin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Furosemide Sodium	C	Unknown	Not Reported
	Hydrochlorothiazide	C		Not Reported
	Naproxen	C		Not Reported
	Nifedipine	C	Unknown	Not Reported
	Palafer	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Toloxin	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Xarelto	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

		Zinc Citrate			C	Unknown				Not Reported
		Synthroid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16875468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2413941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16875902	EXPEDITED (15-DAY)		DS	CA-ROCHE-2414264			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Enbrel		S	Unknown	Not Reported
	Celebrex		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876259	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1115282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Baclofen			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876511	EXPEDITED (15-DAY)		OT	CA-ROCHE-2414153			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876527	EXPEDITED (15-DAY)		OT	CA-ROCHE-2414237		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876623	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1114781		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Eye Disorder; Hyperhidrosis; Intervertebral Disc Protrusion; Joint Swelling;	Hydromorphone Hydrochloride			S	Oral	12 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Malaise; Musculoskeletal Stiffness; Overwork; Peripheral Swelling; Poor Quality Sleep; Therapeutic Product Effect Incomplete; Vomiting	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876845	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2414373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Unknown	Single-Use Vial		Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Plaquenil Sulfate			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Remicade			S					Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876870	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2414098			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S				Not Reported

		Sulfate]								
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Remicade			S					Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876892	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3867		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Arava		S	Oral	Not Reported
	Apo-Naproxen		C	Unknown	Not Reported
	Apo-Prednisone		C	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Ergocalciferol		C	Oral	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Leucovorin Calcium		C	Unknown	Not Reported
	Pantoprazole		C	Unknown	Not Reported
	Tecta		C		Not Reported
	Vitamin C		C	Oral	Not Reported
	Wellbutrin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16876998	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019419406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative Arthritis; Urinary Tract Obstruction	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 1x/Day		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1 Every 2 Days		Not Reported
	Leflunomide			S	Oral	10 Mg, 2x/Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16877009	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019419348		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer

Cartilage Atrophy; Drug Ineffective; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate Sodium	S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium	S	Unknown	20 Mg, Weekly		Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly		Pfizer
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Leflunomide	C	Oral	10 Mg, 1x/Day		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Sulfasalazine	C		1.5 G, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16877124	EXPEDITED (15-DAY)		OT	PHHY2019RO227042		66 YR	Male	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Product Use In Unapproved Indication	Methotrexate			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16878164	NON-EXPEDITED			US-ALMIRALL, LLC-2019AQU000170			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Oedema; Ocular Hyperaemia; Product Administration Error	Fluoroplex			S	Topical	Unk		Almirall
	Plaquenil /00072602/			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16878285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107873		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16878452	EXPEDITED (15-DAY)		OT	CA-SA-2019SA268211			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	More Than Or Equal To 2 Gm, Qd		Not Reported
	Prednisone			S		Unk		Not Reported

	Xeljanz			S	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Oct-2019	16878475	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201909000608			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S		Plaquenil Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	13628306	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170602932			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

		Cortisone Acetate			C	Subcutaneous				Not Reported
		Desoximetasone			C	Oral				Not Reported
		Cortisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	14150758	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-2145793-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Dose: 50 Die		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Imuran			C				Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	15930878	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655607-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

					Otezla		S	Unknown	Not Reported
					Plaquenil		S	Unknown	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Not Reported
					Salazopyrin		S	Unknown	Not Reported
					Simponi		S	Subcutaneous	Not Reported
					Sirukumab		S	Unknown	Not Reported
					Sulfasalazine		S	Unknown	Not Reported
					Ustekinumab		S	Unknown	Not Reported
					Xeljanz		S	Oral	Not Reported
					Methotrexate		C	Unknown	Not Reported
					Orencia		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16089642	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06870		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not	Unknown		Not Reported

						otherwise specified)				
		Arava			S	Unknown	Unknown			Not Reported
		Hydroxychloroquine			S	Unknown	Unknown			Not Reported
		Desoximetasone			C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16178457	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738140-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C		Solution		Not Reported
	Imuran			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16222596	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-011524		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic	Metformin Hydrochloride			S	Unknown			Santarus
	Desoximetasone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

Product Effect Decreased	Altace			C						Not Reported
	Asa			C						Not Reported
	Folic Acid			C						Not Reported
	Methotrexate			C						Not Reported
	Rosuvastatin Calcium			C						Not Reported
	Omega 3			C						Not Reported
	Vitamin D Nos			C						Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16738165	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201908000004			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Ocular Toxicity	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Enbrel			C	Subcutaneous	50 Mg, Weekly		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Salazopyrin			C	Unknown	1 G, Bid		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Weekly		Not Reported
	Prednisone			C	Unknown	Unk Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16792327	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1105405			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Prednisone			S				Actavis
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16864184	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019173510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Glaxosmithkline
	Cortison (Cortisone)			C	Unknown	Unk		Not Reported
	Tramadol			C	Oral	Unk Unk, Tid		Not Reported
	Prednisone			C	Oral	Unk Unk, Qd		Not Reported
	Arthrotec			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Plaquenil			C	Oral	Unk		Not Reported
	Synthroid			C	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879259	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2572995-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single Use Pre Filled Syringe		Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879286	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-28555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Levothyroxine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415335		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

		Sulfasalazine			S	Unknown				Not Reported
		Arava			C	Oral				Not Reported
		Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879470	EXPEDITED (15-DAY)		DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2019-06290		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Paxil [Paroxetine Hydrochloride]			C	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Flomax [Tamsulosin Hydrochloride]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879712	EXPEDITED (15-DAY)		OT	CA-ROCHE-2414291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019425337		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Use Disorder; Musculoskeletal Stiffness; Sleep Disorder; Swelling	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Amitriptyline Hydrochloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879826	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019425293		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	3000 Mg, Unk		Pfizer
	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16879999	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1115292		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Baclofen			S	Unknown			Ivax
	Baclofen			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Oral	1000 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfadiazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Vitamin D	C	Oral		Not Reported
	Vitamin D	C	Oral		Not Reported
	Calcium Carbonate	C	Oral	1500 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown	1 Dosage Forms Daily;	Not Reported
	Hydromorphone	C	Oral	4 Milligram Daily;	Not Reported
	Prednisone	C			Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880019	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201909000779			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choroidal Neovascularisation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880135	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000858			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Simponi			S	Unknown	Unknown		Not Reported

	Humira			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Methotrexate			C		Unk				Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415332			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880417	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415378			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880418	EXPEDITED (15-DAY)		OT	CA-ROCHE-2414610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16880785	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2949507-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache;	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Metotrexate			S	Unknown			Not Reported

Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Gold		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Arava		C	Unknown		Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16881067	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415293		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown	79.0 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Oct-2019	16881662	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Arthritis; Systemic Lupus Erythematosus	Arava		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Diclofenac		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	15622706	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555912-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Cyclosporine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Gold	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ciclosporin	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Azathioprine Sodium	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	15731126	EXPEDITED (15-DAY)		OT	CA-SA-2018SA339535			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S		Unk Unk, Unk		Sanofi
	Arava			S		Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Diphenhydramine Hydrochloride			S		Unk		Sanofi
	Celecoxib			S	Oral	Unk, Unk		Not Reported
	Levofloxacin			S		Unk, Unk		Not Reported
	Cyclophosphamide			S		Unk Unk, Unk		Not Reported
	Methotrexate			S		Unk Unk, Unk		Not Reported
	Azithromycin			S		250 Mg, Qd		Not Reported
	Cimzia			S		Unk, Unk		Not Reported

Enbrel	S		Unk, Unk	Not Reported
Humira	S		Unk, Unk	Not Reported
Imuran [Azathioprine Sodium]	S		Unk	Not Reported
Simponi	S		Unk, Unk	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Oral	5 Unk	Not Reported
Xeljanz	S	Oral	5 Unk	Not Reported
Ezetrol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16021802	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010638		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Liver Disorder; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Clindamycin			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Losartan Tablets			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Cephalexin			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Diazide (Hydralazine Hydrochloride)			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Hctz	S	Unknown	Unk	Not Reported
Keflex	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Penicillin G Potassium	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Lopresor	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Tecta	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	50 Milligram, Two Times A Day	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Daily	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Saccharated Iron Oxide	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Atenolol	C	Unknown	Unk	Not Reported
Cipro	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Coversyl	C	Unknown	Unk	Not Reported

	Leucovorin			C	Unknown	Unk			Not Reported
	Levothyroxine Sodium			C	Unknown	Unk			Not Reported
	Ranitidine			C	Unknown	Unk			Not Reported
	Venofer			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16183340	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1070		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16357131	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2169		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Aspirin (E.C.)			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Penicillin G Procaine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Phenoxymethylpenicillin	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Pregabalin	C	Unknown	At Bedtime		Not Reported
	Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16419273	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2816297-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16532063	EXPEDITED (15-DAY)		HO, LT, OT	AU-ROCHE-2348381			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anaphylactic Reaction; Arthritis; Asthma; Blister; Chest Pain; Costochondritis;	Xolair			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

Cough; Device Issue; Dyspnoea; Fatigue; Feeling Abnormal; Gastric Disorder; Headache; Hypoaesthesia; Injection Site Bruising; Musculoskeletal Stiffness; Nausea; Pain; Photosensitivity Reaction; Pleurisy; Pruritus; Rheumatic Disorder; Skin Exfoliation; Suffocation Feeling; Sunburn; Therapeutic Response Unexpected; Vocal Cord Dysfunction	Sulfate]					
	Endep	S	Unknown			Not Reported
	Warfarin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16769626	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2908030-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Clavulin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tocilizumab	S	Unknown			Not Reported
	Amoxicillin Sodium W/Clavulanate Potassium	S	Unknown			Not Reported
	Plaquenil	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Tridural	C	Unknown	Prolonged Release Tablet		Not Reported
	Tylenol	C	Unknown			Not Reported
	Hydroxychloroquine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16798340	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201908000266			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Cardiac Failure Congestive; Cardiomyopathy; Dilatation Ventricular; Ejection Fraction Decreased; Electrocardiogram Qt Prolonged; Toxicity To Various Agents; Treatment Noncompliance; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	Unk, Restarted		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16836962	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-27328		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting			otherwise specified)			
	Anakinra	S	Subcutaneous			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
	Vaccinia Immunoglobulins	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16882999	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Imuran			S	Unknown			Not Reported
	Leflunomide			S	Oral	Twice A Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16883002	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3924		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16883468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2417262		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16883469	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201908-001855			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Exposure During Pregnancy; Intrauterine Infection; Premature Delivery	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod, (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod (Film-Coated Tablet)		Concordia
	Prednisolone			S	Unknown	10 Mg;		Not Reported
	Metronidazole			S	Oral	1.5 G, Qd		Not Reported
	Ciprofloxacin Hydrochloride			S	Oral	800 Mg, Qd		Not Reported
	Cefmetazole Sodium			S	Parenteral	4 G, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	E Keppra			C		Unk		Not Reported
	Predonine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16883547	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Sulfasalazine		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16883865	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018259680		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diabetic Ulcer; Respiratory Tract Congestion	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Cephalexin			C		500 Mg, 4x/Day		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884091	EXPEDITED (15-DAY)		HO	JP-ADVANZ PHARMA-201909000786			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Myalgia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Nexium			C		Unk		Not Reported
	Etizolam			C		Unk		Not Reported
	Livalo			C		Unk		Not Reported
	Denotas			C		Unk		Not Reported

	Pralia			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884097	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884102	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3971			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative Arthritis; Urinary Tract Obstruction	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral	2x/Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884127	EXPEDITED (15-DAY)		LT	CA-ROCHE-2418242		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Urelumab			C	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884273	EXPEDITED (15-DAY)		OT	GB-ACCORD-051287		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy; Premature Labour; Staphylococcal Sepsis; White Blood Cell Count Decreased	Tacrolimus			S	Unknown	Dose Increased To 3 Mg Twice Daily Due To Exacerbation Of Disease And Then Tacrolimus Was Stopped		Not Reported
	Mycophenolic Acid			S				Accord
	Methylprednisolone			S	Intravenous (not otherwise specified)	Treated With Two Doses (500 Mg Per Dose)		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S		400 Milligram Daily		Not Reported
	Prednisolone			S	Oral	20 Mg/Day		Not Reported
	Mycophenolic Acid			S	Unknown	1000 Milligram Daily		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884373	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201909000458			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Pain	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884438	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Simponi				S	Subcutaneous				Not Reported
	Sulfasalazine				S	Unknown				Not Reported
	Xeljanz				S	Unknown				Not Reported
	Acetaminophen				C	Oral				Not Reported
	Diphenhydramine				C	Oral				Not Reported
	Methylprednisolone				C	Intravenous (not otherwise specified)				Not Reported
	Prednisone				C	Unknown				Not Reported
	Hydroxychloroquine				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2417965		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Wellbutrin			C	Unknown	Tablet (Extendedrelease)		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884524	EXPEDITED (15-DAY)		OT	CA-ROCHE-2417993		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	365.0		Not Reported
	Methotrexate			S	Unknown	19.0 Year(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral	2.0 Year(S)		Not Reported
	Sulfasalazine			S	Unknown	2.0 Year(S)		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418235		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884563	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-28852		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported

	Orencia			S	Unknown	Unknown			Not Reported
	Plaquenil			S	Unknown	Unknown			Not Reported
	Rituximab			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown	Unknown			Not Reported
	Tocilizumab			S	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884710	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201908000949			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst	Hydroxychloroquine			S	Unknown			Concordia
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown			Not Reported
	Celecoxib			S	Unknown	Dose As Necessary		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884770	EXPEDITED (15-DAY)		OT	CA-ROCHE-2417856		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration- 7 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration- 129		Not Reported
	Humira			S	Subcutaneous			Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown				Not Reported
		Remicade		S	Intravenous (not otherwise specified)				Not Reported
		Methotrexate		S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884791	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418229		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Injection Bp		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884815	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Sulfasalazine		S	Unknown		Not Reported
	Warfarin Sodium		S	Unknown		Not Reported
	Imuran [Azathioprine]		C	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Xarelto		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884830	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000935			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk (More Than Or Equal To 2 Gm), Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16884943	EXPEDITED (15-DAY)		OT	CA-ROCHE-2420250		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Desoximetasone		C	Unknown		Not Reported
					Diclofenac		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16885114	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2419342		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16885374	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019424228			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Pain; Vomiting	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16886423	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1115648		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate			S	Unknown			Teva
	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Amlodipine Besilate			S	Oral			Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Asacol			S	Unknown	2400 Milligram Daily;		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz			S	Unknown	Not Reported
	Acetaminophen			C	Oral	Not Reported
	Atacand Plus			C		Not Reported
	Bisoprolol Fumarate			C		Not Reported
	Depo-Medrol			C	Intra-articular	Not Reported
	Diphenhydramine			C	Oral	Not Reported
	Ebastine			C		Not Reported
	Ferrous Gluconate			C		Not Reported
	Folic Acid			C		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium			C		Not Reported
	Tylenol [Paracetamol]			C		Not Reported
	Vitamin D3			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16886446	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1115794		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Bisoprolol			S	Unknown			Teva
	Cefaclor			S	Unknown			Teva
	Erythromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Meperidine Hydrochloride	S	Unknown	Not Reported
	Noritate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16886909	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR173512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Imitrex			S		Unk		Glaxosmithkline
	Colchicine			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Januvia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Oct-2019	16887040	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1115959		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Asacol			S	Oral	2400 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Extremity; Peripheral Swelling; Vitamin D Deficiency	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Omega Allergenic Extracts	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	15650356	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-979380		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Bisoprolol			S	Unknown			Teva
	Erythromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Metronidazole			S	Unknown			Actavis
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Cefaclor			S	Unknown			Teva
	Celecoxib			S	Oral	200 Milligram Daily;		Teva
	Pregabalin			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram Daily;		Not Reported
	Demerol			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Lyrica			S	Unknown				Not Reported
	Meperidine Hydrochloride			S	Unknown				Not Reported
	Plaquenil			S	Oral				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16074745	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022317		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Amlodipine Besilate			S	Oral			Teva
	Methotrexate			S	Subcutaneous			Barr
	Asacol			S	Oral	2400 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Tylenol/00020001/			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Oct-2019	16887830	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1115770		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure	Amlodipine Besilate			S	Unknown			Teva

Fluctuation; Blood Pressure Increased; Colitis; Contraindicated Product Administered; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased	Amlodipine Besilate	S	Oral		Teva
	Amlodipine Besilate	S	Oral	5 Milligram Daily;	Teva
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Unknown		Not Reported
	Asacol	S	Unknown	2400 Milligram Daily;	Not Reported
	Diamicron	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported

	Vitamin D3			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	8227536	NON-EXPEDITED		HO, OT	US-AMGEN-USASP2011038849		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Arthralgia; Arthritis; Arthropathy; Back Pain; Bladder Disorder; Blood Urine Present; Bone Density Abnormal; Chest Expansion Decreased; Cough; Device Issue; Fall; Fractured Sacrum; Gait Disturbance; Hip Fracture; Injection Site Erythema; Injection Site Haemorrhage; Injection Site Mass; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Warmth; Joint Fluid Drainage; Joint Range Of Motion Decreased; Joint Swelling; Joint Warmth; Knee Deformity; Malaise; Micturition Urgency; Mobility Decreased; Musculoskeletal Discomfort; Oesophageal Disorder; Osteoporosis; Pain; Pelvic Fracture; Sinus Disorder; Sinusitis; Sleep Apnoea Syndrome; Spider Vein; Therapeutic Product Effect Incomplete; Tooth Repair; Tuberculosis; Vascular	Single Dose Prefilled Autoinjector(Enbrel)			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Once Weekly		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Once Weekly		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Once Weekly		Amgen
	Prolia			S	Unknown	Unk		Amgen
	Fosamax			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Medrol [Methylprednisolone]			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Cortisone			C		Unk		Not Reported
	Zillion			C		Unk		Not Reported

Rupture

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	14516337	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2248990-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Pantoloc			S	Unknown	(Enteric Coated)		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Palafer Cf			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Atenolol			S	Unknown			Not Reported

Abatacept	S	Unknown	Not Reported
Ascorbic Acid	S	Unknown	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Etanercept	S		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Pantoprazole	S		Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	Not Reported
Vitamin C	S	Oral	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Naprosyn E	S	Oral	Not Reported
Palafer	S	Unknown	Not Reported
Celebrex	C	Oral	Not Reported
Celebrex	C		Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C		Not Reported
Celecoxib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	14648140	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018110532		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Remicade Lyophilisat			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Penicillin [Benzylpenicillin]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	14922042	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044319		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia;	Orencia			S	Intravenous (not otherwise specified)	1 Gram		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported

Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 G, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown	15 Milligram, Qd		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	15622004	EXPEDITED (15-DAY)		CA, OT	CA-ABBVIE-18K-028-2557160-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	15627139	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558100-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

Disorder; Swelling;
Therapy Non-Responder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	15713146	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588360-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Phenoxymethylpenicillin			S	Unknown			Not Reported
	Penicillin G Potassium			S	Unknown			Not Reported
	Penicillin G Procaine			S	Unknown			Not Reported
	Pregabalin			C				Not Reported
	Tylenol			C	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	15930315	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2654615-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Irritable Bowel Syndrome; Joint Swelling; Malaise; Nausea; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Arava	S	Unknown	Therapy Duration-3 Years	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration-11 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Form Of Administration-Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Tylenol	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Advil	C	Unknown		Not Reported
	Pregabalin	C			Not Reported
	Folic Acid	C			Not Reported
	Acetaminophen W/Codeine Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16139643	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2723050-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16407938	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2809480-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific	Adalimumab			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Gammagard			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported

Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Naproxen	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone	S	Other	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	Not Reported
	Immunoglobulin (Iggiv)	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16738654	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2968		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Exposure To Communicable Disease;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hip Arthroplasty; Joint Effusion; Joint Stiffness; Localised Infection; Maternal Exposure During Pregnancy; Musculoskeletal Pain; Musculoskeletal Stiffness; Osteoarthritis	Enbrel		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Influenza Vaccine		S	Unknown	Not Reported
	Ibuprofen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16868678	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015257986		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasopharyngitis; Rheumatoid Arthritis	Xeljanz			S		Unk Unk, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Folic Acid			S		Unk		Pfizer
	Plaquenil			S		400 Mg, Daily		Not Reported
	Plaquenil			S		400 Mg, Daily		Not Reported
	Prednisone			S		20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16876804	EXPEDITED (15-DAY)		OT	ES-ACCORD-156175		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy	Methotrexate			S				Accord
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16888902	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2951194-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cymbalta	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889083	EXPEDITED (15-DAY)		OT	CA-ROCHE-2420123		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889254	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2951774-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Risedronate			C	Oral			Not Reported
	Cimzia			C	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported

	Arava	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889383	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2952012-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889547	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2953404-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Nausea; Oral Discomfort; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889643	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019427367		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mantle Cell Lymphoma	Xeljanz			S		Unk		Pfizer
	Methylprednisolone			S				Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889696	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019425636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate Sodium			S	Oral	15 Mg, 1 Every 1 Week		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 1 Month		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported

		Hydroxychloroquine			S	Unknown	Unk			Not Reported
		Lipitor			C	Oral	10 Mg, Daily			Not Reported
		Xeljanz			C	Oral	5 Mg, 2 Every 1 Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889852	EXPEDITED (15-DAY)		OT	CA-ROCHE-2419996			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889888	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4010		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Use Disorder; Musculoskeletal Stiffness; Sleep Disorder; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16889902	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		61 YR	Female	CAN

PHARMA-TREX2019-3972

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Glomerular Filtration Rate Decreased; Haemoglobin Decreased; Lymphocyte Count Decreased; Mean Cell Volume Decreased; Red Cell Distribution Width Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16890025	EXPEDITED (15-DAY)		OT	CA-ROCHE-2420506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Meloxicam			C	Unknown					Not Reported
	Methotrexate			C	Unknown					Not Reported
	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16890078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2420174		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown	Therapy Duration: 5.0 Year(S)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Month(S)		Not Reported
	Apo-Leflunomide			S	Oral	Therapy Duration: 2.0 Year(S)		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5.0 Year(S)		Not Reported
	Humira			S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 790.0		Not Reported
	Methotrexate			S	Unknown	5.0 Year(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 3.0 Year(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 3.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 8.0 Month(S)		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16890454	EXPEDITED (15-DAY)		OT	GB-EMD SERONO-8050214		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown			Not Reported
	Humira			S	Unknown	Solution For Injection In Pre-Filled Pen		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16890816	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2951359-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Oct-2019	16891346	EXPEDITED (15-DAY)		CA	CA-ROCHE-2420455		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Apo-Leflunomide			S	Oral				Not Reported
	Apo-Prednisone			S	Oral				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Indomethacin [Indometacin]			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Oral				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Cymbalta			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	12047889	EXPEDITED (15-DAY)		OT	CA-ROCHE-1708285		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Insulin	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	12890893	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013200			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Folic Acid			S	Unknown	1 Df, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Nexium /01479302/			S	Unknown	40 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Golden Seal /01446501/			C	Unknown			Not Reported

		Remicade			C	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			C	Unknown	Unk			Not Reported
		Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	13833320	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-2059769-00		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Pneumonia; Rash; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Forms		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported

Actemra	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Plaquenil	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Acetaminophen & Cod. Phosp.	C		Not Reported
Celebrex	C	Oral	Not Reported
Hydromorphone Hydrochloride	C		Not Reported
Meloxicam	C		Not Reported
Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	14062373	NON-EXPEDITED			US-AMGEN-USASP2017150699			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Mtx			S	Unknown	Unk		Not Reported
	Mtx			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	15624173	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557355-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methylprednisolone Acetate			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	15712303	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588012-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	15733141	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1974607-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Haemophilus Influenzae			C				Not Reported
	Prevnar 13			C	Intramuscular			Not Reported

	Tetanus Vaccine		C	Unknown	Not Reported
	Hydroxychloroquine		C		Not Reported
	Folic Acid		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16892990	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2847601-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lipitor			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2420199			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Oral				Not Reported
		Desoximetasone			C	Unknown				Not Reported
		Methotrexate			C	Oral				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2420112		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Imuran [Azathioprine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893141	EXPEDITED (15-DAY)		HO	CA-ROCHE-2421476			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893170	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421244		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893188	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421369		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893318	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421481			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cyst; Drug Hypersensitivity; Drug Ineffective; Furuncle; Hand Deformity; Ovarian Neoplasm; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893391	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893510	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-093561		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	15 Milligram		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893554	EXPEDITED (15-DAY)		HO	CA-ROCHE-2421163		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Zostavax			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893676	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2015357696		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Methotrexate Sodium			S		Unk		Pfizer
	Metformin Hcl			S		Unk		Pfizer
	Humira			S		40 Mg, Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893709	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019425951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer

Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Sulfasalazine	S	1 G, 2x/Day	Pfizer
	Diclofenac	S	75 Mg, 2x/Day	Not Reported
	Naproxen	S	500 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unk	Not Reported
	Hydroxychloroquine	C	400 Mg, 1x/Day	Not Reported
	Leflunomide	C	Unk	Not Reported
	Piroxicam	C	20 Mg, 2x/Day	Not Reported
	Prednisone	C	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893741	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421235		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893749	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019428202		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893754	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019427669			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Pain In Extremity; Rheumatoid Lung; Therapeutic Response Decreased	Methotrexate Sodium			S	Oral	25.0 Mg, Unk		Pfizer
	Plaquenil S			S	Oral	200 Mg, Daily		Not Reported
	Lipitor			C		Unk		Not Reported
	Prednisone			C		12.0 Mg, Daily		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893757	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429628		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Liver Function Test Increased; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	2 G, 1x/Day	Pfizer
	Arava		S	Oral	20 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Mg, 1x/Day	Not Reported
	Leflunomide		S	Oral	20 Mg, 1x/Day	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893782	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019428173			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893841	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019428268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Abatacept			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16893851	EXPEDITED (15-DAY)		OT	CA-ROCHE-2422886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16894247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421453			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2424584		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported

	Synthroid			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895389	EXPEDITED (15-DAY)		DS	CA-ROCHE-2421574			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol [Paracetamol]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421564		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16895405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16896168	EXPEDITED (15-DAY)		HO	CA-CIPHER-2019-CA-002725		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Acetylsalicylic Acid/Clopidogrel			S				Not Reported
	Motrin			S				Not Reported
	Naprosyn			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfamethoxazole And Trimethoprim			S				Not Reported
	Tramadol Hydrochloride			S				Cipher
	Arava			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Diclofenac Potassium			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	16896697	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-29165		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Dexamethasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Oct-2019	17022151	DIRECT	Y				34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea; Product Substitution Issue	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	12392584	NON-EXPEDITED		HO, OT	BR-AMGEN-BRASP2013037734		68 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain; Abdominal Pain Upper; Agitation; Alopecia; Arthralgia; Arthritis; Asphyxia; Back Pain; Back Pain; Blister; Blood Pressure Decreased; Cataract; Cataract; Condition Aggravated; Condition Aggravated; Decreased Appetite; Depressed Mood; Diarrhoea; Drug Ineffective; Eating Disorder; Erythema; Fall; Feeling Abnormal; Feeling Abnormal; Gait Inability; Gastrooesophageal Reflux Disease; Hernia; Hypertension; Influenza; Injection Site Induration; Injection Site Pain; Joint Swelling; Musculoskeletal Stiffness; Myopia; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Rheumatoid Arthritis; Splenomegaly; Swelling; Swelling; Syncope; Tooth Disorder; Visual Impairment; Visual Impairment; Weight Decreased; Weight Increased; Wrong Technique In Device Usage Process; Wrong Technique In Product Usage Process	Enbrel			S	Subcutaneous	50 Mg, 1x/Week		Amgen
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
	Enbrel			S	Unknown	Unk Unk, Weekly		Amgen
	Reuquinol			S	Unknown	Unk		Not Reported
	Reuquinol			S				Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Synthroid			C		75 Milligram, 1x/Day		Not Reported
	Synthroid			C		75 Mg, 1x/Day		Not Reported
	Omeprazol			C		20 Milligram, 1x/Day		Not Reported
	Omeprazol			C		25 Milligram, 1x/Day		Not Reported
	Omeprazol			C		20 Mg, 1x/Day		Not Reported
	Omeprazol			C		25 Mg, 1x/Day		Not Reported
	Addera D3			C		Unk		Not Reported
	Addera D3			C		Unk		Not Reported
	Hydroxychloroquine			C		400 Milligram, 1x/Day		Not Reported
	Hydroxychloroquine			C		400 Mg, 1x/Day		Not Reported
	Predsim			C		5 Milligram,1x/Day		Not Reported
	Predsim			C		5 Mg, 1x/Day		Not Reported
	Zylium			C		1 Tablet Of 300 Milligram, Once Daily		Not Reported
	Zylium			C		1 Tablet Of 300 Mg, Once Daily		Not Reported
	Methotrexate			C		15 Milligram, Once Weekly		Not Reported
	Methotrexate			C		15 Mg, Once Weekly		Not Reported
	Folic Acid			C		5 Milligram, Once Weekly		Not Reported
	Folic Acid			C		5 Mg, Once Weekly		Not Reported
	Ranitidine			C		300 Milligram, 1x/Day		Not Reported
	Ranitidine			C		300 Mg, 1x/Day		Not Reported
	Cortisone			C		One Tablet Of 20 Milligram		Not Reported

Cortisone	C	2 Tablets Of 5milligram (10 Milligram), Daily	Not Reported
Cortisone	C	One Tablet Of 20 Mg, Unk	Not Reported
Cortisone	C	2 Tablets Of 5mg (10 Mg), Daily	Not Reported
Esomex	C	Unk	Not Reported
Prednisone	C	Unk	Not Reported
Valium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	12607016	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2011225506		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Arthralgia; Arthritis; Arthropathy; Back Pain; Bladder Disorder; Blood Urine Present; Bone Density Abnormal; Chest Expansion Decreased; Cough; Device Issue; Exposure Via Skin Contact; Fall; Fractured Sacrum; Gait Disturbance; Hip Fracture; Injection Site Erythema; Injection Site Erythema; Injection Site Haemorrhage; Injection Site Mass; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Warmth; Joint Range Of Motion Decreased; Joint Swelling; Joint Warmth; Knee Deformity; Malaise; Micturition Urgency; Mobility Decreased;	Enbrel			S	Subcutaneous	50 Mg, Once Weekly		Unknown
	Enbrel			S		50 Mg, Weekly		Unknown
	Enbrel			S	Subcutaneous	50 Mg, Once Weekly		Unknown
	Enbrel			S	Subcutaneous	50 Mg, Freq:1 Week; Interval: 1		Pfizer
	Enbrel			S		50 Mg, Freq:1 Week; Interval: 1		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Prolia			S		Unk		Not Reported
	Prolia			S	Unknown	Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Medrol			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported

Musculoskeletal Discomfort; Oesophageal Disorder; Osteoporosis; Pain; Pelvic Fracture; Sinus Disorder; Sinusitis; Sleep Apnoea Syndrome; Spider Vein; Swelling; Therapeutic Product Effect Incomplete; Tooth Disorder; Tuberculin Test Positive; Vascular Rupture; Wrong Technique In Product Usage Process	Cortisone	C	Unk	Not Reported
	Cortisone	C	Unk	Not Reported
	Zillion	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	13429026	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017153602		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Sulfasalazine			S	Oral	1 G, 2x/Day (500 Mg 2 Tablets Twice Daily)		Pfizer
	Plaquenil			S	Oral	200 Mg, 2x/Day		Not Reported
	Plaquenil			S	Oral	200 Mg, 1x/Day		Not Reported
	Prednisone			S		10 Mg, Daily		Not Reported
	Fentanyl			C		2 Patches Alternating Every 72 Hours		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	14639150	EXPEDITED (15-DAY)		HO	CA-ROCHE-2083631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	14765400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107058		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	15247879	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2164538			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	15360066	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180447		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	15623850	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2557394-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Encephalitis; Gastrointestinal Infection;	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

Hypoaesthesia; Infection; Injection Site Reaction; Respiratory Tract Infection; Rheumatoid Arthritis	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen		C	Unknown	Not Reported
	Pregabalin		C	Oral	Not Reported
	Prednisone		C	Intramuscular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16004406	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-199780		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyomyositis; Tuberculosis	Hydroxychloroquine			S	Unknown	200 Milligram, Daily		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			S	Unknown	30 Milligram, Daily		Mutual
	Prednisone			S	Unknown	10 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16675083	NON-EXPEDITED		OT	US-ALEXION PHARMACEUTICALS INC.-A201911655			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Dysmorphic Disorder; Hydrocele; Lipodystrophy Acquired; Lupus Nephritis; Muscle Strain; Nasopharyngitis; Proteinuria; Retinal Degeneration; Testicular Pain; Toxicity To Various	Strensiq			S	Unknown	Unk		Alexion
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16694388	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-076394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16871445	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3784		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Otezla	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Remicade Lyophilisat	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Infliximab	C	Unknown	Not Reported
	Penicillin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897043	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4075			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897063	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2953582-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897085	EXPEDITED (15-DAY)		HO	CA-ROCHE-2421379			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897106	EXPEDITED (15-DAY)		OT	ES-TEVA-2019-ES-1118479		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Maculopathy	Hydroxychloroquine		S	Unknown	200 Milligram Daily;			Teva
	Methotrexate		S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2424522			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Actemra			S	Unknown	Ongoing		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Ongoing		Not Reported
	Metformin			S	Unknown	Ongoing		Not Reported
	Colchicine			S	Unknown	Ongoing		Not Reported
	Januvia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897816	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897968	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429983			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Chloroquine			S	Oral	400 Mg, Daily		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	7 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16897991	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429987		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, 2x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	1 Every 2 Week(S)		Not Reported
	Leflunomide			S	Oral	Unk, 1x/Day		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Clopidrogel Sandoz			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

	Ramipril	C	Unk	Not Reported
	Rosuvastatin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898010	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Mental Disorder; Muscle Injury; Myalgia; Off Label Use; Product Use In Unapproved Indication; Pruritus; Rash	Methotrexate Sodium			S	Unknown	15.0 Mg, Weekly		Pfizer
	Cellcept [Mycophenolate Mofetil]			S	Unknown	1.5 G, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300.0 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429615		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate Sodium			S	Oral	20 Mg, 1 Every 1 Week		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2 Every 1 Day		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	600 Mg, 1 Every 1 Month		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898125	EXPEDITED (15-DAY)		OT	CA-ROCHE-2424566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898176	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Pneumonia			otherwise specified)		
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421922		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C	Oral	Dose: Not Specified		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898348	EXPEDITED (15-DAY)		CA, HO	CA-ROCHE-2421895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2421836		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Hydroxychloroquine Sulfate	S	Unknown		Not Reported
					Leflunomide	S	Unknown		Not Reported
					Methotrexate	S	Oral		Not Reported
					Methotrexate	S	Oral		Not Reported
					Orencia	S	Unknown		Not Reported
					Remicade	S	Unknown		Not Reported
					Simponi	S	Unknown		Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Folic Acid	C	Oral		Not Reported
					Pantoprazole	C	Unknown		Not Reported
					Pantoprazole Magnesium	C	Oral		Not Reported
					Tenofovir Disoproxil	C	Unknown		Not Reported
					Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
					Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2422000			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown	Therapy Duration-7.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported

	Atacand			C	Unknown				Not Reported
	Ergocalciferol			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Hydrodiuril			C	Unknown				Not Reported
	Neurontin			C	Unknown				Not Reported
	Premarin			C	Unknown				Not Reported
	Tylenol [Paracetamol]			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16898997	EXPEDITED (15-DAY)		OT	CA-ROCHE-2422144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16899699	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR178757		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Depression	Benlysta Solution For Injection			S	Subcutaneous	Unk		Glaxosmithkline
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16900791	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1118687			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Atorvastatin Calcium			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Oct-2019	16901313	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2952462-00		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Feeling Abnormal; Immunodeficiency; Impaired Quality Of Life; Joint Swelling; Nausea; Paralysis; Polymyalgia Rheumatica; Somnolence; Synovitis; Wrist Surgery	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Baby Aspirin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	13803443	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017110056		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug	Enbrel			S	Unknown	Unk		Amgen

Intolerance; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Aspirin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Penicillin G [Procaine Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Phenoxymethylpenicillin	S	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	650 Milligram, Q8h	Not Reported
	Pregabalin	C	Unknown	50 Milligram, Qd	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Acetaminophen And Codeine Phosphate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	15372414	EXPEDITED (15-DAY)		HO	CA-ROCHE-2182401		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Deafness Neurosensory;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Gabapentin	S	Oral		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C			Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Nasonex	C	Unknown	Spray, Metered Dose	Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Oral		Not Reported
	Omega-3 Fatty Acids	C			Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Tylenol [Paracetamol]	C	Oral		Not Reported
	D-Alpha Tocopherol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	15622544	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556507-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Deafness; Decreased Appetite; Dizziness; Ear Infection; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Humira	S	Subcutaneous	Not Reported
	Aspirin	S	Unknown	Not Reported
	Arava	S	Subcutaneous	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Motrin	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo Sulfatrim	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	15707915	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181203901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Levothyroxine		S	Unknown		Not Reported
					Levothyroxine		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Ramipril		S	Oral		Not Reported
					Ramipril		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	15712732	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587759-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phenoxymethylpenicillin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Penicillin G Procaine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16045301	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1020405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Baclofen			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16719014	EXPEDITED (15-DAY)		HO, OT	JP-BAUSCH-BL-2019-023081		37 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Intrauterine Infection; Maternal Exposure During Pregnancy; Premature Delivery; Retained Placenta Or Membranes	Prednisolone			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Predonine			C				Not Reported
	E Keppra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16850218	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190927824			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Zostavax	S	Subcutaneous	Powder For Suspension		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported
	Desoximetasone	C	Oral			Not Reported
	Diclofenac	C				Not Reported
	Cortisone Acetate	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16868157	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019414710		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission;	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200.0 Mg, 2x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported

Victim Of Crime	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Folic Acid	C		Unk		Not Reported
	Prednisone	C	Oral	5 Mg, 2x/Day		Not Reported
	Restasis	C		Unk		Not Reported
	Sulfasalazine	C	Oral	1000 Mg, 2x/Day		Not Reported
	Synthroid	C		Unk		Not Reported
	Vitamins Nos	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16896867	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2953458-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Penicillin G Procaine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Penicillin G			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Phenoxymethylpenicillin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16896944	EXPEDITED (15-DAY)		HO	CA-ROCHE-2187398		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16901569	EXPEDITED (15-DAY)		OT	CA-ROCHE-2422093			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous	Therapy Duration-8.0 Month(S)		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Magnesium			C	Unknown					Not Reported
	Metformin			C	Unknown					Not Reported
	Esomeprazole			C	Unknown					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16901588	EXPEDITED (15-DAY)		OT	CA-ROCHE-2422180		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown	9.0 Month(S)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration-365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration-731.0		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	731.0		Not Reported
	Methotrexate			S	Oral	731.0		Not Reported
	Sulfasalazine			S	Oral	Therapy Duration- 365		Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16901591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2422256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16901696	EXPEDITED (15-DAY)		OT	CA-ROCHE-2423825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16901823	EXPEDITED (15-DAY)		OT	CA-ROCHE-2423963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Minocycline Hydrochloride		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium		C	Unknown	Not Reported
	Amoxil [Amoxicillin]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902050	EXPEDITED (15-DAY)		DE, HO, OT	US-ZYDUS-041954		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Facial Paresis; Fall; Hemiparesis; Hypoaesthesia; Muscular Weakness; Peroneal Nerve Palsy; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Paroxetine			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Colecalciferol			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Tamsulosin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902100	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

			Plaquenil		S	Unknown				Not Reported
			Hydroxychloroquine		C	Unknown				Not Reported
			Leflunomide		C	Unknown				Not Reported
			Piroxicam		C	Unknown				Not Reported
			Prednisone		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902105	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4095		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902110	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

				Plaquenil S	S	Unknown		Not Reported
				Rituxan	S	Intravenous (not otherwise specified)		Not Reported
				Acetaminophen	C	Unknown		Not Reported
				Aurothiomalate De Sodium	C	Unknown		Not Reported
				Hydrocortisone Valerate	C	Unknown		Not Reported
				Hydromorphone Hydrochloride	C	Unknown		Not Reported
				Hydroxychloroquine	C	Unknown		Not Reported
				Lyderm	C	Unknown		Not Reported
				Myocrisin	C	Unknown	Cyclic	Not Reported
				Naproxen	C	Unknown		Not Reported
				Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902112	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Abatacept			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902115	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4105			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling;	Methotrexate (Trade Name			S	Oral			Not Reported

Pain In Extremity; Rheumatoid Lung; Therapeutic Response Decreased	Unknown)									
	Plaquenil S			S	Oral					Not Reported
	Lipitor			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4086		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902120	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4087			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Tylenol 8 Hr Arthritis Pain		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902503	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019433637		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Rash; Toxic Epidermal Necrolysis	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902531	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019432366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Methotrexate Sodium			S	Other	Unk Unk, 1 Every 1 Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, 1 Every 1 Week		Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S		200 Mg, 2 Every 1 Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported
	Prednisone			C	Oral	15 Mg, 1 Every 1 Day		Not Reported
	Tylenol [Paracetamol]			C		Unk Unk, 4 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902583	EXPEDITED (15-DAY)		OT	CA-ROCHE-2423881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicort [Desoximetasone]	S	Oral	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Not Reported
	Leflunomide	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902814	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2019438088		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Lipitor			S	Unknown	10 Mg, Unk		Pfizer
	Alendronate Sodium			S	Unknown	70 Mg, Weekly		Not Reported
	Flovent			S	Unknown	Unk		Not Reported
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Lasix [Furosemide]			S	Unknown	40 Mg, Unk		Not Reported
	Losec [Omeprazole]			S	Unknown	20 Mg, Unk		Not Reported
	Losec [Omeprazole]			S	Oral	20 Mg, Unk		Not Reported
	Metformin			S	Unknown	500 Mg, 2x/Day		Not Reported
	Metformin			S	Unknown	1000 Mg, Unk		Not Reported
	Nitrazadon			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Mg, 1x/Day		Not Reported

	Prednisone			S	Unknown	5 Mg, Daily			Not Reported
	Prednisone			S	Unknown	5 Mg, 1x/Day			Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk			Not Reported
	Tylenol [Paracetamol]			S	Unknown	500 Mg, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902868	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425616		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Intolerance; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902923	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-065621		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irregular Breathing; Somnolence	Paracetamol			S	Oral	4 Gram		Aurobindo
	Plaquenil			S	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16902998	EXPEDITED (15-DAY)		DE, HO	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-199768		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Htlv-1 Test Positive; Meningitis Bacterial; Strongyloidiasis	Prednisone			S	Unknown	Unk		Mutual
	Methotrexate			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Leflunamide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16904607	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201909000748			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16904614	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201909000954			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Virus Infection; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S		400 Mg		Concordia
	Prednisone			S		Low Dose		Not Reported
	Sertraline			C				Not Reported
	Clonazepam			C				Not Reported
	Gabapentin			C				Not Reported
	Oxycodone			C				Not Reported
	Simvastatin			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16904616	EXPEDITED (15-DAY)		OT	ES-ADVANZ PHARMA-GSH201803-001079			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Mg, Freq: Unk X 1 Days		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16904617	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201909000772			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Intentional Product Use Issue	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16904618	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201909000773			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Headache	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2019	16905424	EXPEDITED (15-DAY)		OT	NL-BAUSCH-BL-2019-055743		11 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Infarction; Cushingoid; Fatigue; Headache; Osteoporosis	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S	Unknown	Attempts To Taper		Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	15389808	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185458		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	15508569	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1075556		60 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Mylan
	Bisoprolol			S	Unknown	Unk		Not Reported
	Leflunomide Sandoz			S	Unknown	Unk		Mylan
	Arthrotec			S	Unknown	Unk		Mylan
	Humira			S	Subcutaneous	400 Milligram		Mylan
	Plaquenil /00072603/			S	Oral	400 Milligram		Mylan
	Ceclor			S	Unknown	Unk		Mylan
	Demerol			S	Unknown	Unk		Mylan
	Celebrex			S	Oral	200 Milligram, Qd		Mylan
	Meperidine Hydrochloride			S	Unknown	Unk		Mylan
	Erythro Base			S	Unknown	Unk		Mylan
	Arava			S	Unknown	Unk		Mylan
	Lyrica			S	Unknown	Unk		Mylan
	Norfloxacin			S	Unknown	Unk		Mylan
	Erythromycin			S	Unknown	Unk		Mylan
	Prednisone			S		Unk		Mylan
	Levofloxacin Hemihydrate			S		Unk		Mylan
	Sulfasalazine			S	Unknown	Unk		Mylan
	Leflunomide			S	Unknown	Unk		Mylan
	Levofloxacin			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16856065	EXPEDITED (15-DAY)		DE, DS, HO, OT	US-ADVANZ PHARMA-201909000768			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cognitive Disorder; Facial Paresis; Fall; Gait Disturbance; Hemiparesis; Hypoaesthesia; Muscular Weakness; Off Label Use; Peroneal Nerve Palsy; Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Paxil			C		Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Flomax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16905016	EXPEDITED (15-DAY)		CA	JP-BAUSCH-BL-2019-057587			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haemorrhage Neonatal; Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Prednisolone			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Methotrexate		S	Oral	Not Reported
					Methotrexate		S	Oral	Not Reported
					Myochrysine		S	Intramuscular	Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906555	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective For Unapproved Indication; Drug Intolerance; Fatigue; Mental Disorder; Muscle Injury; Myalgia; Product Use In Unapproved Indication; Pruritus; Rash	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906558	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4143			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Chloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Prednisone		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906560	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4135		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Aspirin			C	Unknown			Not Reported
	Clopidrogel Sandoz			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906561	EXPEDITED (15-DAY)		HO	CA-ROCHE-2425931		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Seronegative Arthritis;	Rituxan			S	Intravenous drip			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Orencia		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Naprosyn [Naproxen]		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4151		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Ill-Defined Disorder; Joint Swelling; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Every 1 Day		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425606			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16906691	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907018	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-065171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine			S	Unknown	Unk		Aurobindo
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Naproxen			S	Unknown	Unk				Not Reported
	Sulfasalazine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907259	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425785		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2426901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

	Enbrel			C	Unknown					Not Reported
	Methotrexate			C	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907670	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425921		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907682	EXPEDITED (15-DAY)		CA, DS, OT	FR-AUROBINDO-AUR-APL-2019-065846			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol			S	Transplacental	Unk		Aurobindo
	Keppra			S	Transplacental	Unk		Not Reported
	Plaquenil			S	Transplacental	Unk		Not Reported
	Trileptal			S	Transplacental	Unk		Not Reported
	Actonel			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Transplacental	Unk		Not Reported
	Diffu-K			C	Transplacental	Unk		Not Reported
	Cortancyl			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907773	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2019-FR-001608			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907783	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2019-FR-001609			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine		S	Unknown	400 Milligram, Qd		Ipca
	Prednisone		C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16907941	EXPEDITED (15-DAY)		OT	GB-ROCHE-2425547			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gestational Diabetes; Maternal Exposure During Pregnancy; Premature Labour; Staphylococcal Sepsis	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Prednisolone			S	Oral	20 Mg/Day		Not Reported
	Prednisolone			S	Oral	30 Mg Daily		Not Reported
	Azathioprine			S	Unknown	50 Mg Per Day; Later Increased To 75 Mg/Day		Not Reported
	Azathioprine			S	Unknown	75 Mg Daily		Not Reported
	Tacrolimus			S	Unknown	4 Milligram Daily;		Not Reported
	Tacrolimus			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16908322	EXPEDITED (15-DAY)		OT	CA-ROCHE-2425980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16908361	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2019438401		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atorvastatin Calcium			S	Unknown	10 Mg, Unk		Pfizer
	Alendronate Sodium			S	Unknown	70 Mg, Weekly (1 Every 1 Week(S))		Not Reported
	Combivent			S	Unknown	Unk		Not Reported
	Flovent			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	40 Mg, Unk		Not Reported
	Metformin			S	Unknown	500 Mg, 2x/Day		Not Reported
	Nitrazadon			S	Unknown	10 Mg, Unk		Not Reported
	Omeprazole Magnesium			S	Oral	20 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	5 Mg, 1x/Day		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			S	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16908428	EXPEDITED (15-DAY)		DE, HO	CA-MYLANLABS-2019M1096084		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Disseminated Varicella Zoster Vaccine Virus Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Thrombocytopenia	Methotrexate			S	Unknown	Administered 6 Days A Week; Ongoing For 3 Years		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Tapered One Month Prior To Presentation		Mylan

Zostavax Ii	S	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16908466	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019434382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Methotrexate Sodium			S	Subcutaneous	15 Mg, 4 Every 1 Week		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	776 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, 4 Every 1 Week		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month		Not Reported
	Xeljanz			C	Oral	5.0 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16908585	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019433611			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S	Oral	7.5 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16909274	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019434324			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Dizziness; Gastrointestinal Disorder;	Methotrexate Sodium			S	Subcutaneous	10.0 Mg, Weekly		Unknown

Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Methotrexate Sodium	S	Oral	10 Mg, Weekly		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Leucovorin	S	Oral	5.0 Mg, Weekly		Pfizer
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide	S	Oral	10.0 Mg, 1 Every 1 Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Arava	C		Unk		Not Reported
	Calcium Citrate/Magnesium Citrate	C		Unk		Not Reported
	Citalopram Hydrobromide	C		10.0 Mg, Unk		Not Reported
	Clobetasol Propionate	C	Topical	Unk		Not Reported
	Escitalopram Oxalate	C		10.0 Mg, Unk		Not Reported
	Naproxen	C	Oral	250.0 Mg, Unk		Not Reported
	Pantoprazole Magnesium	C		Unk, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16909277	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019433662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Macrobid [Clarithromycin]			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2019	16910601	EXPEDITED (15-DAY)			US-ELI_LILLY_AND_COMPANY-US201910002065			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Diarrhoea; Fall; Post Procedural Complication	Cialis	S	Unknown	Unk, Unknown		Not Reported
	Cialis	S				Not Reported
	Humira	S	Subcutaneous	40 Mg, 2/M		Not Reported
	Humira	S	Subcutaneous	40 Mg, 2/M		Not Reported
	Humira	S				Not Reported
	Trospium Chloride	S	Unknown	Unk, Unknown		Not Reported
	Hydrochlorothiazide	S	Unknown	Unk, Unknown		Not Reported
	Valsartan	S	Unknown	Unk, Unknown		Not Reported
	Valsartan	S				Not Reported
	Folic Acid	S	Unknown	Unk, Unknown		Not Reported
	Metformin	S	Unknown	Unk, Unknown		Not Reported
	Tamsulosin	S	Unknown	Unk, Unknown		Not Reported
	Tamsulosin	S				Not Reported
	Methotrexate	S	Unknown	Unk, Unknown		Not Reported
	Methotrexate	S				Not Reported
	Vitamin D3	S	Unknown	Unk, Unknown		Not Reported
	Centrum A To Zinc	S	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Unknown		Not Reported
	Omeprazole	S	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2019	16910626	EXPEDITED (15-DAY)		OT	CA-ROCHE-2427570			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varenicline Tartrate	S	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2019	16910643	EXPEDITED (15-DAY)		OT	CA-ROCHE-2427828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Intramuscular				Not Reported
	Apo Hydroxyquine			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2019	16910644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2426764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2019	16911045	EXPEDITED (15-DAY)		OT	CA-ROCHE-2426906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous drip				Not Reported
	Enbrel			S	Unknown				Not Reported
	Gold			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Methotrexate			S	Other				Not Reported
	Methotrexate			S	Oral				Not Reported
	Orencia			S	Unknown				Not Reported
	Celebrex			C	Unknown				Not Reported
	Leflunomide			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2019	13603697	EXPEDITED (15-DAY)		OT	CA-ROCHE-1939731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Kineret			S	Unknown	100mg Per Syringe Single-Use; Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

						otherwise specified) Intravenous			
		Simponi			S	Subcutaneous			Not Reported
		Hydroxychloroquine Sulfate			S	Unknown			Not Reported
		Gold			S	Unknown			Not Reported
		Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2019	15169828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2156441		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2019	16081419	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-013538		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Metronidazole	S	Unknown	5 Milligram	Aurobindo
	Levofloxacin	S	Unknown	Unk	Aurobindo
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Milligram, Daily	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400.0 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Every Week	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400.0 Milligram, Daily	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo Bisoprolol	S	Unknown	Unk	Not Reported
	Apo Leflunomida	S	Unknown	Unk	Not Reported
	Apo-Norflox	S	Unknown	400 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Erythro Base	S	Unknown	Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2019	16455799	NON-EXPEDITED		OT	CA-AMGEN-CANSL2019096874		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Gastric Ulcer; Injection Site Discolouration; Injection Site Pain; Knee Arthroplasty; Urinary Tract Infection	Single Dose Prefilled Autoinjector(Enbrel)			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Candesartan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Oct-2019	16911550	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1119695			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine Besilate			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	15188313	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159087			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16387453	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-209652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Drug Ineffective; Mechanic'S Hand	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			S	Oral	20 Milligram, Daily		Mutual
	Prednisone			S				Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16876893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3828		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Victim Of Crime	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Synthroid	C	Unknown	Not Reported
	Vitamins Nos	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16912142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2427750		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S			Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16912543	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-066264		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Risedronate			S	Unknown	35 Milligram, Once A Week		Aurobindo
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram, Cyclical		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	300 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Methotrexate	S	Subcutaneous	17.5 Milligram		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Risedronate	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16912645	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1119830		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16912678	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1119826			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Joint Swelling; Peripheral Swelling; Skin Laceration; Skin Ulcer; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Rosuvastatin Calcium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Allopurinol			C	Unknown	200 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913061	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4182		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Rash; Toxic Epidermal Necrolysis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913080	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hip Arthroplasty	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913109	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913173	EXPEDITED (15-DAY)		HO	CA-ROCHE-2428710		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

	Alendronate			C	Unknown					Not Reported
	Ciclosporin			C	Unknown					Not Reported
	Prednisone			C	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913600	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019434328		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Visual Impairment	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil S			S	Oral	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Macrobid [Clarithromycin]			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913619	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019434441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk, 2x/Day		Not Reported
	Marijuana			C		Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913625	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019434354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate Sodium	S	Unknown	Unk Unk, Weekly		Pfizer
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913655	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019434331			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Methotrexate Sodium			S		25.0 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		400.0 Mg, Unk		Not Reported
	Leflunomide			S		20.0 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16913874	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019436751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16914132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2427428		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16914395	EXPEDITED (15-DAY)		OT	US-SA-2019SA277443		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chylothorax; Cough; Dyspnoea; Empyema; Pneumothorax; Pulmonary Cavitation; Tachycardia	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methamphetamine [Metamfetamine]			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16914685	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019436759		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-	Methotrexate Sodium			S	Unknown	25 Mg, Weekly (1 Every 1 Week)		Pfizer

Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Actemra	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16914686	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019436787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day		Not Reported
	Synthroid			S	Oral	175 Ug, 1x/Day		Not Reported
	Prednisone			C	Unknown	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16914689	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019438751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Oct-2019	16915025	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-057042		70 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Infection; Bone Abscess; Cachexia; Calcinosis; Delirium; Dermal Sinus; Enterobacter Infection; Mycobacterium Avium Complex Infection; Peptostreptococcus Infection; Sepsis	Prednisolone			S	Unknown			Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rivaroxaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	14545537	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-012117		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthrodesis; Arthropathy; Bone Erosion; Condition Aggravated; Drug Ineffective; Fall; Foot Deformity; Hand Deformity; Impaired Work Ability; Infection; Joint Dislocation; Joint Prosthesis User; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Off Label Use; Pneumonia; Post Procedural Infection; Rheumatoid Arthritis; Rheumatoid Factor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Qd		Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported

Positive; Rheumatoid Nodule; Sensitivity To Weather Change; Synovitis; Treatment Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16808217	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201812-004195			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Crepitations; Cushingoid; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride			S	Oral	75 Mg, Qd		Not Reported
	Naproxen			S	Oral	1000 Mg, Qd		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Naproxen			S	Oral	250 Mg, Bid		Not Reported
	Naproxen			S	Oral	1000 Mg, Qd		Not Reported
	Meloxicam			S	Unknown	150 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Ranitidine Hydrochloride			S	Unknown	300 Mg, Qd		Not Reported
	Ranitidine Hydrochloride			S	Oral	150 Mg, Bid		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	150 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Weekly		Not Reported
	Pantoprazole			S	Oral	Unk		Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Pregabalin			S	Oral	300 Mg, Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported

Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Mobicox (Meloxicam)		S	Unknown	Unk	Not Reported
	Adalimumab		S	Subcutaneous	40 Mg, Unk	Not Reported
	Acetaminophen;Oxycodone Hydrochloride		S	Unknown	Unk	Not Reported
	Depo-Medrol		S	Intra-articular	Unk	Not Reported
	Enbrel		S	Subcutaneous	50 Mg, Weekly	Not Reported
	Esomeprazole Sodium		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk Solution	Not Reported
	Methylprednisolone Acetate		S	Intra-articular	Unk	Not Reported
	Tofacitinib Citrate		S	Oral	10 Mg, Qd	Not Reported
	Esomeprazole Magnesium;Naproxen		S	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]		S	Oral	Unk	Not Reported
	Oxycocet		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	10 Mg, Qd	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Oral	2 Dosage Form, Qd	Not Reported
	Imuran [Azathioprine Sodium]		S	Unknown	150 Mg, Unk	Not Reported
	Plaquenil		C		Unk	Not Reported
	Folic Acid		C		Unk	Not Reported
	Celebrex		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16844381	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3597			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Amoxicillin Trihydrate-Clavulanate Potassium			S	Unknown			Not Reported

	Avelox			S	Oral					Not Reported
	Hydroxychloroquine Sulfate			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917108	EXPEDITED (15-DAY)		OT	CA-ROCHE-2428447		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
		Sulfasalazine			S		Oral			Not Reported
		Xeljanz			C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917125	EXPEDITED (15-DAY)		OT	CA-ROCHE-2429093			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917148	EXPEDITED (15-DAY)		OT	CA-ROCHE-2428516			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Tocilizumab			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Simponi			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Cimzia			C	Unknown				Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917216	NON-EXPEDITED			US-TEVA-2019-US-1122453			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917378	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Synthroid			S	Oral			Not Reported

		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917379	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917383	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4275			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917392	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4238			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917394	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4215			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917455	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4226		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Visual Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil S			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Macrobid			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917456	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Macrobid			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917458	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16917468	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16918282	EXPEDITED (15-DAY)		OT	CA-ROCHE-2428458		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported

Leflunomide	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16918296	EXPEDITED (15-DAY)		DE, OT	US-FRESENIUS KABI-FK201911246		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Hypoxia; Lung Abscess; Pneumonia Bacterial; Pneumonia Pseudomonal	Methylprednisolone (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16920023	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1096575		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Systemic Lupus	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Oct-2019	16921034	EXPEDITED (15-DAY)		OT	PHHY2019FR227528		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Toxic Skin Eruption	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg, Q2w		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			C	Unknown	1.5 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	10053515	NON-EXPEDITED		OT	US-PFIZER INC-2014090886		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Condition Aggravated; Nasopharyngitis; Pneumonia; Pyrexia; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Prednisone			C		5 Mg, Daily		Not Reported
	Folic Acid			C		1 Mg, Daily		Not Reported
	Levothyroxine			C		112 Ug, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	13058525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015728		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

	Gold			S	Unknown	Unk			Not Reported
	Imuran /00001501/			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16291710	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121071			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16293529	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121111			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Spinal Compression Fracture	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk, Unk		Not Reported

	Enbrel			S	Unknown	Unk, Unk		Not Reported
	Humira			S	Unknown	Unk, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16344039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017315344		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Hypersensitivity; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Penicillin G Procaine			S	Unknown	Unk		Pfizer
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Aspirin (E.C.)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Phenoxymethylpenicillin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Pregabalin			C	Unknown	50 Milligram, Qd		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16795508	EXPEDITED (15-DAY)		OT	PHHY2019AR210726			Unknown	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Electrocardiogram Pr Prolongation; Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Transplacental	200 Mg/Dl		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16838921	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000718			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd (Lower Dose)		Concordia
	Methotrexate			S	Subcutaneous	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16912630	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1119561		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol Fumarate			S	Unknown			Teva
	Bisoprolol Fumarate			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported

	Ceclor	S	Unknown			Not Reported
	Celebrex	S	Oral	200 Milligram Daily;		Not Reported
	Demerol	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Lyrica	S	Unknown			Not Reported
	Meperidine Hydrochloride	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Oral			Not Reported
	Metronidazole	S	Unknown			Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Erythromycin	S	Unknown			Not Reported
	Erythromycin Estolate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16922690	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001178			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Tuberculosis	Hydroxychloroquine			S	Unknown			Concordia
	Remicade			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16922703	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4258		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hepatic Enzyme Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Pyrexia; Rheumatoid Arthritis	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16922705	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2019-4273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leucovorin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Citrate/;Magnesium Citrate			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported
	Clobetasol Propionate			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Magnesium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16922771	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4307		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16922987	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-GSH201710-005697			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiocentric Lymphoma; Pain Of Skin; Skin Lesion; Skin Odour Abnormal	Hydroxychloroquine			S	Unknown	400 Mg,Unk		Concordia
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Folic Acid			C		5 Mg, Qd		Not Reported
	Atenolol			C		50 Mg		Not Reported
	Prazosin			C		2 Mg		Not Reported
	Ramipril			C		10 Mg		Not Reported
	Acetylsalicylic Acid			C		100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16923495	EXPEDITED (15-DAY)		OT	CA-ROCHE-2428507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16923640	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-067021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis	Sertraline Capsules			S	Unknown	100 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Belimumab			S	Unknown	930 Milligram		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16923868	EXPEDITED (15-DAY)		OT	NVSC2019NL001729		29 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Infarction; Cushingoid; Fatigue; Headache; Osteoporosis; Weight Increased	Prednisolone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Clopidogrel			C	Unknown	Unk		Not Reported
	Bisphosphonates			C	Unknown	Unk		Not Reported
	Cholecalciferol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16924223	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1095257			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Infarction; Cushingoid; Osteoporosis; Weight Increased	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Carbasalate Calcium			C	Unknown			Mylan
	Clemastine			C	Intravenous (not otherwise specified)			Mylan
	Prednisolone			C	Intravenous (not otherwise specified)			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16925228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2428587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Wellbutrin	C	Unknown	Extended Release		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16925401	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2019AMR185029			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant	Belimumab Subcutaneous			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Aralen			S	Unknown	Unk		Not Reported
	Atabrine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16925667	EXPEDITED (15-DAY)		OT	CA-SA-2019SA280270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Anxiety; Burning Sensation; Drug Ineffective; Hypoaesthesia; Infection; Juvenile Idiopathic	Leflunomide			S	Oral	10 Mg, Unk		Sanofi
	Leflunomide			S	Oral	20 Mg, Unk		Sanofi
	Leflunomide			S	Oral	10 Mg, Unk		Sanofi

Arthritis; Nausea; Neuropathy Peripheral	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Sanofi
	Sulfasalazine	S		2000 Mg, Unk		Not Reported
	Celexa [Celecoxib]	C	Oral	20 Mg, Qw		Not Reported
	Tri-Cyclen Lo	C	Oral	1 Df, Qd		Not Reported
	Cholecalciferol	C	Oral	1000 U, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16925730	EXPEDITED (15-DAY)		OT	NVSC2019US001235		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Infectious Pleural Effusion; Pneumothorax; Pulmonary Cavitation; Pulmonary Mass; Tachycardia	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methamphetamine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16926182	EXPEDITED (15-DAY)		HO, OT	GR-BAUSCH-BL-2019-057288		44 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Condition Aggravated; Drug Ineffective; Ileus Paralytic; Intestinal Ischaemia; Quadriparesis; Sensory Disturbance	Prednisolone			S	Unknown			Bausch And Lomb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16926266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2430501		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16927481	NON-EXPEDITED		HO, OT	US-JAZZ-2019-US-012238			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Dermatomyositis; Intestinal Ischaemia	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4 G, First Dose		Jazz
	Xyrem			S	Oral	3 G, Second Dose		Jazz
	Morphine Sulf			C		Unk		Not Reported
	Azelastine			C		Unk		Not Reported
	Fluticasone Propionate			C		Unk		Not Reported
	Oxycodone Hydrochloride W/Oxycodone Terephtha			C		10-325 Mg		Not Reported
	Oxycodone Hydrochloride W/Oxycodone Terephtha			C		5-325 Mg		Not Reported

Synthroid	C	137 Mg	Not Reported
Synthroid	C	100 Mg	Not Reported
Humatrope	C	Unk	Not Reported
Toviaz	C	Unk	Not Reported
Biotin	C	Unk	Not Reported
Calcium Carbonate And Vitamin D	C	Unk	Not Reported
Cymbalta	C	Unk	Not Reported
Cymbalta	C	Unk	Not Reported
Cymbalta	C	Unk	Not Reported
Ipratropium	C		Not Reported
Miralax	C	Unk	Not Reported
Mometasone Furoate	C	Unk	Not Reported
Pantoprazole Sodium	C	Unk	Not Reported
Restasis	C	Unk	Not Reported
Simvastatin	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Klor-Con	C	Unk	Not Reported
Vitamin D3	C	Unk	Not Reported
Acetazolamide	C	Unk	Not Reported
Aspirin 81	C	Unk	Not Reported
Botox	C	Unk	Not Reported
Climara	C	Unk	Not Reported
Fluconazole	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Nutropin Aq Nuspin	C	Unk	Not Reported
Plavix	C	Unk	Not Reported
Proair Hfa	C	Unk	Not Reported
Promethazine	C	Unk	Not Reported
Metoclopramide	C		Not Reported

Toprol	C	Unk	Not Reported
Lorazepam	C	1 Mg	Not Reported
Lorazepam	C	2 Mg	Not Reported
Primidone	C	Unk	Not Reported
Alka-Seltzer	C	Unk	Not Reported
Armour Thyroid	C		Not Reported
Baclofen	C		Not Reported
Bumetanide	C		Not Reported
Cinnamomum Verum	C		Not Reported
Cortisone Acetate	C	Unk	Not Reported
Cromoglicic Acid	C	Unk	Not Reported
Flonase Allergy Relief	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Hypromellose	C		Not Reported
Zingiber Officinale	C		Not Reported
Hydromorphone	C	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Methadone Hcl	C	Unk	Not Reported
Mupirocin	C	Unk	Not Reported
Nystatin And Triamcinolone	C		Not Reported
Omeprazole	C	Unk	Not Reported
Pataday	C	Unk	Not Reported
Somatropin	C	Unk	Not Reported
Thera Tears	C		Not Reported
Trimethobenzamide	C	Unk	Not Reported
Xiidra	C		Not Reported
Ondansetron	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Oct-2019	16929313	DIRECT		DS			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Dysuria; Fatigue; Flank Pain; Headache; Impaired Work Ability; Myalgia; Product Substitution Issue; Pyrexia; Treatment Failure	Hydroxychloroquine Sulfate	S	Oral	Quantity:60 Tablet(S);		Dr Reddys
	Moduretic 5/50	C				Not Reported
	Multivitamin	C				Not Reported
	Potassium 20 Meq	C				Not Reported
	Gabapentin 300 Mg	C				Not Reported
	Vyvanse 50mg	C				Not Reported
	Ibuprofen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	14858480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114658		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	15023566	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2140626		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	15882869	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004801		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Drug Ineffective; Rash	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Mesalamine			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Entocort			C	Oral	9 Milligram Daily;		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported

	Infliximab			C	Intravenous (not otherwise specified)				Not Reported
	Infliximab			C	Intravenous (not otherwise specified)				Not Reported
	Infliximab			C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16281597	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2771777-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16293530	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Arava			S	Unknown	Unk		Sanofi
	Paracetamol			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi

	Prednisone		S	Unknown	12.5 Mg 1 Every 2 Days	Not Reported
	Morphine Sulfate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk Unk, Unk	Not Reported
	Gold		S	Unknown	Unk, Unk	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Indomethacin [Indometacin]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16536204	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019286454		87 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Chronic Obstructive Pulmonary Disease; Diarrhoea; Gait Disturbance; Insomnia	Xeljanz			S		5 Mg, Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16710985	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888276-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution Dosage Form		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Simponi			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16718777	EXPEDITED (15-DAY)		DS	CA-ABBVIE-18K-028-2461768-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16823986	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019390139		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Arthralgia; Blister; Chills; Erythema; Lethargy; Neutrophil Count Increased; Oedema; Pain; Pain Of Skin; Palmar Erythema;	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported

Pyrexia; Rash Pruritic; Rash Pustular; Rebound Effect; Skin Exfoliation; Swelling; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16928373	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4340		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Cystitis; Gastric Ulcer; Knee Arthroplasty; Urinary Tract Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16930559	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1097400		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chylothorax; Mycobacterium Fortuitum Infection; Pneumonia; Pulmonary Cavitation; Pyopneumothorax	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16931651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2432803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16931652	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019GSK185413			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Premature Baby	Azathioprine			S	Transplacental	Unk		Glaxosmithkline
	Aspirin			S	Transplacental	Unk		Glaxosmithkline
	Tacrolimus			S	Transplacental	Unk		Glaxosmithkline
	Tacrolimus			S	Transplacental	Unk, Dose Increased		Glaxosmithkline
	Epoprostenol			S	Transplacental	2 Ng/Kg, Unk, Per Minute		Glaxosmithkline
	Epoprostenol			S	Transplacental	12 Ng/Kg, Unk, Per Minute		Glaxosmithkline
	Betamethasone			S	Transplacental	Unk		Glaxosmithkline
	Magnesium (Magnesium Salt)			S	Transplacental	Unk		Glaxosmithkline
	Furosemide			S	Transplacental	Unk, Higher-Dose		Glaxosmithkline
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Transplacental	15 Mg, Qd		Not Reported
	Lisinopril			S		Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Enoxaparin			S				Not Reported
	Enoxaparin			S				Not Reported
	Enoxaparin			S				Not Reported

	Enoxaparin			S				Not Reported
	Metoprolol			S	Transplacental	Unk, Higher-Dose		Not Reported
	Metoprolol			S	Transplacental	Unk, Increasing Doses		Not Reported
	Methyldopa			S	Transplacental	Unk, Increasing Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16931807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16931809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Oct-2019	16931955	EXPEDITED (15-DAY)		DE	NVSC2019AU003176			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	13344458	EXPEDITED (15-DAY)		OT	CA-ROCHE-1904129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Codeine			C				Not Reported
	Darifenacin Hydrobromide			C				Not Reported
	Desoximetasone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dilaudid			C				Not Reported
	Hydromorphone			C				Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Unknown			Not Reported

	Kineret	C	Unknown	Not Reported
	Lasix [Furosemide]	C		Not Reported
	Loperamide	C		Not Reported
	Morphine Sulfate	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C		Not Reported
	Kadian	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	13908303	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982381		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	14747056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105435		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Winpred			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	15733341	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2594198-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Contraindicated Product Administered; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Oral	Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Not Reported
					Simponi		S	Subcutaneous	Not Reported
					Hydroxychloroquine		S	Oral	Not Reported
					Hydroxychloroquine		S	Unknown	Not Reported
					Gold		S	Unknown	Not Reported
					Plaquenil		S	Oral	Not Reported
					Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	15935328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657069-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

		Lyrica			C	Oral				Not Reported
		Prednisone			C	Oral				Not Reported
		Xeljanz			C	Oral				Not Reported
		Arava			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	15940434	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658633-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like Illness; Insomnia; Nasopharyngitis; Pain In Jaw; Pelvic Prolapse; Post Procedural Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Calcium Folinate			S	Oral			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Metformin W/Sitagliptin			C	Oral			Not Reported
	Perindopril Erbumine			C	Oral			Not Reported
	Rabeprazole			C	Oral			Not Reported

Pregnancy; Off Label Use; Premature Rupture Of Membranes	Magnesium Oxide	C	Tablet) Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16932991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2433486		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933000	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2962653-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemoglobin Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Vimovo			S	Unknown	Delayed And Immediate Release		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported

Septra	S	Unknown		Not Reported
Ratio-Oxycocet	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Pantoloc	S	Oral	Enteric Coated	Not Reported
Oxycodone And Acetaminophen	S	Unknown		Not Reported
Naproxen	S	Oral	Enteric Coated	Not Reported
Methotrexate	S	Subcutaneous	Solution	Not Reported
Methotrexate	S	Oral		Not Reported
Methylprednisolone Sodium Succinate	S	Unknown	Injection	Not Reported
Mobicox	S	Oral		Not Reported
Imuran	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Apo-Ranitidine	S	Oral		Not Reported
Apo-Ranitidine	S	Oral		Not Reported
Lyrica	S	Oral		Not Reported
Lyrica	S	Oral		Not Reported
Depo-Medrol	S	Intra-articular		Not Reported
Bactrim	S	Unknown		Not Reported
Bactrim	S			Not Reported
Apo-Naproxen	S	Oral	Enteric Coated (500 Mg)	Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Meloxicam	S	Unknown		Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Elavil	S	Oral	10mg/5ml	Not Reported
Amitriptyline	S	Oral		Not Reported
Apo-Amitriptyline	S	Oral		Not Reported
Esomeprazole Magnesium Trihydrate	S	Unknown		Not Reported

	Esomeprazole	S	Unknown	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Trimethoprim	S	Unknown	Not Reported
	Ranitidine	S	Oral	Not Reported
	Pantoprazole	S	Oral	Not Reported
	Amitriptyline Pamoate	S	Oral	Not Reported
	Amitriptyline Hydrochloride	S	Oral	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Oxycocet	S	Oral	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Celecoxib	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2434369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Other			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933547	EXPEDITED (15-DAY)		OT	CA-ROCHE-2432360			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933623	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2434606		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism;	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Humira		S	Subcutaneous	Not Reported
	Humira		S		Not Reported
	Ilaris		S	Unknown	Not Reported
	Ilaris		S		Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S		Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sodium Aurothiomalate		S		Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2434641		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported

					Orencia		S	Subcutaneous			Not Reported
					Remicade		S	Intravenous (not otherwise specified)			Not Reported
					Xeljanz		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933796	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2434624		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16933819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2434657		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16934085	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201807-002648			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Axonal Neuropathy; Hospitalisation; Multiple Sclerosis; Product Use Issue; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Enbrel			S	Unknown	50 Mg Weekly		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Freq: 1 X 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

	Methotrexate			C		Unk				Not Reported
	Sulfasalazine			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16934485	EXPEDITED (15-DAY)		OT	NVSC2019AR002296		44 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Leukopenia; Product Use In Unapproved Indication; Rash; Subacute Cutaneous Lupus Erythematosus	Prednisolone			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16934756	EXPEDITED (15-DAY)		OT	NVSC2019CA004271			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate			S	Unknown			Novartis
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2434417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait	Actemra			S	Unknown			Not Reported

Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Acetaminophen	S	Unknown			Not Reported
	Dorzolamide;Timolol	S	Unknown			Not Reported
	Dorzolamide;Timolol	S	Unknown	Solution Ophthalmic		Not Reported
	Folic Acid	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Levothyroxine	S	Unknown			Not Reported
	Levothyroxine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Ramipril	S	Oral			Not Reported
	Ramipril	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2434455		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo Celecoxib			S	Unknown			Not Reported
	Apo Celecoxib			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Valsartan			C	Unknown					Not Reported
	Xalatan			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936539	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436270		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936705	EXPEDITED (15-DAY)		OT	CA-ROCHE-2426989		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Rituxan		S	Intravenous drip	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936711	EXPEDITED (15-DAY)		OT	CA-ROCHE-2432582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936767	EXPEDITED (15-DAY)		DE	US-ROCHE-2438522			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Sepsis	Bevacizumab			S	Intravenous (not otherwise specified)			Not Reported
	Paclitaxel			S	Intravenous (not			Not Reported

					otherwise specified)				
	Carboplatin			S	Intravenous (not otherwise specified)	Auc=6 Over 15-30 Min			Not Reported
	Hydroxychloroquine			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Oct-2019	16936952	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016127343		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg (8x 2.5 Mg Tablets), Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk, As Needed		Not Reported
	Folic Acid			C		1 Df, Weekly		Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2019	15934567	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656903-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Off Label Use	Humira			S	Subcutaneous	Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2019	16937081	EXPEDITED (15-DAY)		OT	FR-ROCHE-2437316		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Intentional Product Use Issue; Off Label Use; Pericarditis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2019	16937187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436014		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2019	16869355	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-091052		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride;Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Diclofenac			S	Topical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Arthotec			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported

Celecoxib	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Diclofenac Potassium	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Misoprostol	S	Unknown		Not Reported
Naprosyn [Naproxen]	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Nifedipine	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Winpred	S	Unknown	Unk	Not Reported
Apo-Diclo [Diclofenac Potassium]	S	Unknown	Unk	Not Reported

	Tofacitinib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2019	16938916	EXPEDITED (15-DAY)		OT	NVSC2019CA004301			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Aralen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Myocrisne			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2019	16939098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436156		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported

	Enbrel	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Indapamide	C	Oral	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Pantoloc [Pantoprazole]	C	Oral	Not Reported
	Tylenol [Paracetamol]	C	Oral	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2019	16939106	EXPEDITED (15-DAY)		OT	CA-ROCHE-2434588		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

Anakinra	C	Unknown	Not Reported
Ativan	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Furosemide	C		Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprimum	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2019	16939110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435989		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Depo-Medrol	C	Other	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2019	16939122	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia;	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Depo-Medrol	C	Intra-articular	Suspension	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Humira	C	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	15449475	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189268		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Prednisone	C	Oral	Once In Every 24 Hours			Not Reported
Xeljanz	C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16682370	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019334819			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Thyroiditis; Diabetes Mellitus; Systemic Lupus Erythematosus; Total Lung Capacity Decreased; Vasculitis	Solu-Medrol			S		Unk, [Boosts 125 Solumedrol]		Pfizer
	Benlysta			S		Unk, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk, Daily		Not Reported
	Prednisone			S		Unk, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16827323	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2930035-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified)	Intravenous	
	Plaquenil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Tylenol	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported
	Synthroid	C			Not Reported
	Meloxicam	C			Not Reported
	Acetaminophen And Codeine	C			Not Reported
	Codeine Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16939343	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1125644		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chylothorax; Mycobacterium Fortuitum Infection; Pneumonia; Pulmonary Cavitation; Pyopneumothorax	Hydroxychloroquine			S	Unknown			Teva
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16939747	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436179		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)	
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16940277	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201910001244			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abnormal Sensation In Eye; Abnormal Sensation In Eye; Anaphylactic Reaction; Cough; Dyspnoea; Erythema Of Eyelid; Eye Irritation; Nausea; Swelling Of Eyelid; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Vegamox			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16940459	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001242			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Anxiety;	Hydroxychloroquine			S	Unknown	Unk		Concordia

Burning Sensation; Drug Ineffective; Hypoaesthesia; Infection; Juvenile Idiopathic Arthritis; Nausea; Neuropathy Peripheral	Leflunomide	S	Oral	10 Mg, Unk		Not Reported
	Leflunomide	S	Oral	20 Mg, Unk		Not Reported
	Leflunomide	S	Oral	10 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	2000 Mg		Not Reported
	Celexa	C	Unknown	Unk		Not Reported
	Tri-Cyclen Lo	C	Unknown	Unk		Not Reported
	Cholecalciferol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16940503	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019448109		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aleve			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	2.5 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]			C	Unknown	650 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16940516	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-223754		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irregular Breathing;	Paracetamol		Y	S	Oral	4 Gram		Ohm Lab

Somnolence	Plaquenil	S	Oral	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16940758	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16940855	EXPEDITED (15-DAY)		OT	SA-PFIZER INC-2019451357		43 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Destruction; Tenosynovitis	Celebrex			S	Oral	2 Df, Daily (2 Pills Daily)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, Daily (1 Pill Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2019	16941141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435766		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Unknown		Not Reported
	Zingiber Officinale	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	12713974	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0659		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg; Received 8 X 2.5 Mg Tablets		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Simponi	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	12767724	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076689		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	14241454	NON-EXPEDITED			US-AMGEN-USASP2017178429		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Liver Function Test Increased; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk		Amgen
	Methotrexate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Xeljanz Xr	C	Oral	11 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	15099114	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2018M1047149		63 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; C-Reactive Protein Increased; Cheilitis; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Erythema; Hypertension; Hyponatraemia; Leukocytosis; Oral Discomfort; Palpable Purpura; Periorbital Oedema; Pyrexia; Rash; Scab; Skin Discolouration; Skin Reaction; Swelling Of Eyelid	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Naproxen			C		Unk		Mylan
	Co-Codamol			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	15935379	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2656919-00		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Osteoarthritis; Pain; Physical Disability	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	15993864	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015405			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Pregabalin			S	Unknown	150 Milligram Daily;		Teva
	Trazodone			S	Unknown	25 Milligram Daily;		Actavis
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16846897	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019405995		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Actemra	S	Intravenous (not otherwise specified)	508 Mg, Unk		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	250 Mg, Unk		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	250 Mg, 1 Every 4 Weeks		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	500 Mg, 1 Every 4 Weeks		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	508 Mg, 1 Every 4 Weeks		Not Reported
	Apo-Prednisone	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Asa	C	Unknown	Unk		Not Reported
	Bisoprolol	C	Unknown	Unk		Not Reported
	Candesartan	C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
	Tecta	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16943566	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-06711		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystoid Macular Oedema; Drug Interaction; Maculopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Taxotere			S	Unknown	Unk, 4 Cycles		Not Reported
	Endoxan [Cyclophosphamide]			C	Unknown	Unk, 4 Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16943794	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-201910001243			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Virus Infection; Rash; Stevens-Johnson Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Baktar			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16943962	EXPEDITED (15-DAY)		OT	CA-SA-2019SA288781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg (2 In The Morning And 3 In The Afternoon)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16944170	EXPEDITED (15-DAY)		HO	CA-ROCHE-2437078		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Atenolol		C	Oral	Not Reported
	Hydrochlorothiazide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16944404	NON-EXPEDITED			US-APPCO PHARMA LLC-2075908		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Rash	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Levothyroxine			C	Unknown			Not Reported
	Citalopram			C	Unknown			Not Reported
	Adderall			C	Unknown			Not Reported
	Clobetasol Propionate			C	Unknown			Not Reported
	Fluconazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16944762	EXPEDITED (15-DAY)		HO	CA-ROCHE-2436007		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Folic Acid		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16944803	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436155		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16944991	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2019452096		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	15 Mg, Daily		Not Reported

	Rituximab			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16945903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437275		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16945913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Depo-Medrol	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16945977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437493		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16947183	EXPEDITED (15-DAY)		OT	NVSC2019FR010224		58 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Urticarial Vasculitis	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2019	16947846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435856		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression Fracture	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	13393764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-068945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Arava		S	Oral	20 Mg, Qd	Not Reported
	Arava		S	Unknown	20 Milligram	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	15455542	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2018JPN173532		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Constipation; Dyslipidaemia	Belimumab Subcutaneous			S	Subcutaneous	200 Mg, We		Glaxosmithkline
	Belimumab Subcutaneous			S	Subcutaneous	200 Mg, We		Glaxosmithkline
	Belimumab Subcutaneous			S	Subcutaneous	200 Mg, We		Glaxosmithkline
	Cellcept			S	Oral	Unk		Glaxosmithkline
	Cellcept			S	Oral	Unk		Glaxosmithkline
	Plaquenil (Hydroxychloroquine Sulfate)			S	Oral	Unk		Not Reported
	Predonine Tablet			S	Oral	10 Mg, 1d		Not Reported
	Predonine Tablet			S	Oral	9 Mg, 1d		Not Reported
	Predonine Tablet			S	Oral	8 Mg, 1d		Not Reported
	Prograf			C		Unk		Not Reported
	Onealfa Tablets			C		Unk		Not Reported

		Arotinolol Hydrochloride		C		Unk			Not Reported
		Prednisolone Tablets		C		9 Mg, 1d			Not Reported
		Prednisolone Tablets		C		8 Mg, 1d			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	15626864	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558798-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	15930910	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655564-00		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Methotrexate Solution		Not Reported
	Orencia			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Prolia	S	Subcutaneous	Preservative Free		Not Reported
	Cymbalta	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	15994463	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2676413-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol Fumarate			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Diclofenac Sodium And Misoprostol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Metronidazole			S	Unknown			Not Reported

	Norfloxacin	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Enteric Coated	Not Reported
	Arthrotec	S	Unknown		Not Reported
	Bisoprolol	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Levofloxacin Hemihydrate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Erythromycin Estolate	S	Unknown		Not Reported
	Meperidine	S	Unknown		Not Reported
	Apo-Bisoprolol	S	Unknown		Not Reported
	Apo-Norflox	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16923302	NON-EXPEDITED			NVSC2019US002081		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 6 Months)		Novartis
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Oral	100 Mg, Bid (For Over One Year)		Not Reported
	Fluocinonide			S	Topical	0.05 %, Bid		Not Reported
	Clindamycin			S	Topical	Unk, Qd		Not Reported

	Tacrolimus	S	Topical	0.1 %, Qd		Not Reported
	Minoxidil	S	Unknown			Not Reported
	Finasteride	S	Unknown			Not Reported
	Ustekinumab	C	Subcutaneous	90 Mg (Every 12 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16929875	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20191008868		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Catatonia; Cogwheel Rigidity; Cyclothymic Disorder; Delusion; Distractibility; Drug Ineffective; Drug Resistance; Euphoric Mood; Extrapyramidal Disorder; Hallucination, Auditory; Immobile; Insomnia; Logorrhoea; Muscle Rigidity; Mutism; Negativism; Pneumonia Aspiration; Psychomotor Hyperactivity; Salivary Hypersecretion; Tremor; Waxy Flexibility; Withdrawal Syndrome	Haloperidol			S	Oral			Not Reported
	Valproic Acid			S	Unknown	Up To 2g/D		Not Reported
	Amisulpride			S	Unknown			Not Reported
	Tropatepine			S	Unknown			Not Reported
	Diazepam			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Loxapine			S	Intramuscular	100 Mg/ Intramuscular		Not Reported
	Loxapine			S				Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg, Intravenously		Not Reported
	Methylprednisolone			S				Not Reported
	Olanzapine			S				Not Reported
	Prednisolone			S				Not Reported
	Cyamemazine			S	Unknown	High-Dose/ Pver 3 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949011	EXPEDITED (15-DAY)		OT	NVSC2019US011930			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949092	EXPEDITED (15-DAY)		OT	NVSC2019US011929			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949456	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949486	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972375-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Sulfasalazine	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949619	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4537		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphoma	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949622	EXPEDITED (15-DAY)		DS, OT	US-SA-2019SA280821		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cataract Nuclear; Cystoid Macular Oedema; Macular Degeneration; Maculopathy; Retinal Thickening; Vision Blurred	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Taxotere			S		Unk Unk, Qcy		Sanofi
	Endoxan [Cyclophosphamide]			C		Unk Unk, Qcy		Not Reported
	Corticosteroid Nos			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949629	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4538		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Aleve	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949724	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437587		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949739	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported
	Levofloxacin			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Benadryl			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Ezetrol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16949804	EXPEDITED (15-DAY)		DS	CA-ROCHE-2438097		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral	00072603		Not Reported
	Methotrexate	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16950239	NON-EXPEDITED			US-PFIZER INC-2019456311		62 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16950319	NON-EXPEDITED			US-PFIZER INC-2019456075			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Ampicillin Sodium			S		Unk		Unknown
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Mineral Oil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16950650	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2019-NL-			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Bone Infarction; Cushingoid; Drug Ineffective; Haemophagocytic Lymphohistiocytosis; Osteoporosis; Pancytopenia; Urticaria; Weight Increased	Cotrimoxazole			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Teva
	Prednisolone			S	Unknown	Unspecified Form		Actavis
	Prednisolone			S				Actavis
	Plasma			S	Unknown	15 Ml/Kg, Administered One To Four Times Per Month. Initially Administered Every Week, Then Admin...		Not Reported
	Hepatitis B Vaccine			S	Unknown			Not Reported
	Carbasalate Calcium			C	Unknown			Not Reported
	Clemastine			C	Intravenous (not otherwise specified)			Not Reported
	Prednisolone Iv			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16950738	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019452601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Oral Herpes; Pain In Extremity; Rheumatoid Nodule; Skin Papilloma	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk Unk, 2x/Day		Not Reported
	Myochrysine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16950749	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019452118		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Celebrex			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	200 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk, Monthly		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, 2x/Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S	Unknown	14 Mg, 1x/Day		Not Reported
	Dilaudid			C	Unknown	4 Mg, 3x/Day		Not Reported
	Furosemide			C	Unknown	Unk Unk, 1x/Day		Not Reported
	Hydromorph Contin			C	Unknown	18 Mg, 3x/Day		Not Reported
	Lyrica			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16951613	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019043710			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Cimzia			S	Subcutaneous			Ucb
	Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Milligram, Once Daily (Qd)		Not Reported
	Alendronate Sodium			C	Oral	70 Milligram		Not Reported

	Atenolol	C		3.0 Dosage Forms	Not Reported
	Chlordiazepoxide;Clidinium Bromide	C	Oral		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	40 Milligram	Not Reported
	Hydrochlorothiazide	C	Oral	25 Milligram, Once Daily (Qd)	Not Reported
	Lorazepam	C	Oral	1.0 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	C			Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Trimebutine	C		1 Dosage Form, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16951636	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437055		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16951969	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191005907		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Granuloma; Headache; Hepatic Enzyme Increased; Insomnia	Otezla			S	Oral	60 Milligram		Celgene
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Clonazepam			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Metformin			C	Unknown			Not Reported
	Rabeprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16952034	EXPEDITED (15-DAY)		OT	US-ZYDUS-042551		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Mycobacterium Fortuitum Infection; Pulmonary Mass; Pyopneumothorax; Respiratory Tract Infection; Tachycardia	Hydroxychloroquine			S				Zydus Pharm
	Leflunomide			S				Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16952191	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019043714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Actemra			S				Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once Daily		Not Reported

				(Qd)	
	Hydroxychloroquine	S		Unk	Not Reported
	Leflunomide	C			Not Reported
	Methotrexate	S	Oral	20 Milligram, Weekly (Qw)	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Orencia	S			Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16952359	EXPEDITED (15-DAY)		HO	CA-ROCHE-2437304			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16952722	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1099958		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Maculopathy	Hydroxychloroquine	S	Unknown	Receiving Since 33 Years		Not Reported
	Taxotere	S	Unknown	Completed 4 Cycles		Mylan
	Endoxan /00021101/	C	Unknown	Completed 4 Cycles		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16952903	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191005924		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Otezla			S	Oral	60 Milligram		Celgene
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	30 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16952973	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191005964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16953757	EXPEDITED (15-DAY)		HO	CA-CELGENEUS-CAN-20191006432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2019	16954133	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2019-057640		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Resistance	Prednisolone			S	Oral	Starting Dose		Not Reported
	Lorazepam			S	Unknown	Low Dose		Not Reported
	Lorazepam			S	Unknown	Psychotic Symptoms Reappeared After Switching To Lorazepam		Not Reported
	Diazepam			S	Intramuscular			Not Reported
	Diazepam			S				Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported

	Haloperidol		S	Unknown		Not Reported
	Olanzapine		S	Unknown	Up To 20 Mg/Day	Not Reported
	Cyamemazine		S	Unknown	High Dose Over 3 Weeks	Not Reported
	Valproate		S	Unknown		Not Reported
	Valproate		S	Unknown	Dose Increased Up To 2 G/D Due To Manic Syndrome	Not Reported
	Amisulpride		S	Unknown		Not Reported
	Loxapine		S	Intramuscular		Not Reported
	Loxapine		S	Intramuscular	Reintroduced At Lower Doses	Not Reported
	Tropatepine		S	Oral		Not Reported
	Tropatepine		S	Intramuscular	Reintroduced At Lower Doses	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	11526218	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1466240-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Mg/1 .0 Ml		Not Reported
	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

					Plaquenil	S	Oral		Not Reported
					Apo-Folic Acid	S	Unknown		Not Reported
					Apo-Ibuprofen	S	Unknown		Not Reported
					Apo-Leflunomide	S	Unknown		Not Reported
					Prednisone	C		On And Off Of Prednisone Therapy	Not Reported
					Prednisone	C			Not Reported
					Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	14309183	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015030379		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Swelling	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Arava			S		Unknown		Not Reported
	Enbrel			S	Subcutaneous	Formulation: Solution		Not Reported
	Methotrexate Sodium			S		Unknown		Not Reported
	Plaquenil			S		Unknown		Not Reported
	Prednisone			S		Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Formulation: Solution, Total		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16368252	EXPEDITED (15-DAY)		HO, OT	PHHY2019FR115443		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Aneurysm; Drug Ineffective; Drug Resistance; Hiccups; Retinal Toxicity	Amoxicillin			S	Unknown	3 G, Qd		Novartis
	Amoxicillin			S				Novartis
	Clarithromycin			S	Unknown	1 G, Qd		Not Reported

			Doxycycline		S	Unknown	200 Mg, Qd			Not Reported
			Levofloxacin		S	Unknown	500 Mg, Qd			Not Reported
			Hydroxychloroquine		S	Unknown	600 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16569563	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1075212		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Codeine			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16839185	NON-EXPEDITED			US-PFIZER INC-2019404420		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Hyperhidrosis; Nausea; Presyncope	Xeljanz			S	Oral	11 Mg, 1x/Day		Pfizer
	Meloxicam			S		Unk		Not Reported

	Hydroxychloroquine			S	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16855054	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3711		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tecta			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16870338	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1114464		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased;	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Teva
	Leflunomide			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Ulcer	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Unknown		Not Reported
	Rituximab		S	Unknown	2000 Milligram Daily;	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tocilizumab		S	Unknown	12.8571 Milligram Daily;	Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Cyclosporin		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Unknown	10 Milligram Daily;	Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16954747	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201811-004031			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Ineffective; Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Cosentyx			S	Unknown	150 Mg, Monthly		Not Reported
	Methotrexate			C	Oral	15-25 Mg Weekly		Not Reported
	Prednisone			C		10-40 Mg, Od, Prn		Not Reported
	Arava			C		20 Mg, Qd		Not Reported
	Sulfasalazine			C				Not Reported

	Xeljanz			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16954795	EXPEDITED (15-DAY)		DE	CA-ORION CORPORATION ORION PHARMA-TREX2019-4546		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Diffuse Large B-Cell Lymphoma; Product Use In Unapproved Indication	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16955321	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1126053			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sufate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
					Rituxan		S	Unknown	Solution Intravenous	Not Reported
					Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Prednisone		C			Not Reported
					Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956098	EXPEDITED (15-DAY)		DS, OT	CA-CELGENEUS-CAN-20191005930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956127	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019452274		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported

					Arava	S	Unknown	200 Mg, Daily	Not Reported
					Meloxicam	S	Unknown	Unk	Not Reported
					Plaquenil S	S	Unknown	Unk	Not Reported
					Prednisone	S	Unknown	5 Mg, Daily	Not Reported
					Simponi	S	Subcutaneous	Unk	Not Reported
					Tylenol [Paracetamol]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956231	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019454692			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		20 Mg, Daily		Not Reported
	Arava			S		10 Mg, Daily		Not Reported
	Cimzia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956243	EXPEDITED (15-DAY)		OT	CA-ROCHE-2444496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Mycophenolate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956259	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2019-06824			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Laboratory Test Interference; Somnolence; Toxicity To Various Agents	Hydroxychloroquine Sulfate Tablets			S	Oral	20 Dosage Form (4 Gram)		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Oral	20 Dosage Form (12 Gram)		Lupin
	Fluoxetine			C	Unknown	Unk		Not Reported
	Risperidone			C	Unknown	Unk		Not Reported
	Lamotrigine			C	Unknown	Unk		Not Reported
	Lisdexamfetamine Dimesylate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956563	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1099533			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Ethinylestradiol/Norethisterone			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental	Three Times A Day		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Restarted		Not Reported
	Ramipril			S	Transplacental			Not Reported
	Carvedilol			S	Transplacental			Not Reported
	Atorvastatin			S	Transplacental			Not Reported
	Aspirin /00002701/			S	Transplacental			Mylan
	Epratuzumab			S	Transplacental			Mylan
	Plaquenil /00072602/			S	Transplacental			Mylan
	Plaquenil /00072602/			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956678	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-225216		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Potentiating Drug Interaction	Docetaxel			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019458502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956736	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1099532		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy On Contraceptive; Rebound Effect; Systemic Lupus	Ethinylestradiol/Norethisterone			S	Unknown			Not Reported
	Azathioprine			S	Oral	Three Times A Day		Not Reported
	Azathioprine			S				Not Reported

Erythematosus	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Restarted	Not Reported
	Carvedilol	S	Unknown		Not Reported
	Aspirin /00002701/	S	Oral	81 Milligram, Qd	Mylan
	Epratuzumab	S	Unknown		Mylan
	Plaquenil /00072602/	S	Oral		Mylan
	Plaquenil /00072602/	S			Mylan
	Atorvastatin	S	Unknown		Mylan
	Ramipril	S	Unknown		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019456590		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, 1 Every 4 Weeks		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Cetirizine			C		Unk		Not Reported
	Cranberry			C		Unk		Not Reported
	Olopatadine			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Quinapril Hydrochloride			C		Unk		Not Reported
	Sandoz Rabeprazole			C		Unk		Not Reported
	Singulair			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956930	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16956996	EXPEDITED (15-DAY)		HO	CA-ROCHE-2438132		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Aclasta	C		Not Reported
	Nasonex	C		Not Reported
	Omega-3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol [Paracetamol]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16957606	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1125473		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Disseminated Varicella Zoster Vaccine Virus Infection; Gastrointestinal Disorder; Leukopenia; Lung Disorder; Multiple Organ Dysfunction Syndrome; Thrombocytopenia	Methotrexate			S	Unknown	2.5 Milligram Daily; Administered 6 Days A Week; Ongoing For 3 Years		Barr
	Prednisone			S	Unknown	10 Milligram Daily; Tapered One Month Prior To Presentation		Actavis
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Zostavax Ii			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16957713	EXPEDITED (15-DAY)		OT	NVSC2019TW013949		72 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epstein Barr Virus Positive Mucocutaneous Ulcer	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported

	Prednisolone			S	Unknown	10 Mg, Qd				Novartis
	Hydroxychloroquine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16958319	NON-EXPEDITED			US-NEOPHARMA INC-000215			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea	Augmentin			S				Neopharma
	Lyrica			S	Oral	1 Capsule By Mouth Two Times Daily		Not Reported
	Dilaudid			S				Not Reported
	Plaquenil			S				Not Reported
	Cymbalta			S				Not Reported
	Codeine Sulfate			S				Not Reported
	Tramadol Hcl			S				Not Reported
	Lyrica			S	Oral	1 Capsule By Mouth Two Times Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16958366	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1125723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Sulfasalazine	S	Unknown			Not Reported
	Rituxan	S	Unknown	2000 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Xeljanz	C				Not Reported
	Prednisone	C		10 Milligram Daily;		Not Reported
	Ciclosporin	C		150 Milligram Daily;		Not Reported
	Alendronate Sodium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Oct-2019	16958473	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019452805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Cimzia			C	Subcutaneous	Unk			Not Reported
	Enbrel			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	13103546	EXPEDITED (15-DAY)		OT	CA-ROCHE-1849921		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported

	Cimzia		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Piroxicam		C			Not Reported
	Prednisone		C	Unknown		Not Reported
	Morphine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	15934490	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656818-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16058862	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020430		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16058871	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020995			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16187907	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036583		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Methotrexate		S	Unknown	Barr
	Codeine		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16381260	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2805084-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Prednisone	S	Oral		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16652233	EXPEDITED (15-DAY)		HO, OT	PR-MALLINCKRODT-T201903922			Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Arthralgia; Asthma; Blindness Unilateral; Blood Pressure Increased; Bronchitis; Carotid Artery Aneurysm; Carotid Artery Stent Insertion; Conjunctival Haemorrhage; Contusion; Cushingoid; Depression; Dysarthria; Emotional Distress; Fatigue; Feeling Abnormal; Gait Disturbance; Haematoma; Hypertension; Insomnia; Limb Injury; Macular Oedema; Oedema; Peripheral Swelling; Pleural Effusion; Pleurisy; Pneumonia; Pulmonary Hypertension; Skin Erosion; Systemic Lupus Erythematosus; Tinnitus; Transient Ischaemic Attack; Weight Fluctuation; Wheelchair User	Repository Corticotropin Injection			S	Subcutaneous	60 Units/0.75 Ml, Every 3 Days/Every 72 Hours		Mallinckrodt
	Repository Corticotropin Injection			S				Mallinckrodt
	Symbicort			S	Unknown	Unk, Unk		Not Reported
	Albuterol			S	Unknown	Unk, Unk		Not Reported
	Solumedrol			S	Unknown	Unk, Unk		Not Reported
	Solumedrol			S	Unknown	Unk		Not Reported
	Coreg			S	Unknown	Unk, Unk		Not Reported
	Cellcept			S	Unknown	Unk, Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Breo Ellipta			C	Respiratory (inhalation)	Unk (Inhalation), Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16940441	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019448486		53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Methotrexate Sodium			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959391	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201910001248			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Qrs Axis Abnormal; Suicide Attempt; Urine Abnormality	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		12 G (60 Tablets)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959392	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201910001330			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Therapy Non-Responder	Hydroxychloroquine			S		200 Mg, Qd		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S		200 Mg, Qod		Concordia
	Clobetasol			C	Topical			Not Reported
	Lnfliximab			C		300 Mg, Every 6 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959459	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1126271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local	Codeine			S	Unknown			Not Reported

Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Morphine	S	Unknown		Not Reported
	Aclasta	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Plantago Afra	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown	2000 Iu (International Unit) Daily;	Not Reported
	Asa	C	Unknown	81 Milligram Daily;	Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lipitor	C	Unknown	10 Milligram Daily;	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Tums	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959536	EXPEDITED (15-DAY)		CA, OT	DE-TEVA-2019-DE-1125971		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolon			S	Transplacental	5 [Mg/D]		Actavis
	Quensyl			S	Transplacental	200 [Mg/D]/ Varying Dosage Between 150 And 200 Mg Daily		Not Reported
	Mono-Embolex			C	Transplacental	3000 [Ie/D]		Not Reported
	L-Thyroxin Jod			C	Transplacental	37.5 [Mcg/D] / 75 [Mcg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2440478		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959901	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4650		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported

Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Actemra			S	Intravenous (not otherwise specified)		Not Reported
	Arava			S	Unknown		Not Reported
	Enbrel			S	Subcutaneous		Not Reported
	Enbrel			S	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Hydroxychloroquine			S			Not Reported
	Prednisone			S	Unknown		Not Reported
	Dilaudid			C	Unknown		Not Reported
	Furosemide			C	Unknown		Not Reported
	Hydromorph Contin			C	Unknown		Not Reported
	Lyrica			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16959909	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2019-4653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Oral Herpes; Pain In Extremity; Rheumatoid Nodule; Skin Papilloma	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16960531	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001341			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown			Not Reported

			Methotrexate		S	Unknown	Unk		Not Reported
			Sulfasalazine		S	Unknown	500 Mg (2 In The Morning And 3 In The Afternoon)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16961048	EXPEDITED (15-DAY)		OT	CA-ROCHE-2440551		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16961110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2440458		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Cellcept [Mycophenolate Mofetil]			S				Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure			otherwise specified)		
	Rituxan	S			Not Reported
	Mycophenolate Sodium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Procytox	S	Intravenous (not otherwise specified)		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Domperidone	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16961195	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Otezla			S	Unknown			Celgene
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotraxate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16961323	EXPEDITED (15-DAY)		LT, OT	NVSC2019US015716		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypotension; Overdose; Suicide Attempt	Hydroxychloroquine			S	Unknown	12 G (200 Mg X 60 Tablets)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16961545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019454695		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Multimorbidity; Off Label Use; Product Use Issue; Synovitis	Methotrexate Sodium			S	Subcutaneous	15 Mg, Unk		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Azathioprine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16961789	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2019457698		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Lymphadenopathy; Mantle Cell Lymphoma; Pyrexia	Xeljanz			S	Oral	10 Mg, Daily		Pfizer
	Reumaflex [Methotrexate Sodium]			S	Subcutaneous	12.5 Mg, Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Daily		Not Reported
	Medrol [Methylprednisolone Acetate]			C	Oral	4mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2019	16963645	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1126387			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Propofol			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

	Acetaminophen		S	Unknown	Not Reported
	Prednisone		S	Unknown	Actavis
	Cimzia Single-Use Prefilled Syringe		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Lyrica		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2019	16964090	EXPEDITED (15-DAY)		OT	NVSC2019CA017032			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	13670135	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2017SA106085		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Liver Function Test Increased; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia;	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Unk		Not Reported
	Abatacept			S	Unknown	Unk Unk,Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Advair			C	Unknown	500 Ug,Unk		Not Reported

Rheumatoid Arthritis; Rheumatoid Arthritis; Stomatitis; Treatment Failure; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Actonel	C	Unknown	135 Mg,Qw	Not Reported
	Amlodipine	C	Unknown	5 Mg,Qd	Not Reported
	Ascorbic Acid	C	Oral	1000 Mg,Qd	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg,Qd	Not Reported
	Calcium	C	Unknown	500 Mg,Bid	Not Reported
	Citalopram	C	Unknown	30 Mg,Qd	Not Reported
	Ascorbic Acid	C			Not Reported
	Docusate Sodium	C			Not Reported
	Ergocalciferol	C	Unknown	3000 Df,Qd	Not Reported
	Ferrous Gluconate	C	Oral	300 Mg,Qd	Not Reported
	Folic Acid	C	Oral	5 Mg,Qd	Not Reported
	Hydrochlorothiazide	C	Unknown	25 Mg,Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	2 Df,Qd	Not Reported
	Olmesartan Medoxomil	C	Unknown	40 Mg,Qd	Not Reported
	Docosahexaenoic Acid	C			Not Reported
	Oxybutynin	C	Unknown	2.5 Mg,Qd	Not Reported
	Prednisone	C	Unknown	9 Mg,Qd	Not Reported
	Rabeprazole	C	Unknown	20 Mg,Qd	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg,Bid	Not Reported
	Senna Alexandrina	C			Not Reported
	Spiriva	C	Unknown	Unk Unk,Unk	Not Reported
	Tiotropium Bromide	C	Unknown	18 Ug,Unk	Not Reported
	Cyanocobalamin	C	Unknown	1500 Mg,Qd	Not Reported
	Zinc Gluconate	C	Unknown	25 Mg,Qd	Not Reported
	Zopiclone	C	Unknown	7.5 Mg,Qd	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk Unk, Qid	Not Reported
	Folinic Acid	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	15285039	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803574		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Otezla			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Celgene
	Cosentyx			S	Unknown			Celgene
	Humira			S	Subcutaneous			Celgene
	Remicade			S	Intravenous drip			Celgene
	Simponi			S	Subcutaneous			Celgene
	Stelara			S	Subcutaneous			Celgene
	Sulfasalazine			S	Unknown	2 Gram		Celgene
	Sulfasalazine			S	Unknown			Celgene
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Celgene
	Methotrexate			C				Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	15370433	NON-EXPEDITED			US-AMGEN-USASP2018124517			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	15558393	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-966186		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Barr
	Naproxen Sodium	S	Unknown	Teva
	Methotrexate	S	Unknown	Barr
	Medroxyprogesterone Acetate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Actavis
	Prednisone	S	Unknown	Actavis
	Cyclosporin A	S	Unknown	Ivax
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Elavil	S	Unknown	Not Reported
	Depo-Provera	C	Unknown	Not Reported
	Cyclosporine A	C		Not Reported
	Depo-Provera Sterile Aqueous Suspension (Suspension Intramuscular)	C		Not Reported
	Hydroxychloroquine	C		Not Reported
	Kineret 100mg Per Syringe Single-Use	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16716177	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803954			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Otezla			S	Oral			Celgene

Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Simponi			S	Subcutaneous	Not Reported
	Stelara			S	Subcutaneous	Not Reported
	Xeljanz			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16941587	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000626			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dyspnoea; Exposure During Pregnancy; Fatigue; Hypotension; Pneumonia; Productive Cough; Rhinorrhoea; Sepsis; Staphylococcal Infection	Furosemide			S	Unknown	Unk		Validus
	Furosemide			S	Unknown	80 Mg, Qd		Validus
	Prednisone			S	Oral	20 Mg, Qd		Not Reported
	Prednisone			S	Oral	Prednisone Dose Was Increased To 20 Mg/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	81 Mg, Qd		Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Ceftriaxone Sodium			S	Unknown	Unk		Not Reported
	Ceftriaxone Sodium			S				Not Reported
	Calcium			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Oral	150 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Not Reported
	Ciclosporin			S	Oral	100 Mg, Bid		Not Reported

	Ciclosporin	S	Oral	Increased To A Dose Of 125 Mg Twice A Day		Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	16 Mg, Qd		Not Reported
	Vancomycin	C		Unk		Not Reported
	Ursodiol	C		Unk		Not Reported
	Labetalol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16964692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4701			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16964883	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2019-US-1128834		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Pregnancy On Contraceptive; Rebound Effect; Systemic Lupus Erythematosus	Carvedilol			S	Unknown			Teva
	Ramipril			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown	Restarted		Actavis
	Ethinylestradiol/Norethisterone			S	Unknown			Not Reported

	Acetate Epratuzumab	S	Unknown			Not Reported
	Azathioprine	S	Oral	150 Milligram Daily; Three Times A Day		Not Reported
	Azathioprine	S				Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil	S				Not Reported
	Atorvastatin	S	Unknown			Not Reported
	Aspirin	S	Oral	81 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16965142	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2019-4696			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16965144	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cetirizine			C	Unknown			Not Reported
	Cetirizine			C	Unknown			Not Reported

Cetirizine	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Cetirizine	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Cranberry	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Olopatadine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Quinapril Hydrochloride	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Sandoz Rabeprazole	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported
Singulair	C	Unknown	Not Reported

	Singulair			C	Unknown					Not Reported
	Singulair			C	Unknown					Not Reported
	Singulair			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16965321	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019459596		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Insomnia; Therapeutic Product Effect Incomplete	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, 1 Every 1 Week		Unknown
	Arava			S		20 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Erythromycin			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16965502	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019458788		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus			S	Unknown	6 Df, 1x/Day		Not Reported
	Tacrolimus			S	Unknown	5 Df, 1x/Day		Not Reported
	Prednisone			C	Oral	17.0 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16967227	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1101141		26 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Meningitis Aseptic; Off Label Use	Mycophenolate Mofetil			S	Unknown	1000 Milligram, Qd		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Prednisolone			S	Unknown	10 Milligram, Qd		Not Reported
	Prednisolone			S		Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Mylan
	Cyclophosphamide			S	Unknown	Unk		Mylan
	Rituximab			S		Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Belimumab			C	Unknown	Unk		Mylan
	Belimumab			C	Unknown	Unk		Mylan
	Fresh Frozen Plasma			C	Unknown	Initially Up To 4 Units		Mylan
	Fresh Frozen Plasma			C	Unknown	2 Units		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16967651	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1127223		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydrochlorothiazide			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported

		Humira (Adalimumab)			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Plaquenil			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16967928	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1128864		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy	Hydroxychloroquine			S	Unknown	Receiving Since 33 Years		Teva
	Taxotere			S	Unknown	Completed 4 Cycles		Not Reported
	Endoxan			C	Unknown	Completed 4 Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16968039	EXPEDITED (15-DAY)		OT	NVSC2019CA016408			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Methotrexate			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Aralen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Myochrysine			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Oct-2019	16968046	EXPEDITED (15-DAY)		OT	NVSC2019CA015197			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell	Etanercept			S	Unknown	Unk		Novartis
	Gold			S	Unknown	Unk (For Over 3 Months)		Not Reported

Sedimentation Rate Increased	Plaquenil		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Qw	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	10 Mg, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	12885311	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2016-0007126		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Dilaudid			S	Unknown	Unk		Rhodes
	Hydromorphone Hydrochloride			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 1/Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Day/Week		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	14267318	NON-EXPEDITED			US-PFIZER INC-2017526732		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Arthrotec			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported

	Bactrim			S		Unk				Not Reported
	Hydroxychloroquine			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	15624306	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557524-00		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Ibuprofen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	15631313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-082237			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Cough; Diarrhoea; Drug	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Off Label Use; Peripheral Swelling; Retinopathy; Sinus Disorder; Sinusitis; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Hydroxychloroquine /00072603/	S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Prolia	S	Subcutaneous			Not Reported
	Cymbalta	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16058865	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1021043		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrochlorothiazide			S	Oral	25 Milligram Daily;		Ivax
	Plaquenil			S	Unknown			Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16257470	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110700			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Contraindicated Product Administered;	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil		S	Unknown	Unk	Sanofi
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Prednisone		C		Unk	Not Reported
	Lyrica		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16681584	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201903835		78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Disorder; Blood Pressure Increased; Drug Ineffective; Eye Disorder; Eye Infection; Fall; Headache; Immunosuppression; Systemic Lupus Erythematosus	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week Monday/Thursday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1ml, 2 Times A Week As Directed		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, Monday/Thursday		Mallinckrodt
	Plaquenil			S	Unknown	Unk		Not Reported
	Clobetasol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16892593	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1118778		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Teva
	Paxil			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported

	Flomax			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16903169	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2019436020		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16928471	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201910001195			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chylothorax; Cough; Dyspnoea; Empyema; Pneumothorax; Pulmonary Cavitation; Tachycardia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Methamphetamine			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16944594	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-201910001270			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cataract Nuclear; Macular Degeneration; Macular Oedema; Maculopathy; Retinal Thickening; Vision Blurred	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Taxotere			S	Unknown	4 Cyclical		Not Reported
	Endoxan			C		4 Cyclical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16968580	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2979003-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Infection; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Risedronate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16968668	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4691		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16969335	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001345			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	300 Mg		Concordia
	Methotrexate			S	Unknown	20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16969488	EXPEDITED (15-DAY)		DS, OT	GR-ADVANZ PHARMA-201910001378			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Retinal Tear; Vitreous Detachment	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16969651	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4692			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16969808	EXPEDITED (15-DAY)		OT	NL-APPCO PHARMA LLC-2076129		11 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Infarction; Cushingoid; Osteoporosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16969931	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2979042-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Hypersensitivity; Drug Intolerance; Infection; Pancytopenia; Rash	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zantac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Oct-2019	16970082	EXPEDITED (15-DAY)		OT	NVSC2019CA017029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Erelzi (Etanercept) 50 Mg/1 Ml Solution For Injection In Pre-Filled Au			S	Subcutaneous	50 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	12911280	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016507870		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Incontinence; Nausea	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	13965982	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA166805		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery;	Hydroxychloroquine			S	Oral	400 Mg,Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported

Synovitis	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz	S	Oral	5 Mg,Bid		Not Reported
	Folic Acid	C				Not Reported
	Methotrexate	C				Not Reported
	Hydroxychloroquine Phosphate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	15569161	NON-EXPEDITED		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2018-05501		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Overdose; Sinus Tachycardia; Ventricular Tachyarrhythmia	Hydroxychloroquine			S	Oral	36 G, Single		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	15722341	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587611-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Infection	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Indometacin			C					Not Reported
	Prednisone			C					Not Reported
	Tramadol			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	15949339	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2660873-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Off Label Use; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16041015	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058407		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diarrhoea; Drug Intolerance; Influenza; Musculoskeletal Pain; Rash Macular; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	1.0 Ml, Qw		Not Reported
	Leflunomide			S	Unknown	20 Mg,Once Every 2 Days		Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Acetaminophen			C		Unk, Pm, As Required		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C	Subcutaneous	1.0 Ml Qw		Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16231128	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Ineffective; Interstitial Lung Disease; Pulmonary Fibrosis	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		25 Mg, Qiw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16261602	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA110610		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16702827	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2888402-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Simponi	S	Subcutaneous	Form Of Administration-Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S			Not Reported
	Arava	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported

Fosamax	S			Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Cutaneous		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Topical		Not Reported
Actemra	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Cortisone Acetate	S	Topical		Not Reported
Cetirizine	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Topicort	S	Topical	Cream	Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cortisone	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported

	W/Pseudoephedrine				
	Apo Hydroxyquine	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown		Not Reported
	Apo-Prednisone	C			Not Reported
	Atasol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16703008	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210850		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete	Arava			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk, Unk		Sanofi
	Leflunomide			S		Unk, Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk, Unk		Not Reported
	Plaquenil			S		Unk, Unk		Sanofi
	Sodium Aurothiomalate			S		Unk, Unk		Not Reported
	Sulfasalazine			S		Unk, Unk		Not Reported
	Enbrel			S		Unk, Unk		Not Reported
	Orencia			S		Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16972676	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268191			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis; Unevaluable Event	Leflunomide	S	Oral	20 Mg,Unk		Sanofi
	Hydroxychloroquine	S	Oral	400 Mg, Unk		Sanofi
	Hydroxychloroquine	S	Oral	400 Mg,Unk		Sanofi
	Sulfasalazine	S	Oral	1 G,Unk		Not Reported
	Enbrel	S	Unknown	50 Mg,Qw		Not Reported
	Prednisone	C	Unknown	10 Mg,Unk		Not Reported
	Prednisone	C	Oral	5 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16972695	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2979276-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16972929	EXPEDITED (15-DAY)		CA	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2019-09178		91 DAY	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Haematoma; Cerebral Ventricle Dilatation; Developmental Delay; External Auditory Canal Atresia; External Ear Disorder; Foetal Exposure During Pregnancy; Inguinal Hernia; Iris Coloboma;	Mycophenolate Mofetil			S	Transplacental	Unnknown		Alkem
	Hydrochloroquine Sulphate			S	Transplacental	Unnknown		Not Reported
	Venlafaxine			S	Transplacental	Unknown		Not Reported

Kidney Duplex; Renal Aplasia; Retinal Coloboma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973094	NON-EXPEDITED		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-05415		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (Daily Dose Of 5.71mg/Kg Of Real Body Weight Or 6.32 Mg/Kg Of Ideal Body Weight)		Lupin
	Methotrexate			C	Unknown	12.5 Milligram Per Week		Not Reported
	Propranolol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973103	NON-EXPEDITED			IE-LUPIN PHARMACEUTICALS INC.-2019-04500		38 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973110	NON-EXPEDITED			IE-LUPIN PHARMACEUTICALS INC.-2019-04499		38 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973111	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2019-04990		48 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Skin Hyperpigmentation	Hydroxychloroquine	S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973112	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-04797		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Chloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973113	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-05800		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Ineffective	Hydroxychloroquine			S	Unknown	5 Milligram/Kilogram		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 Gram		Lupin
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16973473	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-495		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cataract Nuclear; Cystoid Macular Oedema; Maculopathy	Hydroxychloroquine			S	Unknown			Hikma
	Taxotere			S	Unknown			Not Reported
	Endoxan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16974161	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019467247			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Mobicox			S				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16974198	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-201910001379			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Dermatitis Bullous; Migraine; Nausea; Off Label Use	Hydroxychloroquine			S	Unknown	1 Dosage Form (Film-Coated Tablet), Qd (Started In January In Unknown Year)		Concordia
	Hydroxychloroquine			S	Unknown	1 Dosage Form, Qd (Started 3-Oct In Unknown Year		Concordia
	Zofenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16974268	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1128755		43 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Zika Virus Infection	Methotrexate			S	Unknown			Barr
	Prednisolone			S	Oral	High Dose		Actavis
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16975613	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-496		27 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Atypical Haemolytic Uraemic Syndrome; Maternal Exposure During Pregnancy; Pneumonia; Renal Failure; Sepsis; Staphylococcal Infection	Ceftriaxone			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Oral	Was Increased To 20 Mg/Day		Westward
	Prednisone			S	Oral			Westward
	Prednisone			S	Oral			Westward
	Hydroxychloroquine			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Calcium & Vitamin D			C	Unknown			Not Reported
	Levothyroxine			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported
	Labetalol			C	Oral			Not Reported
	Ursodiol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16975825	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-GSH201804-001109			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; C-Reactive Protein Increased; Cheilitis; Dermatitis Allergic; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Erythema; Hypertension; Hyponatraemia; Leukocytosis; Oral	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Naproxen			C				Not Reported
	Co-Codamol			C				Not Reported

Discomfort; Palpable Purpura; Periorbital Oedema; Pyrexia; Rash; Rash; Rash; Scab; Skin Discolouration; Swelling Of Eyelid

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16975989	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-055		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Systolic Increased; Headache; Maternal Exposure During Pregnancy; Pre-Eclampsia; Vision Blurred	Prednisone			S	Unknown			Westward
	Prednisone			S	Unknown			Westward
	Azathioprine			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enoxaparin			S	Unknown			Not Reported
	Epoprostenol			S	Unknown	12 Ng/Kg/Min		Not Reported
	Epoprostenol			S	Unknown	2 Ng/Kg/Min		Not Reported
	Betamethasone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2019	16976446	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019469549		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dizziness; Drug Ineffective; Infection; Malaise; Nasopharyngitis; Product Dose Omission; Rheumatoid Arthritis; Tendon Rupture	Methotrexate Sodium	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Simponi	S	Unk	Not Reported
	Naproxen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	15707064	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018509435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16226845	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA110472			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S		Unk, Unk		Not Reported

Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S				Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Folic Acid	C				Not Reported
	Methotrexate	C		20 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16231126	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110630		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Plaquenil			S				Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	15 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg		Not Reported
	Arava			S				Sanofi
	Remicade			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S				Not Reported

	Actemra			S	Intravenous (not otherwise specified)	592 Mg			Not Reported
	Desoximetasone			C					Not Reported
	Infliximab			C					Not Reported
	Infliximab			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16231136	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110771		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Leflunomide			S		Unk Unk, Unk		Sanofi
	Methotrexate			S		Unk, Unk		Not Reported
	Sulfasalazine			S		Unk, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk, Unk		Sanofi
	Tofacitinib			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Diovan			C	Unknown	Unk, Unk		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			C	Unknown	Unk, Unk		Not Reported
	Sertraline			C	Unknown	Unk, Unk		Not Reported
	Valtrex			C	Unknown	Unk, Unk		Not Reported
	Dexilant			C		Unk		Not Reported
	Serax [Serrapeptase]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16257462	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110611		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-	Arava			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi

Hodgkin'S Lymphoma; Rheumatoid Arthritis	Hydroxychloroquine	S	Oral	400 Mg		Sanofi
	Plaquenil	S	Unknown	400 Mg		Sanofi
	Methotrexate	S	Subcutaneous	25 Mg		Not Reported
	Methotrexate	S				Not Reported
	Minocycline Hydrochloride	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine	S	Unknown	100 Mg		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid		Not Reported
	Xeljanz	S				Not Reported
	Bcg	C	Intravenous (not otherwise specified)			Not Reported
	Amoxicillin Sodium;Clavulanate Potassium	C	Unknown			Not Reported
	Leflunomide	C				Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16260828	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Arava			S	Endocervical	20 Mg, Unk		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Actemra			S	Unknown	567 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan			S		Unk			Not Reported
	Celebrex			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16260829	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Musculoskeletal Stiffness; Myalgia; Pain; Rheumatoid Arthritis; Rheumatoid Lung	Arava			S				Sanofi
	Diclofenac			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Pantoprazole Magnesium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16260843	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110670		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Fatigue; Hypersensitivity; Malaise; Nasal Congestion; Neuralgia; Pain In Extremity; Productive Cough; Rheumatoid Arthritis; Vision Blurred; Visual Impairment	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Folic Acid			C	Unknown	Unk, Qd		Not Reported
	Methotrexate			C	Oral	20 Mg, Qw		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	200 Mg, Bid		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16847128	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2019-US-1112152		23 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Cardiac Failure Congestive; Cardiotoxicity; Ejection Fraction Decreased; Electrocardiogram Qt Prolonged; Toxicity To Various Agents; Ventricular Fibrillation	Hydroxychloroquine	S	Unknown		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16906530	EXPEDITED (15-DAY)		LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4131		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disease Progression; Dysphonia; Dyspnoea; Odynophagia; Rheumatoid Arthritis; Stridor	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16977580	EXPEDITED (15-DAY)		HO, OT	CH-TEVA-2019-CH-1128706		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fasciitis; Gastritis; Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Increased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16977693	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1128212		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin Sodium /Clavulanate Potassium			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Plaquenil			C	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	7.5 Milligram Daily;		Not Reported
	Tridural			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16977771	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4850		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine		S	Unknown	Not Reported
	Mycophenolate Mofetil		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Tacrolimus		S	Unknown	Not Reported
	Tacrolimus		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16978039	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2019-US-001804			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	60 Dosage Form, Single		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16978141	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-11		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Oral Infection; Therapeutic Product Effect Decreased; Tooth Abscess	Mobicox			S	Unknown			Boehringer Ingelheim
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Unknown	Dosage Form: Solution		Not Reported

						Subcutaneous			
	Xeljanz			S	Oral				Not Reported
	Xeljanz			S	Oral				Not Reported
	Leflunomide			C	Unknown				Not Reported
	Meloxicam			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16978572	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019469265		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Hepatitis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16978575	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019469584		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Product Use Issue; Psoriasis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Daily		Not Reported
	Alprazolam			C	Oral	0.5 Mg, Daily		Not Reported
	Celebrex			C	Oral	200 Mg, Unk		Not Reported
	Levothyroxine Sodium			C	Oral	50 Ug, Daily		Not Reported
	Prednisone			C		5 Mg, Unk		Not Reported
	Salmeterol/Fluticason Orion			C	Respiratory (inhalation)	2 Df, 2 Every Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16978628	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1128465		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16979000	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019463053		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Macular Degeneration	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16979027	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019467311			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Pain; Skin Irritation; Weight Increased	Methotrexate Sodium	S	Unknown			Pfizer
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Cimzia	S	Unknown			Not Reported
	Plaquenil S	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Ibuprofen	C	Unknown	600 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16979168	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2019M1103680		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Symptom; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Laboratory Test Interference; Somnolence; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	60 Tablets Of Hydroxychloroquine200 Mg(Total 12g)		Not Reported
	Fluoxetine			C	Unknown	Unk		Mylan
	Risperidone			C	Unknown	Unk		Mylan
	Lamotrigine			C	Unknown	Unk		Mylan
	Lisdexamfetamine Dimesylate			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16979572	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension; Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity;	Arava			S		Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Desoximetasone	C	Unk	Not Reported
	Hydroxychloroquine	C	Unk	Not Reported
	Leflunomide	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16979706	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-059100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

					Orencia	S	Intravenous (not otherwise specified)		Not Reported
					Orencia	S	Subcutaneous		Not Reported
					Phthalylsulfathiazole	S	Unknown		Not Reported
					Plaquenil	S	Unknown		Not Reported
					Prednisone	S	Oral		Not Reported
					Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
					Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
					Remicade	S	Intravenous (not otherwise specified)		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Simponi	S	Subcutaneous		Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16980351	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1128474		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Rituximab			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown	3000 Milligram Daily;			Not Reported
		Tocilizumab			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16980942	NON-EXPEDITED			US-SA-2019SA121847			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Kevzara			S				Sanofi
	Hydroxychloroquine			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Oct-2019	16981082	EXPEDITED (15-DAY)		OT	NVSC2019CA004850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Cosentyx			S	Unknown	300 Mg, Q4w		Novartis
	Cosentyx			S	Unknown	Unk, Q2w		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Pfizer			S	Unknown	12.5 Mg, Unknown		Not Reported
	Methotrexate Pfizer			S	Unknown	12.5 Mg, Unknown		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	200 Mg, Q2w		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Lipitor			S	Oral	5 Mg, Unknown		Not Reported
	Dovobet			C	Topical	Unk (50cmg-0.5mg/G, Bid Or Prn)		Not Reported

	Folic Acid	C	Oral	5 Mg (1 Or 5 Mg), Qd		Not Reported
	Omeprazole	C	Oral	20 Mg, Qd (Delayed Release Capsule)		Not Reported
	Flovent	C	Respiratory (inhalation)	250 Mg, Unknown (As Directed)		Not Reported
	Ventolin	C	Respiratory (inhalation)	100 Ug, Prn		Not Reported
	Vitamin D2	C	Oral	1000 U, Unknown		Not Reported
	Multi Vitamin	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	11359928	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-045043		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Graft; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Foot Operation; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Oral	Unk Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	125 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	2.5 Mg/Die		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	12923481	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2233		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Incontinence; Nausea; Synovitis	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	13212360	EXPEDITED (15-DAY)		OT	CA-SA-2015SA111836		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk,Unk		Not Reported
	Methotrexate Bellon			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	15632089	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978052		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug Intolerance; Renal Failure; Treatment Failure; Treatment Failure; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	15716339	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3672			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	15993819	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016334			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva

	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	15993843	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016320			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16232163	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110596		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		50 Mg		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Ergocalciferol			C		Unk Unk, Qw		Not Reported
	Estradiol			C				Not Reported
	Estrogel			C		0.6 %, Tid		Not Reported
	Furosemide			C		40 Mg, Qd		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C		Unk Unk, Bid		Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C		1500 Mg, Qd		Not Reported

Valsartan	C		320 Mg, Qd		Not Reported
Xalatan	C		50 Ug, Qd, Ophthalmic Solution		Not Reported
Zingiber Officinale	C	Oral	500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16260832	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk, Unk		Sanofi
	Meloxicam			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk, Unk		Sanofi
	Orencia			S	Unknown	Unk, Unk, For 7 Years		Not Reported
	Actemra			S	Subcutaneous	160 Mg, Qw		Not Reported
	Hydroxychloroquine Sulfate			C		Unk, Unk		Not Reported
	Depo-Medrol			C	Unknown	80 Mg, Qd		Not Reported
	Diclofenac			C		Unk, Unk		Not Reported
	Humira			C	Unknown	Unk Unk, Unk, For 7 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16287352	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019190187			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Carbon Dioxide Increased; Cough; Dyspnoea; Pulmonary Function Test Abnormal; Rheumatoid Arthritis	Xeljanz			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16291304	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019193410			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Oral	17.5 Mg, Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16879155	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2019-06255		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisone			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16879156	EXPEDITED (15-DAY)		HO, OT	FR-LUPIN PHARMACEUTICALS INC.-2019-06258		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16977700	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1128886		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hypoxia; Lung Abscess; Pneumonia; Pseudomonas Infection; Treatment Failure	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Cytoxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16981819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2448587		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16981890	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4896		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Macular Degeneration	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16981894	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4929		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Infection; Malaise; Nasopharyngitis; Product Dose Omission; Rheumatoid Arthritis; Tendon Rupture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16981903	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16982087	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129047		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition	Azathioprine			S	Unknown			Not Reported

Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Ciclosporin		S	Unknown		Ivax
	Methotrexate		S	Unknown		Barr
	Methotrexate		S	Unknown		Barr
	Mycophenolate Mofetil		S	Unknown		Teva
	Pregabalin		S	Unknown		Teva
	Actemra		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Certolizumab Pegol		S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16982088	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity;	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva

Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cellcept	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Piroxicam	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16982722	EXPEDITED (15-DAY)		OT	CA-ROCHE-2449470			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Simponi		S	Subcutaneous	Not Reported
					Sulfasalazine		S	Oral	Not Reported
					Acetaminophen;Codeine Phosphate		C	Unknown	Not Reported
					Celebrex		C	Oral	Not Reported
					Hydromorphone Hydrochloride		C	Unknown	Not Reported
					Meloxicam		C	Unknown	Not Reported
					Methotrexate		C	Unknown	Not Reported
					Synthroid		C	Unknown	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
01-Nov-2019	16982974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2448420			Female	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**	
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not			Not Reported	

					otherwise specified)				
	Phthalylsulfathiazole			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Pseudoephedrine Hcl			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16983100	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg		Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Pregabalin			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Lyrica	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16983223	EXPEDITED (15-DAY)		DE, HO	NVSC2019US019851		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Escherichia Infection; Fungal Skin Infection; Haematochezia; Haemophagocytic Lymphohistiocytosis; Hypotension; Hypoxia;	Prednisone			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Liver Injury; Mental Disorder; Myositis; Pancytopenia; Pyrexia; Respiratory Tract Infection Fungal; Splenomegaly; Ulcer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16983311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2448335			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16984010	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019469370		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Unknown
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Actemra			S		Unk		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Isoniazid			S		Unk		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16984916	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129098		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Lyrica	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16986131	EXPEDITED (15-DAY)		OT	US-BAXTER-2019BAX021830			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytopenia; Drug Ineffective; Exposure During Pregnancy	Vancomycin Injection, Usp			S	Unknown			Baxter
	Vancomycin Injection, Usp			S				Baxter
	Ceftriaxone Injection, Usp (In Dextrose)			S	Unknown			Baxter
	Ceftriaxone Injection, Usp (In Dextrose)			S				Baxter
	Cyclophosphamide For Injection, Usp			S	Unknown			Baxter
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Unknown	Dose Increased		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Calcium			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported
	Ursodiol			S	Oral			Not Reported
	Labetalol			S	Oral			Not Reported
	Levothyroxine			S	Oral			Not Reported
	Aspirin			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Furosemide	S	Unknown			Not Reported
Furosemide	S	Unknown	Increased Dose		Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)			Not Reported
Mycophenolate Mofetil	S	Unknown			Not Reported
Tacrolimus	C	Unknown			Not Reported
Belimumab	C	Unknown			Not Reported
Azathioprine	C	Unknown			Not Reported
Rituximab	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Ivig	C	Intravenous drip	Infusion		Not Reported
Ciclosporin	C	Unknown			Not Reported
Mycophenolate Mofetil	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16986201	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019194697			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Back Pain; Dyspepsia; Gait Disturbance; Limb Immobilisation; Pain; Rheumatoid Arthritis; Swelling	Trelegy Ellipta			S	Respiratory (inhalation)	1 Puff(S), Qd 100/62.5/25 Ug		Glaxosmithkline
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Warfarin			C	Unknown	Unk		Not Reported
	Sotalol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16986578	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129587		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Azathioprine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Barr
	Mycophenolate Mofetil		S	Unknown	Teva
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tacrolimus		S	Unknown	Not Reported
	Prednisone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Nov-2019	16986812	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate			S	Unknown			Barr
	Mycophenolate Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2019	16986495	EXPEDITED (15-DAY)		OT	CA-SA-2019SA302599		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug	Desoximetasone			S	Oral	Unk		Sanofi
	Arava			S		Unk		Sanofi

Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Prednisone	S		Unk	Not Reported
	Cetirizine Hydrochloride	S		10 Mg	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Cortisone Acetate	S		Unk	Not Reported
	Folic Acid	S		5 Mg	Not Reported
	Folic Acid	S		Unk	Not Reported
	Alendronate Sodium	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Sanofi
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Plaquenil	S		Unk	Sanofi
	Plaquenil	S		400 Mg, Qd	Sanofi
	Prednisone	S		40 Mg	Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Sanofi
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported

				otherwise specified)		
	Simponi		S	Subcutaneous	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Diclofenac		C		50 Mg	Not Reported
	Salazopyrin		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	12137035	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-014026			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Orencia			S	Unknown	1 Df, Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	12911484	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2000-000013		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pneumonia; Product Dose Omission; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	1 Df, Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Dorzolamide Hcl/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Methotrexate			C	Unknown	15 Milligram, Qd		Not Reported
	Estrogel			C	Unknown	0.6 %, Tid		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram, Qd		Not Reported

	Xalatan	C	Ophthalmic	50 Milligram		Not Reported
	Ergocalciferol	C	Unknown	1 Df, Qwk		Not Reported
	Calcium	C	Unknown	500 Mg, Qd		Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, Qd		Not Reported
	Estradiol	C	Unknown	0.6 %, Tid		Not Reported
	Gravol	C	Unknown			Not Reported
	Baclofen	C	Unknown	10 Milligram, Bid		Not Reported
	Levaquin	C	Unknown	500 Milligram, Qd		Not Reported
	Morphine	C	Unknown			Not Reported
	Zingiber Officinale	C	Oral	500 Mg, Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	12913742	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092678			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported

	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Cortisone	C	Unknown	Unk	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Rabeprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	12930360	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092641		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Off Label Use; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported

	Methotrexate			C	Unknown	Unk				Not Reported
	Desoximetasone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	13070607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	13101292	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017003985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Disability; Drug Ineffective; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Oral	17.5 Mg, Unk		Pfizer
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	13107805	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0120			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Disability; Drug Ineffective; Fatigue; Pneumonia; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	13519875	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038008		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram 1 Every 1 Day		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	200 Mg, Qd	Not Reported
	Methotrexate Sodium		S	Unknown	20 Mg, Qwk	Not Reported
	Methotrexate Sodium		S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide		S	Unknown	20 Mg, Qd	Not Reported
	Advil [Mefenamic Acid]		C	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported
	Ketorolac		C	Unknown	As Required	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate		C	Unknown	Unk	Not Reported
	Leflunomide		C	Unknown	20 Milligram,1every 1week	Not Reported
	Acetaminophen;Caffeine		C	Unknown		Not Reported
	Methotrexate		C	Unknown	20 Milligram,1 Every 1 Week	Not Reported
	Advil [Ibuprofen]		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	13844582	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-067794		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Apo Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Therapy Non-Responder; Tuberculin Test Positive	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Toradol	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Tramadol	C	Unknown	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16142594	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-037726		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Headache; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Prescribed Overdose; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Thyroid Neoplasm; Toxicity To Various Agents; Treatment Failure	Orencia			S	Subcutaneous	250 Milligram		Bristol Myers Squibb
	Arava			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	50 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Celebrex			S	Unknown	50 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	300 Milligram		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine		S	Unknown	2 Milligram, Qd	Not Reported
	Sulfasalazine		S	Unknown	500 Unk	Not Reported
	Hydroxychloroquine		S	Unknown	300 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	300 Milligram	Not Reported
	Tofacitinib		S	Unknown		Not Reported
	Leflunomide		S	Oral	20 Milligram	Not Reported
	Leflunomide		S	Oral	10 Milligram	Not Reported
	Tofacitinib Citrate		S	Unknown		Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Actemra		S	Subcutaneous	Unk	Not Reported
	Xeljanz		C	Oral	5.0 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16226500	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qow		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)		
	Folic Acid		C	Unknown		Not Reported
	Tofacitinib Citrate		C			Not Reported
	Leflunomide		C	Unknown		Not Reported
	Methotrexate		C	Oral	25 Mg, Qw	Not Reported
	Orencia		C			Not Reported
	Hydroxychloroquine		C		Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16648954	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1082829		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Cefazolin			S	Intramuscular			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Arava			C				Not Reported
	Naproxen			C	Unknown	1000 Milligram Daily;		Not Reported

	Viread			C					Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16987961	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16988027	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000079			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Unk		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Sulfasalazine			S	Oral	1 G, Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16988655	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-102182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16989141	EXPEDITED (15-DAY)		OT	SA-PFIZER INC-2019473297		56 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Destruction; Synovitis	Xeljanz			S	Oral	2 Df, Daily		Pfizer
	Celebrex			S	Oral	1 Df, Daily		Pfizer
	Methotrexate Sodium			S	Oral	6 Df, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16990155	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019471447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye;	Methotrexate Sodium			S				Pfizer
	Actemra			S	Subcutaneous	160 Mg, Once Weekly		Not Reported
	Arava			S				Not Reported
	Leflunomide			S				Not Reported
	Meloxicam			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Depo-Medrol	C	80 Mg	Not Reported
	Diclofenac	C		Not Reported
	Humira	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16990593	EXPEDITED (15-DAY)		OT	US-HQ SPECIALTY-US-2019INT000283			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis	Paclitaxel			S	Intravenous (not otherwise specified)	200 Mg/M2, Over 3 H On Day 1		Hq Specialty
	Carboplatin			S	Intravenous (not otherwise specified)	Auc = 6, Over 15-30 Min On Day 1		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, Bid, On Days 1–21		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Nov-2019	16990609	EXPEDITED (15-DAY)		DE, OT	US-HQ SPECIALTY-US-2019INT000284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Sepsis	Paclitaxel			S	Intravenous (not otherwise specified)	200 Mg/M2, Over 3 H On Day 1		Hq Specialty

		Carboplatin			S	Intravenous (not otherwise specified)	Auc = 6, Over 15–30 Min On Day 1				Not Reported
		Hydroxychloroquine			S	Oral	200 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	11126079	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-023023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Inflammation; Interstitial Lung Disease; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Pneumonia; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Naproxen			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram,Every 10 Days		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	17 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	2 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Subcutaneous	500 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Rabeprazole Sodium	C	Unknown	20 Milligram, Qd	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Allopurinol	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown	Unk	Not Reported
Bisoprolol	C	Unknown	Unk	Not Reported
Digoxin	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Palafer	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Toloxin [Digoxin]	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Zinc Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	12771268	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076851		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	12901853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Pain; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	Unk	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1.0 Gram	Not Reported
	Cyclosporine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Penicillamine	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Doxycycline	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Tobramycin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	12930177	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093180			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated;	Abatacept			S	Unknown			Bristol Myers Squibb

Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatitis; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Off Label Use; Skin Reaction; Synovitis; Thyroid Cancer	Methotrexate	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown	50 Mg, (Therapy Duration 99 Days)	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Leflunomide	S	Endocervical		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Etanercept	S	Unknown	50 Milligram	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Metformin Hydrochloride	C	Unknown		Not Reported
	Metformin Hydrochloride	C	Unknown	Unk	Not Reported
	Nystatin	C	Unknown		Not Reported
	Biaxin	C	Unknown		Not Reported
	Insulin	C	Oral		Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Avapro	C	Unknown		Not Reported
	Humalog	C	Unknown		Not Reported
	Lantus	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	13519786	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Off Label	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	25 Mg, Qwk		Not Reported

Use; Rheumatoid Arthritis; Soft Tissue Swelling	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Arava	S	Unknown	25 Mg, Qwk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	25 Mg, Qwk	Not Reported
	Myochrysine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	14627761	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018102695		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Erythromycin			S	Subcutaneous	Unk		Pfizer
	Erythromycin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Novo-Rythro			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Risedronate			C	Oral	35 Mg, Weekly		Not Reported

	Risedronate	C	Unknown	Unk	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	4000 Iu, 1x/Day	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, 1x/Day	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	200 Mg, 2x/Day	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, 1x/Day	Not Reported
	Bupropion	C	Unknown	300 Milligram, Qd	Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	14852311	NON-EXPEDITED			US-PFIZER INC-2018179959		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported
	Naltrexone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	14921713	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044750		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Arthropathy; Breast Cancer Stage Iii; Condition Aggravated; Depression; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Hand Deformity; Infection; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Off Label Use; Ovarian Cancer; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Unevaluable Event; Urticaria	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qwk	Not Reported
	Cefazolin	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	400 Milligram, Q2wk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	15286354	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Doage Form Not Specified		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Meloxicam			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	15631038	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Joint Stiffness; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Oral			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	L-Thyroxine [Levothyroxine]			C	Unknown	Unk		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Unknown	Unk		Not Reported

	Tylenol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	15977915	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013598		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16201182	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Teva-Doxycycline			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

		Prednisone			C	Unknown					Not Reported
		Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16201190	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16923355	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1121572		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisolone			S	Oral	5 Mg		Teva
	Prednisone			S	Oral	5 Mg		Actavis
	Plaquenil			S	Oral	2 Df		Not Reported
	Imeth			S	Subcutaneous	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992145	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000152			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992225	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2076431		52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chylothorax; Mycobacterium Fortuitum Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992275	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201810-003694			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia
	Azilva			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			C		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported

Famotidine	C	Unk	Not Reported
Febuxostat	C	Unk	Not Reported
Rosuvastatin Calcium	C	Unk	Not Reported
Carvedilol	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Isosorbide Dinitrate	C	Unk	Not Reported
Alendronate Sodium	C	Unk	Not Reported
Nifedipine	C	Unk	Not Reported
Warfarin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992316	EXPEDITED (15-DAY)		HO	JP-ADVANZ PHARMA-201910001407			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992320	EXPEDITED (15-DAY)		OT	CH-APPCO PHARMA LLC-2076432		59 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Immune Reconstitution Inflammatory Syndrome; Night Sweats; Polyp; Whipple'S Disease	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			S	Unknown			Not Reported
	Doxycycline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992540	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-MAPI_00010593			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia

Protein Abnormal; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown	Frequency Is Every 2 Day	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Naproxen	S	Intracardiac	Unk	Not Reported
	Prednisone	S	Intracardiac	Unk	Not Reported
	Enbrel	S	Intracardiac	Unk	Not Reported
	Humira	S	Intracardiac	Unk	Not Reported
	Orencia	S	Intracardiac	Unk	Not Reported
	Actemra	S	Intracardiac	Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Plaquenil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992590	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1130880		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Mycophenolate Mofetil			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992599	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1130958		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica;	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992604	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1130879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Ill-Defined Disorder; Mental Disorder; Muscle Injury; Myalgia; Pruritus; Rash	Mycophenolate Mofetil			S	Unknown	3 Gram Daily;		Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16992612	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1130794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cefazolin	S	Unknown			Not Reported
	Leflunomide	S	Oral			Barr
	Methotrexate	S	Subcutaneous			Barr
	Apo-Leflunomide	S	Oral			Not Reported
	Enbrel	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Arava	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Viread	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16993629	EXPEDITED (15-DAY)		OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-226613		72 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epstein Barr Virus Positive Mucocutaneous Ulcer	Prednisolone			S	Unknown	10 Milligram, Daily		Taro
	Methotrexate			S	Unknown	10 Milligram, Weekly		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16993754	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019473744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16993761	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019471646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Naproxen			C		500 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16994121	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-042747		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Systemic Lupus Erythematosus	Carvedilol/Carvedilol Hydrochlodride			S	Unknown			Zydus Pharm
	Plaquenil			S	Oral			Not Reported
	Azathioprine			S	Oral			Zydus Pharm
	Epratuzumab			S	Unknown			Not Reported

	Ethinylestradiol/Norethisterone		S	Unknown		Not Reported
	Ramipril		S	Unknown		Zydus Pharm
	Atorvastatin/Atorvastatin Calcium		S	Unknown		Not Reported
	Azathioprine		S	Oral		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16994527	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-102180		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Abatacept			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16994530	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-102576		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, (2 Every 1 Week)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram (2 Every 1 Week)	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram (2 Every 1 Week)	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Vioxx		S	Oral	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram (2 Every 1 Day)	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Wellbutrin		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16994536	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-102194		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Celebrex			S	Oral	200 Milligram, As Required		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram, Bid			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Milligram, Bid			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16994800	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019471543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Methotrexate Sodium			S	Subcutaneous	15 Mg, Cyclic (4 Every 1 Week)		Unknown
	Actemra			S	Intravenous (not otherwise specified)	776 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Cyclic (4 Every 1 Week)		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	750 Mg, Monthly		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16995082	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131132			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis;	Doxycycline			S	Unknown			Actavis
	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr

Treatment Failure	Methotrexate		S	Unknown		Barr
	Bromocriptine		S	Unknown		Not Reported
	Colchicine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Unknown	11.4286 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Pamidronate Disodium		S	Unknown		Not Reported
	Ustekinumab		S	Unknown		Not Reported
	Dilaudid		C	Unknown		Not Reported
	Mercaptopurine		C	Unknown		Not Reported
	Tenoxicam		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16995084	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline Hyclate			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16995254	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131109		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Interstitial Lung Disease; Treatment Failure	Doxycycline Hyclate			S	Unknown			Actavis
	Doxycycline Hyclate			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Ivax
	Mercaptopurine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Bromocriptine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16995257	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018029497		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered;	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Abatacept			S		Unk		Not Reported

Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra	S		Unk	Not Reported
	Etanercept	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S		Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Ev 8 Weeks	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Leflunomide	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly (Qw)	Not Reported
	Methylprednisolone	S		80 Milligram	Not Reported
	Plaquenil	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Tofacitinib	S		Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Arava	S			Not Reported
	Enbrel	S			Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Milligram, Ev 8 Weeks	Not Reported
	Xeljanz	S			Not Reported
	Rituxan	C			Not Reported
	Prednisone	C			Not Reported
	Naproxen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16995546	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131138			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Liver Function Test Increased; Sepsis; Therapeutic Product Effect	Doxycycline			S	Unknown			Actavis
	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr

Decreased	Ciclosporin	S	Unknown	Ivax
	Bromocriptine	S	Unknown	Not Reported
	Colchicine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Pamidronate Disodium	S	Unknown	Not Reported
	Dilaudid	C		Not Reported
	Mercaptopurine	C		Not Reported
	Methylprednisolone	C		Not Reported
	Sulfasalazine	C		Not Reported
	Tenoxicam	C		Not Reported
	Ustekinumab	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16995968	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-225545			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk (12g)		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Nov-2019	16996114	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Doxycycline			S	Unknown			Actavis

Ineffective; Rheumatoid Arthritis	Leflunomide		S	Unknown	20 Milligram Daily;	Barr
	Hydroxychloroquine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported
	Prednisone		C	Unknown	10 Milligram Daily;	Not Reported
	Simponi		C	Subcutaneous		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	11909048	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-092211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

	Methotrexate				S	Unknown	25 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	12769015	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076278		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Nodule; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Parenteral	50 Milligram		Not Reported
	Apo Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	13153188	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005845		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, 4 Months		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram,1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, 17 Days	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Bid	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Furosemide [Furosemide Sodium]	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Nifedipine	C	Unknown	Unk	Not Reported
	Palafer	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported

	Zinc Citrate			C	Unknown	Unk	Not Reported
	Hydrochlorothiazide			C	Unknown	Unk	Not Reported
	Prednisone			C	Unknown	Unk	Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone			C	Unknown	10 Milligram, Bid	Not Reported
	Toloxin [Digoxin]			C	Unknown	Unk	Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd	Not Reported
	Leflunomide			C	Unknown	20 Milligram, Qd	Not Reported
	Atorvastatin Calcium			C	Unknown	Unk	Not Reported
	Tocilizumab			C	Unknown	Unk	Not Reported
	Gold			C	Unknown		Not Reported
	Lyrica			C	Unknown	75 Milligram, Qd	Not Reported
	Trazodone			C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	13846403	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070150		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Orencia			S	Unknown	200 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	20 Ng, Unk		Not Reported
	Rituxan			S	Intravenous (not	2 G, Q6mo		Not Reported

					otherwise specified)				
	Sulfasalazine			S	Unknown	500 Mg, Bid			Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid			Not Reported
	Prednisone			S	Unknown	20 Ng, Unk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram			Not Reported
	Actonel			C	Unknown	Unk			Not Reported
	Risedronate Sodium			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	14286093	NON-EXPEDITED			US-PFIZER INC-2017529637		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	14312586	NON-EXPEDITED			US-PFIZER INC-2017542533		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	14546982	NON-EXPEDITED			US-PFIZER INC-2018066039		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	14917261	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069816		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16623149	EXPEDITED (15-DAY)		DE, OT	GB-ROCHE-2358380			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Biliary Sepsis; Cholangiocarcinoma; Cushingoid; Glucose Tolerance Impaired; Intentional Product Use	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Issue; Off Label Use; Opportunistic Infection; Osteopenia; Osteoporosis; Rash	Mercaptopurine	S	Unknown		Not Reported
	Tacrolimus	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16799193	NON-EXPEDITED			US-PFIZER INC-2019393084		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ketorolac Tromethamine			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16971709	NON-EXPEDITED			US-SA-2019SA296137			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16996498	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201709-005391			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood	Hydroxychloroquine			S	Oral	400 Mg, Freq: Unk X 1 Days		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Humira	S	Subcutaneous	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Hydroxychloroquine Phosphate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997029	EXPEDITED (15-DAY)		DS, HO, OT	CA-ADVANZ PHARMA-GSH201706-003721			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Liver Function Test Increased; Malaise; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Rheumatoid Arthritis; Stomatitis; Treatment Failure; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Freq: Unk X 1 Days		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Oral	15 Unk, Freq: Unk X 1 Weeks		Not Reported
	Advair			C				Not Reported
	Actonel			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Aspirin 81			C				Not Reported
	Calcium			C				Not Reported

Citalopram	C	Unk	Not Reported
Copper Sulfate Ferrous Gluconate Folic Acid Manganese Sulfate Vitamin	C		Not Reported
Docusate Sodium Senna Alexandrina	C		Not Reported
Ergocalciferol	C		Not Reported
Ferrous Gluconate	C		Not Reported
Folic Acid	C		Not Reported
Hydrochlorothiazide	C	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unk	Not Reported
Olmesartan Medoxomil	C		Not Reported
Docosahexaenoic Acid	C		Not Reported
Oxybutynin	C		Not Reported
Prednisone	C		Not Reported
Rabeprazole	C		Not Reported
Rabeprazole Sodium	C		Not Reported
Senna Alexandrina	C		Not Reported
Spiriva	C	Unk	Not Reported
Tiotropium Bromide	C		Not Reported
Vitamin B12	C		Not Reported
Zinc Gluconate	C		Not Reported
Zopiclone	C	Unk	Not Reported
Tylenol	C		Not Reported
Folinic Acid	C		Not Reported
Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997295	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5171			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Not Reported
	Meloxicam	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997396	NON-EXPEDITED		OT	DE-LUPIN PHARMACEUTICALS INC.-2018-09265			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epilepsy	Topiramate			S	Unknown	Unk		Lupin
	Quensyl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997447	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2019-US-1132114		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Symptom; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia;	Hydroxychloroquine			S	Oral	60 Tablets Of Hydroxychloroquine 200 Mg (Total 12g)		Teva
	Fluoxetine			C	Unknown			Not Reported

Intentional Overdose; Laboratory Test Interference; Somnolence; Suicide Attempt; Toxicity To Various Agents	Risperidone	C	Unknown		Not Reported
	Lamotrigine	C	Unknown		Not Reported
	Lisdexamfetamine Dimesylate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997471	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Yringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997546	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1131787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Diclofenac Sodium			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997554	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist Deformity	Diclofenac Sodium			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997567	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1131569		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac			S	Unknown			Barr
	Diclofenac			S	Unknown			Barr
	Diclofenac			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Sulfamethoxazole And Trimethoprim			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Motrin [Naproxen]			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16997791	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1130964		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16999211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2451805		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	16999665	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1131637		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Feeding Disorder; Gait Disturbance; Gastric Ulcer; Gastric Ulcer Perforation; Joint Swelling; Pain In Extremity; Weight Decreased	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Dexilant			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	17000159	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1131371		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Risedronate Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	300 Milligram Daily;		Not Reported
	Hydroxychloroquine/00072603/			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	17001242	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131180			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Doxycycline			S	Unknown			Actavis
	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Mercaptopurine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methylprednisolone			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	17001753	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1131826		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight;	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis

Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium	S	Unknown	Actavis
	Diclofenac Potassium	S	Unknown	Actavis
	Diclofenac Potassium	S	Unknown	Actavis
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Sulfamethoxazole And Trimethoprim	S	Unknown	Teva
	Aspirin	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Ascorbic Acid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Motrin		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Naprosyn		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Parenteral	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Tramadol		S	Unknown	Not Reported
	Tramadol Hydrochloride		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	17001774	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Diclofenac			S	Unknown	100 Milligram Daily;		Actavis
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Indometacin			S	Unknown	150 Milligram Daily;		Actavis
	Naproxen Sodium			S	Unknown	2000 Milligram Daily;		Teva
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	17001776	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131183		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Doxycycline			S	Unknown			Actavis
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Aurothiomalate Sodium			S	Unknown			Not Reported
	Aurothiomalate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

					Sulfasalazine		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Rituximab;Urelumab		C	Unknown		Not Reported
					Simponi		C	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
06-Nov-2019	17001794	EXPEDITED (15-DAY)		OT		CA-TEVA-2019-CA-1131781			Female	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis		
	Prednisone			S	Unknown			Actavis		
	Methotrexate			S	Unknown			Barr		
	Methotrexate			S	Unknown			Barr		
	Actemra			S	Unknown			Not Reported		
	Arava			S	Oral			Not Reported		
	Cetirizine Hydrochloride			S	Unknown			Not Reported		
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported		
	Enbrel			S	Subcutaneous			Not Reported		
	Folic Acid			S	Unknown			Not Reported		
	Fosamax			S	Oral			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Hydroxychloroquine			S	Unknown			Not Reported		
	Hydroxychloroquine Sulfate			S	Oral			Not Reported		
	Orencia			S	Intravenous (not otherwise specified)			Not Reported		
	Phthalylsulfathiazole			S	Unknown			Not Reported		

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Nov-2019	17002029	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1131803		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Oral		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Oral		Not Reported
Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
Topicort	S	Cutaneous		Not Reported

		Atasol			C	Unknown				Not Reported
		Salazopyrin			C	Unknown				Not Reported
		Salazopyrin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	12405572	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016063959		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram, Q4wk		Not Reported
	Methotrexate			S	Parenteral	22.5 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported

Adalimumab	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Infliximab	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk Unk, Qwk (For 20 Weeks)	Not Reported
Gold	S	Unknown	Unk Unk, Qd (One Every One Day)	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	22.5 Mg, Qwk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk Unk, Qwk	Not Reported
Prednisone	C	Unknown	6 Milligram, Bid	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk, Unk, Qd (One Every One Day)	Not Reported
D-Penicillamine	C		Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Prednisolone	C		6 Milligram, Qd	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Phenylbutazone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	12913722	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092838			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Ibuprofen	S	Unknown	Unk	Bristol Myers Squibb
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Ibuprofen	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	25 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	13167861	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005498		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Asa			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	5 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Calcium Carbonate W/Vitamin D [Calcium Carbonate;Ergocalciferol]	C	Unknown	1500 Milligram, Qd	Not Reported
	Citalopram	C	Unknown	Unk	Not Reported
	Domperidone	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	5 Milligram	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Gliclazide	C	Unknown	Unk	Not Reported
	Lipitor	C	Unknown	Unk	Not Reported
	Nifedipine	C	Unknown	Unk	Not Reported
	Pantoprazole Sodium	C	Unknown	Unk	Not Reported
	Risedronate	C	Unknown	35 Milligram, Qwk	Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	650 Milligram, Bid	Not Reported
	Actonel	C	Unknown	35 Milligram	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminofen Tramadol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	13266763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Rituxan			S	Unknown			Not Reported

Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis; Weight Decreased	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Champix	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Valacyclovir [Valaciclovir]	C			Not Reported
	Vimovo	C			Not Reported
	Crestor	C			Not Reported
	Oxycocet	C	Oral		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	13562239	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-042730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Neutropenia; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Treatment Failure;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	25 Milligram, Cyclical		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Unevaluable Event; Urinary Tract Infection; Wheelchair User	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Oral	15 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Bid	Not Reported
	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Tofacitinib	C	Oral	5.0 Mg, Bid	Not Reported
	Dilaudid	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	14634857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019446		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported

Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Plaquenil Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	1 Dosage Form, Qd	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Q4wk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	14900180	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-041965		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Morphine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Miliaria; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Celebrex	S	Unknown	200 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Lorazepam	S	Unknown	1 Mg (Bedtime) (1 Every One Hour)	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	200 Milligram, Bid	Not Reported
	Gold	S	Unknown		Not Reported
	Citalopram	S	Unknown	10 Mg, Qd	Not Reported
	Gold	C	Unknown		Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	40 Mg, Bid	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	40 Milligram, 2 Every 1 Week	Not Reported
	Morphine	C	Unknown		Not Reported
	Celebrex	C	Unknown	200 Milligram, Bid	Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Citalopram	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	14921808	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044109		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported

Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Actonel	C	Unknown	135 Mg, Qwk	Not Reported
	Advair	C	Unknown	500 Mg, Unk	Not Reported
	Amlodipine	C	Unknown	5 Mg, Qd	Not Reported
	Ascorbic Acid	C	Oral	1000 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Qd	Not Reported
	Calcium	C	Unknown	500 Mg, Bid	Not Reported
	Citalopram	C	Unknown	30 Mg, Qd	Not Reported
	Co-Enzyme Q10	C	Unknown		Not Reported
	Copper Sulfate	C	Unknown		Not Reported
	Tocopherol	C	Unknown	Unk	Not Reported
	Fish Oil [Fish Oil;Tocopheryl Acetate]	C	Unknown		Not Reported
	Docosahexaenoic Acid	C	Unknown	Unk	Not Reported
	Docusate Sodium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	3000 Dosage Form, Qd	Not Reported
	Fatty Acid (Unspecified)	C	Unknown		Not Reported
	Ferrous Gluconate	C	Oral	300 Mg, Qd	Not Reported
	Folic Acid	C	Oral	5 Mg, Qd	Not Reported
	Hydrochlorthiazid	C	Unknown	25 Mg, Qd	Not Reported
	Hydroxychloroquine	C	Oral	2 Dosage Form, Qd	Not Reported
	Magnesium Sulfate	C	Unknown		Not Reported
	Olmesartan Medoxomil	C	Unknown	40 Mg, Qd	Not Reported
	Omega-3 Marine Triglycerides	C	Unknown		Not Reported
	Omega 3 [Fish Oil;Tocopherol]	C	Unknown		Not Reported

	Oxybutin			C	Unknown	2.5 Mg, Qd	Not Reported
	Prednisone			C	Unknown	9 Mg, Qd	Not Reported
	Rabeprazole			C	Unknown	20 Mg, Qd	Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Bid	Not Reported
	Senna Alexandrina			C	Oral	Unk	Not Reported
	Spiriva			C	Unknown		Not Reported
	Tiotropium Bromide			C	Unknown	18 Mg,	Not Reported
	Tylenol			C	Unknown	Unk, Qid	Not Reported
	Vitamin B12 [Cyanocobalamin]			C	Unknown	1500 Mg, Qd	Not Reported
	Vitamin C [Ascorbic Acid]			C	Unknown		Not Reported
	Zinc Gluconate			C	Unknown	25 Mg, Qd	Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd	Not Reported
	Vitamin C Mse Matrix			C	Oral	1000 Mg, Qd	Not Reported
	Fish Oil			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	15441402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	15580373	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018153819		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	15621696	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-975890		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension;	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Oral			Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Hydroxychloroquine Sulfate	S	Oral	5 Milligram Daily;	Not Reported
	Immunoglobulins (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone	S			Not Reported
	Triamcinolone Hexacetonide	S	Other		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	15659619	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018168313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Etanercept			S	Subcutaneous	50 Milligram		Amgen
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Enbrel	S	Unknown	50 Milligram, Qwk	Amgen
	Enbrel	S	Unknown	50 Milligram	Amgen
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz	C		11 Milligram, Qd	Not Reported
	Xeljanz	C		5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	16449342	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019095212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	16449722	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019096378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	16455677	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019095315		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	16944569	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201910001249			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Dyspnoea;	Hydroxychloroquine			S	Oral	200 Mg, Qd By Mouth		Concordia

Exposure During Pregnancy; Fatigue; Hypotension; Pneumonia; Productive Cough; Rhinorrhoea; Sepsis; Staphylococcal Infection	Prednisone	S	Oral	20 Mg, Qd By Mouth	Not Reported
	Prednisone	S	Oral	Unk (Prednisone Dose Was Increased To 20 Mg/Day)	Not Reported
	Methylprednisolone Hydrogen Succinate	S	Intravenous (not otherwise specified)	16 Mg, Qd Intravenous Nos	Not Reported
	Cyclophosphamide	S		Unk	Not Reported
	Aspirin	S	Oral	81 Mg, Qd, By Mouth	Not Reported
	Vitamin D	S		Unk	Not Reported
	Ceftriaxone Sodium	S		Unk	Not Reported
	Ceftriaxone Sodium	S			Not Reported
	Calcium Salt Not Specified	S		Unk	Not Reported
	Furosemide	S	Unknown	Unk	Not Reported
	Furosemide	S	Unknown	80 Mg, Qd	Not Reported
	Levothyroxine Sodium	S	Oral	150 Ug, Qd	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	3 G, Qd	Not Reported
	Ciclosporin	S	Oral	100 Mg, Bid (By Mouth Twice A Day)	Not Reported
	Ciclosporin	S	Oral	125 Mg, Bid (Increased To A Dose Of 125mg Twice A Day)	Not Reported
	Ursodiol	S	Oral	300 Mg, Tid	Not Reported
	Labetalol	S	Oral	400 Mg, Bid	Not Reported
	Vancomycin	C		Unk	Not Reported
	Vancomycin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17002427	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-E2B_00008027			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Concordia

Breast Cancer; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S		Unk	Concordia
	(Authorized Generic),Plaquenil Arava	S	Unknown	Unknown	Not Reported
	Arava	S		Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sodium Aurothiomalate	S		Unk	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S		Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unknown	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown Iv Nos	Not Reported
	Rituxan	S		Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Simponi	S		Unk	Not Reported
	Gold	S	Intracardiac	Unknown	Not Reported
	Gold	S		Unk	Not Reported
	Humira	S	Intracardiac	Unknown	Not Reported
	Humira	S		Unk	Not Reported
	Methotrexate Bellon	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17002434	EXPEDITED (15-DAY)		DS	CA-ROCHE-2453000		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral	Actemra			S	Intravenous (not	7.0 Year(S)		Not Reported

Sclerosis			otherwise specified)			
	Rituxan	S	Intravenous (not otherwise specified)	579 Therapy Duration		Not Reported
	Humira	S	Subcutaneous	7.0 Month(S)		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Unknown	2.0 Year(S)		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17002748	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-120021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

	Prednisone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17002942	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131990			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Sodium			S	Unknown	150 Milligram Daily;		Actavis
	Naproxen Sodium			S	Unknown	1000 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Piroxicam			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17002944	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Diclofenac			S	Unknown	100 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Naproxen			S	Unknown	2000 Milligram Daily;		Teva
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indocid			S	Unknown	150 Milligram Daily;		Not Reported

	Xeljanz			S	Unknown	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17003113	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17003125	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilic Pneumonia	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Lupin
	Betamethasone			C	Oral	0.5 Milligram, Qd (3 Years Before)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17003138	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

			Plaquenil/00072602/			S	Unknown			Not Reported
			Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
			Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported
			Remicade			S	Intravenous (not otherwise specified)			Not Reported
			Rituxan			S	Intravenous (not otherwise specified)			Not Reported
			Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17003355	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132890		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid	Diclofenac			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Hydrocortisone Acetate			S	Subcutaneous			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate Sodium			S	Oral			Barr
	Paracetamol			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Topicort	S	Subcutaneous	Not Reported
	Topicort	S	Other	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol	C		Not Reported
	Salazopyrin	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17003441	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	160 Milligram		Not Reported

	Azathioprine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17003578	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17004586	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1105941		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Ineffective	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Milligram		Not Reported
	Prednisolone			S	Oral	Starting Dose		Not Reported
	Amisulpride			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Mylan
	Cyclophosphamide			S	Unknown			Mylan
	Loxapine			S	Intramuscular	Single Intramuscular Administration Of Loxapine		Mylan
	Loxapine			S				Mylan
	Tropatepine			C	Oral	10 Milligram		Mylan
	Valproate			C	Unknown			Mylan

			Diazepam		C	Intramuscular	Single Intramuscular Administration Of Diazepam			Mylan
			Diazepam		C					Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17004746	EXPEDITED (15-DAY)		OT	CA-ROCHE-2453073		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Spleen Disorder; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17004881	EXPEDITED (15-DAY)		OT	CA-ROCHE-2453713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

						otherwise specified)				
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17005791	EXPEDITED (15-DAY)		DS	CA-ROCHE-2453059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1.0 Month(S)		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	4.0 Year(S)		Not Reported
	Etanercept			S	Subcutaneous	404.0 Day(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	5.0 Year(S)		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17005810	EXPEDITED (15-DAY)		HO	CA-ROCHE-2453993		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17005858	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1131791		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Sulfamethoxazole And Trimethoprim			S	Unknown			Teva
	Aspirin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Motrin	S	Unknown		Not Reported
	Naprosyn	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Diclofenac	C			Not Reported
	Tramadol Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17005889	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131819		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling;	Acetaminophen			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate Sodium			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Hydrocortisone Acetate			S	Subcutaneous			Actavis
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]	S	Oral	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine[Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported

	Stelara		S	Unknown		Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Subcutaneous		Not Reported
	Sulfathalidine		S	Unknown		Not Reported
	Topicort[Hydrocortisone Acetate]		S	Unknown		Not Reported
	Topicort[Hydrocortisone Acetate]		S	Subcutaneous		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Atasol /00020001/		C	Unknown		Not Reported
	Salazopyrin		C	Unknown		Not Reported
	Tofacitinib Citrate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17006140	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1132435		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17006177	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1132433		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17006382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1130810		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported

Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Hydroxychloroquine Sulfate Tablets Usp	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Lasix	C		Not Reported
	Methylprednisolone Nos	C		Not Reported
	Naprosyn	C		Not Reported
	Oxycontin	C		Not Reported
	Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17006555	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132348		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2019	17007225	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456208		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	12578529	EXPEDITED (15-DAY)		DS	CA-ROCHE-1798559		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Taken For 5 Months Dates Not Specified		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 148.0 Day(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 295.0 Day(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Taken For 5 Years; Dates Not Specified		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 11.0 Year(S)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

			otherwise specified)			
	Methotrexate	S	Subcutaneous	11 Year		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown			Not Reported
	Ramipril	C				Not Reported
	Oxycodone Terephthalate	C				Not Reported
	Morphine	C	Unknown			Not Reported
	Celebrex	C	Oral			Not Reported
	Furosemide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	13120663	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878964		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Dependence; Drug Ineffective; Drug Intolerance; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	13297892	EXPEDITED (15-DAY)		OT	CA-ROCHE-1900612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	14213329	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017174736		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram, Qd	Not Reported
	Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate		S	Oral	20 Milligram, Qwk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Asa		C	Unknown	81 Milligram	Not Reported
	Clonazepam		C	Oral	0.5 Milligram	Not Reported
	Desipramine		C	Unknown	50 Milligram	Not Reported
	Gabapentin		C	Oral	300 Milligram	Not Reported
	Nitroglycerin		C		Unk	Not Reported
	Rosuvastatin Calcium		C	Oral	20 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	14921331	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043977		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	5 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported

	Leflunomide		S	Unknown	20 Milligram	Not Reported
	Leflunomide		S	Oral	5 Milligram	Not Reported
	Leflunomide		S	Oral	10 Milligram	Not Reported
	Methotrexate		S	Unknown	5 Milligram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Gold		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Arava		C	Unknown		Not Reported
	Prednisone		C	Unknown	50 Milligram, Qd	Not Reported
	Prednisone		C	Unknown	Unk, Qwk	Not Reported
	Methotrexate		C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	14921592	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
	Tocilizumab	S	Unknown	160 Milligram		Not Reported
	Azathioprine	C	Subcutaneous	50 Milligram, Qd		Not Reported
	Imuran [Azathioprine]	C	Subcutaneous	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	15949298	EXPEDITED (15-DAY)		OT	CA-ROCHE-2261475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	15988707	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015333		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Migraine; Myocardial Infarction; Nausea; Oral Fungal Infection	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Plaquenil			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

	Enbrel			S	Unknown					Not Reported
	Humira			S	Subcutaneous					Not Reported
	Depo-Medrol			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	16040114	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020202		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Intra-articular			Barr
	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	16050341	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1020144		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product	Atenolol			S	Unknown	25 Milligram Daily;		Not Reported
	Pantoprazole Sodium Anhydrous			S				Teva
	Pantoprazole Sodium Anhydrous			S	Unknown	40 Milligram Daily;		Teva
	Ferrous Fumarate			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram Daily;		Barr

Administered; Disability; Drug Ineffective; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Methotrexate	S	Unknown	20milligram, 1every 1weeks	Barr
	Methotrexate	S	Oral	25milligram, 1every 1weeks	Barr
	Methotrexate	S	Oral	25milligram	Barr
	Methotrexate	S	Oral	25milligram, 1every 2weeks	Barr
	Methotrexate	S	Oral	20milligram, 1every 2weeks	Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral	1.4286 Milligram Daily;	Barr
	Methotrexate	S	Oral		Barr
	Naproxen Sodium	S	Oral	1000 Milligram Daily;	Teva
	Naproxen Sodium	S			Teva
	Pantoprazole	S			Teva
	Pantoprazole	S	Unknown	40 Milligram Daily;	Teva
	Prednisone	S	Unknown	5 Milligram Daily;	Actavis
	Prednisone	S	Unknown		Actavis
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Ascorbic Acid	S	Unknown	1every 24hours	Not Reported
	Co Atenolol	S	Unknown	25 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;	Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;	Not Reported

Naproxen	S	Oral	100 Milligram Daily;	Not Reported
Naproxen	S	Oral	1000 Milligram Daily;	Not Reported
Naproxen	S	Oral	1000 Milligram Daily;	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Palafer Cf	S	Unknown	1every 24hours	Not Reported
Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported
Ferrous Fumarate/Folic Acid	S	Unknown	1every 1days	Not Reported
Cyto-Matrix Vitamin C	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Actemra	S	Unknown		Not Reported
Folic Acid	C	Unknown	10 Milligram Daily;	Not Reported
Folic Acid	C	Unknown	5milligram, 2every 1weeks	Not Reported
Folic Acid	C	Unknown	5milligram, 2every 1weeks	Not Reported
Celebrex	C	Oral	200 Milligram Daily;	Not Reported
Celebrex	C	Unknown		Not Reported
Celecoxib	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	16081448	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022800			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Barr

Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Naproxen	S	Unknown		Teva
	Naproxen	S	Unknown		Teva
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Forms Daily;	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	.0333 Dosage Forms Daily;	Not Reported
	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
	Lozide/00340101/	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lantus	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported
	Vitamin D/00107901/	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	16201271	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1038746		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	16634764	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081753		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	13.5714 Milligram Daily;		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Lasix	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Oxycontin	C	Unknown	Not Reported
	Oxyneo	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	16635857	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081780		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported

					Celebrex		S	Unknown		Not Reported
					Enbrel		S	Subcutaneous		Not Reported
					Gold		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007350	EXPEDITED (15-DAY)		HO	CA-ROCHE-2454156		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007435	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456050		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007627	NON-EXPEDITED		OT	SA-AMGEN-SAUSP2019184216		66 YR	Female	SAU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Destruction	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, Weekly (1 Pill Weekly)		Not Reported
	Prednisolone			S	Oral	2.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007768	EXPEDITED (15-DAY)		HO	CA-ROCHE-2456095		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz			S	Oral				Not Reported
	Methotrexate			C	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455429			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007796	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Lipitor			C	Oral					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007856	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1132344		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17007864	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201910001356			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Hydroxychloroquine			S		Unk		Concordia
	Kevzara			C	Subcutaneous	200 Mg, Every 14 Days (200 Mg/1.14) (2 Pens/Box)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008057	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008250	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456016		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008322	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455800			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008356	EXPEDITED (15-DAY)		DS	CA-ROCHE-2455907		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008362	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455960		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455612		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Anakinra	C		Not Reported
	Ativan	C		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Desoximetasone	C	Intra-arterial	Not Reported
	Desoximetasone	C	Intramuscular	Not Reported
	Dilaudid	C		Not Reported
	Enablex [Darifenacin]	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Leflunomide	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Synthroid	C		Not Reported
	Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008438	EXPEDITED (15-DAY)		OT	CA-SA-2019SA302277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Leflunomide			S				Sanofi
	Orencia			S				Not Reported
	Rituximab			S		Unk		Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008473	EXPEDITED (15-DAY)		DS	CA-ROCHE-2454415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Actemra			S	Intravenous (not			Not Reported

Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis					otherwise specified)					
	Arava			S	Oral					Not Reported
	Enbrel			S	Subcutaneous					Not Reported
	Indometacin			S	Oral					Not Reported
	Methotrexate			S	Oral					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Indomethacin [Indometacin]			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456087		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17008727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2454297		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; C-Reactive	Actemra			S	Unknown			Not Reported

Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Arava	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported
	Simponi	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17009112	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2019M1105927		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Escherichia Infection; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Pseudomonas Infection	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17009168	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455783		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported

Peripheral Swelling; Swelling	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Tramadol Hydrochloride		C	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17009323	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132590		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17009461	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1132427		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17009569	EXPEDITED (15-DAY)		OT	CA-ROCHE-2455445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown	1.0 Month(S)		Not Reported
	Asa			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	12.0 Month(S)		Not Reported
	Xeljanz			S	Oral	3.0 Month(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011103	EXPEDITED (15-DAY)		DS	CA-ROCHE-2456949		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Joint Lock; Mass; Pain; Peripheral Swelling; Physical Disability	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Xeljanz			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456985		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Secretion Discharge; Spinal Stenosis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456746		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011711	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456740		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported

	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Urethral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011886	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1132537			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Naproxen Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

					Tocilizumab	S	Unknown		Not Reported
					Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
					Methotrexate	C	Unknown		Not Reported
					Folic Acid	C	Unknown		Not Reported
					Plaquenil /00072602/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456732		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Cannabis			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011926	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis;	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456763		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

	Calcium Carbonate		C	Unknown	Not Reported
	Cymbalta		C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]		C	Unknown	Not Reported
	Hydrochlorothiazide		C	Unknown	Not Reported
	Imitrex [Sumatriptan]		C	Unknown	Not Reported
	Lyrica		C	Unknown	Not Reported
	Premarin		C	Unknown	Not Reported
	Sumatriptan Succinate		C	Unknown	Not Reported
	Tenormin		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17011990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456972		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Singleuse Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17012325	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Diclofenac Sodium		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Nov-2019	17012467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458521		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012561	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456970		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458359			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012796	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132840			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution\ Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012801	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1132869			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	S	Oral	5 Milligram Daily;		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012802	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1081734		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported
	Oxyneo			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012806	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1133854		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012818	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1132844		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012822	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1132903		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Naproxen Sodium			S	Unknown			Teva
	Leflunomide			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012830	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1132898		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Oreencia	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid	C				Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17012912	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131752		43 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Cephalexin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Arava			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Nov-2019	17016202	DIRECT		OT			54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia; Oral Mucosal Erythema; Oral Pain; Oral Pain; Rash; Rash Erythematous; Rash Pruritic; Tongue Dry; Tongue Erythema	Plaquenil			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Prednisone 10mg			C				Not Reported
	Omega 369			C				Not Reported
	Centrum Silver Multivitamin			C				Not Reported
	Collagen 4000mg			C				Not Reported
	Triflex Joint Health Supplements			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Nov-2019	17013761	EXPEDITED (15-DAY)		DS, HO, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-11			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abscess; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Intramuscular	Dosage Form: Solution Intramuscular		Not Reported
	Naproxen			S	Unknown			Not Reported
	Remicade			S	Unknown	Dosage Form: Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	11734288	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015119854		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Single Dose Prefilled Syringe(Enbrel)			S	Unknown	Unk		Amgen
	Prolia			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	12928179	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016156155		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis;	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Urticaria	Methotrexate	S	Unknown	Unk	Not Reported
	Apo Oxycodone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	7 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Times/Wk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Oxycodone	C	Unknown	10 Milligram	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Cannabis Sativa	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	14227552	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017504924		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

Product Effect Decreased	Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported
	Asa	C	Unknown	81 Mg, Unk		Not Reported
	Clonazepam	C	Oral	0.5 Mg, Unk		Not Reported
	Desipramine	C	Unknown	50 Milligram		Not Reported
	Gabapentin	C	Oral	300 Mg, Unk		Not Reported
	Nitroglycerin	C		Unk		Not Reported
	Rosuvastatin Calcium	C	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	14731423	EXPEDITED (15-DAY)		OT	CA-ROCHE-2102630		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	790.0		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	14894599	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-085064		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis; Sinus Operation; Sinusitis; Sinusitis Noninfective	Abatacept			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Mg, Qd		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Unknown	Unk		Not Reported
	Vitamins [Ascorbic Acid;Ergocalciferol;Nicotinamide; Retinol;Riboflavin			C	Unknown	Unk		Not Reported
	Vagifen			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	400 Mg, 6 Every 1 Week		Not Reported
	L-Thyroxine [Levothyroxine]			C	Unknown	Unk		Not Reported
	Tylenol Arthritis			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	40 Mg, Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	40 Mg, Unk		Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Acetaminophen			C	Unknown	Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	15208772	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018100973		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Qwk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	15590565	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018454098		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Potassium Chloride	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	15635408	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	15636606	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105453		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Off Label Use; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported

				Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
				Remicade	S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk	Not Reported
				Rituxan	S	Intravenous (not otherwise specified)		Not Reported
				Rituximab	S	Intravenous (not otherwise specified)		Not Reported
				Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	15675876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018494620			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Etanercept			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown	1000 Milligram, Q6mo		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	16444181	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019095393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	16463805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019266672		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	16674710	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Erythromycin			S	Unknown			Not Reported
	Risedronic Acid			S	Unknown			Teva
	Novo-Rythro			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Erythro-Base			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Ergocalciferol			C	Unknown	400 Iu (International Unit) Daily;		Not Reported
	Hydroxychloroquine			C	Oral	400 Milligram Daily;		Not Reported
	Leflunomide			C	Oral	20 Milligram Daily;		Not Reported
	Orencia			C	Unknown			Not Reported
	Risedronate			C	Oral			Not Reported
	Risedronate			C				Not Reported
	Wellbutrin			C	Unknown	300 Milligram Daily;		Not Reported
	Wellbutrin			C				Not Reported
	Marijuana			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	16866462	EXPEDITED (15-DAY)		OT	GR-GLAXOSMITHKLINE-GR2019EME173000			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatic Cirrhosis; Therapy Interrupted; Transaminases Increased	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	16987850	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001429			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17013942	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001499			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Fall; Insomnia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	40 Mg (40mg/0.4ml)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014131	EXPEDITED (15-DAY)		HO	CA-ROCHE-2457095			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Cimzia			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Arava			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014144	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported

					Cimzia		S	Subcutaneous		Not Reported
					Enbrel		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014242	EXPEDITED (15-DAY)		HO	CA-ROCHE-2458184		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous (Single Use)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014282	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2019SP005580			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Off Label Use	Mycophenolate Mofetil			S	Oral	380 Mg, Bid		Strides
	Losartan			S	Unknown	25 Mg Daily		Strides
	Plaquenil /00072602/			S	Unknown	20 Mg Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014319	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1133109			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Chloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral	7 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014342	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457922		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Vaginal	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported
	Ativan	C		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine	C		Not Reported
	Enablex [Darifenacin]	C		Not Reported
	Loperamide	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Pantoprazole Sodium	C	Oral	Not Reported
	Plantago Ovata	C		Not Reported
	Synthroid	C		Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014409	EXPEDITED (15-DAY)		HO, LT	GB-ORION CORPORATION ORION PHARMA-19_00007415		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Panic Attack; Psychotic Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456967		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Powder Solution		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17014795	EXPEDITED (15-DAY)		HO	CA-ROCHE-2458329			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015071	EXPEDITED (15-DAY)		OT	NVSC2019AU026309		39 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anaphylactic Reaction; Arthritis; Asthma; Blister; Chest Pain; Costochondritis; Cough; Device Issue; Dyspnoea; Fatigue; Feeling Abnormal; Gastric Disorder; Headache; Hypoaesthesia; Injection Site Bruising; Musculoskeletal Stiffness;	Xolair			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Warfarin Sodium			S	Unknown	Unk		Not Reported
	Endep			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Nausea; Pain; Photosensitivity Reaction; Pleurisy; Pruritus; Rheumatic Disorder; Skin Exfoliation; Suffocation Feeling; Sunburn; Therapeutic Response Unexpected; Vocal Cord Dysfunction

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458363		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015259	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000018			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458354		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015578	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457943		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	4.0 Month		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	4.0 Year		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	731.0		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous	6.0 Month		Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015618	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458340			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015697	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457914		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

						Sulfasalazine		S	Oral	Not Reported
						Acetaminophen;Codeine Phosphate		C	Unknown	Not Reported
						Meloxicam		C	Unknown	Not Reported
						Methotrexate		C	Unknown	Not Reported
						Synthroid		C	Unknown	Not Reported
						Tylenol With Codeine No.3		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015850	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457996		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17015934	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458344		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

						otherwise specified)	Intravenous			
		Sulfasalazine			S	Unknown				Not Reported
		Naproxen			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17016055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2458181		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration 3.0 Year(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17017109	EXPEDITED (15-DAY)		OT	CA-SA-2019SA305936		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia;	Prednisolone			S				Not Reported
	Actonel			S				Not Reported
	Leflunomide			S	Oral	20.0 Mg, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Celecoxib			S				Not Reported

Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine	S			Sanofi
	Plaquenil	S			Sanofi
	Prednisone	S			Not Reported
	Methotrexate	S	Subcutaneous	20.0 Mg, Qw	Not Reported
	Methotrexate	S		Unk	Not Reported
	Sulfasalazine	S	Oral	500.0 Mg	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Actemra	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cyclobenzaprine	C		10.0 Mg	Not Reported
	Desoximetasone	C		5.0 Mg, Qd	Not Reported
	Desoximetasone	C		5.0 Unk	Not Reported
	Leflunomide	C			Not Reported
	Prednisone Acetate	C		5.0 Mg, Qd	Not Reported
	Tylenol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2019	17018585	EXPEDITED (15-DAY)		LT	NVSC2019US031044		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Feeling Abnormal; Ill-Defined Disorder; Influenza; Nausea	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	12419514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016264085		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly		Pfizer

Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate Sodium	S	Oral	22.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Parenteral	25 Mg, Weekly	Unknown
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk, Weekly (For 20 Weeks)	Not Reported
	Gold	S		Unk, 1x/Day	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk Unk, Qwk	Not Reported

	Prednisolone	C		6 Milligram, Qd	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd (One Every One Day)	Not Reported
	D-Penicillamine	C		Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Cyclosporine	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	6 Milligram, Bid	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Phenylbutazone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	12580891	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015386106		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Retinopathy; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S		400 Milligram, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10-20mg		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Prolia			S		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	12913909	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091821		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	13229406	EXPEDITED (15-DAY)		OT	CA-ROCHE-1892000			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Ramipril			S	Unknown				Not Reported
		Tylenol			S	Unknown				Not Reported
		Acetaminophen			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	14228937	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748896			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Therapy Duration: 5.0		Not Reported

							otherwise specified)	Years		
					Remicade	S	Unknown			Not Reported
					Simponi	S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
					Simponi	S	Unknown			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Methotrexate Sodium	S	Unknown			Not Reported
					Cortisone	S	Unknown			Not Reported
					Desoximetasone	S	Unknown			Not Reported
					Hydroxychloroquine Sulfate	S	Unknown	Therapy Duration: 212.0		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	15560458	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016512162		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil			S		400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Minocycline			S		Unk		Not Reported
	Oxycodone			S		10 Mg, Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Apo Oxycodone			S		Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported

	Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Marijuana	C		Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
	Prednisone	C	Unknown	7 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, 2 Times/Wk	Not Reported
	Cannabis Sativa	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	15929234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2258804		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral	Actemra			S	Unknown	Therapy Duration: 365.0		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 366		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 366.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 16.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 396.0		Not Reported
	Arava			S	Oral			Not Reported

Swelling; Rash; Syncope; Urticaria	Arava		S	Oral	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prevacid		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	16227030	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Celebrex			C	Oral	200 Mg, Bid		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported

	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Hydromorphone Hydrochloride			C	Unknown	Unk		Not Reported
	Enbrel			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	16456459	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019264235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	16456470	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019264172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Qwk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	16945163	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449531		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Heart Rate Increased; Heart Rate Increased; Hypersensitivity; Hypertension; Hypotension; Immunosuppression; Influenza; Infusion Related Reaction; Insomnia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nasopharyngitis; Nasopharyngitis; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain;	Methotrexate Sodium			S		20.0 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk Unk, Monthly (Every Four Weeks)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, Monthly (1 Every 4 Weeks)		Not Reported
	Plaquenil S			S		Unk		Not Reported
	Rosuvastatin Calcium			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Sertraline Hydrochloride			C				Not Reported
	Synthroid			C		Unk		Not Reported

Pain In Extremity; Pertussis; Productive Cough; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	16982778	EXPEDITED (15-DAY)		CA, OT	US-BAYER-2019-197044			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Foetal Exposure During Pregnancy; Premature Baby	Acetylsalicylic Acid (Pain And Fever)		Y	S				Bayer
	Nifedipine			S				Bayer
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Belimumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17011867	NON-EXPEDITED			US-PFIZER INC-2019485724		54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Pain In Extremity	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Folic Acid			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17018765	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456799		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Arava			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Desoximetasone			C	Unknown				Not Reported
	Infliximab			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17019031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported

	Atacand	C	Unknown		Not Reported
	Benzethonium Chloride	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydrodiuril	C	Unknown		Not Reported
	Neurontin	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17019324	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038082		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Milligram		Not Reported
	Haemophilus Influenzae			C	Unknown	Unk		Not Reported
	Prevnar 13			C	Intramuscular	Unk		Not Reported
	Tetanus Vaccine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17019418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2458073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17019442	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457981		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

		Potassium Chloride			C	Unknown				Not Reported
		Valsartan			C	Unknown				Not Reported
		Xalatan			C	Unknown				Not Reported
		Zingiber Officinale			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020275	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-105305			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020278	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012741		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	50 Mg, Qwk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	20 Milligram		Not Reported
Methotrexate	S	Subcutaneous	20 Milligram		Not Reported
Neoral	S	Oral	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	20 Milligram		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	20 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020412	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019486243			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Polyarthritis; Product Use Issue	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Xeljanz			C	Unknown	Unk, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020413	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019485732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Fatigue; Joint Swelling; Nausea; Product Dose Omission; Quality Of Life Decreased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Skin Discolouration; Visual Impairment; Vomiting	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020414	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019482829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S				Pfizer
	Lyrica			S				Pfizer
	Sulfasalazine			S				Pfizer
	Propofol			S				Unknown
	Acetaminophen			S				Not Reported
	Cimzia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020451	EXPEDITED (15-DAY)		HO	CA-ROCHE-2458183		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Increased; Septic Shock; Synovitis; Vomiting	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Other	Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17020943	EXPEDITED (15-DAY)		DE	US-AMNEAL PHARMACEUTICALS-2019-AMRX-02607		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Aspergillosis; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Pseudomonas Infection	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17021214	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019484189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Liver Function Test Increased; Off Label Use; Physical Disability; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Celebrex			C	Oral	200 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17022627	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019484376		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Exposure During Pregnancy; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Oral	200.0 Mg, Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	10.0 Mg, 1x/Day		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Domperidone			C	Unknown	3.0 Df, 1 Every 8 Hours		Not Reported
	Esomeprazole Sodium			C	Unknown	20.0 Mg, 1 Every 12 Hours		Not Reported
	Gabapentin			C	Unknown	400.0 Mg, 1x/Day		Not Reported
	Metonia			C	Unknown	5.0 Mg, Unk		Not Reported
	Prednisone			C	Unknown	8.0 Mg, 1x/Day		Not Reported
	Ranitidine			C	Unknown	1 Every 12 Hours		Not Reported
	Xeljanz			C	Oral	5.0 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5.0 Mg, 1 Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17023133	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019486179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Abatacept			S	Unknown	Unk		Not Reported

	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Amitriptyline	C		Unk	Not Reported
	Cefazolin	C		Unk	Not Reported
	Clindamycin	C		Unk	Not Reported
	Prednisone	C		10 Mg, Unk	Not Reported
	Tylenol W/Codeine No. 3	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2019	17026952	DIRECT					34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nightmare	Hydrochloroquine			S	Oral	Quantity:45 Tablet(S);		Not Reported
	Lyrica			C				Not Reported
	Lamictal			C				Not Reported
	Cymbalta			C				Not Reported
	Buspar			C				Not Reported
	Pilocarpine			C				Not Reported
	Meclizine			C				Not Reported
	Levothyroxine			C				Not Reported
	Cytomel			C				Not Reported
	Zyrtec			C				Not Reported
	Singulair			C				Not Reported
	Hydroxyzine			C				Not Reported
	Amoxicillin			C				Not Reported
	Promethazine Dm			C				Not Reported
	Vitamin D			C				Not Reported
	Vitamin B12			C				Not Reported
	Tumeric			C				Not Reported
	Glucosamine With Msm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	13348376	EXPEDITED (15-DAY)		OT	CA-ROCHE-1907789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	15206459	NON-EXPEDITED			CA-AMGEN-CANSP2018100979			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk; Maternal Exposure During Pregnancy	Enbrel			S	Transmammary	Unk		Amgen
	Enbrel			S	Transplacental	Unk		Amgen
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transplacental	400 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Transmammary	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Leflunomide			S	Transmammary	Unk		Not Reported
	Leflunomide			S	Transplacental	20 Milligram, Qd		Not Reported

			Methotrexate		S	Transmammary	Unk		Not Reported
			Methotrexate		S	Transplacental	Unk		Not Reported
			Hydroxychloroquine Sulfate		S	Transplacental	Unk		Not Reported
			Prednisone		C	Transmammary	Unk		Not Reported
			Prednisone		C	Transplacental	Unk		Not Reported
			Sulfasalazine		C	Transmammary	Unk		Not Reported
			Sulfasalazine		C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	15266480	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018318512		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Unk				Not Reported
					Hydroxychloroquine		S	Unknown	Unk				Not Reported
					Hydroxychloroquine		S	Unknown	Unk				Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Unk				Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk				Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk				Not Reported
					Desoximetasone		C	Unknown	Unk				Not Reported
					Desoximetasone		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	15317463	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172747		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown	6.0 Month		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	16893121	EXPEDITED (15-DAY)		OT	PT-ROCHE-2424637		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Disease Progression; Dyspnoea; Fatigue; Gastrointestinal Disorder; Off Label Use; Product Use In Unapproved Indication; Pulmonary Embolism	Rituximab			S	Unknown	1 G Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	16898012	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019429767		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic;	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	160 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Depo-Medrol			C		80 Mg, 1x/Day		Not Reported
	Diclofenac			C		Unk		Not Reported
	Pantoprazole Magnesium			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	16985300	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019467239		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	160 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, 1x/Day		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023604	EXPEDITED (15-DAY)		DS	CA-ROCHE-2459894			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023619	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459739		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459446		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown	Dossage Form : Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dossage Form : Not Specified		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Dossage Form : Not Specified		Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown	Dossage Form : Not Specified		Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023737	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459732		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown	84.0 Day(S)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported

					Meloxicam		C	Unknown	Not Reported
					Methotrexate		C	Unknown 730.0	Not Reported
					Orencia		C	Unknown	Not Reported
					Orencia		C	Unknown 171.0 Day(S)	Not Reported
					Remicade		C	Unknown	Not Reported
					Sulfasalazine		C	Unknown	Not Reported
					Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023842	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytology Abnormal; Drug Ineffective; Drug Intolerance; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023854	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459592			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra		S	Subcutaneous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023940	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019485767			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Once Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17023943	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019484514		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Mg, 1x/Day		Not Reported

	Enbrel	S		25 Mg, 2x/Day	Not Reported
	Enbrel	S		25 Mg, 2x/Week	Not Reported
	Humira	S	Subcutaneous	40 Mg (1 Every 2 Weeks)	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
	Leflunomide	S		20 Mg, 1x/Day	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S		200 Mg, 2x/Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg (1 Every 6 Weeks)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		1 G, 2x/Day	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024068	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024172	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024325	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459693		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Alendronate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024500	EXPEDITED (15-DAY)		OT	FI-ADVANZ PHARMA-201910001550			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Stenosis; Blood Pressure Decreased; Cerebral Infarction; Dizziness; Drug Interaction; Labelled Drug-Drug Interaction Medication Error; Pain In Extremity; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	300 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	Unk		Concordia
	Cardace (Ramipril)			S	Unknown	0.5 Df Two Times A Day, On Alternating Days With Diurex Mite / Dose Text: 1 Df Daily		Not Reported
	Cardace (Ramipril)			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Oral	1 Df Daily In The Morning		Not Reported
	Methotrexate			S	Oral	5 Dosage Form, Weekly		Not Reported
	Amiloride Hydrochloride/Hydrochlorothiazide			S	Oral	0.5 Df Every Other Day, On Alternating Days With Cardace / 1 Df Daily		Not Reported
	Amiloride Hydrochloride/Hydrochlorothiazide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024648	EXPEDITED (15-DAY)		DE, HO	CA-ROCHE-2459737		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024666	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459909			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Spinal Compression Fracture	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Specified		Not Reported
	Methotrexate	S	Oral	Solution For Injection		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024716	EXPEDITED (15-DAY)		HO	CA-ROCHE-2462090		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460792		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Therapy Partial Responder	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Orencia			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Actonel			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024756	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024881	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201911001592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Hydroxychloroquine			S	Unknown	Unk (400mg Daily On 3 Days Of The Week And 200mg Daily On 4 Days Of The Week)		Concordia
	Azathioprine			S	Unknown	150 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qow		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462065			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported

	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Celebrex			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459708		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dossage : Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Oral			Not Reported
	Gabapentin			C	Oral	Not Specified		Not Reported
	Nitroglycerin			C	Unknown	Not Specified		Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024984	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459692		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Alendronate	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17024990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459482		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Rheumatoid Arthritis; Scar; Vomiting	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17025048	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459741		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain;	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17025159	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019486761		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17025350	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

					Humira		S	Subcutaneous	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Methotrexate		S	Unknown	Not Reported
					Orencia		S	Unknown	Not Reported
					Phthalylsulfathiazole		S	Unknown	Not Reported
					Prednisone		S	Unknown	Not Reported
					Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17025673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17025790	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459743		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported

Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Gabapentin	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C	Unknown	Not Reported
	Ascorbic Acid	C	Unknown	Not Reported
	Biotin	C		Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Ferrous Fumarate	C	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Nicotinamide	C		Not Reported
	Nortriptyline Hydrochloride	C	Oral	Not Reported
	Nortriptyline Hydrochloride	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Pyridoxine Hydrochloride	C		Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Methotrexate			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17025959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461161		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026082	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460710			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026185	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459688		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026233	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019484997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Leflunomide			C		20 Mg, 1x/Day		Not Reported
	Meloxicam			C		Unk		Not Reported
	Sulfasalazine			C		3 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026271	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Oral				Not Reported
		Desoximetasone			C	Unknown				Not Reported
		Methotrexate			C	Oral				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026277	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460122		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Off Label Use; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026290	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459593		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Hydroxychloroquine	S	Unknown	Therapy Duration 5.0 Month(S)	Not Reported
	Methotrexate	S	Unknown	Therapy Duration 4.0 Month(S)	Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral	Therapy Duration -229.0	Not Reported
	Morphine	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460802		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisolone			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026681	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460632		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461157		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

			Sulfasalazine		S	Oral				Not Reported
			Rituxan		C	Intravenous (not otherwise specified)				Not Reported
			Xeljanz		C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026849	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

		Methotrexate			C	Subcutaneous				Not Reported
		Synthroid			C					Not Reported
		Acetaminophen;Codeine Phosphate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026851	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459588		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17027944	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019485742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17027954	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019487158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	50 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17028205	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1135736			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Aspirin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Penicillin G			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Acetaminophen/Codeine Phosphate			C				Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17028212	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1135772			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical	Penicillin G			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr

Condition, Insomnia Type; Sleep Disorder Due To General Medical Condition, Insomnia Type	Aspirin	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Pregabalin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17028596	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-227131		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dizziness; Intentional Overdose; Seizure; Toxicity To Various Agents; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	Took Approximately Twenty 200mg Tablets		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17028610	EXPEDITED (15-DAY)		DE, HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-226629		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Escherichia Infection; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Pseudomonas Infection	Prednisone			S	Unknown			Mutual
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	11173619	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1589861		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown	Therapy Duration: 10.0 Month		Not Reported
	Cimzia			S	Unknown	Single Use Pre-Filled Syringe		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	5-20 Mg As Necessary		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	13074317	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2252		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo Oxycodone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

	Cannabis Sativa			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15301715	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172130			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Oral			Not Reported
	Ezetrol			C	Oral			Not Reported
	Niaspan			C	Unknown			Not Reported
	Nitroglycerin			C	Transdermal			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Tylenol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15377600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184324		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye	Actemra			S	Unknown	Therapy Duration: 365.0		Not Reported
	Rituxan			S	Intravenous (not	Therapy Duration: 366.0		Not Reported

Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Rash; Syncope; Urticaria			otherwise specified)		
	Arava	S	Oral	Therapy Duration: 365.0	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 3 Months	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 366.0	Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 16.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 638.0	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 8.0 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 396.0	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15535250	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0858		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Product Complaint; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Parenteral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Adalimumab	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Abatacept	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
D-Penicillamine	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Cyclosporine	C	Unknown	Not Reported

		Ciclosporin			C	Unknown				Not Reported
		Actemra			C	Unknown				Not Reported
		Penicillamine			C	Unknown				Not Reported
		Phenylbutazone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15680066	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	2 Times/Wk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Presnisone			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15801207	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996367			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Penicillin G			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pregabalin			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15810407	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2019011348		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Pantoprazole			S	Unknown	Unk		Pfizer
	Pantoprazole			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	2 Df, 1x/Day		Pfizer
	Folic Acid			S	Unknown	Unk		Pfizer
	Lisinopril			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	1 Df, Weekly		Unknown

	Diclofenac	S	Oral	75 Milligram, Bid	Not Reported
	Diclofenac	S	Oral	Unk	Not Reported
	Diclofenac	S	Oral	Unk Unk, Qd	Not Reported
	Diclofenac [Diclofenac Potassium]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	1 Df, 1x/Day	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Voltaren Sr	S	Oral	75 Milligram, Bid	Not Reported
	Voltaren Sr	S	Oral	Unk	Not Reported
	Voltaren [Diclofenac]	S	Oral	75 Mg, Bid	Not Reported
	Voltaren [Diclofenac]	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	1 Df, 1x/Day	Not Reported
	Cambia	S	Oral	75 Milligram, Bid	Not Reported
	Cambia	S	Oral	Unk	Not Reported
	Cambia	S	Oral	Unk, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15861110	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	15936783	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-026580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk Unk, Qd		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S	Vaginal	25 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 4 Times Every 1 Week		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz			S	Unknown	Unk Absent		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Gold			S	Unknown	Unk Absent		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk Absent	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk Absent	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Tocilizumab	S	Unknown	Unk Absent	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram, Qd	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk Unk, Prn	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Synthroid	C	Unknown	Unk Absent	Not Reported
Lasix [Furosemide]	C	Unknown	40 Milligram, Tid	Not Reported
Enablex [Darifenacin]	C	Oral	Unk Unk, Prn	Not Reported
Ativan	C	Unknown	1 Milligram, Qhs (Qd)	Not Reported
Ativan	C	Unknown	1 Gram, Qd	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Orphenadrine	C	Unknown	1 Dosage Form, Bid	Not Reported
Omnaris	C	Unknown	Unk Absent	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Dilaudid	C	Unknown	4 Milligram	Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported
Kineret	C	Unknown	100 Milligram	Not Reported

Diphenhydramine Hydrochloride	C	Unknown	Unk Unk, Prn	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk Unk, Bid	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Milligram	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Intravenous (not otherwise specified)	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Morphine Sulphate	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk Unk, Prn	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dexmethasone	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Orphenadrine Citrate	C	Unknown	Unk Unk, Q12h	Not Reported
Orphenadrine Citrate	C	Unknown	1 Dosage Form, Bid	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Desoximetasone	C	Intra-articular	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	16340598	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1518		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

		Rabeprazole Sodium			C	Unknown				Not Reported
		Metformin			C	Unknown				Not Reported
		Synthroid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	16476743	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1987		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	16751639	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1097703		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness;	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported

Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine/00072603/		S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Plaquenil		S	Oral	400 Milligram Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Ergocalciferol		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	16950760	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4604		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis; Cardiac Disorder; Contusion; Croup	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported

Infectious; Drug Ineffective; Fatigue; Fibromyalgia; Foot Deformity; Gastroenteritis Viral; Headache; Heart Rate Increased; Hypersensitivity; Hypertension; Hypotension; Immunosuppression; Influenza; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Oropharyngeal Pain; Pain; Pain In Extremity; Pertussis; Productive Cough; Rash; Stress; Therapeutic Response Decreased; Treatment Failure; Weight Decreased; Weight Increased	Cimzia	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Humalog	C	Unknown	Not Reported
	Sertraline Hydrochloride	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	16976325	EXPEDITED (15-DAY)		DS, OT	US-009507513-1910USA015036			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Choking; Cough; Drug Ineffective; Dysphagia; Gait Inability; Lupus-Like Syndrome; Rheumatoid Arthritis	Prinivil			S	Oral	10 Milligram, Once A Day		Merck
	Prinivil			S				Merck
	Prednisone			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Metoprolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028740	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461163		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Singleuse Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028755	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460613		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Remicade			S	Unknown				Not Reported
		Rocuronium			S	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028805	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461825		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461162		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460644		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported

Scar; Vomiting	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Cymbalta		C	Unknown	Not Reported
	Hydromorphone		C	Unknown	Not Reported
	Synthroid		C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028975	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2461196			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17028988	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461156		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029144	EXPEDITED (15-DAY)		DS	CA-ROCHE-2460055		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Solution		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	/00072603/		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cymbalta			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029202	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461624			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Enbrel			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Meloxicam			C	Unknown			Not Reported

		Methotrexate			C	Unknown				Not Reported
		Synthroid			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029261	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460783		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029308	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Propofol			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported

		Cimzia			S	Unknown				Not Reported
		Humira			S	Subcutaneous				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029358	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5357		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	2x/Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029366	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1135786		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Penicillin G			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Penicillin G Procaine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Phenoxymethylpenicillin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported
	Pregabalin			C	Unknown	50 Milligram Daily;		Not Reported
	Tylenol[Paracetamol]			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029418	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1135759			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance;	Aspirin			S	Unknown			Not Reported

Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Barr
	Leflunomide	S	Oral	Barr
	Penicillin G Procaine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Pregabalin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029421	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136218		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Methotrexate			S	Oral			Barr
	Prednisone			S	Oral	15 Milligram Daily;		Actavis
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029467	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136518		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Prednisone			S	Oral	15 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029485	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136124		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Discomfort; Lower Respiratory Tract Infection; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Humira				S	Subcutaneous				Not Reported
	Arava				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17029890	NON-EXPEDITED			US-TEVA-2019-US-1137942			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030107	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461153		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Toe Amputation; Victim Of Crime	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	00072603		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Ophthalmic			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030122	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001619			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Increased; Psoriasis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Concordia
	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461756		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461478		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462423			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462382		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030755	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Used Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

					Orencia		S	Subcutaneous		Not Reported
					Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Topicort [Desoximetasone]		S	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030854	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030911	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461989		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 731.0		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tylenol	S	Unknown			Not Reported
	Hydromorphone Hcl	C				Not Reported
	Meloxicam	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Synthroid	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17030974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463126		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031025	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463516			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031036	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463529			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031037	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463639		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031063	EXPEDITED (15-DAY)		OT	CA-SA-2019SA316700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Leflunomide	S	Oral	20 Mg, Qd		Sanofi
	Methotrexate	S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk Unk, Unk		Sanofi
	Azathioprine	S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031067	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463729			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Codeine			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enablex [Darifenacin]			C				Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C				Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Intra-articular			Not Reported
	Oxyneo			C				Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C				Not Reported
	Trimethoprim			C				Not Reported
	Urispas			C	Unknown			Not Reported

	Vagifem			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17031083	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463937		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17032711	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136368			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Failure; Treatment Failure; Treatment Failure	Etanercept			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17033088	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1136349			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Bacteraemia; Clostridium Difficile Infection; Colitis; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Escherichia Infection; Gastrointestinal Haemorrhage; Headache; Htlv-1 Carrier; Nausea; Pyrexia; Seizure; Somnolence; Stress Ulcer; Strongyloidiasis; Venous Thrombosis; Vomiting; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2019	17033764	EXPEDITED (15-DAY)		OT	NVSC2019FR032441			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	400 Mg, Qd		Novartis
	Betamethasone			S	Transplacental	12 Mg		Not Reported
	Dexamethasone			S	Transplacental	4 Mg, Qd		Not Reported
	Acetylsalicylic Acid			S	Transplacental	75 Mg, Qd		Not Reported

	Enoxaparin			S	Transplacental	4000 Unk, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	11042903	EXPEDITED (15-DAY)		OT	CA-ROCHE-1565162		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 990.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hcl			C	Oral			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	11703790	EXPEDITED (15-DAY)		DS, HO, OT	CA-009507513-1510CAN014496		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair;	Lisinopril			S	Unknown	Unk		Merck
	Prinivil			S	Unknown			Merck
	Prinivil			S				Merck
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qw		Not Reported
	Methotrexate Sodium			S		1 Dosage Form, 1 Every 1 Week; Dosage Form: Not Specified		Not Reported

Spinal Stenosis; Tenderness; Treatment Failure	Sulfasalazine	S	Oral	500 Mg, 1 Every 1 Day	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Oral	2 Gram, 1 Every 1 Day	Not Reported
	Tecta	S	Oral	Unk, Unknown	Not Reported
	Plaquenil	S	Oral	200 Milligram, 1 Every 1 Day	Not Reported
	Plaquenil	S	Oral	1 Dosage Form, 1 Every 1 Day	Not Reported
	Voltaren Sr	S	Oral	75 Mg, 2 Every 1 Day	Not Reported
	Voltaren Sr	S	Oral	75 Milligram, Prn	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Synthroid	S			Not Reported
	Folic Acid	S	Unknown	Dosage Form: Not Specified	Not Reported
	Cambia	S	Oral	75 Milligram, 2 Every 1 Da; Dosage Form: Powder For Oral Solution	Not Reported
	Cambia	S	Oral	1 Dosage Form; Dosage Form: Powder For Oral Solution	Not Reported
	Cambia	S	Oral	2 Dosage Form, 1 Every 1 Day; Dosage Form: Powder For Oral Solution	Not Reported
	Diclofenac Potassium	S	Oral	75 Milligram, As Required	Not Reported
	Diclofenac Potassium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	1 Dosage Form, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, 1 Every 1 Day	Not Reported
	Pantoprazole	S	Oral		Not Reported
	Xeljanz	S	Oral	2 Dosage Form, 1 Every 1 Day	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2 Every 1 Day	Not Reported

	Xeljanz		S		10 Milligram, 1 Every 1 Day	Not Reported
	Apo Diclofenac Ophthalmic		S	Oral	75 Milligram, 2 Every1 Day	Not Reported
	Diclofenac		S	Oral	75 Milligram, 2 Every 1 Day	Not Reported
	Diclofenac		S	Oral	1 Dosage Form	Not Reported
	Diclofenac		S		2 Dosage Form, 1 Every 1 Day	Not Reported
	Lisinopril		S	Unknown		Not Reported
	Pantoprazole Magnesium		S	Oral		Not Reported
	Gold Sodium Thiomalate		S	Unknown		Not Reported
	Apo Lisinopril		S	Unknown		Not Reported
	Gold		C			Not Reported
	Depo-Medrol		C	Intramuscular	Unk, Once; Formulation: Suspension Intra Articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	13104598	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877747		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	14454685	EXPEDITED (15-DAY)		CA, HO, OT	PT-MYLANLABS-2018M1005012		23 DAY	Male	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; C-Reactive Protein Increased; Cardiomegaly; Foetal Exposure During Pregnancy; Heart Block Congenital; Hypoxia; Leukopenia; Lung Infiltration; Lupus Pneumonitis; Patent Ductus Arteriosus; Premature Baby; Pulmonary Embolism; Rash Erythematous; Respiratory Failure; Sepsis; Staphylococcal Infection; Tachypnoea; Thrombocytopenia	Dexamethasone			S	Transplacental	Maternal Dose 8 Mg/D On Week 26		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Mylan			S	Transplacental	Unk		Mylan
	Salbutamol			S	Transplacental	Maternal Dose: 32mg/D On Week 26		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	15388750	EXPEDITED (15-DAY)		DS	CA-ROCHE-2184811		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Duloxetine Hydrochloride			C	Unknown				Not Reported
	Ergocalciferol			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Humira			C	Subcutaneous				Not Reported
	Methotrexate			C	Unknown				Not Reported
	Orencia			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	15801060	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996369			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Penicillin G			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Pregabalin			C				Not Reported
	Tylenol			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	15804308	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996077			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Prednisone		S	Unknown	Actavis
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	15865767	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003069		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	15960760	EXPEDITED (15-DAY)		OT	CA-ROCHE-1195070			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Aphthous Ulcer; Aphthous Ulcer; Flatulence;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Intentional Product Use Issue; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Subcutaneous	Suspended	Not Reported
	Actemra	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Meloxicam	C			Not Reported
	Tramadol	C			Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C			Not Reported
	Feramax	C			Not Reported
	Prednisone	C			Not Reported
	Methotrexate	C			Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16003983	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1017724		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Warfarin		S	Unknown	Not Reported
	Amitriptyline		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16081449	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022790		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like Illness; Insomnia; Nasopharyngitis; Pain In Jaw; Pelvic Prolapse; Post Procedural Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Oral	5 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	1.7857 Milligram Daily;		Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Fentanyl	C	Unknown		Not Reported
	Gabapentin	C	Oral	800 Milligram Daily;	Not Reported
	Metformin/Sitagliptin	C	Oral		Not Reported
	Perindopril Erbumine	C	Oral	8 Milligram Daily;	Not Reported
	Rabeprazole	C	Oral	180 Milligram Daily;	Not Reported
	Ranitidine	C	Oral	150 Milligram Daily;	Not Reported
	Rosuvastatin Calcium	C	Oral	10 Milligram Daily;	Not Reported
	Synthroid	C	Oral	1 Dosage Forms Daily;	Not Reported
	Vitamin B 12	C	Oral	1 Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Zopiclone	C	Oral	7.5 Milligram Daily;	Not Reported
	Acetaminophen	C	Oral		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Sitagliptin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16170378	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Reactine//Cetirizine Hydrochloride		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16388586	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-029930		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Alendronic Acid			S	Unknown	70 Milligram, 1 Every Week		Aurobindo
	Atorvastatin			S	Unknown	10 Microgram		Not Reported
	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo
	Metformin			S	Unknown	1000 Milligram		Aurobindo
	Omeprazole			S	Oral	20 Milligram		Aurobindo
	Combivent			S	Unknown	Unk		Not Reported
	Flovent			S	Unknown	Unk		Not Reported
	Lasix			S	Unknown	40 Milligram		Not Reported
	Nitrazadon			S	Unknown	10 Milligram		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	500 Milligram		Not Reported

	Losec			S	Unknown	20 Milligram		Not Reported
	Losec			S	Oral	20 Milligram		Not Reported
	Liptor			S	Unknown	10 Milligram		Not Reported
	Ipratropium Bromide;Salbutamol Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16473785	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16749979	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201908000006			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Mycobacterial Infection; Eczema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			S	Oral	25 Mg Qd		Not Reported

Prednisolone	S	Oral	20 Mg, Qd	Not Reported
Prednisolone	S	Oral	15 Mg Qd	Not Reported
Prednisolone	S	Oral	20 Mg Qd	Not Reported
Prednisolone	S	Oral	40 Mg Qd	Not Reported
Prednisolone	S	Oral	35 Mg Qd	Not Reported
Prednisolone	S	Oral	30 Mg Qd	Not Reported
Prednisolone	S	Oral	40 Mg Qd	Not Reported
Prednisolone	S	Oral	30 Mg Qd	Not Reported
Prednisolone	S	Oral	25 Mg Qd	Not Reported
Prednisolone	S	Oral	22.5 Mg Qd	Not Reported
Prednisolone	S	Oral	20 Mg Qd	Not Reported
Prednisolone	S	Oral	15 Mg Qd	Not Reported
Fluorometholone	S	Ophthalmic	Unk, Prn	Not Reported
Methaderm	S	Topical	Unk, Prn	Not Reported
Calonal	C		Unk	Not Reported
Diquas	C		Unk	Not Reported
Hyaluronate Na	C		Unk	Not Reported
Mazulenin	C		Unk	Not Reported
Lansoprazole	C		Unk	Not Reported
Lansoprazole	C			Not Reported
Thyradin S	C		Unk	Not Reported
Edirol	C		Unk	Not Reported
Alendronate	C		Unk	Not Reported
Fungizone	C		Unk	Not Reported
Baktar	C		Unk	Not Reported
Baktar	C			Not Reported
Voglibose	C		Unk	Not Reported
Brotizolam	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16826006	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3505			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Eye Disorder; Headache; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Skin Erosion	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 10 Mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16856491	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019410635		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Unknown
	Clindamycin Phosphate			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Cephalexin [Cefalexin]			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	16913149	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4155		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17014126	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prevacid			C	Unknown					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463706		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034469	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-227529		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Disease Progression; Drug Ineffective; Pneumonia Aspiration	Prednisolone			S	Oral	1 Microgram/Kilogram, Daily		Taro
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Milligram, Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Sun
	Amisulpride			S	Unknown	Unk		Not Reported
	Diazepam			S	Intramuscular	10 Milligram, 1 Dose		Not Reported
	Zolpidem			S	Oral	10 Milligram		Sun
	Hydroxychloroquine			S	Oral	Unk		Sun

	Haloperidol	S	Oral	5 Milligram, Daily	Sun
	Lorazepam	S	Unknown	4 Milligram, Daily	Sun
	Olanzapine	S	Unknown	20 Milligram, Daily	Sun
	Cyamemazine	S	Unknown	Unk	Not Reported
	Loxapine	S	Intramuscular	100 Milligram, 1 Dose	Not Reported
	Cyclophosphamide	S	Unknown	Unk	Not Reported
	Tropatepine	S	Oral	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034742	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034765	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034777	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5383		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Exposure During Pregnancy; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Plaquenil S			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Azithromycin			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Metonia			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034782	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461891			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Actemra			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034811	EXPEDITED (15-DAY)		HO	CA-ROCHE-2462395			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034821	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5392			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Disability; Fatigue; Joint Swelling; Nausea; Product Dose Omission; Quality Of Life Decreased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Skin Discolouration; Visual Impairment; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17034829	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5465		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Renal Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid			S	Unknown		Not Reported
	Fosamax			S	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole			S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035043	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown	Solution		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Reactine//Cetirizine			S	Unknown			Not Reported

Hydrochloride					
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035096	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035124	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136513		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr

Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Apo-Prednisone	S	Oral	5 Milligram Daily;		Not Reported
	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Humira	S	Subcutaneous	20 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Actemra	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035517	EXPEDITED (15-DAY)		OT	NVSC2019FR032440			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Foetal Exposure During Pregnancy; Growth Retardation; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine			S	Transplacental	Unk, Maternal Dose: 400mg, Qd		Novartis
	Betamethasone			S	Transplacental	Unk, Maternal Dose: 12mg		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk, Maternal Dose: 75mg, Qd		Not Reported
	Enoxaparin			S	Unknown	Unk, Maternal Dose: 4000iu, Qd		Not Reported
	Dexamethasone			S	Transplacental	Unk, Maternal Dose: 4mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035569	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136235		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Joint Swelling; Mobility Decreased;	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Musculoskeletal Stiffness; Peripheral Swelling	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035674	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-043058		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Intentional Overdose; Laboratory Test Interference; Prescription Drug Used Without A Prescription; Somnolence; Suicide Attempt; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Ingested An Estimated 60 Tablets Of 200 Mg (12 G)		Zydus Pharm
	Hydroxychloroquine			S	Oral	Ingested An Estimated 60 Tablets Of 200 Mg (12 G)		Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17035735	EXPEDITED (15-DAY)		HO, LT	GB-ACCORD-161091		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Panic Attack; Psychotic Disorder; Self-Injurious Ideation; Suicidal Ideation	Methotrexate			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Lansoprazole			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036100	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug	Prednisone			S	Unknown			Actavis

Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Etanercept	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Risedronate Sodium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036105	EXPEDITED (15-DAY)		HO	CA-ROCHE-2462699		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Asthenia; Blood Pressure Fluctuation; Blood Pressure Increased; Cellulitis; Dermatitis; Fatigue; Gait Disturbance; Haematuria; Haemorrhage; Heart Rate Irregular; Infection; Lymphadenopathy; Musculoskeletal Stiffness; Nasopharyngitis; Oedema Peripheral; Pain; Product Administration Error; Rheumatoid Arthritis; Rheumatoid Factor Increased; Stress; Weight Decreased; Weight Fluctuation; Weight	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Quetiapine			C	Unknown			Not Reported
	Quetiapine Fumarate			C	Unknown			Not Reported
	Wellbutrin			C				Not Reported
	Paroxetine			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported

Increased; White Blood Cell Count Decreased; Wound Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036106	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036119	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036121	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136709		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461973		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Subcutaneous		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Methotrexate		S	Oral		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036125	EXPEDITED (15-DAY)		DS	CA-ROCHE-2463943			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Imuran [Azathioprine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036174	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172763		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 6 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462021		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported

	Acetaminophen	C		Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine	C		Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Restasis	C		Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462384		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]									
	Sulfasalazine			S	Oral					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463980		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036420	EXPEDITED (15-DAY)		DS	CA-ROCHE-2463970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown					Not Reported
	Rituxan			S	Intravenous drip					Not Reported
	Cimzia			S	Subcutaneous					Not Reported
	Enbrel			S	Unknown					Not Reported
	Humira			S	Subcutaneous					Not Reported
	Methotrexate			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported
	Imuran [Azathioprine]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036451	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463132		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036512	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463398		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Pantoprazole Sodium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036646	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462270		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported

Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Synovitis	Anakinra	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036673	EXPEDITED (15-DAY)		HO, LT, OT	GB-PFIZER INC-2019490877		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Panic Attack; Psychotic Disorder; Self-Injurious Ideation; Suicidal Ideation	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036783	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2461761		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported

Increased; Renal Failure; Sepsis; Thrombosis	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Ilaris	S	Unknown	Single-Use Vial		Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S				Not Reported
	Sodium Aurothiomalate	S	Intramuscular			Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462717		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Malignant Melanoma; Product Dose Omission; Toe Amputation	Methotrexate			S	Oral				Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)				Not Reported
	Folic Acid			C					Not Reported
	Prednisone			C	Unknown				Not Reported
	Restasis			C					Not Reported
	Synthroid			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036929	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463209		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 505.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 11.0 Year(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous	Therapy Duration: 151.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 13.0 Year(S)		Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17036963	EXPEDITED (15-DAY)		HO, LT, OT	US-APPCO PHARMA LLC-2076892		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Symptom; Electrocardiogram Abnormal; Hypokalaemia;	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

Intentional Overdose; Suicide Attempt; Toxicity To Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037019	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136740		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown	10 Milligram Daily;		Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037117	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective;	Actemra			S	Unknown			Not Reported

Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037194	EXPEDITED (15-DAY)		HO	CA-ROCHE-2462381		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

	Ilaris		C	Subcutaneous	Single-Use Vial, Powder For Solution			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037204	EXPEDITED (15-DAY)		OT	AU-ROCHE-2472206		39 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anaphylactic Reaction; Arthritis; Asthma; Blister; Chest Pain; Costochondritis; Cough; Device Issue; Dyspnoea; Fatigue; Feeling Abnormal; Gastric Disorder; Headache; Hypoaesthesia; Injection Site Bruising; Musculoskeletal Stiffness; Nausea; Pain; Photosensitivity Reaction; Pleurisy; Pruritus; Rheumatic Disorder; Skin Exfoliation; Suffocation Feeling; Sunburn; Therapeutic Response Unexpected; Vocal Cord Dysfunction	Xolair			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Endep			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037215	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136485		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective;	Methotrexate			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis

Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/ Pseudoephedrine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported

	Salazopyrin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037218	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2463342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	9.0 Month(S)		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	2.0 Year(S)		Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Enbrel			S	Unknown	730.0		Not Reported
	Enbrel			S	Unknown	731.0		Not Reported
	Enbrel			S	Unknown	4.0 Year(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	5.0 Month(S)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	1.0 Month(S)		Not Reported
	Leflunomide			S	Unknown	5.0 Month(S)		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate			S	Subcutaneous	8.0 Year(S)		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	2.0 Year(S)		Not Reported
	Simponi			S	Subcutaneous	2.0 Month(S)		Not Reported
	Arthrotec			C	Unknown			Not Reported
	Gold			C				Not Reported
	Imuran [Azathioprine]			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462726		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037627	EXPEDITED (15-DAY)		OT	CA-ROCHE-2462407		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037722	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1109688		196 DAY	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Dexamethasone			S	Transplacental	4 Milligram, Qd		Not Reported
	Dexamethasone			S				Not Reported
	Acetylsalicylic Acid			S	Transplacental	75 Milligram, Qd		Not Reported
	Enoxaparin			S	Transplacental	Dose: 4000 Ui Per Day		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Milligram, Qd		Mylan
	Betamethasone			S	Transplacental			Mylan
	Isoprenalin /00006301/			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17037780	EXPEDITED (15-DAY)		LT	CA-ROCHE-2461506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	5.0 Month(S)		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S				Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	2.0 Month(S)		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	4.0 Month(S)		Not Reported
	Kineret			S	Subcutaneous	1.0 Year(S)		Not Reported
	Kineret			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	2.0 Month(S)		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17038086	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136240			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Prednisone	S	Unknown	20 Milligram Daily;		Actavis
	Prednisone	S	Unknown	20 Milligram Daily;		Actavis
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Intramuscular			Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17038270	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136353		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported

Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Plaquenil	S	Unknown	200 Milligram Daily;		Not Reported
	Prednisone	S	Unknown	9 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Unknown	1 Dosage Forms Daily;		Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Dexamethasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17038509	EXPEDITED (15-DAY)		OT	CA-SAOL THERAPEUTICS-2019SAO00457		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective For Unapproved Indication; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Varicella Zoster Immune Globulin			S	Subcutaneous	Unk		Saol Therapeutics
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17038578	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-060449			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Product	Prednisolone			S	Unknown			Bausch And Lomb

Use In Unapproved Indication	Hydroxychloroquine		S	Unknown	Not Reported
	Mycophenolate Mofetil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Nov-2019	17038585	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-060366		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Jc Virus Granule Cell Neuronopathy	Prednisolone			S	Unknown			Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039918	NON-EXPEDITED			US-ZYDUS-032489		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Eye Contusion; Fall; Flatulence; Gait Disturbance; Nausea	Hydroxychloroquine			S	Oral			Zydus Pharm
	Primidone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039919	EXPEDITED (15-DAY)			US-ZYDUS-041075			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039920	EXPEDITED (15-DAY)			US-ZYDUS-038183			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039921	NON-EXPEDITED			US-ZYDUS-030818			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039922	NON-EXPEDITED			US-ZYDUS-034052		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dizziness	Hydroxychloroquine			S	Oral			Zydus Pharm
	Folic Acid			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039923	NON-EXPEDITED			US-ZYDUS-031005		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Odour Abnormal	Hydroxychloroquine			S	Oral			Zydus Pharm
	Benazepril/Benazepril Hydrochloride			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Potassium			C	Unknown			Not Reported
	Rosuvastatin			C	Oral			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Pramipexole			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Ferrous Aminopropane			C	Unknown			Not Reported

	Dicarboxy/Ferrous Ascorbate/Ferrous Aspartate/Ferrous Carbonate/Ferrous Chlorid Cyanocobalamin			C	Unknown					Not Reported
	Aspirin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039924	NON-EXPEDITED			US-ZYDUS-034572		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral			Zydus Pharm
	Levocetirizine			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Doxepin/Doxepin Hydrochloride			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Buspirone			C	Unknown			Not Reported
	Lamotrigine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039925	NON-EXPEDITED			US-ZYDUS-027777		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Vomiting	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Nov-2019	17039926	EXPEDITED (15-DAY)			US-ZYDUS-038354		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Disturbance In Attention; Gait	Hydroxychloroquine			S	Oral			Zydus Pharm

Disturbance; Muscle Spasms; Muscular Weakness; Pain In Extremity; Visual Impairment

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2019	16341509	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028399		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis;	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	468 Milligram, Every Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram,Every Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Once In A Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Every Month		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Daily		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Apo Celecoxib			S	Oral	Unk		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram,Every Month		Not Reported

Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Aclasta	C	Intravenous (not otherwise specified)	75 Milligram, 1 Every 2 Weeks,1 Every 4 Weeks	Not Reported
	Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Lomotil	C	Unknown	2.5 Milligram, Once A Day	Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Two Times A Day	Not Reported
	Esomeprazole	C	Unknown	400 Milligram, Two Times A Day	Not Reported
	Esomeprazole	C	Unknown	40 International Unit, Once A Day	Not Reported
	Fergon	C	Unknown	300 Milligram, Once A Day	Not Reported
	Loperamide	C	Unknown	2.5 Milligram	Not Reported
	Nasonex	C	Unknown	20 Milligram, Two Times A Day	Not Reported
	Nasonex	C	Nasal	2 Dosage Form	Not Reported
	Nortriptyline	C	Oral	10 Milligram, Cyclical,Every 1 Day	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
	Pantoprazole Magnesium	C	Unknown	400 Milligram, Once A Day	Not Reported
	Percocet	C	Unknown	1 Dosage Form,As Required	Not Reported
	Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
	Tecta	C	Unknown	40 Milligram, Once A Day	Not Reported
	Trazodone	C	Unknown	50 Milligram, Once A Day,1 Every 1 Hour	Not Reported
	Tylenol	C	Oral	1000 Milligram, Once A	Not Reported

			Day	
Vitamin D	C	Unknown	400 Dosage Form, Once A Day	Not Reported
Multivitamins	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid;Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Nexium	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day,Once A Day	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Diphenoxylate	C	Unknown	1 Dosage Form, Once A Day	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	C	Unknown	Unk	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Vitamin E	C	Unknown	Unk	Not Reported

	Vitamin C			C	Unknown	Unk			Not Reported
	Fish Oil			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Nov-2019	17007418	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-070847		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Lower; Arthralgia; Asthenia; Condition Aggravated; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Aurobindo
	Methotrexate Sodium			S	Subcutaneous	22.5 Milligram, Every Week		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported
	Esomeprazole Magnesium Trihydrate			S	Oral	40 Milligram, Once A Day		Not Reported
	Folic Acid			S	Unknown	1 Dosage Form Two Times A Week		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	13099811	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Rheumatoid Factor Negative; Synovitis	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Lyrica		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Mirtazapine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	13169280	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005325		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, 4 Every 1 Week		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	13735259	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1356654		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Pressure Decreased; Blood Pressure Fluctuation; Blood Pressure Increased; Body Temperature Decreased; Cataract; Chills; Colitis Microscopic; Cough; Diarrhoea; Ear Pruritus; Fatigue; Headache; Hypertension; Hypotension; Hypotension; Hypotension; Malaise; Nasal Congestion; Nasopharyngitis; Nasopharyngitis; Oral Pruritus; Perforated Ulcer; Procedural Pain; Pyrexia; Renal Disorder; Single Functional Kidney; Sleep Disorder; Throat Irritation; Weight Decreased; Weight Increased; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)	Form Strength: 500 Mg/50 Ml Most Recent Dose Was On 19/Jun/2014 Most Recent Rituxan Dose On 18/Jan/2		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Stopped Approx. Aug 2013		Not Reported
	Prednisone			S	Unknown	Stopped Approx. Jan 2013		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Pms-Sulfasalazine			C				Not Reported
	Eltroxin			C				Not Reported
	Gabapentin			C				Not Reported
	Hydromorphone			C				Not Reported
	Lansoprazole			C				Not Reported
	Lorazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	14909761	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076622		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate	S	Endocervical	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	15 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	15242988	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0982		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not	Not Reported

							otherwise specified)			
					Simponi	S	Subcutaneous			Not Reported
					Simponi	S	Subcutaneous			Not Reported
					Simponi	S	Subcutaneous			Not Reported
					Apo-Hydroxyquine	S	Unknown			Not Reported
					Plaquenil	S	Unknown			Not Reported
					Plaquenil	S	Oral			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Hydroxychloroquine	S	Unknown			Not Reported
					Desoximetasone	C	Oral			Not Reported
					Cortisone	C	Unknown			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
18-Nov-2019	15374470	EXPEDITED (15-DAY)		OT		CA-APOTEX-2018AP020179			Female	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex		
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex		
	Actemra			S	Unknown	Unk		Not Reported		
	Arava			S	Unknown	20 Mg, Qd		Not Reported		
	Cimzia			S	Subcutaneous	Unk		Not Reported		
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported		
	Humira			S	Subcutaneous	Unk		Not Reported		
	Orencia			S	Unknown	Unk		Not Reported		
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported		
	Rituxan			S	Intravenous (not	Unk		Not Reported		

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16003957	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1017660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Prednisone			S	Oral			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Gram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16010829	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1018870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid	Methotrexate			S	Oral			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Arthritis; Stress; Vomiting	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Domperidone		C	Oral	10 Milligram Daily;	Not Reported
	Prednisone Acetate		C	Oral	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16033221	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16053716	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023661		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown	30 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Indometacin			C	Unknown					Not Reported
	Risedronate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16054820	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020188		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Hypersensitivity; Full Blood Count Decreased; Gastrointestinal Disorder; Intentional Product Misuse; Malaise; Sjogren'S Syndrome; Weight Decreased; White Blood Cell Count Decreased	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16075959	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022648		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion;	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Prednisone			S				Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine/00072603/		S	Oral	5 Milligram Daily;	Not Reported
	Intravenous Immunoglobulins		S	Intravenous (not otherwise specified)		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral	250 Milligram Daily;	Not Reported
	Prednisone		S	Oral	2.6 Milligram Daily;	Not Reported
	Prednisone		S	Oral	6 Milligram Daily;	Not Reported
	Prednisone		S	Oral	6 Milligram Daily;	Not Reported
	Triamcinolone Hexacetonide		S	Unknown		Not Reported
	Triamcinolone Hexacetonide		S	Other		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16658084	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1085034			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Acetaminophen			S	Unknown			Not Reported
	Teva-Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Morphine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis
	Arava			S	Unknown			Not Reported
	Gold Injections			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Unknown		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Statex [Morphine Sulfate]		S	Unknown		Not Reported
					Plaquenil /00072602/		S	Unknown		Not Reported
					Morphine Sulfate Injection 1mg/Ml		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	16908798	NON-EXPEDITED			US-PFIZER INC-2019434599		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Epinephrine			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Humira			S		Unk		Not Reported
	Benazepril			S		Unk		Not Reported
	Macrobid [Clarithromycin]			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Evista			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17040920	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041184	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136712		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041344	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041345	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041358	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041550	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1007736		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diarrhoea; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Inflammation; Nausea; Synovitis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported
	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041626	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-072804		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Nausea; Rash; Therapeutic Product Effect Decreased	Cephalexin Tablets			S	Unknown	Unk		Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo
	Losartan			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Avelox			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cipro			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Penicillin Nos			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported

	Gold			C	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	Unk			Not Reported
	Saccharated Iron Oxide			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041648	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136747			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Intravenous (not			Not Reported

						otherwise specified)				
		Sulfasalazine			S	Unknown				Not Reported
		Enbrel			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17041978	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136741			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Prednisone			S	Oral	3 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042231	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465088		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Leflunomide		S	Unknown		Not Reported
					Naproxen Sodium		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Xeljanz		S	Oral		Not Reported
					Folic Acid		C	Unknown		Not Reported
					Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2465221			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown	Not Specified		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	411.0		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	Not Specified		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042329	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465225		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042342	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465406		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464645			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042419	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465413		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Actemra			S	Unknown		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Leflunomide			S	Unknown		Not Reported
	Methotrexate			S	Unknown		Not Reported
	Enbrel			S	Unknown		Not Reported
	Naproxen Sodium			S	Unknown		Not Reported
	Orencia			S	Unknown		Not Reported
	Prednisone			S	Unknown		Not Reported
	Prednisone Acetate			S	Unknown		Not Reported
	Xeljanz			S	Oral		Not Reported
	Folic Acid			C	Unknown		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown		Not Reported
	Naproxen			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042555	EXPEDITED (15-DAY)		OT	CA-ROCHE-2465471			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042658	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465443		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042753	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466078			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042779	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP024683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Cough; Gait Disturbance; Pain; Rheumatoid Arthritis; White Blood Cell Count Decreased	Acetaminophen			S	Unknown			Apotex
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			C	Unknown	1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466705		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bone Graft; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Ecchymosis; Impaired Work Ability; Joint Range Of Motion Decreased; Liver Disorder; Loss Of Personal Independence In Daily Activities; Lung Disorder; Mobility Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042831	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466559		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	200.0 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	175.0 Day(S)		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2465577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Naproxen				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466230		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17042920	EXPEDITED (15-DAY)		HO	CA-ROCHE-2464747		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Sputum Discoloured;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Thrombosis	Prednisone		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Warfarin Sodium		S	Unknown	Not Reported
	Warfarin Sodium		S	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17043662	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491581		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Irbesartan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17043669	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491512		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Dizziness; Nausea; Vomiting	Sulfasalazine			S		Unk		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Plaquenil S			S				Not Reported
	Irbesartan			C		Unk		Not Reported
	Atorvastatin Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17043687	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17044145	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-107251		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17044391	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-060384		60 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Ataxia; Dysarthria; Holmes Tremor; Jc Virus Granule Cell Neuronopathy; Nystagmus; Product Use In Unapproved Indication	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S				Bausch And Lomb
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17044450	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain In Extremity; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17044474	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136515		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Fatigue; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Prednisone	S	Oral			Actavis
	Methotrexate	S	Subcutaneous			Barr
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Celebrex	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17044794	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Intramuscular			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Prednisone			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Nov-2019	17045332	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136943		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Risedronate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	11456791	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015090784		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

	Methotrexate Sodium		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	577 Milligram		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk		Not Reported
	Desoximetasone		C		Unk		Not Reported
	Desoximetasone		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	15345785	EXPEDITED (15-DAY)		HO	CA-ROCHE-2177341		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatic Lesion; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Every 1 Day(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Cryptococcal; Pulmonary Mass; Pyrexia; Renal Cyst	Remicade		S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Day(S)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Day(S)	Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Zostavax		S	Subcutaneous		Not Reported
	Gold		S	Intramuscular		Not Reported
	Celebrex		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	15544382	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-965038		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Headache; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium/ Cholecalciferol			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported

	Humira	C	Not Reported
	Hydrocortisone	C	Not Reported
	Hyzaar	C	Not Reported
	Methylprednisolone	C	Not Reported
	Orencia	C	Not Reported
	Remicade	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	15861169	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Gram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	16155553	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728553-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Methotrexate	S	Oral			Not Reported
Orencia	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Prednisone	C	Oral			Not Reported
Xeljanz	C	Unknown			Not Reported
Folic Acid	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	16193460	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036633			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Gabapentin			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Folic Acid			S	Unknown			Not Reported
	Nexium			S	Unknown	40 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Esomeprazole			S	Unknown	40 Milligram Daily;		Teva
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	16248784	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570069-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Arava	C	Unknown			Not Reported
	Ativan	C	Unknown			Not Reported
	Darifenacin Hydrobromide	C	Unknown			Not Reported
	Dilaudid	C	Unknown			Not Reported
	Diphenhydramine	C	Unknown			Not Reported
	Furosemide	C	Unknown			Not Reported
	Loperamide	C	Unknown			Not Reported
	Norflex	C	Unknown			Not Reported
	Omnaris	C	Unknown	Spray,Metered Dose		Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Vagifem	C	Vaginal			Not Reported
	Plantago Ovata	C				Not Reported
	Desoximetasone	C	Oral			Not Reported
	Lasix	C	Unknown			Not Reported
	Pantoprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17045946	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464621		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis			otherwise specified)			
	Arava	S	Oral			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Mobicox	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17045959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466597		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration 200.0 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	Therapy Duration 175.0 Day(S)		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046074	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046111	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-072817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug	Alendronic Acid			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every Week		Not Reported

Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, 4 Eevry 1 Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram,4 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 4 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 4 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 4 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 4 Every 1 Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, 4 Every 1 Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046114	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-072819		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo

Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month(S)	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046115	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-072820		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Acetazolamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Infliximab			S				Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046117	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2465588			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Gold	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Humira	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Ilaris	S	Subcutaneous	Single-Use Vial		Not Reported
Ilaris	S	Intravenous (not otherwise specified)			Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S				Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046175	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive	Actemra			S	Unknown			Not Reported

Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046203	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046208	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1137043		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Angiopathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Venous Injury; Visual Impairment	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown	8 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046209	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136962		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Interstitial Lung Disease; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046210	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137064		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Migraine; Mobility Decreased; Nausea; Pain	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

In Extremity; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Vomiting; X-Ray Abnormal	Hydroxychloroquine			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Pantoprazole			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046271	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046348	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown	Solution		Barr
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Levothyroxine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046612	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-073056		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Losartan			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17046739	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1138579		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Escherichia Infection; Haemophagocytic Lymphohistiocytosis; Pseudomonas Infection	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown			Teva
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047055	EXPEDITED (15-DAY)		HO	CA-ROCHE-2466802		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Alendronic Acid			S	Unknown			Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047073	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464595		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Cyclical		Not Reported

Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral	Cyclical	Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	/00072603/	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Cyclical	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate	S	Oral		Not Reported
	Risedronate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2465018		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product	Actemra			S	Subcutaneous			Not Reported

Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Rituxan	S	Subcutaneous		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Piroxicam	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown	1.0 Dosage Forms	Not Reported
	Pregabalin	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047401	EXPEDITED (15-DAY)		HO	NVSC2019JP039297		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Eosinophilic Pneumonia Acute; Erythema; Rash	Hydroxychloroquine			S	Oral	200 Mg, Qd		Novartis
	Betamethasone			C	Oral	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491586		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Leflunomide			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047587	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491509		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Sulfasalazine			S	Unknown	Unk		Pfizer
	Cymbalta			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17047681	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2019-FR-1138398		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Catatonia; Drug Ineffective; Extrapyramidal Disorder; Pneumonia Aspiration	Amisulpride			S	Unknown			Not Reported
	Prednisolone			S	Oral	1 Mg/Kg Daily; Starting Dose		Actavis
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Haloperidol			S	Oral	5 Milligram Daily;		Not Reported
	Loxapine			S	Intramuscular	Single Intramuscular Administration Of		Not Reported

					Loxapine	
	Loxapine	S				Not Reported
	Tropatepine	S	Oral			Not Reported
	Valproate	C	Unknown			Not Reported
	Diazepam	C	Intramuscular	Single Intramuscular Administration Of Diazepam		Not Reported
	Diazepam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17048303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466094			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17048417	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466493		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049222	EXPEDITED (15-DAY)		HO, OT	NVSC2019TW036487		27 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lesion; Clumsiness; Diplegia; Dizziness;	Methotrexate			S	Unknown	15 Mg, Qw		Novartis
	Methotrexate			S				Novartis

Dysmetria; Extensor Plantar Response; Gait Disturbance; Gaze Palsy; Headache; Hemiparesis; Hypoaesthesia; Infusion Related Reaction; Jc Virus Infection; Muscular Weakness; Nausea; Nystagmus; Progressive Multifocal Leukoencephalopathy; Quadriparesis; Quadriplegia; Therapeutic Product Effect Decreased; Vomiting	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Prednisolone	S	Unknown	10-20 Mg, Qd	Not Reported
	Prednisolone	S	Unknown	5 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S			Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S			Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049516	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191105383		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Rheumatoid Arthritis; Uveitis	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Celgene
	Cosentyx			S	Unknown			Celgene
	Enbrel			S	Subcutaneous			Celgene
	Humira			S	Subcutaneous			Celgene
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Celgene
	Remicade			S	Intravenous drip			Celgene
	Simponi			S	Subcutaneous			Celgene
	Stelara			S	Subcutaneous			Celgene
	Sulfasalazine			S	Unknown	2 Gram		Celgene
	Sulfasalazine			S				Celgene
	Methotrexate			C	Unknown	20 Milligram		Celgene
	Methotrexate			C				Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049648	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137110		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049661	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1110046		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lupus Nephritis; Nephrotic Syndrome; Phospholipidosis; Proteinuria; Renal Disorder	Ramipril			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Mylan
	Thalidomide			C	Unknown	Unk		Mylan
	Rituximab			C	Unknown	Four Injections		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049733	EXPEDITED (15-DAY)		DS, OT	CA-CELGENEUS-CAN-20191105375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Simponi			S	Subcutaneous				Not Reported
		Stelara			S	Subcutaneous				Not Reported
		Xeljanz			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049862	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136956		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Ill-Defined Disorder; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Ulcer	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5 Milligram Daily;		Not Reported
	Betaloc/00376902/			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Losec/00661201/			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049863	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137006		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia;	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Humira (Adalimumab)	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acidophilus /00079701/	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Deflazacort	C		Not Reported
	Dilaudid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride Injection Usp	C		Not Reported
	Januvia	C		Not Reported
	Lidocaine	C		Not Reported
	Metronidazole	C		Not Reported
	Nitroglycerin	C		Not Reported
	Pantoloc	C		Not Reported
	Pregabalin	C		Not Reported
	Risedronate Sodium	C		Not Reported
	Rosuvastatin	C		Not Reported
	Rosuvastatin	C		Not Reported
	Salicylic Acid	C		Not Reported
	Triamcinolone	C		Not Reported
	Triamcinolone	C	Unknown	Not Reported
	Tylenol	C		Not Reported
	Xeljanz	C		Not Reported
	Salbutamol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17049967	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137047		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Diverticular Perforation;	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Apo-Prednisone			S	Unknown			Not Reported

Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Naprosyn	S	Unknown	1000 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Gabapentin	C	Unknown			Not Reported
	Lovastatin	C	Unknown			Not Reported
	Metoprolol	C	Unknown			Not Reported
	Naproxen Sodium	C	Unknown	1000 Milligram Daily;		Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Rosuvastatin	C	Unknown			Not Reported
	Tramadol Hydrochloride	C	Unknown			Not Reported
	Vitamin D3	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17050258	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1110378			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Delivery; Premature Separation Of Placenta	Esomeprazole			S	Oral	20 Milligram, Qd		Not Reported
	Diffu-K			S	Oral	1 Dosage Form, Qd		Mylan
	Imurel /00001501/			S	Oral	150 Milligram, Qd		Mylan
	Cortancyl			S	Oral	1 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17050624	EXPEDITED (15-DAY)		HO, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000779			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder;	Furosemide			S	Unknown	Unk		Validus
	Ceftazidime			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	500 Mg, Unk		Not Reported
	Piperacillin Sodium And Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Actonel			C	Unknown	Unk		Not Reported
	Apo Amlo			C	Unknown	Unk		Not Reported
	Apo-K			C	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Unknown	Unk		Not Reported
	Epoetin Alfa			C	Unknown	Unk		Not Reported

Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Escitalopram	C	Unknown	Unk		Not Reported
	Hydrochlorothiazide	C	Unknown	Unk		Not Reported
	Insulin Lispro	C	Unknown	Unk		Not Reported
	Januvia	C	Unknown	Unk		Not Reported
	Hydroxychloroquine	C	Unknown	Unk		Not Reported
	Kcl	C	Unknown	Unk		Not Reported
	Metformin	C	Unknown	Unk		Not Reported
	Methylprednisolone	C	Unknown	Unk		Not Reported
	Metoprolol	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported
	Risedronate	C	Unknown	Unk		Not Reported
	Slow-K	C	Unknown	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Ventolin /00139501/	C	Unknown	Unk		Not Reported
	Pantoloc /01263201/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17050686	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-11			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown	Form Of Admin: Solution Subcutaneous		Not Reported

	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2019	17052642	DIRECT		OT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chills; Depressed Mood; Dizziness; Feeling Abnormal; Insomnia; Malaise; Pyrexia	Hydroxychloroquine Tabs 200mg Generic			S	Oral	Quantity:1 Tablet(S);		Prasco

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	14284090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2034993		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	Therapy Duration: 2 Years		Not Reported
	Xeljanz			C	Oral	Subsequent Therapy Duration: 3 Months		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	15861102	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003092		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown	300 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

	Pantoprazole			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	15865832	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003864		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16057868	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020300		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral	2dosage Forms		Actavis
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	5milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16075841	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022064		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Hydromorphone Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	25milligram, 1everyy 1weeks		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16081540	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Unknown			Barr

Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone	S	Oral	Actavis
	Actemra	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Reactine//Cetirizine Hydrochloride	S	Unknown	Not Reported
	Reactine//Cetirizine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram Daily;	Not Reported
	Cetirizine Hydrochloride		S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown		Not Reported
	Reactine (Cetirizine)		S	Unknown		Not Reported
	Reactine (Cetirizine)		S	Unknown		Not Reported
	Reactine (Cetirizine)		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16082587	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1022957		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Indometacin			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Oral			Actavis
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

			Rituxan		S	Intravenous (not otherwise specified)			Not Reported
			Sulfasalazine		S	Oral	2 Gram Daily;		Not Reported
			Cymbalta		C				Not Reported
			Folic Acid		C				Not Reported
			Xeljanz		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16082762	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022826		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603//			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16082875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022919		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchiectasis; Bursitis Infective; Infection; Localised Infection; Pneumonia; Rheumatoid Arthritis; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Azathioprine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Barr
	Prednisone	S	Unknown		Actavis
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Aspirin	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Deflazacort	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Januvia	C	Unknown		Not Reported
	Kenalog	C	Unknown		Not Reported
	Lactobacillus Acidophilus	C	Unknown		Not Reported
	Lidocaine	C	Unknown		Not Reported
	Metronidazole	C	Unknown		Not Reported
	Nitroglycerin	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Pregabalin	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Salbutamol	C	Unknown		Not Reported
	Triamcinolone	C			Not Reported
	Tylenol	C	Unknown		Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16103848	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1025831		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Urinary Tract Infection	Methotrexate			S	Oral			Barr
	Prednisone			S	Oral	15 Milligram Daily;		Actavis
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Gold			C				Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16174494	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035692		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain;	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16174727	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16193549	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037276		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling;	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation				otherwise specified)		
	Alendronate Sodium		C			Not Reported
	Fosamax		C	Unknown		Not Reported
	Ibuprofen		C	Unknown		Not Reported
	Lisinopril		C	Unknown		Not Reported
	Vitamin D3		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16195314	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037288		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily; Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16346219	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-028343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Vancomycin Hydrochloride			S	Unknown	Unk		Aurobindo
	Ceftazidime			S	Unknown	Unk		Not Reported

Cellcept	S	Unknown	500 Milligram, Two Times A Day	Not Reported
Cellcept	S	Unknown	500 Milligram, Two Times A Day	Not Reported
Lasix	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
Prednisone	S	Unknown	10 Milligram, Daily	Not Reported
Prednisone	S	Unknown	7.5 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Acetaminophen	C	Oral	650 Milligram	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Apo Amlo	C	Unknown	Unk	Not Reported
Apo K	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Oral	50 Milligram	Not Reported
Epoetin Alfa	C	Unknown	Unk	Not Reported
Escitalopram	C	Unknown	10 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Insulin Lispro	C	Unknown	Unk Unk, 3 Times A Day	Not Reported
Januvia	C	Unknown	Unk	Not Reported
Kcl	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported

	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Metoprolol	C	Unknown	Unk		Not Reported
	Pantoloc	C	Unknown	40 Milligram, Daily		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported
	Risedronate	C	Unknown	35 Milligram, Every Week		Not Reported
	Slow K	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Ventolin	C	Unknown	Unk		Not Reported
	Eprex	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16346220	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028344		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Vancomycin Hydrochloride			S	Unknown	Unk		Aurobindo
	Ceftazidime			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	500 Milligram, 2 Every One Day		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Plaquenil			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Unknown	7.5 Milligram		Not Reported
	Prednisone			S	Unknown	10 Milligram, Once A Day		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Apo Amlo	C	Unknown	Unk	Not Reported
	Apo-K	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
	Epoetin Alfa	C	Unknown	Unk	Not Reported
	Escitalopram	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Humalog	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Januvia	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Pantoloc	C	Unknown	Unk	Not Reported
	Risedronate	C	Unknown	Unk	Not Reported
	Slow-K	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Ventolin	C	Unknown	Unk	Not Reported
	Apo-Amiodarone	C	Unknown	Unk	Not Reported
	Apo-Ketorolac	C	Unknown	Unk	Not Reported
	Eprex	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	16950736	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Pain; Pain In Extremity	Celebrex			S	Oral	400 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	2 G, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Apo-Leflunomide			S	Unknown	20 Meq, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Azathioprine			S	Unknown	150 Mg, 3x/Day		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, 3x/Day		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17002532	EXPEDITED (15-DAY)		CA, DE, HO, OT	US-ADVANZ PHARMA-201910001435			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Escherichia Infection; Fungal Skin Infection; Haematochezia; Haemophagocytic Lymphohistiocytosis; Hypotension; Hypoxia; Liver Injury; Mental Status Changes; Multiple Organ Dysfunction Syndrome; Myositis; Off Label Use; Pancytopenia; Pyrexia; Respiratory Tract Infection Fungal; Splenomegaly; Ulcer	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2467496		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051420	EXPEDITED (15-DAY)		HO	CA-ROCHE-2466644		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051433	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1139189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

					Desoximetasone		S	Oral		Not Reported
					Enbrel		S	Subcutaneous		Not Reported
					Folic Acid		S	Unknown		Not Reported
					Fosamax		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Oral		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Reactine//Cetirizine Hydrochloride		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051471	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051751	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137078		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Folate			C	Unknown	1 Milligram Daily;		Not Reported
	Prevacid			C	Unknown	30 Milligram Daily;		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051924	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN-001910			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Meconium Aspiration Syndrome; Pulmonary Hypertension; Respiratory Distress	Hydroxychloroquine			S	Transplacental	200 Milligram, Qd		Ipca
	Cetrizine Hydrochloride 10 Mg Tablets			S	Transplacental	Unk		Not Reported
	Sulfasalazine Delayed Release Tablets 1gm			S	Transplacental	1 Gram, Qd		Not Reported
	Prednisolone			S	Transplacental	5 Milligram, Qd		Not Reported

	Naproxen			S	Transplacental	500 Milligram, Prn			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051925	EXPEDITED (15-DAY)		HO, OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN-001909			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Hepatosplenomegaly; Hepatotoxicity; Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Ipca
	Cetrizine Hydrochloride 10 Mg Tablets			S	Unknown	10 Milligram, Bid		Not Reported
	Prednisolone Tablets			S	Unknown	5 Milligram, Qd		Not Reported
	Sulfasalazine Tablets 1gm			S	Unknown	1 Gram, Qd		Not Reported
	Naproxen			S	Unknown	500 Milligram, Prn		Not Reported
	Naproxen			S				Not Reported
	Naproxen			S				Not Reported
	Naproxen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17051930	EXPEDITED (15-DAY)		HO, OT	IN-ACCORD-161640		42 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Endocarditis; Streptococcal Infection	Methotrexate			S				Accord
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17052086	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-111779		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Orencia			S	Unknown	125 Mg/Ml		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Xeljanz	S	Oral	5 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17052091	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191105409			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Otezla			S	Unknown			Celgene
	Cosentyx			S	Oral	300 Milligram		Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leucovorin Calcium			S	Oral	5 Milligram		Not Reported
	Meloxicam			S	Oral	7.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Oral	4 Dosage Forms		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Pantoprazole			S	Oral	1 Dosage Forms		Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Diltiazem Hydrochloride			C	Oral	240 Milligram		Not Reported
	Fluticasone Propionate			C	Respiratory (inhalation)			Not Reported
	Mar-Pantoprazole			C	Unknown			Not Reported
	Mometasone Furoate			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Respiratory (inhalation)			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17052309	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-058		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Calciphylaxis	Prednisone			S	Unknown			Westward
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17052323	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019496176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Sulfasalazine			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17052372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2466844		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration :- 3.0 Year		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Month		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration:- 4.0 Year		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration:- 11.0 Month		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration:- 11.0 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17052559	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019496185		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intracranial Pressure Increased; Meningitis; Meningitis Aseptic	Salazopyrin			S	Unknown	1 G, 2x/Day		Pfizer
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17054063	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019496147			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure;	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		20 Mg, Unk		Not Reported

Vomiting	Humira	S	Subcutaneous	40 Mg, Once Every 2 Weeks		Not Reported
	Hydroxychloroquine	S		400 Mg, Daily		Not Reported
	Orencia	S		Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17054368	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Cymbalta			C	Oral	60 Milligram Daily;		Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17054370	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1138034		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Pulmonary Fibrosis; Treatment Failure	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr

	Methotrexate	S	Unknown			Barr
	Ao-Leflunomide	S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Desoximetasone	S	Oral			Not Reported
	Desoximetasone	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2019	17054513	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)		
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	3 Milligram Daily;	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	11167942	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015166621		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Diverticulum; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Plaquenil			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	15238152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015284987		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer

Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate Sodium	S		Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S		Unk	Not Reported
	Arava	S		577 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S	Unknown	577 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	577 Milligram	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	577 Milligram	Not Reported
	Actemra	S	Unknown	577 Milligram	Not Reported
	Actemra	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported

	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	577 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Desoximetasone	C	Oral	Unk		Not Reported
	Desoximetasone	C	Unknown	Unk		Not Reported
	Cortisone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	15432634	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189357		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17032999	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1109173		55 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dysphonia; Infection Reactivation; Sensation Of Foreign Body; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17056412	EXPEDITED (15-DAY)		DS	CA-ROCHE-2468973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17056416	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5664		70 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17056417	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5668		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17056580	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1138027		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Swelling; Therapy Non-Responder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17056615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17056988	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471501		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia			S	Unknown					Not Reported
	Methotrexate			C	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17057031	EXPEDITED (15-DAY)		HO	CA-ROCHE-2468921			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17057460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471492		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17057784	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201911001827			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Neutropenia; Photosensitivity Reaction; Skin Plaque; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Kevzara			S	Subcutaneous	200 Mg Qow		Not Reported
	Kevzara			S	Subcutaneous	150 Mg, Qow		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17057819	EXPEDITED (15-DAY)		OT	NVSC2019PT039635		42 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Bronchopulmonary Aspergillosis; Cough; Cytomegalovirus Colitis; Gastrointestinal Haemorrhage; Pyrexia; Staphylococcal Infection	Prednisolone			S	Unknown	60 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	0.75 G/M2, Qmo		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17057926	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019497740		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Pulmonary Mass	Sulfasalazine		S	Unknown	Pfizer
	Apo-Hydroxyquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17058100	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019498283		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess Limb; Muscle Disorder; Muscle Rupture; Musculoskeletal Disorder; Nodule; Pain In Extremity; Soft Tissue Infection; Synovitis	Sulfasalazine			S	Oral	1 G, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17058442	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2019496914		18 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Neuropathy Peripheral	Ciprofloxacin			S		500 Mg, 2x/Day		Unknown
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Prednisone			C	Oral	60 Mg, Daily		Not Reported
	Prednisone			C	Oral	10 Mg, 1x/Day (Tapered)		Not Reported
	Prednisone			C	Oral	30 Mg, Daily (Dose Was Increased)		Not Reported
	Prednisone			C	Oral	60 Mg, Daily (Increased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17058665	EXPEDITED (15-DAY)		DS	US-APPCO PHARMA LLC-2077086			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Flank Pain; Headache;	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Product Substitution Issue; Pyrexia; Urine Output Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17058748	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2019-062012			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolon			S	Transplacental	((5 Mg/D (Bis 4))/ Initially 5 Mg/D Until Gestational Week 6 Plus 2, Then Discontinued.		Not Reported
	Quensyl			S	Transplacental	200 Mg/D		Not Reported
	Folsaure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17060343	EXPEDITED (15-DAY)		OT	NVSC2019CA036044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Chest Pain; Drug Intolerance; Rheumatoid Arthritis	Naproxen			S	Unknown	Unk		Novartis
	Demerol			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17060399	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1138838			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Prednisone			S	Oral	15 Milligram Daily;		Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17061186	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1138872		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.7143 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous	2.8571 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	9 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Cetirizine Hydrochloride	C	Unknown			Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Gabapentin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2019	17061288	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1138751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Macrobid /00024401/			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	13267370	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0609		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulum; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	15410811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186798		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	15415976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186728		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Sedimentation Rate Increased; Urticaria	Cimzia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	16994799	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019471439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, 1x/Day		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17003175	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1132141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062154	EXPEDITED (15-DAY)		HO	CA-ROCHE-2471548		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Arava	C			Not Reported
	Naproxen	C	Unknown		Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062445	EXPEDITED (15-DAY)		OT	PT-LUPIN PHARMACEUTICALS INC.-2019-07595		42 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Bronchopulmonary Aspergillosis; Cytomegalovirus Colitis; Staphylococcal Infection	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisolone			S	Unknown	60 Milligram, Qd, (1 Mg/Kg Daily)		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	0.75 Gram Per Square Metre Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471571		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2470947		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)		Not Reported
	Apo-Azathioprine			S	Unknown		Not Reported
	Arava			S	Unknown		Not Reported
	Enbrel			S	Unknown		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Methotrexate			S	Subcutaneous		Not Reported
	Minocycline Hydrochloride			S	Unknown		Not Reported
	Sulfasalazine			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062575	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471617		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062613	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1139310		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Prednisone			S	Unknown	40 Mg		Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily; 25 Mg		Barr
	Methotrexate			S				Barr
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	20 Milligram Daily; 20 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062617	EXPEDITED (15-DAY)		OT	CA-ROCHE-2470961		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062812	EXPEDITED (15-DAY)		HO, LT, OT	US-APPCO PHARMA LLC-2077111		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dizziness; Overdose; Toxicity To Various Agents; Ventricular Tachycardia	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062913	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1139331		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Treatment Failure	Prednisone			S	Oral	20 Milligram Daily;		Actavis
	Prednisone			S	Oral	50 Milligram Daily;		Actavis
	Prednisone			S				Actavis
	Prednisone			S				Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulin G (Human)			C	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulin G (Human)			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	3.5714 Milligram Daily;		Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062970	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17062979	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063042	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471629			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063268	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Arava			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063566	NON-EXPEDITED			US-MYLANLABS-2019M1106785			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Nausea	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063576	EXPEDITED (15-DAY)		HO	CA-ROCHE-2472424			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063605	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063661	EXPEDITED (15-DAY)		HO, OT	PT-BAUSCH-BL-2019-061326		42 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchopulmonary Aspergillosis; Cytomegalovirus Colitis; Staphylococcal Infection	Prednisolone			S	Unknown	(1mg/Kg Daily)		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2469680		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064088	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019498274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hypotension; Mobility Decreased; Nausea; Vomiting; Weight Increased	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Citalopram Hydrobromide			C	Oral	10 Mg, Unk		Not Reported
	Clobetasol Propionate			C	Topical	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Escitalopram Oxalate			C	Oral	10 Mg, Unk		Not Reported
	Leflunomide			C	Oral	10 Mg, Daily		Not Reported
	Leucovorin [Calcium Folinate]			C	Oral	5 Mg, Weekly		Not Reported
	Methotrexate Sodium			C	Oral	10 Mg, Unk		Not Reported
	Methotrexate Sodium			C	Subcutaneous	10 Mg, Weekly		Not Reported
	Naproxen			C	Unknown	250 Mg, Unk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, Daily		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019502552		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate Sodium			S		25 Mg, Unk (4 Every 1 Week(S))		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly (1 Every 1 Week)		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Prednisone			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064157	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019502566		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064624	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus;	Actemra			S	Subcutaneous			Not Reported

Systemic Lupus Erythematosus	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064679	EXPEDITED (15-DAY)		DS	CA-ROCHE-2471523		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064736	EXPEDITED (15-DAY)		OT	CA-ROCHE-2470987		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064810	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1139591		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Prednisone			S	Oral			Actavis

Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like Illness; Insomnia; Nasopharyngitis; Pain In Jaw	Leflunomide	S	Oral		Barr
	Arava	S	Unknown		Not Reported
	Calcium Folinate	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen/Oxycdone Hydrochloride	C	Oral		Not Reported
	Celebrex	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Fentanyl	C	Unknown		Not Reported
	Gabapentin	C	Oral	800 Milligram Daily;	Not Reported
	Metformin;Sitagliptin	C	Oral		Not Reported
	Perindopril Erbumine	C	Oral	8 Milligram Daily;	Not Reported
	Rabeprazole	C	Oral	180 Milligram Daily;	Not Reported
	Ranitidine	C	Oral	150 Milligram Daily;	Not Reported
	Rosuvastatin Calcium	C	Oral	10 Milligram Daily;	Not Reported
	Synthroid	C	Oral	1 Dosage Forms Daily;	Not Reported
	Vitamin B12 /00056201/	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Zopiclone	C	Oral	7.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17065536	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019502608		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Oestradiol Increased	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17065773	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1139359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	10 Milligram Daily;		Actavis
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17066467	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1139924			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis; Rheumatoid	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported

Arthritis	Arava			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Plaquenil			S	Oral				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17066599	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1139919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Indometacin			S	Oral	200 Milligram Daily;		Actavis
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17066952	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1139427			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Pneumonia	Prednisone			S	Unknown			Actavis
	Plaquenil			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17067535	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-062300		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Doxycycline			S	Oral			Not Reported
	Metronidazole			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Tavanic			S	Oral	Breakable		Not Reported
	Atorvastatine			S	Oral			Not Reported
	Ceftriaxone Base			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone Base			C	Intravenous (not otherwise specified)	Reduced Dose		Not Reported
	Lansoprazole			C	Oral			Not Reported
	Clopidogrel Base			C	Oral			Not Reported
	Fluconazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17068155	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472917		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]					
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Risedronate Sodium	S	Oral			Not Reported
	Risedronate Sodium	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2019	15405660	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187434		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2019	17068239	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472536		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Azathioprine		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Minocycline		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Amoxicillin;Clavulanate Potassium		C	Unknown	Not Reported
	Amoxil [Amoxicillin]		C	Unknown	Not Reported
	Bcg Vaccine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2019	17068241	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472439		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2019	17068243	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472598		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2019	17068246	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472427		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Nov-2019	17068331	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1139535		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Infusion Related Reaction; Infusion Related Reaction; Off Label Use; Pharyngeal Swelling; Poor Venous Access; Vasculitis	Prednisone			S	Unknown			Actavis
	Epinephrine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Fentanyl			C	Unknown			Not Reported
	Immune Globulin (Human)			C				Not Reported
	Losartan			C	Unknown			Not Reported
	Mirtazapine			C				Not Reported
	Progesterone			C				Not Reported
	Rabeprazole			C				Not Reported
	Sertraline			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2019	17068843	EXPEDITED (15-DAY)		DS, HO	GB-DEXPHARM-20191032		53 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Dyspepsia; Dyspnoea; Electrocardiogram Qt Prolonged; Heart Rate Decreased; Hypersensitivity; Loss Of Consciousness	Methotrexate			C				Not Reported
	Diclofenac			S	Oral			Not Reported
	Ramipril			C				Not Reported
	Levothyroxine			C				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	13596397	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941961		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Voltaren [Diclofenac]			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

	Xeljanz			C	Unknown				Not Reported
	Zostavax			C	Subcutaneous	Powder For Suspension Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	14147488	EXPEDITED (15-DAY)		HO	CA-ROCHE-2013417			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Meningitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral	For 6 Month		Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	14354394	EXPEDITED (15-DAY)		HO, OT	JP-ASTELLAS-2009JP000585		21 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Bacterial Infection; Bronchitis; Diarrhoea; Diarrhoea; Erythema; Faeces Soft; Gastritis; Hyperuricaemia; Influenza; Lymphadenitis; Lymphadenopathy; Lymphadenopathy;	Tacrolimus			S	Oral			Astellas
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

Melanocytic Naevus; Metrorrhagia; Myalgia; Nasopharyngitis; Nausea; Nausea; Neck Pain; Oral Candidiasis; Oral Candidiasis; Oral Candidiasis; Pharyngitis; Pharyngitis; Pleurisy; Pyrexia; Pyrexia; Rash; Skin Mass; Systemic Lupus Erythematosus; Upper Respiratory Tract Inflammation; Urticaria	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Prednisolone	S	Oral		Not Reported
	Augmentin /00756801/	S	Oral		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral	2.0 Mg, Once Daily	Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral	2.0 Mg, Once Daily	Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral		Not Reported
	Decadron /00016001/	S	Oral	1.25 Mg/Day, Unknown Freq.	Not Reported

Decadron /00016001/	S	Oral	1 Mg/Day, Unknown Freq.	Not Reported
Decadron /00016001/	S	Oral	0.75 Mg/Day, Unknown Freq.	Not Reported
Decadron /00016001/	S	Oral	0.5 Mg/Day, Unknown Freq.	Not Reported
Gaster	C	Oral		Not Reported
Gaster	C	Oral		Not Reported
Gaster	C	Oral		Not Reported
Calcium Lactate	C	Oral		Not Reported
Onealfa	C	Oral	0.5 Mg, Once Daily	Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral	100 Mg, At Pyrexia	Not Reported
Mucosta	C	Oral	100 Mg, At Pyrexia	Not Reported
Mucosta	C	Oral	100 Mg, At Pyrexia	Not Reported
Mucosta	C	Oral	100 Mg, At Pyrexia	Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Mucosta	C	Oral		Not Reported
Primperan	C	Oral		Not Reported
Lac-B	C	Oral		Not Reported
Takepron	C	Oral		Not Reported
Takepron	C	Oral		Not Reported
Takepron	C	Oral		Not Reported

Loxonin	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported
Loxonin	C	Oral	60 Mg, At Pyrexia	Not Reported
Loxonin	C	Oral	60 Mg, At Pyrexia	Not Reported
Loxonin	C	Oral	60 Mg, At Pyrexia	Not Reported
Loxonin	C	Oral	60 Mg, At Pyrexia	Not Reported
Loxonin	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported
Flomox	C	Oral		Not Reported
Flomox	C	Oral		Not Reported
Flomox	C	Oral		Not Reported
Flomox	C	Oral		Not Reported
Rocephin	C	Unknown		Not Reported
Dogmatyl	C	Oral		Not Reported
Mucodyne	C	Oral		Not Reported
Mucodyne	C	Unknown	Unk Unk, Unknown Freq.	Not Reported
Ebastel	C	Oral		Not Reported
Antebate	C	Topical	Unknown Dose, 2-3 Times Daily	Not Reported
Antebate	C	Other	Unk Unk, Unknown Freq.	Not Reported
Omepral /00661201/	C	Oral		Not Reported
Pl Gran.	C	Oral		Not Reported
Inavir /00587301/	C	Respiratory (inhalation)		Not Reported
Calonal	C	Oral		Not Reported
Tamiflu	C	Oral		Not Reported
Cravit	C	Oral		Not Reported
Cravit	C	Oral		Not Reported

Cravit	C	Oral		Not Reported
Cravit	C	Oral		Not Reported
Cravit	C	Oral		Not Reported
Cravit	C	Oral		Not Reported
Cravit	C	Oral		Not Reported
Cravit	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral		Not Reported
Farom	C	Oral	600 Mg/Day, Unknown Freq.	Not Reported
Klaricid /00984601/	C	Oral		Not Reported
Miya Bm	C	Oral		Not Reported
Miya Bm	C	Oral		Not Reported
Miya Bm	C	Oral		Not Reported
Predonine /00016201/	C	Oral		Not Reported
Predonine /00016201/	C	Oral		Not Reported
Predonine /00016201/	C	Oral		Not Reported
Fungizone	C	Oral		Not Reported
Fungizone	C	Unknown	Unk Unk, Unknown Freq.	Not Reported
Fungizone	C	Oral	3 Ml/Day, Unknown Freq.	Not Reported
Fungizone	C	Oral	3 Ml/Day, Unknown Freq.	Not Reported
Ferromia	C	Oral		Not Reported
Celecox	C	Oral		Not Reported
Celecox	C			Not Reported
Adona /00056903/	C	Unknown	Unk Unk, Unknown Freq.	Not Reported

	Transamin	C	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Transamin	C	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Nauzelin	C	Oral		Not Reported
	Olopatadine Hydrochloride	C	Oral		Not Reported
	Restamin A Kowa	C	Other	Unk Unk, Unknown Freq.	Not Reported
	Locoid	C	Other	Unk Unk, Unknown Freq.	Not Reported
	Talion /01587402/	C	Oral		Not Reported
	Gentacin	C	Other	Unk Unk, Unknown Freq.	Not Reported
	Loxoprofen	C	Oral		Not Reported
	Ceftriaxone Sodium	C	Intravenous (not otherwise specified)		Not Reported
	Rebamide	C	Oral		Not Reported
	Levofloxacin	C	Oral		Not Reported
	Mysera	C	Other	Unk Unk, Unknown Freq.	Not Reported
	Protopic	C	Other	Unk Unk, Unknown Freq.	Not Reported
	Dequalinium	C	Oral	0.25 Mg, Once Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	15020197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2138969		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			C	Unknown			Not Reported
	Leflunomide			C	Unknown	Therapy Duration: 11 Years		Not Reported

	Remicade			C	Unknown					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	15364714	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2181752		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo Hydromorphone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium;Colecalciferol			C	Unknown			Not Reported
	Humira			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hyzaar			C	Unknown			Not Reported
	Methylprednisolone			C				Not Reported
	Orencia			C				Not Reported
	Remicade			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	15462009	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2436007-00		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Cyst Rupture; Deep Vein Thrombosis; Fall; Ingrowing Nail; Malignant Melanoma; Malignant Melanoma In Situ; Musculoskeletal Disorder; Nail Bed Bleeding; Nail Disorder; Nodule; Onychomadesis; Pain; Pain; Poor Peripheral Circulation; Post Procedural Complication; Postoperative Thrombosis; Pruritus; Rheumatoid Arthritis; Skin Discolouration; Skin Discolouration; Skin Fissures; Skin Haemorrhage; Upper Limb Fracture; Varicose Vein; Venous Operation; Visual Impairment	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobic			C				Not Reported
	Amitriptyline			C				Not Reported
	Folic Acid			C				Not Reported
	Biotin			C				Not Reported
	Vitamin B			C				Not Reported
	Vitamin D			C				Not Reported
	Fish Oil			C				Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	15635778	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978074			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax

Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Infliximab		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Unknown	Not Reported
	Anakinra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Methotrexate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	15638895	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-978071			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Hypersensitivity; Infection; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Thyroid Disorder; Vision Blurred	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

		Simponi			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16003978	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1017734		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral			Actavis
	Diclofenac			S	Oral	2 Dosage Forms Daily;		Actavis
	Diclofenac			S	Oral			Actavis
	Diclofenac			S	Oral	150 Milligram Daily;		Actavis
	Diclofenac			S	Oral	150 Milligram Daily;		Actavis
	Diclofenac			S	Oral			Actavis
	Lisinopril			S	Unknown			Ivax
	Lisinopril			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Pantoprazole Magnesium			S	Unknown			Teva
	Pantoprazole Magnesium			S	Unknown			Teva
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	500 Milligram Daily;		Not Reported
	Synthroid			S	Unknown			Not Reported
	Voltaren Sr			S	Oral			Not Reported
	Voltaren Sr			S	Oral			Not Reported
	Xeljanz			S	Oral	2 Dosage Forms Daily;		Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16069608	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16079331	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020519			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Xeljanz		S	Unknown	10 Milligram Daily;				Not Reported
		Hydroxychloroquine		C	Unknown					Not Reported
		Leflunomide		C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16081605	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022915		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16082790	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine /00072603			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16126102	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200.0 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported

	Folic Acid			C	Oral	5 Milligram		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16161347	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035606		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Etanercept			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16721983	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094098			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Ciclosporin	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold Injections	S	Unknown	Not Reported
	Humira (Adalimumab)	S	Subcutaneous	Not Reported
	Hydroxychloroquine/00072603/	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	16947680	NON-EXPEDITED			US-PFIZER INC-2019457071			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Cipro [Ciprofloxacin]			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472529		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Lymphoma; Rheumatoid Arthritis	Apo-Azathioprine			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Minocycline			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069487	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-994083			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Impaired Work Ability; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069728	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472845		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In	Rituxan			S	Intravenous drip			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472865		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069733	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate] Sulfasalazine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069783	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2472623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069831	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473509		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown	1.0 Dosage Form		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Lyrica	C	Unknown			Not Reported
	Prednisone	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069945	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473173		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17069964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473185		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Hip	Actemra			S	Unknown			Not Reported

Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Arava	C	Unknown			Not Reported
	Gold	C				Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	489 Days		Not Reported
	Leflunomide	C	Unknown	366 Days		Not Reported
	Remicade	C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472963		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Tofacitinib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070107	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070115	EXPEDITED (15-DAY)		DS	CA-ROCHE-2473913		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070136	EXPEDITED (15-DAY)		HO	CA-ROCHE-2474304			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070169	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201911001960			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Hydroxychloroquine			S	Unknown			Concordia
	Methotrexate			S	Unknown			Not Reported
	Infliximab			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070175	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201911001914			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombotic Thrombocytopenic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk (Film-Coated Tablet)		Concordia

Purpura

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070210	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2473400		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070456	NON-EXPEDITED			US-JNJFOC-20191124065		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Chest Discomfort; Fatigue; Headache; Ocular Discomfort	Simponi Aria			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070586	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019502859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Unknown	2.5 G, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070587	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019502856		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	100 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070614	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473377		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070758	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019506710			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Nausea; Oral Pain; Rheumatoid Arthritis; Stomatitis	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S		Unk, 1 Every 2 Days		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported
	Humira			C		40 Mg, 1 Every 2 Week(S)		Not Reported
	Methotrexate			C		20 Mg, Weekly		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17070947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2474295		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Xeljanz			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17071474	NON-EXPEDITED			US-PFIZER INC-2019506246		75 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cefdinir			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Sodium Chloride			S		Unk		Unknown
	Cephalexin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072030	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2019-BI-11		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

	Atorvastatin Calcium	C	Unknown			Not Reported
	Gabapentin	C	Unknown			Not Reported
	Lansoprazole	C	Unknown	Dosage Form: Capsule, Delayed Release		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Symbicort Turbuhaler	C	Unknown	Dosage Form: Powder		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072580	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140344			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis; Synovitis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072620	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140287		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension;	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Pneumonia; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072731	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019503222		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anorectal Discomfort; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Dyspepsia; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Skin Hyperpigmentation; Treatment Failure	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Prednisone			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day		Not Reported
	Fentanyl			C	Unknown	2 Df, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072784	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019503140			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Nausea; Pyrexia	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Apo-Hydroxyquine			S	Unknown	200 Mg, 2x/Day		Not Reported

	Celebrex			C	Unknown	200 Mg, 1x/Day		Not Reported
	Methotrexate Sodium			C	Subcutaneous	12.5 Mg, Unk		Not Reported
	Folinic Acid			C	Unknown	Unk, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019503111			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Pneumonia; Treatment Failure	Sulfasalazine			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17072906	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Nov-2019	17073240	EXPEDITED (15-DAY)		OT	CA-SA-2019SA317422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Plaquenil			S		300 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd, Few Weeks		Sanofi
	Mycophenolate Mofetil			S	Oral	1 G, Bid		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Not Reported
	Risedronate Sodium			S	Oral	35 Mg, Qw		Not Reported
	Imuran [Azathioprine]			C	Oral	100 Mg, Bid		Not Reported
	Imuran [Azathioprine]			C	Oral	50 Mg, Qd		Not Reported
	Imuran [Azathioprine]			C	Oral	150 Mg, Qd		Not Reported
	Humira			C	Subcutaneous	40 Mg, Qow, 4-6 Weeks		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)	1 G, And Day 15 Every 6 Months		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qw, 2-3 Months		Not Reported
	Methotrexate			C	Oral	Unk, 2-3 Weeks		Not Reported
	Prolia			C	Subcutaneous	60 Mg, Q6m		Not Reported
	Ketoprofen			C		Unk,Qid Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	13153151	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005302		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Plaquenil Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	13740477	EXPEDITED (15-DAY)		OT	CA-ROCHE-1959252		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	14759261	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2106242		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Decreased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Fosavance			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	15258583	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167477		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	15660577	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-979205		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder;	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Treatment Failure	Oxycontin	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Thiamine Hydrochloride	S	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Ascorbic Acid (Vitamin C)	C	Unknown		Not Reported
	Biotin	C			Not Reported
	D-Alpha Tocopherol	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram Daily;	Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	400 Iu (International Unit) Daily;	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	80 Milligram Daily;	Not Reported
	Ferrous Fumarate	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C		4 Dosage Forms Daily;	Not Reported
	Nicotinamide	C			Not Reported
	Nortriptyline Hydrochloride	C	Oral		Not Reported
	Pantoprazole Magnesium	C	Unknown	40 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	5 Gbq Daily;	Not Reported
	Pyridoxine Hydrochloride	C			Not Reported
	Retinol Palmitate	C			Not Reported
	Riboflavin	C			Not Reported
	Sodium Ascorbate	C			Not Reported
	Thiamine Mononitrate	C			Not Reported

	Trazodone Hydrochloride	C	Oral	50 Milligram Daily;	Not Reported
	Tylenol	C	Oral	1000 Milligram Daily;	Not Reported
	Vitamin A	C			Not Reported
	Vitamin B12	C	Unknown		Not Reported
	Vitamin C	C			Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Lomotil	C			Not Reported
	Lomotil	C			Not Reported
	Thiamine	C			Not Reported
	Thiamine	C			Not Reported
	Thiamine Hydrochloride Sandoz	C			Not Reported
	Vitamin D	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Omega-3 Fatty Acid	C			Not Reported
	Perphenazine	C			Not Reported
	Teva-Oxycocet	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16058757	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1021051		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin	Methotrexate			S	Subcutaneous			Barr
	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

Lesion; Sleep Disorder; Treatment Failure	Sulfasalazine		S	Oral	2.5 Gram Daily;	Not Reported
	Tylenol		C	Oral	1000 Milligram Daily;	Not Reported
	Aclasta		C	Intravenous (not otherwise specified)		Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid		C	Unknown		Not Reported
	Nasonex		C	Unknown		Not Reported
	Prednisone		C	Unknown	5 Milligram Daily;	Not Reported
	Trazodone Hydrochloride		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16083232	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022927		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia;	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram Daily;		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Calcium	C	Unknown			Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram Daily;		Not Reported
	Genteal /00445101/	C	Unknown			Not Reported
	Lomotil	C	Unknown	2.5 Milligram Daily;		Not Reported
	Lomotil	C				Not Reported
	Nasonex	C	Unknown			Not Reported
	Nasonex	C				Not Reported
	Omega-3 Fatty Acids	C	Unknown	2400 Milligram Daily;		Not Reported
	Nexium /01479302/	C	Unknown	80 Milligram Daily;		Not Reported
	Nortriptyline Hydrochloride	C	Oral			Not Reported
	Oxycodone Terephthalate	C	Unknown			Not Reported
	Trazodone Hydrochloride	C	Oral			Not Reported
	Tylenol	C	Oral	1000 Milligram Daily;		Not Reported
	Vitamin D /00107901/	C	Unknown			Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16341521	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028115		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug	Gabapentin			S	Oral	100 Milligram, Two Times A Day (2 Every 1 Day)		Aurobindo
	Gabapentin			S	Oral	100 Milligram, Once Every Two Weeks		Aurobindo
	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib			S	Oral	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 4 Weeks		Not Reported

Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Oral	Unk	Not Reported
	Celebrex	S	Oral	Unk, Once A Day	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	Unk, 1 Every 1 Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Week	Not Reported
	Orencia	S	Vaginal	750 Milligram, 1 Evry 1 Month	Not Reported
	Orencia	S	Subcutaneous	1 Dosage Form, Every Week	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram, 1 Every 1 Hour	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk, Once A Week	Not Reported
	Apo-Gabapentin	S	Oral	100 Milligram, Two Times A Day	Not Reported
	Arava	S	Oral	20 Milligram, Once A Day	Not Reported
	Lomotil	C	Unknown	2.5 Milligram, Once A Day	Not Reported
	Lomotil	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported

Nexium	C	Unknown	40.0 Milligram, Two Times A Day	Not Reported
Nortriptyline	C	Oral	10 Gigabecquerel, 1 Every 1 Hour	Not Reported
Omega 3	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Omega 3	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750.0 Milligram	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Trazodone	C	Oral	50 Milligram, 1 Every 1 Hour	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	36 Milligram, Once A Day	Not Reported
Calcium	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hour	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Once A Day	Not Reported

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Fergon	C	Unknown	300 Milligram, Once A Day	Not Reported
Genteal	C	Unknown	Unk	Not Reported
Aclasta	C	Unknown	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram	Not Reported
D-Alpha Tocopherol	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk Unk, Once A Day	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
Pantoprazole Magnesium	C	Unknown	400 Milligram, Once A Day	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Salmo Salar Oil	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Two Times A Day	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Fish Oil	C	Unknown	1200 Milligram, Two Times	Not Reported

				A Day	
	Folic Acid	C	Unknown	Unk	Not Reported
	Pyridoxine	C	Unknown	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Sodium	C	Unknown	Unk	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hcl	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Vitamin A	C	Unknown	Unk	Not Reported
	Vitamin B12	C	Unknown	Unk	Not Reported
	Vitamin B3	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Once A Day	Not Reported
	Zoledronic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16388054	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029815		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Gabapentin			S	Oral	100.0 Milligram, Two Times A Day		Aurobindo
	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Every Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488.0 Milligram, Every Month		Not Reported
	Enbrel			S	Unknown	50.0 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl Matrix			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	400.0 Milligram, Daily	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Every Week	Not Reported
	Myochrysine	S	Intramuscular	Unk, Every 3 Weeks	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Daily	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Diphenoxylate Hcl	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Oxycodone And Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16648695	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085255		14 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication; Renal Cell Carcinoma	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Amlodipine			S	Unknown			Teva

Enalapril Maleate	S	Unknown	Teva
Ferrous Fumarate	S	Unknown	Not Reported
Prednisone	S	Unknown	Actavis
Ranitidine	S	Unknown	Teva
Cyclophosphamide	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Infliximab	S		Not Reported
Insulin (Human)	S	Unknown	Not Reported
Metformin	S	Unknown	Actavis
Nutropin	S	Unknown	Not Reported
Protropin	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Actavis
Calcium Carbonate	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Ivax
Ciclosporin	S	Unknown	Ivax
Leflunomide	S	Unknown	Barr
Leflunomide	S	Unknown	Barr
Acetazolamide	S	Unknown	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16684005	EXPEDITED (15-DAY)		HO	CN-ASTRAZENECA-2019SF11310		62 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Erythema; Mass	Nexium			S	Oral			Astrazeneca

		Hydroxychloroquine Sulfate			S	Oral				Not Reported
		Teprenone			C	Oral				Not Reported
		Ciclosporin			C	Oral				Not Reported
		Adalat			C	Oral				Not Reported
		Prednisone Acetate			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	16732595	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054351			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Disorder; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Aurobindo
	Nexium			S	Unknown	40 Milligram, Once A Day		Not Reported
	Folic Acid			S	Unknown	1 Dosage Form, Two Times A Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Golden Seal			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17003939	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472620		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472921		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2.0 Year(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	489 Days		Not Reported
	Leflunomide			C	Unknown	11 Years		Not Reported
	Remicade			C	Unknown	2.0 Years		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073560	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472793		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073568	EXPEDITED (15-DAY)		OT	CA-ROCHE-2472709		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C	Unknown			Not Reported
	Remicade			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073569	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201804-001406			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Uveitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Predonine			C		Unk		Not Reported
	Edirol			C		Unk		Not Reported
	Edirol			C				Not Reported
	Actonel			C		Unk		Not Reported
	Actonel			C				Not Reported
	Pariet			C		Unk		Not Reported
	Pariet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073570	EXPEDITED (15-DAY)		OT	CA-ROCHE-2474211		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073749	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140392			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown	Solution		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073768	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Magnesium			C	Unknown			Not Reported
	Nexium /01479302/			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Metformin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073786	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140483		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Azathioprine			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Barr
	Methotrexate			S	Unknown	Barr
	Actemra			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Humira			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073891	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5710		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Oestradiol Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17073942	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140439			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

			Enbrel			S	Unknown			Not Reported
			Sulfasalazine			S	Unknown			Not Reported
			Orencia			S	Unknown			Not Reported
			Imuran			C				Not Reported
			Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17074056	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140404		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Plaquenil	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown	10 Nanogram Daily;	Not Reported
	Adalimumab	C	Unknown		Not Reported
	Amoxicillin	C	Unknown		Not Reported
	Amoxicillin And Clavulanate Potassium	C	Unknown		Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown		Not Reported
	Amoxil /00249601/	C	Unknown		Not Reported
	Bacillus Calmetteguerin	C	Intravesical		Not Reported
	Bacillus Calmetteguerin	C	Intravenous (not otherwise specified)		Not Reported
	Gold	C	Unknown		Not Reported
	Risedronate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17074060	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140418		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Leflunomide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17074264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2474232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17074388	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1140988		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia;	Doxycycline			S	Oral	200 Mg		Actavis

Hepatocellular Injury; Weight Loss Poor	Plaquenil	S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17075308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473722			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			C				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17075433	EXPEDITED (15-DAY)		HO	CA-ROCHE-2473916		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported

Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Arava	C		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17075445	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17075601	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019505316		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Sulfasalazine			S	Unknown	Unk		Pfizer
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Metformin Hydrochloride			S	Unknown	500 Mg, 2x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Altace			C	Unknown	5 Mg, 1x/Day		Not Reported
	Asa			C	Unknown	81 Mg, 1x/Day		Not Reported
	Folic Acid			C	Unknown	1 Df, Unk		Not Reported
	Methotrexate			C	Oral	15 Mg, 1x/Day		Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Mg, 1x/Day		Not Reported
	Vitamin D			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17076075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2474305		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17076086	EXPEDITED (15-DAY)		OT	CA-ROCHE-2473760		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Rituxan			S	Intravenous drip			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Amlodipine Besilate			C				Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Crestor			C				Not Reported
	Depo Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Ebastine			C				Not Reported
	Ferrous Gluconate			C				Not Reported

		Folic Acid			C					Not Reported
		Methylprednisolone			C	Intravenous (not otherwise specified)				Not Reported
		Tylenol			C					Not Reported
		Vitamin D3			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17077651	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17077696	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140316			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr

Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Oral			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	1.7857 Milligram Daily;		Not Reported
	Gold	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Milligram Daily;		Not Reported
	Tiaprofenic Acid	C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2019	17077952	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140391		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methyl Salicylate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	12689253	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-065600		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk, Qd		Not Reported
	Sulfathalidine			S	Oral	1 Gram		Not Reported
	Cortisone			S	Oral			Not Reported
	Folic Acid			S	Unknown	5.0 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Simponi	S	Subcutaneous			Not Reported
Desoximetasone	S	Oral			Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Sulfasalazine	S	Oral	1 G, Bid		Not Reported
Cetirizine Hydrochloride	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported
Methotrexate	S	Oral	25 Mg, Qd		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk, Qd		Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	14676148	EXPEDITED (15-DAY)		HO	PHHY2018IL051076		64 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Crohn'S Disease; Diarrhoea; Drug Ineffective; Granuloma; Normocytic Anaemia; Pyrexia	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis
	Etanercept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	15095095	EXPEDITED (15-DAY)		OT	CA-ROCHE-2147188		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Arthritis; Therapeutic Product Effect Decreased	Rituxan		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Methotrexate		C	Oral	Not Reported
	Prednisone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	15205849	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159742		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Morphine			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	15797481	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995461		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Scar;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Vomiting	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Synthroid	C				Not Reported
	Aspirin	C				Not Reported
	Cymbalta	C				Not Reported
	Hydromorphone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	15797597	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995767		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	1 Every 1 Week		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	15801199	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996357			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Phenoxymethylpenicillin			S	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	15846468	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1000984		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Sulfasalazine		S	Unknown		Not Reported
	Naprosyn /00256201/		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17078590	EXPEDITED (15-DAY)		DS, OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-228973		27 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Prednisolone			S	Unknown	10-20 Mg/Day		Taro
	Methotrexate			S	Unknown	15 Milligram, Weekly		Sun
	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17078769	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201911001959			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Indentation; Spinal Compression Fracture	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk (200 Mg, Film-Coated Tablet)		Concordia
	Neoral			S	Oral	Unk		Not Reported
	Risedronate Sodium			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17078927	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201911002110			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Concordia
	Arava			S	Oral	20 Mg, Qd,Few Weeks		Not Reported
	Mycophenolate Mofetil			S	Oral	1 G, Bid		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Not Reported

	Risedronate Sodium	S	Oral	35 Mg, Weekly		Not Reported
	Imuran	C		Unk		Not Reported
	Humira	C		Unk		Not Reported
	Rituxan	C		Unk		Not Reported
	Methotrexate	C		Unk		Not Reported
	Prolia	C		Unk		Not Reported
	Ketoprofen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17079673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475698			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17079724	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140514		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Azathioprine			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Cephalexin Monohydrate	C	Unknown		Not Reported
	Cephalexin Monohydrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17079814	EXPEDITED (15-DAY)		HO	CA-ROCHE-2473997		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Arava		C	Unknown	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tofacitinib Citrate		C	Unknown	Not Reported
	Viread		C	Unknown	Not Reported
	Amlodipine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17079824	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-112397		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

					Simponi		S	Subcutaneous			Not Reported
					Sulfasalazine		S	Unknown			Not Reported
					Codeine		C	Unknown			Not Reported
					Leflunomide		C	Unknown	20 Milligram, Qd		Not Reported
					Meloxicam		C	Unknown			Not Reported
					Methotrexate		C	Unknown	Unk, Qwk		Not Reported
					Synthroid		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080122	EXPEDITED (15-DAY)		DE, HO	US-HORIZON-PRE-0521-2019		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Escherichia Infection; Haemophagocytic Lymphohistiocytosis; Pseudomonas Infection	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080207	EXPEDITED (15-DAY)		OT	CA-ROCHE-2474964			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

					Sulfasalazine		S	Unknown		Not Reported
					Varicella Zoster Vaccine Live		S	Subcutaneous		Not Reported
					Varicella Zoster Vaccine Live		S	Intravenous (not otherwise specified)		Not Reported
					Xeljanz		S	Oral		Not Reported
					Xeljanz		S	Oral		Not Reported
					Cortisone Acetate		C	Subcutaneous		Not Reported
					Desoximetasone		C	Subcutaneous		Not Reported
					Diclofenac		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080257	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142337		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2474837		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Swelling	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475244		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported

Arthritis; Thyroid Neoplasm	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080815	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475440		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Rituxan			S	Intravenous drip	Therapy Duration:- 397.0 Days		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration:- 6.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration :- 560.0		Not Reported
	Orencia			S	Unknown	Therapy Duration :- 471.0 Days		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration :- 10.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration :- 471.0 Days		Not Reported
	Sulfasalazine			S	Oral	Therapy Duration :- 471.0 Days		Not Reported
	Xeljanz			S	Oral	Therapy Duration :- 471.0 Days		Not Reported

	Arava			C	Unknown					Not Reported
	Arava			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17080886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475610		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17081625	NON-EXPEDITED			US-UCBSA-2018055688		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S		Unk		Not Reported
	Vitamin D			C				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082245	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019507495		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Sulfasalazine			S				Pfizer

Drug Ineffective; Haemoglobin Decreased	Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475598		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082294	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019510055		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cardiac Failure; Cytopenia; Generalised Oedema; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Prednisone			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082660	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141263			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082690	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082704	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Mobicox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082886	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141261		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Sulfasalazine			C	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17082934	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019510139		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate Sodium	S		Unk	Pfizer
	Actemra	S		1 Df, Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Calcium	C		500 Mg, 1x/Day	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C		Unk, 2x/Day	Not Reported
	Ergocalciferol	C		Unk, Weekly	Not Reported
	Estradiol	C		0.6 %, 3x/Day	Not Reported
	Estrogel	C		0.6 %, 3x/Day	Not Reported
	Furosemide	C		40 Mg, 1x/Day	Not Reported
	Gravol	C		Unk	Not Reported
	Potassium Chloride	C		1500 Mg, 1x/Day	Not Reported
	Valsartan	C		320 Mg, 1x/Day	Not Reported
	Xalatan	C		50 Ug, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17083180	EXPEDITED (15-DAY)		OT	NVSC2019CA045888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Codeine Phosphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17083811	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084153	EXPEDITED (15-DAY)		OT	NVSC2019TW043890			Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Auditory Disorder; Congenital Anomaly; Foetal Exposure During Pregnancy; Foetal Malformation; Hypertelorism Of Orbit; Micrognathia; Microtia	Mycophenolate Mofetil			S	Transplacental	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	200 Mg, Qd		Novartis
	Irbesartan			S	Transplacental	150 Mg, Qd		Not Reported
	Prednisolone			S	Transplacental	30 Mg, Qd		Not Reported
	Felodipine			S	Transplacental	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084283	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported

					Humira		S	Unknown		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Hydroxychloroquine Sulfate		C	Unknown		Not Reported
					Desoximetasone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084285	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141344		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084290	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain;	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Xeljanz		C		Not Reported
	Acetaminophen		C		Not Reported
	Gabapentin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084292	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084305	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142628			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate	S	Unknown		Barr
	Actemra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084306	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141834		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084327	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142601		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Intolerance; Glaucoma; Glaucoma Surgery; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	.1429 Dosage Forms Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Lyrica	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084335	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141337		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Actonel	C	Unknown		Not Reported
Alprazolam	C	Unknown		Not Reported
Amlodipine	C	Unknown		Not Reported
Bisoprolol Fumarate	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Paroxetine	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Risedronate	C	Unknown		Not Reported
Simvastatin	C	Unknown		Not Reported
Telmisartan	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084364	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1140930		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Actavis

Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Oxycontin	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;		Not Reported
	Aclasta	C				Not Reported
	Actonel	C				Not Reported
	Esomeprazole	C				Not Reported
	Ferrous Gluconate	C				Not Reported
	Genteal	C				Not Reported
	Lomotil	C				Not Reported
	Mixed Tocopherol Vitamin E 400 Iu	C				Not Reported
	Nasonex	C				Not Reported
	Nexium	C				Not Reported
	Nortriptyline	C				Not Reported
	Prednisone	C				Not Reported
	Trazodone	C				Not Reported
	Tylenol	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084422	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1141104		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased;	Fentanyl			S	Unknown			Cephalon

Contraindicated Product Administered	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Gabapentin	S	Oral	200 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	2400 Milligram Daily;	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	80 Milligram Daily;	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram Daily;	Not Reported
	Loperamide Hydrochloride	C			Not Reported
	Nasonex	C	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazol Magnesium	C	Unknown	40 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	55 Milligram Daily;	Not Reported
	Risedronate Sodium	C	Unknown	5.1429 Milligram Daily;	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram Daily;	Not Reported
	Tylenol /00020001/	C	Oral	1000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084533	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141350		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2019	17084579	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019510205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15797466	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995453		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral	12.5 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15798320	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995400		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Pregabalin			C	Oral	50 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15801015	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996376			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rash; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Arthrotec			S	Oral	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Milligram .		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
	Mefenamic Acid	C	Oral			Not Reported
	Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15801286	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996055			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

	Tofacitinib Citrate			C	Unknown					Not Reported
	Valtrex			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15801978	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil/00072602/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15804309	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995739		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15840627	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15847896	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-100024		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Haemorrhage	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15848043	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001107		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Naprosyn			C	Unknown			Not Reported
	Naprosyn			C				Not Reported
	Rabeprazole			C	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Prednisone			C		5 Milligram Daily;		Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	15998495	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1016597		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Pancytopenia; Vomiting	Methotrexate			S	Oral			Barr

			Prednisone		S	Unknown				Teva
			Prednisone		S	Unknown				Teva
			Hydroxychloroquine Sulfate		S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	16982085	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129080		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Ivax
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituxan	S	Unknown	Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17085367	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-074710		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokinesia; Nerve Compression; Product Use In Unapproved Indication	Gabapentin			S	Unknown	300.0 Milligram, Once A Day		Aurobindo
	Leflunomide			S	Unknown	20.0 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17085421	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201911001952			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Diarrhoea; Drug Ineffective; Drug Ineffective; Gait Disturbance; Gait Disturbance; Headache;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg,1 In 2 Wk		Not Reported
	Leflunomide			S	Unknown			Not Reported

Hot Flush; Hypoaesthesia; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nausea; Neck Pain; Night Sweats; Paraesthesia; Rash Papular; Rash Pruritic; Swelling

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17085505	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201812-004153			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Chondrocalcinosis Pyrophosphate; Constipation; External Ear Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Tablet 200 Mg, Administered Every Day		Concordia
	Ferrous Sodium Citrate			C		Unk		Not Reported
	Rimatil			C		Unk		Not Reported
	Bonalon			C	Oral	Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Feburic			C		Unk		Not Reported
	Diclofenac Sodium			C		Unk		Not Reported
	Loxonin			C		Unk		Not Reported
	Tramcet			C		Unk		Not Reported
	Primperan			C		Unk		Not Reported
	Calonal			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17086584	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019048632		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cutaneous T-Cell Lymphoma; Drug Ineffective; Gait Inability; Herpes Zoster; Hiatus	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		Unk		Not Reported

Hernia; Insomnia; Muscle Spasms; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Sarcoidosis; Skin Cancer; Sleep Disorder Due To General Medical Condition, Insomnia Type	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S			Not Reported
	Methotrexate		S			Not Reported
	Orencia		S			Not Reported
	Leflunomide		C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C			Not Reported
	Sulfasalazine		C			Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17086756	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141877		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Hydroxychloroquine			C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17086782	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141933			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance;	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr

Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Off Label Use; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Myochrysine		S	Unknown	Solution Intramuscular	Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Intramuscular		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine /00072603/		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17086783	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141902		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17086848	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Cardiac Failure; Cytopenia; Generalised Oedema; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17087067	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142089		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17087343	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019511891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Infliximab Hospira			S	Intravenous (not otherwise specified)	520 Mg, Unk		Not Reported
	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Cosentyx			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Otezla			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17087476	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019048440			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17087534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2475774		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)	411.0		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Arthritis	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown	365.0			Not Reported
	Leflunomide			S	Oral	365.0			Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088021	NON-EXPEDITED			US-UCBSA-2018027063			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cimzia			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088197	EXPEDITED (15-DAY)		DE, HO, OT	GR-ALLERGAN-1948464US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Confusional State; Emotional Disorder; Encephalitis Japanese B; Speech Disorder	Prednisolone Unk			S				Allergan
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088385	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019048435		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Methotrexate			S		25 Milligram		Not Reported
	Methotrexate			S		17.5 Milligram		Not Reported
	Methotrexate			S		25 Milligram, Once Daily (Qd)		Not Reported
	Penicillin G [Procaine Benzylpenicillin]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, 2x/Day (Bid)		Not Reported
	Calcium			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Prednisone			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported
	Vitamin D [Colecalciferol]			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088391	EXPEDITED (15-DAY)		DS	CA-ROCHE-2475266		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ibuprofen	S	Oral	Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Stelara		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Endocervical		Not Reported
					Benadryl [Diphenhydramine Hydrochloride]		C			Not Reported
					Colchicine		C	Oral		Not Reported
					Dexilant		C			Not Reported
					Febuxostat		C			Not Reported
					Folic Acid		C			Not Reported
					Gravol		C			Not Reported
					Mogadon		C	Oral		Not Reported
					Nitrazepam		C	Unknown		Not Reported
					Oxycodone		C			Not Reported
					Prednisone		C			Not Reported
					Uloric		C	Unknown		Not Reported
					Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088675	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141930			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

	Folic Acid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088691	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142333		85 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088697	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported
	Xeljanz Xr			C				Not Reported
	Infliximab			C				Not Reported
	Prednisone			C	Oral	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088698	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141341			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Nausea; Retinal Toxicity; Therapeutic Product Effect	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported

Decreased; Vomiting	Enbrel			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Humira			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088710	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1141484		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue; Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Methotrexate			S	Unknown	1 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Rectal	2 Gram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088733	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141492			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Folic Acid			C				Not Reported
	Celebrex			C				Not Reported
	Arava			C		20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088734	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088737	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1141815		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen/Tramadol			S	Oral			Not Reported
	Leflunomide			S	Unknown			Barr
	Aclasta			S	Intravenous (not			Not Reported

Physical Health Deterioration; Hepatic Enzyme Increased; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Red Blood Cell Sedimentation Rate Abnormal; Sleep Disorder; Spinal Operation; Spinal Operation; Spinal Stenosis			otherwise specified)			
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Actonel	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Lorazepam	C	Unknown			Not Reported
	Lyrica	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Methylprednisolone Acetate	C	Unknown			Not Reported
	Methylprednisolone Acetate	C	Unknown			Not Reported
	Nortriptyline	C	Unknown			Not Reported
	Nortriptyline	C	Unknown			Not Reported
	Premarin	C	Unknown			Not Reported
	Tylenol Arthritis Pain 8h	C	Unknown			Not Reported
	Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17088748	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Unknown				Not Reported
	Arava			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported
	Simponi			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089217	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142088			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089464	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1141785		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Aclasta			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tramacet			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Depo-Medrol			C	Intramuscular			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Nortriptyline Hydrochloride			C	Unknown			Not Reported

		Premarin			C	Unknown				Not Reported
		Tylenol			C	Unknown				Not Reported
		Vagifem			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089468	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141677		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089476	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1141860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; No Adverse Event; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis;	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr

Treatment Failure	Methotrexate	S	Subcutaneous	Barr
	Methotrexate	S	Oral	Barr
	Ciclosporin	S	Unknown	Ivax
	Leflunomide	S	Unknown	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089502	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142523		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089519	NON-EXPEDITED			PHHY2018US023649		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Decreased	Methylprednisolone			S	Intravenous (not otherwise specified)	30 Mg/Kg, Unk		Novartis
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown	750 Mg/M2, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089535	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr

Intolerance; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate	S	Oral			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous	3.5714 Milligram Daily;		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2019	17089602	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-35245			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Bacitracin			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Neomycin Sulfate			S	Unknown	Unknown		Not Reported
	Polymyxin B Sulfate			S	Unknown	Unknown		Not Reported
	Prednisone			C	Intramuscular	Unknown		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	14692329	EXPEDITED (15-DAY)		OT	US-UCBSA-2018012947			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete; Tuberculosis	Cimzia	S	Unk		Not Reported
	Enbrel	S	Unk		Not Reported
	Methotrexate	S	Unk		Not Reported
	Plaquenil	S	Unk		Not Reported
	Simponi	S	Unk		Not Reported
	Actemra	S	Unk		Not Reported
	Orencia	S	Unk		Not Reported
	Arava	S	Unk		Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	15917020	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007696			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	15917234	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

		Humira			S	Subcutaneous				Not Reported
		Plaquenil			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	15920483	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1007780			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	15920660	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1007761		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	16424184	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210336		1 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17044929	EXPEDITED (15-DAY)		OT	NVSC2019CA037424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unknown		Not Reported
	Zopiclone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Novartis
	Pantoprazole			S	Unknown	Unk		Not Reported
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported

	Imuran			S	Oral	100 Mg, Unknown			Not Reported
	Nifedipine			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Zantac			S	Unknown	Unk			Not Reported
	Rivotril			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17090199	NON-EXPEDITED			US-UCBSA-2018021530			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Cimzia			S		Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Dose		Not Reported
	Methotrexate			S		Unknown		Not Reported
	Hydroxychloroquine			S		Unknown		Not Reported
	Leflunomide			S		Unknown Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17090518	NON-EXPEDITED			US-UCBSA-2018026206			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Rash	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Injection		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17091440	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142526		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Investigation Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Intravenous (not otherwise specified)			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral	20 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17091490	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143590		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mycobacterium Test Positive; Mycobacterium Tuberculosis Complex Test Positive	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Oral	200 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17091625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481057		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Imuran [Azathioprine]	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Xeljanz	C	Oral	Therapy Duration: 79.0 Days		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17091678	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5768		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Dorzolamide Hydrochlorid-Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported

		Furosemide			C	Unknown				Not Reported
		Gravol			C	Unknown				Not Reported
		Potassium			C	Unknown				Not Reported
		Valsartan			C	Unknown				Not Reported
		Xalatan			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17092355	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1948441US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Asacol			S	Unknown	800 Mg, Tid		Allergan
	Amlodipine Besilate			S	Oral	5 Mg, Qd		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unknown		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q Week		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unknown		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Crestor			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral	50 Mg, Unk		Not Reported
	Ebastine			C				Not Reported
	Ferrous Gluconate			C				Not Reported

	Folic Acid	C				Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Tylenol	C				Not Reported
	Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17092934	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Subcutaneous	125 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg, 1 Week		Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intramuscular	125 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	125 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Intramuscular	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	40 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Subcutaneous	12.5 Mg		Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine/00072603/	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported

	Rituxan			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17092935	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	20 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17092993	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142579			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz Xr	S	Unknown			Not Reported
	Acetaminophen	C	Oral			Not Reported
	Diphenhydramine	C	Oral			Not Reported
	Hydroxychloroquine	C				Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093129	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093172	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143509		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Factor Positive	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093175	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142486			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093196	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093203	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Endocervical			Barr
	Methylprednisolone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Apo-Leflunomide		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Certolizumab Pegol		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Etanercept		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Naproxen		C	Unknown	Not Reported
	Rituxan		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093214	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142910		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C		20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093253	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143007		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Hair Texture Abnormal; Neuropathy Peripheral; Pain In Extremity; Pain Of Skin; Rash Macular; Skin Discolouration; Skin Disorder; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Methotrexate			S	Oral			Barr
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17093264	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1142507		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		5 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17094228	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143345			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methylprednisolone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Nov-2019	17094503	EXPEDITED (15-DAY)		HO	NVSC2019FR047303		37 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Irregular Breathing; Somnolence	Paracetamol			S	Oral	4 G		Novartis
	Plaquenil			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2019	17094833	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481114		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Actemra		S	Unknown		Not Reported
	Cellcept [Mycophenolate Mofetil]		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Lyrica		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Piroxicam		C			Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Nov-2019	17094843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481585		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Lyrica	S	Oral			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Piroxicam	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2019	16848284	NON-EXPEDITED			CA-AMGEN-CANSP2019156482		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Condition Aggravated; Insomnia; Musculoskeletal Pain; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	15 Milligram, Weekly (2.5 Mg Tabs (Tablets), 6 Tabs)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 2x/Day (Enteric Coated Tablet)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15924086	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007486			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Pain; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Imuran			S	Unknown				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15930665	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1007381		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Joint Swelling; Nausea; Platelet Count Increased; Vitamin D Decreased; Vomiting	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Betahistine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Vitamin C			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15930794	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007502		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Celebrex	S	Oral	200 Milligram Daily;		Not Reported
	Celebrex	S	Oral	400 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C	Unknown			Not Reported
	Tramadol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15930804	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007766		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not			Not Reported

							otherwise specified)			
			Arava		S		Unknown			Not Reported
			Enbrel		S		Subcutaneous			Not Reported
			Enbrel		S		Subcutaneous			Not Reported
			Enbrel		S		Subcutaneous			Not Reported
			Humira		S		Subcutaneous			Not Reported
			Plaquenil		S		Unknown			Not Reported
			Remicade		S		Unknown			Not Reported
			Desoximetasone		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15936139	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15936148	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010048			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

		Humira			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Remicade			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15939918	EXPEDITED (15-DAY)		CA, HO, OT	CA-TEVA-2019-CA-1008093			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15942075	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007294		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Methotrexate			S	Unknown			Barr

Enzyme Increased; Pneumonia	Actemra		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15942208	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007582		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Naprosyn			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15945502	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010899		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown	2.5 Milligram Daily;		Not Reported
	Tylenol			C	Unknown	1300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15998611	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017443		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased; Sleep Disorder Due To A General Medical Condition	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported

Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Arava	S	Unknown	Not Reported
Co-Syntex	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Stelara	S	Unknown	Not Reported
Stelara	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	16904610	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201803-000961			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebral Vasoconstriction; Headache; Interleukin Level Increased; Neuropsychiatric Lupus; Pericardial Effusion; Pyrexia; Reversible Cerebral Vasoconstriction Syndrome; Tremor; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Endoxan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Neoral			C		Unk		Not Reported
	Neoral			C		Increased Dose		Not Reported
	Prednisolone			C		Unk		Not Reported
	Prednisolone			C		Increased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	16947693	NON-EXPEDITED			US-PFIZER INC-2019456482		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	8 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	6 Mg, Weekly		Pfizer
	Prednisone			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17096243	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17096244	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Methotrexate (Trade Name			S	Unknown			Not Reported

Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Unknown)						
	Apo-Hydroxyquine		S	Unknown			Not Reported
	Enbrel		S	Unknown			Not Reported
	Plaquenil		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097256	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1144225		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097258	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143916		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
	Lyrica	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	C	Oral		Not Reported
	Prednisone	C	Unknown	15 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097316	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144419		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097328	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097329	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			C		2.5 Milligram Daily;		Not Reported
	Gabapentin			C		400 Milligram Daily;		Not Reported

	Prednisone			C	Intravenous (not otherwise specified)	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097333	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145351		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Prednisone			C		10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097339	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144262		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Prednisone	C				Not Reported
	Prevacid	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097354	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144386		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097355	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144259		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness;	Methotrexate			S	Unknown			Barr
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure				otherwise specified)	
	Plaquenil		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481383		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097689	EXPEDITED (15-DAY)		OT	NVSC2019US051742		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Facial Paralysis	Gsk2118436			S	Oral	150 Mg, Bid		Novartis

Gsk1120212	S	Oral	2 Mg, Qd		Not Reported
Hydroxychloroquine Sulfate Tablets Usp	S	Oral	600 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097955	EXPEDITED (15-DAY)		OT	NVSC2019GB053585		16 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Product Use In Unapproved Indication; Pulmonary Alveolar Haemorrhage	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisolone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg (Three Times Weekly)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17098068	EXPEDITED (15-DAY)		CA	GB-PFIZER INC-2019510857		1 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Maternal Exposure During Pregnancy	Sulfasalazine			S	Transplacental	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Transplacental	200 Mg, Daily		Not Reported
	Folic Acid			C	Transplacental	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17098354	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019512755		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Atorvastatin Calcium			S	Oral	40 Mg, 1x/Day		Pfizer
	Doxycycline			S	Oral	200 Mg, 1x/Day		Not Reported
	Metronidazole			S	Oral	1500 Mg, 1x/Day		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

	Lansoprazole			C	Oral	15 Mg, 1x/Day			Not Reported
	Clopidogrel			C	Oral	75 Mg, 1x/Day			Not Reported
	Fluconazole			C	Oral	200 Mg, 1x/Day			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17099182	EXPEDITED (15-DAY)		HO	NVSC2019FR049563		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrophic Cardiomyopathy; Ventricular Arrhythmia	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Novartis
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Levothyrox			C	Oral	1 Df, Qd		Not Reported
	Renitec			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100227	EXPEDITED (15-DAY)		HO	CA-ROCHE-2481058		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100374	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1115977		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Bisoprolol			S	Oral	2.5 Milligram, Qd		Not Reported
	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Flagyl /00012501/			S	Oral	1500 Milligram, Qd		Mylan
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan
	Lovenox			S	Subcutaneous	0.4 Milliliter, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100967	NON-EXPEDITED			US-BAYER-2019-206506		41 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Hypersensitivity; Lip Swelling; Nausea; Pruritus; Vision Blurred	Cipro			S		Unk		Bayer
	Bactrim			S		Unk		Not Reported
	Keflex [Cefalexin]			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported
	Topamax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100995	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144426		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr

Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Treatment Failure	Ciclosporin	S	Unknown			Ivax
	Leflunomide	S	Unknown			Barr
	Leflunomide	S	Oral	20 Milligram Daily;		Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram Daily;		Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Hydroxychloroquine	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Neoral	S	Oral			Not Reported
	Neoral	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101001	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144417		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Joint	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr

Arthroplasty; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Leflunomide	C	Unknown	20 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101002	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate		S	Unknown	Barr
	Leflunomide		S	Unknown	Barr
	Cosentyx		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101005	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Off Label Use; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101007	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144443			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101402	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143891		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101409	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Subcutaneous		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101410	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144083		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101579	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituxan		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tofacitinib		S	Unknown		Not Reported
	Acetaminophen		C	Unknown		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101591	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144442		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	4000 Mol Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101595	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2019M1117199		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hypertrophic Cardiomyopathy	Prednisone			S	Oral	8 Milligram, Qd		Not Reported
	Imurel /00001501/			S	Oral	2 Milligram/Kilogram, Qd		Mylan
	Lyrica			S	Oral	Unk		Mylan
	Plaquenil /00072602/			S	Oral	Unk		Mylan
	Endoxan /00021102/			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101919	EXPEDITED (15-DAY)		DE, HO	GR-BAUSCH-BL-2019-063444		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Encephalitis Japanese B; Meningitis Bacterial; Product Use In Unapproved Indication; Speech Disorder; Treatment Failure	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S				Bausch And Lomb
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102033	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201913271		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
West Nile Viral Infection	Methylprednisolone (Manufacturer Unknown)			S	Unknown	High-Dose		Fresenius Medical Care
	Methotrexate (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care

	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102285	EXPEDITED (15-DAY)		OT	CA-MAYNE PHARMA-2019MYN000843			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Erythromycin			S	Unknown	Unk		Mayne
	Cephalexin /00145501/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102516	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144355			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Lyrica		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Piroxicam		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102520	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143961		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102521	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1144351		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102532	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

			Orencia		S	Unknown				Not Reported
			Remicade		S	Intravenous (not otherwise specified)				Not Reported
			Sulfasalazine		C					Not Reported
			Meloxicam		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15939608	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008100		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lower Respiratory Tract Infection; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15939789	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Rituxan			S	Unknown				Not Reported
		Celebrex			C	Unknown				Not Reported
		Leflunomide			C	Unknown				Not Reported
		Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15942237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010011		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15949861	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Discomfort; Joint Stiffness; Respiratory Tract Infection; Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported

Sinusitis	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	L-Thyroxine	C	Unknown	Not Reported
	Nexium	C	Unknown	Not Reported
	Tylenol Arthritis Pain 8hour	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15952040	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010726		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15954621	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Plaquenil			S	Oral					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15957503	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15963930	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Acetaminophen			C		1300 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported

					Aluminum Acetate\Benzethonium Chloride	C	Unknown		Not Reported
					Atacand	C	Unknown		Not Reported
					Ergocalciferol	C	Unknown		Not Reported
					Folic Acid	C	Unknown		Not Reported
					Hydrodiuril	C	Unknown		Not Reported
					Neurontin	C	Unknown	1800 Milligram Daily;	Not Reported
					Premarin	C	Unknown		Not Reported
					Tylenol	C	Unknown	1300 Milligram Daily;	Not Reported
					Aluminium Acetate	C	Unknown		Not Reported
					Benzethonium Chloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15983876	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15993644	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015603		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass; Mass Excision; Pain; Rheumatoid Arthritis;	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported

Therapeutic Product Effect Decreased	Enbrel		S	Unknown			Not Reported
	Plaquenil		S	Unknown			Not Reported
	Rituxan		S	Unknown			Not Reported
	Sulfasalazine		S	Unknown			Not Reported
	Xeljanz		C	Unknown			Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15993951	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015570		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15998585	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016696		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Vomiting	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15998600	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016844		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Loss Of Personal Independence In Daily Activities; Pneumonia; Pruritus; Pulmonary Fibrosis; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16073266	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1021604			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia;	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported

Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine/ 00072603/	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16565754	NON-EXPEDITED			US-PFIZER INC-2019298276		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Cefpodoxime Proxetil			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Amoxicillin Sodium And Potassium Clavulanate			S		Unk		Not Reported
	Erythromycin Base			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Amitriptylline			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Oxycodone And Acetaminophen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16866076	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1113892			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated;	Ibuprofen			S	Unknown			Actavis

Contraindicated Product Administered; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Naprosyn	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16996290	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019476158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis;	Methotrexate Sodium			S	Unknown	1 Every 2 Weeks		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Enbrel			S	Unknown			Pfizer
	Infliximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Remicade			S	Unknown			Not Reported

Tenosynovitis; Therapeutic Product Effect Incomplete	Acidophilus	C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported
	Deflazacort	C	Unknown			Not Reported
	Dilaudid	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Hydromorphone Hydrochloride	C	Unknown			Not Reported
	Januvia	C	Unknown			Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown			Not Reported
	Lidocaine	C	Topical			Not Reported
	Metronidazole	C	Unknown	Unk		Not Reported
	Nitroglycerin	C	Unknown			Not Reported
	Pantoloc [Pantoprazole]	C	Unknown			Not Reported
	Pregabalin	C	Unknown			Not Reported
	Risedronate	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Unknown			Not Reported
	Salbutamol	C	Unknown			Not Reported
	Triamcinolone	C	Unknown			Not Reported
	Tylenol [Paracetamol]	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17101401	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144348		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster;	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Arava	C				Not Reported
	Lyrica	C				Not Reported
	Prednisone	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17102538	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17103648	EXPEDITED (15-DAY)		HO	CA-ROCHE-2481388		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Imuran [Azathioprine]	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104636	NON-EXPEDITED			US-UCBSA-2017051005			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance	Cimzia			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tofacitinib			C	Oral	1 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104656	NON-EXPEDITED			US-UCBSA-2018003810		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Butterfly Rash; Drug Ineffective; Gastrointestinal Disorder; Mental Status Changes; Pruritus	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481093		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104914	EXPEDITED (15-DAY)		CA, DS, OT	NVSC2019FR050452			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Trileptal			S	Transplacental	Unk		Novartis
	Paracetamol			S	Transplacental	Unk		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Plaquenil			S	Transplacental	Unk		Not Reported
	Actonel			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Unknown	Unk		Not Reported
	Diffu-K			C	Transplacental	Unk		Not Reported

	Cortancyl			C	Transplacental	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2482153			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspnoea; Hypertension; Neoplasm Malignant	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105083	EXPEDITED (15-DAY)		HO	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-058		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disseminated Aspergillosis; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Pseudomonas Infection	Prednisone			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105146	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1144448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue;	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tofacitinib		S	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Arava		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Wellbutrin		C	Unknown		Not Reported
					Sulfasalazine		C	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105283	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143920		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105318	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144409			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Enzyme Increased; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Subcutaneous			Barr
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine	C	Oral	5 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144290		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tylenol	C				Not Reported
	Prednisone	C	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Oral	6 Milligram Daily;		Not Reported
	Mefenamic Acid	C	Unknown			Not Reported
	Mefenamic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105397	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144410		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105411	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145570		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Naprosyn			S	Unknown	1000 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105418	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105547	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1144279		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis	Methotrexate			S	Subcutaneous			Barr

Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
	Desoximetasone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105570	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1143964		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105666	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1144286		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported

		Simponi			S	Subcutaneous					Not Reported
		Sulfasalazine			S	Unknown					Not Reported
		Piroxicam			C						Not Reported
		Prednisone			C						Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
03-Dec-2019	17105916	EXPEDITED (15-DAY)		OT		CA-PFIZER INC-2019521803		52 YR	Female	CAN	
Preferred Term	**Product**		**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**		**Duration**		**Mfr**
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Infliximab				S	Unknown					Not Reported
	Methotrexate Sodium				S	Unknown					Pfizer
	Sulfasalazine				S	Unknown					Pfizer
	Etanercept				S	Unknown					Pfizer
	Actemra				S	Intravenous (not otherwise specified)	624 Mg, Unk				Not Reported
	Hydroxychloroquine				S	Unknown					Not Reported
	Kineret				S	Unknown					Not Reported
	Leflunomide				S						Not Reported
	Naproxen				S	Unknown					Not Reported
	Rituxan				S	Intravenous (not otherwise specified)	1000 Mg, Unk				Not Reported
	Acetaminophen				C						Not Reported
	Diphenhydramine Hydrochloride				C						Not Reported
	Oxyneo				C						Not Reported
	Ferrous Gluconate				C						Not Reported
	Folic Acid				C						Not Reported
	Lasix [Furosemide]				C						Not Reported
	Methylprednisolone				C						Not Reported
	Naprosyn [Naproxen]				C						Not Reported
	Oxycontin				C						Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
03-Dec-2019	17105973	EXPEDITED (15-DAY)		OT		CA-ROCHE-2403354			Female	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107120	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144642		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion;	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Plaquenil		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107204	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107205	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145583		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	2.8571 Milligram Daily;		Not Reported

						Hydroxychloroquine Sulfate		S	Unknown				Not Reported
						Orencia		S	Unknown				Not Reported
						Remicade		S	Unknown				Not Reported
						Xeljanz		S	Oral				Not Reported
						Prednisone		C	Endocervical	50 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107868	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Nausea; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

	Tylenol Arthritis Pain 8h			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107899	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144969		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107903	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144962		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Off Label Use; Prescribed	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported

Overdose; Rheumatoid Arthritis; Synovitis; Vomiting	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Celebrex	C	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Naprosyn /00256201/	C	Unknown	1000 Milligram Daily;	Not Reported
	Naprosyn /00256201/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107906	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107908	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17108802	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-063176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Desoximetasone			S	Oral	Not Specified		Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Not Specified		Not Reported

Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Intra-arterial	Not Specified	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Prednisone		S	Unknown	Not Specified	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljan		S	Unknown		Not Reported
	Cortisone Acetate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	9010565	EXPEDITED (15-DAY)		HO, OT	DK-SANOFI-AVENTIS-2013SA001345		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Weight Decreased	Hydroxychloroquine			S	Unknown	250 Mg,Qd		Sanofi
	Prednisolone			S	Unknown	20 Mg,Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	13894400	EXPEDITED (15-DAY)		OT	CA-ROCHE-1980860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 320 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Therapy Duration: 171 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15598164	NON-EXPEDITED			US-PFIZER INC-2018447319		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Depo-Medrol			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15743077	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-990533		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15866035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003135		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Rheumatoid Arthritis;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported

Therapeutic Response Decreased; Thyroid Neoplasm	Arava		S	Unknown	Not Reported
	Celebrex		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15917142	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007217		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15932517	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008051			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr

Intolerance; Insomnia; Rheumatoid Arthritis	Anakinra		S	Unknown		Not Reported
	Arava		S	Oral	10 Milligram Daily;	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Naprosyn		S	Oral	1000 Milligram Daily;	Not Reported
	Naprosyn		S			Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Vioxx		S	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15949858	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010881			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15951929	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011460		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram Daily;		Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15954579	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011476		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15954603	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1010142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective;	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported

Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz		S	Unknown	25 Milligram Daily;	Not Reported
	Arava		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15959671	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1012950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Cimzia			C	Subcutaneous					Not Reported
	Enbrel			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15959677	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012969		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15965246	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Methotrexate		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Cetirizine Hydrochloride		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15969555	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15992817	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2019-CA-1015846			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral	1000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16134028	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019136528			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib			S		200 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Sertraline Hcl			S		25 Mg, Unk		Pfizer
	Citalopram			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Indomethacin [Indometacin]			S		50 Mg, 3x/Day		Not Reported
	Indomethacin [Indometacin]			S				Not Reported

	Leflunomide	S		20 Mg, Unk	Not Reported
	Temazepam	S		Unk	Not Reported
	Toradol	S	Intramuscular	10 Mg, Unk	Not Reported
	Toradol	S			Not Reported
	Zopiclone	S		7.5 Mg, Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Lidocaine	C		Unk	Not Reported
	Methylprednisolone Acetate	C		80 Mg, Unk	Not Reported
	Naproxen	C		500 Mg, 2x/Day	Not Reported
	Prednisone	C		Unk	Not Reported
	Vitamin D [Colecalciferol]	C		50000 Iu, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16476438	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2831359-00		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Atrial Fibrillation; Coeliac Disease; Diarrhoea; Food Allergy; Gait Disturbance; Immobile; Injection Site Rash; Injection Site Urticaria; Peripheral Swelling; Rash; Spinal Osteoarthritis; Swelling; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16826822	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Not Reported

Protein Increased; Contraindicated Product Administered; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Barr
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16984941	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129084		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown			Not Reported
	Lyrica	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16993855	EXPEDITED (15-DAY)		DS, OT	FR-ADVANZ PHARMA-201910001445			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Maculopathy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Bid,(1-0-1) 2,Tablets In The Morning (Film Coated Tablet)		Concordia
	Prednisone			C		1 Mg		Not Reported
	Tramadol			C		200 Mg		Not Reported
	Levothyrox			C		Unk		Not Reported
	Alprazolam			C		50 Mg		Not Reported
	Laroxyl			C	Unknown	40 Milligram Per Millilitre		Not Reported
	Furosemide			C		40 Mg		Not Reported
	Propanolol			C		160 Mg		Not Reported
	Esomeprazole			C		40 Mg		Not Reported
	Rocgel			C		Unk		Not Reported
	Psyllium Husks			C		3.6 G		Not Reported
	Spasfon			C		Unk		Not Reported

	Hydrocortisone Roussel			C		Unk Unk, Qd			Not Reported
	Hydrocortisone Roussel			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16995999	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131115		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Doxycycline Hyclate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Aurothiomalate Sodium			S	Unknown			Not Reported
	Aurothiomalate Sodium			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Rituximab;Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17003952	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Product Use Issue; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acidophilus			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported

	Kenalog	C	Unknown	Not Reported
	Lidocaine	C	Topical	Not Reported
	Metronidazole	C	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Pregabalin	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Triamcinolone	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17107357	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201807-002265			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Exposure During Pregnancy; Glaucoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Once Daily		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			S	Oral	8 Mg, Freq: Unk X 1 Days		Not Reported
	Colchicine			C		Unk		Not Reported
	Heparin Calcium			C		Unk		Not Reported
	Miya Bm			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17108708	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Cellcept [Mycophenolate Mofetil]	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17108882	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481074		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109034	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1145459			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolon			S	Transplacental	5 [Mg/D (Bis 4)]/ Initially 5 Mg/D Until Gw 6+2, Then Discontinued. From Gw 23+3 Until Delivery 4 M		Actavis
	Quensyl			S	Transplacental	200 [Mg/D]		Not Reported
	Folsäure			C	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109097	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144713		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109098	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1144948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109100	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109105	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113430		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109110	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145062		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	500 Milligram Daily;		Not Reported
	Arava			C	Oral	20 Milligram Daily;		Not Reported
	Risedronate			C	Oral			Not Reported

	Xeljanz			C	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109123	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109124	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145408			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

		Meloxicam			C	Unknown				Not Reported
		Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109125	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145464		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous	Solution Subcutaneous		Not Reported
	Lozide /00340101/			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109126	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145588			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Apo-Prednisone	S	Oral	3 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109129	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)			
				Sarilumab	S	Unknown			Not Reported
				Simponi	S	Subcutaneous			Not Reported
				Sulfasalazine	S	Unknown			Not Reported
				Tocilizumab	S	Unknown			Not Reported
				Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
				Rabeprazole Sodium	C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109133	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109135	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145193		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis; Treatment Failure	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109136	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Mirtazapine			S	Unknown			Teva
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109139	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145418		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use;	Methotrexate			S	Oral			Barr

Treatment Failure	Methotrexate		S	Subcutaneous		Barr
	Ciclosporin		S	Unknown		Barr
	Leflunomide		S	Unknown		Barr
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Neoral		S	Subcutaneous		Not Reported
	Neoral		S	Oral		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109140	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145519		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Label Use; Spinal Column Injury; Surgical Failure	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Mobicox		C	Unknown	15 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109168	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144915		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sufate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109169	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144913		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109181	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145069		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109184	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109190	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144805		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Decreased				otherwise specified)		
	Plaquenil		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Arava		C	Unknown		Not Reported
	Lyrica		C	Oral		Not Reported
	Prednisone		C	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109192	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144907			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109208	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145585			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine	S	Unknown	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109236	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1145189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145043		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109273	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Celebrex			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109373	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17110218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483730		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Cellcept [Mycophenolate Mofetil]		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Lyrica		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17111246	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483719		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17111666	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019523826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Sulfasalazine			S	Unknown			Pfizer
	Enbrel			S	Unknown			Pfizer
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112210	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144993		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr

	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Wellbutrin		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112214	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145733		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112215	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144719		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol/00020001/			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112240	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145845		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Tramadol Hydrochloride	C	Oral			Not Reported
	Xeljanz	C		100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112247	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112369	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145538		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue;	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Irritable Bowel Syndrome; Malaise; Nausea; Stress	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Advil /00044201/	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112373	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144706		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112381	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145007		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

		Acetaminophen			C	Unknown				Not Reported
		Gabapentin			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112386	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112389	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144811		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis; Unevaluable Event	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112390	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144835			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112392	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112584	EXPEDITED (15-DAY)		OT	NVSC2019AU055143			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Graft Versus Host Disease In Skin	Cyclosporine			S	Unknown	100 Mg, Bid		Novartis
	Prednisolone			S	Unknown	10 Mg, Qd (Upto 75 Mg Daily)		Not Reported
	Mabthera			S	Unknown	375 Mg/M2 (4 Doses)		Not Reported
	Ibrutinib			S	Unknown	300 Mg, Qd		Not Reported
	Sirolimus			S	Unknown	2 Mg, Qd		Not Reported
	Hidroxicloroquina			S	Unknown	200 Mg, Qd		Not Reported
	Quetiapine			C	Unknown	25 Mg, Qd		Not Reported
	Lamotrigine			C	Unknown	200 Mg, Bid		Not Reported
	Valaciclovir			C	Unknown	500 Mg, Bid		Not Reported
	Bactrim Ds			C	Unknown	1 Df 3 Times Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112711	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112712	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported

	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112794	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145633			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	20 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112795	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144937		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Dexamethasone			C	Unknown	5 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112796	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145618		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Oral	10 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported

	Sulfasalazine			C	Unknown	3 Gram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112814	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145025		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	5 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisoloneacetate			C	Unknown	5 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Tylenol/00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112836	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112869	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145850		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112881	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1145553		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram Daily;		Not Reported

	Ketorolac		C	Unknown			Not Reported
	Naproxen		C	Unknown			Not Reported
	Prednisone		C	Unknown			Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112884	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145046			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprosyn			S	Oral	500 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112886	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Methotrexate			S	Unknown			Barr

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112887	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145082		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112888	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145779		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112889	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate	S	Oral	25 Milligram Daily;		Barr
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112892	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112895	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1145019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Methotrexate	S	Oral			Barr
	Actemra	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Infliximab	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Subcutaneous			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Arava	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112896	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145031			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition	Methotrexate			S	Oral			Barr

Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous			Barr
	Anakinra	S	Unknown			Not Reported
	Arava	S	Oral	10 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Vioxx	S	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112900	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145021		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Methotrexate	S	Unknown		Barr
Leflunomide	S	Oral	20 Milligram Daily;	Barr
Leflunomide	S	Oral	10 Milligram Daily;	Barr
Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram Daily;	Not Reported
Celebrex	S	Oral		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram Daily;	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	300 Milligram Daily;	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	200 Milligram Daily;	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Prednisone	C	Unknown		Not Reported

Apo-Prednisone	C	Oral	15 Milligram Daily;	Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram Daily;	Not Reported
Cipralex /01588501/	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Oral		Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported
Gabapentin	C	Oral		Not Reported
Hydrochlorothiazide	C	Oral		Not Reported
Hydromorphone Hydrochloride	C	Oral	60 Milligram Daily;	Not Reported
Hydromorphone Hydrochloride	C	Oral	6 Milligram Daily;	Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc /01263201/	C	Unknown	20 Milligram Daily;	Not Reported
Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
Prednisone	C	Oral	15 Milligram Daily;	Not Reported
Prednisone	C	Oral		Not Reported
Shark Liver Oil	C	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown		Not Reported
Taro-Mupirocin	C	Topical		Not Reported
Tramacet	C	Oral		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112902	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145621		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Oral			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Prevacid			C	Unknown	60 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112903	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1145650		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Therapy Non-Responder	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	8 Mg/Kg Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112920	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145746		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Mirtazapine			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112995	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Lock; Pain In Extremity; Psoriatic Arthropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Calcium			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Imuran	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Actonel	C			Not Reported
	Depo-Medrol	C			Not Reported
	Depo-Medrol	C			Not Reported
	Ergocalciferol	C		2000 Dosage Forms Daily;	Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Otezla	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17113075	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145734		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C		7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	13045102	EXPEDITED (15-DAY)		OT	CA-ROCHE-1869641		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Folinic Acid	C	Unknown	Not Reported
	Apo-Hydroxyquine	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Leucovorin [Folinic Acid]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	15628419	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US049166		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Tacrolimus			S	Unknown	Unk Unk, Unknown Freq.		Astellas
	Cellcept /01275102/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Imuran /00001501/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil /00072602/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16000467	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016832			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rheumatoid Arthritis; Swelling	Methotrexate			S	Intramuscular			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arthrotec			C	Unknown	100 Milligram Daily;		Not Reported
	Tylenol /00020001			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16010306	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016833			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Xeljanz			C	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16015826	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017617		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16027828	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019034		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported

		Orencia			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16027969	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019700		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16033202	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Methotrexate	S	Subcutaneous			Barr
	Azathioprine	S	Unknown			Not Reported
	Minocycline	S	Unknown			Actavis
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium	C				Not Reported
	Amoxil	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16044426	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1018980		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Barr

	Azathioprine			S	Unknown					Not Reported
	Celecoxib			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16425226	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210555		35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematuria; Phospholipidosis; Proteinuria	Hydroxychloroquine			S	Unknown	Unk		Sun
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16859793	EXPEDITED (15-DAY)		OT	CA-ROCHE-1844081		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Diarrhoea; Heart Rate Increased; Hypertensive Crisis; Nausea; Pneumonia; Pneumonitis; Vomiting	Rituxan			S	Intravenous (not otherwise specified)	Last Infusion: 29/May/2019		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Effexor			C				Not Reported
	Tylenol			C	Oral			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Oral			Not Reported
	Solumedrol			C	Intravenous (not otherwise specified)			Not Reported
	Vit D			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17011158	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1132830		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Limb Deformity; Malaise; Osteoporosis; Pain; Rash; Synovitis	Naproxen Sodium	S	Unknown			Not Reported
	Leflunomide	S	Oral			Barr
	Methotrexate	S	Unknown			Barr
	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Cosentyx	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Acetaminophen/Codeine	C	Unknown			Not Reported
	Celebrex	C	Unknown	2 Dosage Forms Daily;		Not Reported
	Insulin	C	Unknown			Not Reported
	Metformin	C	Unknown	4 Dosage Forms Daily;		Not Reported
	Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17053752	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2019M1110466		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Decreased; Blood Pressure Increased; Generalised Oedema; Lupus Nephritis; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery; Protein Total; Proteinuria; Weight	Azathioprine			S	Unknown	100 Milligram, Qd		Not Reported
	Magnesium Sulfate			S	Intravenous (not otherwise specified)	Bolus Dose 2 G, Then Infusion Of 1.5 G/H		Mylan
	Labetalol			S	Intravenous (not otherwise specified)	50-100 Mg/8 H		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Methylprednisolone			S	Unknown	60 Milligram, Qd		Mylan

Increased	Vitamin D /00107901/	C		Unk	Mylan
	Prednisone	C		5 To 10 Mg Per Day	Mylan
	Prednisone	C	Unknown	5 Milligram, Qd	Mylan
	Folic Acid	C	Unknown	Unk	Mylan
	Calcium	C	Unknown	Unk	Mylan
	Betamethasone	C	Intramuscular	2 Doses	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17113464	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-076306		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight	Quetiapine			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk, As Required		Not Reported
	Liptor			C	Unknown	Unk		Not Reported
	Methadone			C	Oral	10 Milligram, Once A Day		Not Reported
	Pantoloc			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Valtrex			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17113706	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin/Neomycin Sulfate/Polymyxin B Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114110	EXPEDITED (15-DAY)		OT	CA-SA-2019SA336230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Not Specified (1 Mg)		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg,1 In 1 D		Sanofi
	Methotrexate			S	Intra-arterial	Not Specified (25 Mg,1 In 1 D)		Not Reported
	Prednisone			S	Unknown	Not Specified		Not Reported

Failure; Wound	Sulfasalazine		S	Unknown	500 Mg	Not Reported
	Sulfasalazine		S	Unknown	2 Gm (1 Gm,2 In 1 D)	Not Reported
	Cortisone Acetate		S	Unknown	25 Mg	Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate		S	Unknown	400 Mg, Qd	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114173	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145946		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Meloxicam			C	Oral					Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114180	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	Solution		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114182	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Methotrexate			S	Unknown	Solution		Barr
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114183	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1146091		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown	Solution		Barr
	Minocycline			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported

Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Thrombosis	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ilaris Single-Use Vial	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114184	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145955			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported

		Lyrica			C	Unknown				Not Reported
		Naproxen			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114321	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145896		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114661	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114780	EXPEDITED (15-DAY)		HO, OT	JP-APPCO PHARMA LLC-2077490		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilic Pneumonia Acute	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Betamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114880	EXPEDITED (15-DAY)		HO, OT	TW-APPCO PHARMA LLC-2077491		27 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115037	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145983		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure; Visual Impairment	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115049	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145890		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C				Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C				Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115051	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145899		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115052	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145987		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown			Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram Daily;		Not Reported
	Aspirin	C	Unknown			Not Reported
	Cymbalta	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115225	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019519686		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Sciatica	Methotrexate Sodium			S	Subcutaneous	25 Mg, Every 1 Week(S)		Unknown
	Acetaminophen			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Prednisone			S		7 Mg, Every 24 Hour(S)		Not Reported
	Apo-Ramipril			S		1 Every 24 Hour(S)		Not Reported
	Folic Acid			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Every 24 Hour(S)		Not Reported
	Levothyroxine			S		1 Every 24 Hour(S)		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen;Codeine			C		Unk		Not Reported
	Acetaminophen;Caffeine;Dihydrocodeine Bitartrate			C		Unk		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Ophthalmic	2 Every 1 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		400 Mg, Every 24 Hour(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115477	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145937			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Norflex			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115531	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1119604		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Enteritis; West Nile Viral Infection	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Methotrexate	S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	As Part Of A Regimen That Involved Tapering Of The Dose		Not Reported
	Rituximab	S	Unknown	Unk		Mylan
	Methylprednisolone	S	Unknown	High-Dose		Mylan
	Cotrimoxazole	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17116698	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1146476		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Atorvastatine			S	Oral	40 Mg		Teva
	Doxycycline			S	Oral	200 Mg		Actavis
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	3 Dosage Form		Not Reported
	Tavanic 500 Mg, Comprime Pellicule Secable			S	Oral	1 Dosage Form		Not Reported
	Metronidazole			S	Oral	1500 Mg		Not Reported
	Lansoprazole			C	Oral	15 Mg		Not Reported
	Clopidogrel Base			C	Oral	75 Mg		Not Reported
	Fluconazole			C	Oral	200 Mg		Not Reported
	Ceftriaxone Base			C	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17116982	EXPEDITED (15-DAY)		OT	NVSC2019CA054057		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panniculitis; Product Use In Unapproved Indication	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis

	Tofacitinib			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17117311	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145884		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Unknown	50 Milligram Daily;		Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17117322	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

Erythematosus	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17117560	NON-EXPEDITED			US-NEOPHARMA INC-000252			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Urticaria	Augmentin			S				Neopharma
	Lyrica			S	Oral	Take 1 Capsule Per Oral 4 Times A Day		Not Reported
	Cymbalta			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17118141	EXPEDITED (15-DAY)		LT	CA-TEVA-2019-CA-1145959		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sodium Aurothiomalate Injection			S	Unknown			Not Reported

	Bp									
	Sulfasalazine			S	Unknown					Not Reported
	Sulfasalazine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	9248366	EXPEDITED (15-DAY)		OT	FR-SANOFI-AVENTIS-2013SA038588		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Omeprazole			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Mycophenolate Mofetil			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	11683978	EXPEDITED (15-DAY)		OT	PHHY2015GB136731		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Humira			S	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	12809314	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016037802		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Cellcept			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S		1 Ml, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S		7 Mg, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	13645771	EXPEDITED (15-DAY)		OT	CA-ROCHE-1947729		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Unknown	Therapy Duration: 9 Years		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	13984922	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083241			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	14311574	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050883		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	14813831	NON-EXPEDITED			US-PFIZER INC-2018170458		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Intolerance; Gastrointestinal Disorder; Headache; Nausea; Tuberculin Test Positive	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	14824752	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110723		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15333427	EXPEDITED (15-DAY)		DS	CA-ROCHE-2175438		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Duloxetine Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15619732	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105993			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qwk		Not Reported
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qwk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5.0 Milligram/Kilogram, Qd		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15635117	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105457			Unknown	CAN

Preferred Term | Product | Comp. | OTC | Role | Route | Dosage Text | Duration | Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qmo	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown	Unk	Bristol Myers Squibb
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk (4 Every 1 Week)	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, Qd	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Mg, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Qd (2 Every 1 Day)	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported

	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Apo Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd (2 Every 1 Day)	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Qd (2 Every 1 Day)	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unk	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	1 Df, Qwk	Not Reported
	Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15846816	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthropathy; Blood Cholesterol Increased; Breast Cancer; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Hand Deformity; Headache; Herpes Zoster; Infection; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Vomiting	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	50 Milligram Daily;	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported

	Arava	C	Unknown		Not Reported
	Arava	C			Not Reported
	Ativan	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin Hydrobromide	C	Unknown		Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Furosemide	C	Unknown	120 Milligram Daily;	Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex /00018303/	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Kenalog /00031902/	C	Intra-articular		Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Desoximetasone	C	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15925771	EXPEDITED (15-DAY)		OT	CA-ROCHE-2260693		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16033405	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019340		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16045302	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020374		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate			S	Intravenous (not			Barr

Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis			otherwise specified)			
	Methotrexate	S	Oral			Barr
	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Intravenous (not otherwise specified)			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16059282	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1021632		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Disseminated Strongyloidiasis; Escherichia Infection; Strongyloidiasis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	Various Doses		Actavis
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16059882	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020742		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site	Codeine Phosphate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Methotrexate			S	Subcutaneous			Barr

Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Levothyroxine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown	7 Milligram Daily;	Actavis
	Prednisone	S	Unknown		Actavis
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cosopt	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen/Caffeine	C	Unknown		Not Reported
	Plaquenil	C	Unknown	400 Milligram Daily;	Not Reported
	Tylenol 2	C	Unknown		Not Reported
	Acetaminophen/Caffeine/Dihydrocodeine	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram Daily;	Not Reported
	Tylenol/00020001/	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Caffeine	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Dorzolamide Hydrochloride	C	Ophthalmic		Not Reported

	Folic Acid	C	Unknown			Not Reported
	Levothyroxine	C	Unknown			Not Reported
	Meprobamate	C	Unknown			Not Reported
	Prednisone	C	Unknown	7 Milligram Daily;		Not Reported
	Ramipril	C	Unknown			Not Reported
	Timolol Maleate	C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16069616	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022918		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Amoxicillin Sodium/Clavulanate Potassium			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Clavulin			S	Unknown			Not Reported
	Plaquenil/00072602/			C	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	7.5 Milligram Daily;		Not Reported

		Tridural			C	Unknown					Not Reported
		Tylenol/00020001/			C	Unknown					Not Reported
		Plaquenil (Hydroxycholroquine Sulfate)			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16081129	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022928		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Methylprednisolone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

	Naproxen	C				Not Reported
	Prednisone	C	Unknown			Not Reported
	Rituxan	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16193605	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036909		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral	10 Mg, 1 Every 1 Week,		Barr
	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week,		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral	10 Mg, 1 Every 1 Week,		Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily; Duration- 2 Years		Not Reported
	Enbrel			S	Unknown	50 Mg,		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Duration- 5 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Dosage Forms		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily; Duration-730		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16498662	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026467		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Solution Subcutaneous		Ucb
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			C		Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17118621	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912002578			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml(40 Milligram)			S	Subcutaneous	40 Mg (1 In 2 Weeks)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17118631	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201912002577			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Injury	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40mg/0.4ml, 40 Mg (1 In 2 Week)		Not Reported
	Pravastatin Sodium			C		10 Mg		Not Reported
	Zetia			C		10 Mg		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17118701	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488466		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17119744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17119954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2484475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Lyrica		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Piroxicam		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17119955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486166		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

					Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Sulfasalazine		S	Unknown	Not Reported
					Naproxen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120611	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483718		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483749		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy;	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported

Rash; Sinusitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120769	EXPEDITED (15-DAY)		HO	DK-MYLANLABS-2019M1120144		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Mycoplasmal	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Mylan
	Insulin			C	Unknown	On A Pump		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120794	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051770		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		4.0 Mg/Kg		Not Reported
	Adalimumab			S				Not Reported
	Celebrex			C				Not Reported
	Diclofenac			C				Not Reported

Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S		200 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
Leflunomide	S		20 Milligram, Once Daily (Qd) For 6 Months	Not Reported
Lyrica	C		Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Weekly (Qw)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram For 6 Years	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	C			Not Reported
Tocilizumab	S			Not Reported
Valsartan	C			Not Reported
Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120847	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

						Humira		S	Subcutaneous					Not Reported
						Hydroxychloroquine Sulfate		S	Oral					Not Reported
						Orencia		S	Unknown					Not Reported
						Remicade		S	Intravenous (not otherwise specified)					Not Reported
						Sodium Aurothiomalate		S	Parenteral					Not Reported
						Sulfasalazine		C	Unknown					Not Reported
						Meloxicam		C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120943	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145984			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous	10 Milligram Daily;		Not Reported
	Tofacitinib			S	Unknown	20 Milligram Daily;		Not Reported
	Celebrex			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported
	Lipitor			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121205	EXPEDITED (15-DAY)		OT	US-UCBSA-2017020170			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Headache; Pruritus; Rash; Rheumatoid Arthritis	Cimzia		S		Unk		Not Reported
	Methotrexate		S	Oral	20 Mg, Weekly (Qw)		Not Reported
	Enbrel		S		Unk		Not Reported
	Hydroxychloroquine		S		Unk		Not Reported
	Folic Acid		C	Oral	3 Mg, Once Daily (Qd)		Not Reported
	Nexium		C	Oral	20 Mg Daily		Not Reported
	Tofacitinib		C	Oral	11 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121430	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1118994		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Heart Transplant; Nephrotic Syndrome; Renal Transplant	Methylprednisolone			S	Unknown	5000 Milligram		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	2 Milligram/Kilogram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Ramipril			C	Unknown	5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121462	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146153		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Rituxan		S	Intravenous (not otherwise specified)			Not Reported
	Rituximab		S	Unknown			Not Reported
	Simponi		S	Subcutaneous			Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121496	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2019218576		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Benlysta			S		Unk		Glaxosmithkline
	Prednisolon			S		Unk		Glaxosmithkline
	Quensyl			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121577	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146246		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121826	EXPEDITED (15-DAY)		HO	NVSC2019US058006		51 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Mycobacterium Avium Complex Infection; Productive Cough; Pyrexia	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Fluticasone W/Salmeterol			S	Unknown	1 Df, Bid (1 Inhalation Twice Daily)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121830	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007679		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Leflunomide			S	Unknown			Barr
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported

	Neoral			S	Oral				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Sulfasalazine			S		2 Gram Daily;			Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported
	Rituxan			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121916	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146206		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17123737	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486162		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Meloxicam		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17123744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2485939		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

					Tenofovir		C	Unknown		Not Reported
					Tenofovir Disoproxil		C	Unknown		Not Reported
					Tenofovir Disoproxil Fumarate		C	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported
					Zopiclone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17124330	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1146711		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral			Barr
	Methotrexate Sodium			S	Oral			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17124829	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA201941459			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Human Normal Immunoglobulin	S	Intravenous (not otherwise specified)	Unk		Shire
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125168	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488200		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Amoxicillin Sodium;Clavulanate Potassium	C	Unknown		Not Reported
	Amoxil [Amoxicillin]	C	Unknown		Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)		Not Reported
	Bcg Vaccine	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488687		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488231		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125220	EXPEDITED (15-DAY)		HO	CA-ROCHE-2485004		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea; Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Mycophenolate Mofetil			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Colchicine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486098		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection;	Actemra			S	Unknown	3.0 Year(S)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	9.0 Month(S)		Not Reported

Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Arava	S	Oral	9.0 Month(S)	Not Reported
	Arava	S	Oral	9.0 Month(S)	Not Reported
	Cimzia	S	Subcutaneous	2.0 Year(S). Single-Use Prefilled Syringe	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	2.0 Year(S)	Not Reported
	Enbrel	S	Unknown	730.0	Not Reported
	Enbrel	S	Unknown	4.0 Year(S)	Not Reported
	Enbrel	S	Unknown	731.0	Not Reported
	Humira	S	Subcutaneous	5.0 Month(S)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown	1.0 Month(S)	Not Reported
	Leflunomide	S	Unknown	5.0 Month(S)	Not Reported
	Methotrexate	S	Subcutaneous	8.0 Year(S)	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	2.0 Year(S)	Not Reported
	Simponi	S	Subcutaneous	2.0 Month(S)	Not Reported
	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Imuran [Azathioprine]	C	Unknown		Not Reported
	Vitamin D [Colecalciferol]	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	12076304	EXPEDITED (15-DAY)		DS	CA-ROCHE-1678552		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	For 2 Years		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Subcutaneous			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Oral	Theraoy Duration -158.0 Nos		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Orencia	S	Subcutaneous	Therapy Duration: 3.0 Year(S)		Not Reported
	Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	14309271	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2017050897		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

Nail Disorder; Onychomadesis; Onychomycosis	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tofacitinib	S		5 Mg, Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Infliximab	S			Not Reported
	Orencia	C		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Arava	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16053731	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023712		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Oral			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16058867	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16059884	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Leflunomide			S	Unknown			Barr

Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S	Oral	10 Milligram Daily;		Barr
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16060796	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1024063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16961068	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019043848		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder;	Cimzia			S	Subcutaneous	200 Milligram, Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S		5 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported

Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Tuberculin Test Positive; Urinary Tract Infection	Humira	S	Subcutaneous	40 Milligram; Solution For Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S		5 Milligram	Not Reported
	Methotrexate	S		5 Milligram	Not Reported
	Orencia	S		750 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Arava	S		Unk	Not Reported
	Hydroxychloroquine	S		5 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Leflunomide	S		5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	5 Milligram	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Prednisone	C		50 Milligram, Once Daily (Qd)	Not Reported
	Gold	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	17125243	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486138		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration 13.0 Months	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	17125248	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486257		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure			otherwise specified)	
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	17125249	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486415		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration:- 10.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Oral	Therapy Duration:- 13.0 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	15940202	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010066		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Crying; Drug Ineffective	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Unknown	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Leucovorin /00566701/		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16009439	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016503		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16044415	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019798		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Otezla			S	Unknown	60 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16045316	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020425		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Orencia			C	Unknown			Not Reported

	Simponi			C	Subcutaneous					Not Reported
	Aspirin			C	Unknown					Not Reported
	Cymbalta			C	Unknown					Not Reported
	Hydromorphone			C	Unknown					Not Reported
	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16047237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16049926	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	C	Unknown		Not Reported
	Prednisone	C	Unknown	10.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16049940	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020827		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Apo-Azathioprine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16050526	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020942		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16050530	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020786		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Arthrotec	C	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Imuran	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16051151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16051154	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1023406		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Viral Infection	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Cymbalta	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16054839	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020448		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16057945	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020981		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	25milligram, 2every		Not Reported

						1weeks			
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Imuran			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058720	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020936			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058860	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021148		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Oral			Not Reported

Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Apo-Leflunomide		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Orencia		S	Oral		Not Reported
	Remicade		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058882	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020905		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Fatigue; Hypersensitivity; Malaise; Nasal Congestion; Neuralgia; Pain In Extremity; Productive Cough; Rheumatoid Arthritis; Vision Blurred; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral	20 Milligram Daily;		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	40 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil			C	Oral	400 Milligram Daily;		Not Reported
	Prednisone			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058974	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16059878	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020699		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16060463	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Hepatotoxicity; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported

	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16060509	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024084		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Mol Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16061828	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020940		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion;	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16062133	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1020894		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16069174	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021716			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16073284	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021434		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16073285	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021500		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral	37.5 Milligram Daily;		Teva

	Venlafaxine Hydrochloride	C	Oral	37.5 Milligram Daily;		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydrodiuril	C	Unknown	12.5 Milligram Daily;		Not Reported
	M-Eslon	C	Unknown	20 Milligram Daily;		Not Reported
	Morphine	C	Unknown			Not Reported
	Morphine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16752157	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097379			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Barr
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	17035514	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-107291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	17079806	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pain; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	17125718	NON-EXPEDITED			US-AMGEN-USASP2019202478		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen

	Depo-Medrol			S	Unknown	Unk				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	12767722	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076641		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	10 Milligram, 1 Every 24 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, 1 Every 24 Hours		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, 1 Every 24 Hours		Not Reported
	Asa			C	Unknown	81 Mg, Unk		Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported

	Naproxen			C	Unknown	Unk			Not Reported
	Calcium			C	Unknown	Unk			Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	14298460	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050715		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day (Bid)		Not Reported
	Methotrexate Sodium			S		20 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly (Qw)		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	14410966	EXPEDITED (15-DAY)		OT	US-UCBSA-2017008470			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Cardiac Disorder; Fatigue; Iron Deficiency Anaemia; Rhinorrhoea; Sjogren'S Syndrome; Suicidal Behaviour; Viral Infection	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Gold			S				Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

	Iron			C						Not Reported
	Sotalol			C			Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	14703375	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2018012990		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Abatacept			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Gold			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Celebrex			C				Not Reported
	Humira			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	15635162	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105536		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous	50 Mg, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	70 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram/Sq. Meter, 1 Every 1 Week		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	280 Milligram, Q2wk		Not Reported

					Humira	S	Subcutaneous			Not Reported
					Naproxen	S	Unknown			Not Reported
					Gammagard	S	Unknown			Not Reported
					Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	15635195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105899		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported
	Fosamax			C	Unknown			Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	15936038	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010077		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

					Enbrel		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Meloxicam		C	Unknown		Not Reported
					Sulfasalazine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16058873	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020938		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16070053	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021612			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Teva-Mycophenolate			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16387418	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Synthroid			C	Unknown			Not Reported
	Acetaminophen			S	Unknown	325 Milligram		Not Reported

	Rituximab	S	Intravenous drip		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Acetaminophen;Codeine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16591529	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2019307864		80 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Stenosis; Blood Pressure Decreased; Cerebral Infarction; Dizziness; Drug Interaction; Labelled Drug-Drug Interaction Medication Error; Pain In Extremity; Rheumatoid Arthritis	Trexan			S	Oral	5 Df, Weekly		Pfizer
	Cardace (Ramipril)			S	Unknown	1 Df, 1x/Day		Pfizer
	Cardace (Ramipril)			S		Unk		Pfizer
	Diurex Mite			S	Oral	1 Df, 1x/Day		Not Reported
	Primaspan			S	Oral	1 Df, 1x/Day (In The Morning)		Not Reported
	Oxiklorin			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16675382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086690		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

	Hydroxychloroquine/00072603/	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Barr
	Methotrexate	C	Subcutaneous			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16902124	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR181621			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Benlysta Powder For Infusion			S	Intravenous (not otherwise specified)	600 Mg, Q4wks		Glaxosmithkline
	Benlysta Powder For Infusion			S		Unk		Glaxosmithkline
	Calcium Unknown			S	Oral	1000 Mg, 1d		Glaxosmithkline
	Levothyroxine			S	Oral	88 ?G, 1d		Glaxosmithkline
	Triamcinolone Cream			S	Topical	Unk Unk, Bid Prn		Glaxosmithkline
	Vitamin D3			S	Oral	1000 Df, Bid		Glaxosmithkline
	Alprazolam			S	Oral	Unk, Prn		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Zoloft			S	Oral	1.5 Df, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17126131	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127253	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-114365		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cefazolin	S	Unknown			Not Reported
	Arava	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Viread	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127375	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1799		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg Tablet, 10 Mg Every Friday Am And 10 Mg Friday Pm		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Sertraline Hcl			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lidocaine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Baclofen			C	Unknown	Qhs		Not Reported
	Temazepam			C	Unknown	Qhs		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methylprednisolone Acetate		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Vitamin D		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127378	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5818		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Oxyneo			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Oxycontin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127573	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Magnesium			C				Not Reported
	Metformin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-114359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported

Erythematosus; Transaminases Increased; Treatment Failure	Azathioprine	S	Unknown			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk, Q6wk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Unknown	5 Milligram, Qd		Not Reported
	Pariet	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17128620	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019523918			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17128972	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019526097		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer

Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Rocuronium Bromide	S	Unknown	Unknown
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17128982	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051665		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Azathioprine			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S		Unk		Not Reported

Laceration; Skin Ulcer; Swelling; Treatment Failure	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rosuvastatin	S		Unk	Not Reported
	Rosuvastatin Calcium	S	Oral	0.5 Milligram, 2x/Day (Bid)	Not Reported
	Rosuvastatin Calcium	S		Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Allopurinol	C		200 Milligram, Once Daily (Qd)	Not Reported
	Coversyl [Perindopril Arginine]	C		Unk	Not Reported
	Cephalexin [Cefalexin]	C		500 Milligram, 4x/Day (Qid)	Not Reported
	Prednisone	C		10 Milligram, Once Daily (Qd)	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130553	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1148831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Cimzia		S	Subcutaneous	28.5714 Milligram Daily;		Not Reported
	Arava		S	Unknown			Not Reported
	Actemra		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130572	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2019-CA-1148952			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130605	EXPEDITED (15-DAY)		OT	CA-ROCHE-2485962		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130678	EXPEDITED (15-DAY)		HO, OT	NVSC2019FR056968		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aggression; Agitation; Catatonia; Cogwheel Rigidity; Cyclothymic Disorder; Delusion; Distractibility; Drug Ineffective; Drug Resistance; Euphoric Mood; Extrapyramidal Disorder; Hallucination, Auditory; Immobile; Insomnia; Logorrhoea; Mania; Muscle Rigidity; Mutism; Negativism; Pneumonia Aspiration; Psychomotor Hyperactivity; Salivary Hypersecretion; Tremor; Waxy Flexibility; Withdrawal Syndrome	Valproate	S	Unknown	Up To 2g/D	Novartis
	Amisulpride	S	Unknown	Unk	Not Reported
	Cyclophosphamide	S	Unknown	Unk	Not Reported
	Cyclophosphamide	S			Not Reported
	Olanzapine	S	Unknown	Up To 20 Mg/D	Not Reported
	Prednisolone	S	Unknown		Not Reported
	Prednisolone	S	Oral	Starting Dose Of 1mg/Kg Per Day	Not Reported
	Tropatepine	S	Unknown	Unk	Not Reported
	Diazepam	S	Unknown	Unk	Not Reported
	Diazepam	S	Intramuscular	10 Mg, Once/Single	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Loxapine	S	Intramuscular	100 Mg	Not Reported
	Loxapine	S			Not Reported
	Haloperidol	S	Unknown	Unk	Not Reported
	Methylprednisolone	S	Unknown	Unk	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Cyamemazine	S	Unknown	High-Dose/ Over 3 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130732	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA026984			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	520 Mg, Unk		Not Reported
	Methotrexate Sodium			S		20 Mg, Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Not Reported

Leflunomide	S	20 Mg, Unk		Not Reported
Otezla	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17131229	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027018			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	1 Every 2 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Remicade			S	Unknown			Not Reported
	Acidophilus, Lactobacillus			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Unknown			Not Reported
	Lidocaine			C	Topical			Not Reported
	Metronidazole			C	Unknown	Unk		Not Reported

					Nitroglycerin	C	Unknown		Not Reported
					Pantoloc [Pantoprazole]	C	Unknown		Not Reported
					Pregabalin	C	Unknown		Not Reported
					Risedronate	C	Unknown		Not Reported
					Rosuvastatin Calcium	C	Unknown		Not Reported
					Salbutamol	C	Unknown		Not Reported
					Triamcinolone	C	Unknown		Not Reported
					Tylenol [Paracetamol]	C	Unknown		Not Reported
					Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17132019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488361		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C	Unknown	Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	11449568	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2015009724		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Cefazolin			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Leflunomide	S	Oral	10 Mg, Unk	Not Reported
	Plaquenil	S		200 Mg, 2x/Day (Bid)	Not Reported
	Naproxen	C		1000 Mg	Not Reported
	Methotrexate	C		1 Cc	Not Reported
	Amlodipine	C		5 Mg	Not Reported
	Prednisone	C			Not Reported
	Benadryl	C			Not Reported
	Viread	C		Unk	Not Reported
	Arava	C		Unk	Not Reported
	Tofacitinib Citrate	C		5 Mg, 2x/Day (Bid)	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	14308490	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051040		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S		Unk		Not Reported

	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Aspirin	C		Unk	Not Reported
	Cymbalta	C		Unk	Not Reported
	Hydromorphone	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	14489729	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007329		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort; Nasopharyngitis; Nausea;	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Bristol Myers Squibb
	Calcium Folinate			S	Oral	5 Milligram, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Ergocalciferol			C	Unknown			Not Reported

Night Sweats; Off Label Use; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Vitamin B 12	C	Oral	1 Df, Qd	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral		Not Reported
	Fentanyl	C	Unknown	1 Df, Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, Bid	Not Reported
	Metformin Hydrochloride;Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, Qd	Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd	Not Reported
	Ranitidine	C	Oral	150 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd	Not Reported
	Celebrex	C	Unknown	Unk, Prn	Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Varicella Zoster Vaccine	C	Unknown	Unk, Total	Not Reported
	Tylenol	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Acetaminophen	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	15428288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189244		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	15719706	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1828272US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Myopathy; Orthostatic Hypotension	Risedronate Sodium Unk			S		35 Mg, Unk		Allergan
	Lipase;Amylase;Protease Unk			S		10 Mg, Tid		Allergan
	Prednisolone Unk			S		7.5 Mg, Daily		Pacific Pharma
	Domperidone Maleate			S		10 Mg, Q8hr		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Unknown	Unk		Not Reported
	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Uniphyllin			S	Intravenous (not otherwise specified)	200 Mg, Bid Intermittent Ivig Infusions		Not Reported
	Levothyroxine Sodium			S	Unknown	75 Mg, Qd		Not Reported
	Carbocisteine			S	Unknown	750 Mg, Bid		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Iviglob-Ex			S				Not Reported
	Creon			C	Unknown	10 Mg, Tid		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Theophylline			C		200 Mg, Bid		Not Reported

	Pancreatin			C		10 Mg, Q8hr			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16070493	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024279		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16079633	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16079691	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Butterfly Rash; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Golimumab	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S			Not Reported
Plaquenil /00072602/	S	Unknown	400 Milligram Daily;	Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Reactine /00884302/	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Winpred	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Diclofenac	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16811034	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Topical	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Topicort [Desoximetasone]			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17046198	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201911001747			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid Film-Coated Tablet		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly, Once In A Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17063408	EXPEDITED (15-DAY)		DE, HO	US-ZYDUS-043320		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Escherichia Infection; Haemophagocytic Lymphohistiocytosis; Pseudomonas Infection; Pyrexia; Skin Lesion	Hydroxychloroquine			S		Mixed Connective Tissue Disorder		Zydus Pharm
	Prednisone			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489266			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Leflunomide			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)				Not Reported
	Desoximetasone			C	Oral				Not Reported
	Diclofenac			C	Oral				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

			Xeljanz		S	Unknown				Not Reported
			Hydroxychloroquine		C	Unknown				Not Reported
			Hydroxychloroquine		C	Unknown				Not Reported
			Leflunomide		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132537	EXPEDITED (15-DAY)		HO	DK-ACCORD-164185		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Weight Decreased	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132694	EXPEDITED (15-DAY)		DS	CA-ROCHE-2489243		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C				Not Reported

	Naproxen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133078	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051809		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Actonel			S				Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Arava			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisone			S				Not Reported
	Simponi			S	Subcutaneous	Solution, Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Cyclobenzaprine			C		10 Milligram		Not Reported
	Desoximetasone			C		5 Milligram, Once Daily (Qd)		Not Reported
	Desoximetasone			C		5 Unk		Not Reported
	Leflunomide			C				Not Reported
	Prednisone Acetate			C		5 Milligram, Once Daily (Qd)		Not Reported
	Tylenol [Paracetamol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133101	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488057		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488643		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133920	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191207495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting	Motrin			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin /00002701/			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold (198 Au) Colloidal			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Vitamin C /00008001/			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489342		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489360		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Weight Decreased	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134176	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051895		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral	25 Milligram, Weekly (Qw)		Not Reported

		Morphine Sulfate			S					Not Reported
		Sulfasalazine			S		1000 Milligram, 2x/Day (Bid)			Not Reported
		Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134324	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Nausea; Retinal Disorder; Rheumatoid Arthritis; Vomiting	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Isoniazid;Pyridoxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134410	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489289			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

						Sulfasalazine		S	Unknown					Not Reported
						Varicella Zoster Vaccine Live		S	Subcutaneous					Not Reported
						Desoximetasone		C	Oral					Not Reported
						Diclofenac		C	Unknown					Not Reported
						Xeljanz		C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2487298		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Endocervical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134515	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051845			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134543	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019526632		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	5 Mg, Unk		Not Reported
	Orencia			S		750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134648	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5882		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Enbrel		S	Unknown	Not Reported
	Rocuronium Bromide		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134891	EXPEDITED (15-DAY)		LT	CA-ROCHE-2485918		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction;	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S		Not Reported

	Kineret			C	Unknown					Not Reported
	Lyrica			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134894	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051860		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Increased; Colitis; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		15 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		15 Milligram		Not Reported
	Orencia			S				Not Reported
	Actemra			S		1 Dosage Form		Not Reported
	Arava			S				Not Reported
	Baclofen			C				Not Reported
	Calcium			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estradiol			C				Not Reported
	Estrogel			C				Not Reported
	Furosemide			C				Not Reported
	Levaquin			C				Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Zingiber Officinale			C				Not Reported
	Gravol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134922	EXPEDITED (15-DAY)		CA, OT	NVSC2019DE058830		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Quensyl			S	Transplacental	Maternal Dose: 200 [Mg/D]/ Varying Dosage Between 150 And 200 Mg Daily		Not Reported
	Mono-Embolex			C	Transplacental	Maternal Dose: 3000 Iu, Qd		Not Reported
	L-Thyroxin-Jod Beta			C	Transplacental	Maternal Dose: 37.5 [Mg/D] / 75 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17135808	EXPEDITED (15-DAY)		DE, LT	CA-ROCHE-2486058		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Leflunomida			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported

Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Gold	S		Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C	Unknown	Not Reported

Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17136162	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051907		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Ev 4 Weeks		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		200 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral	15 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Weekly (Qw)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		1 Gram, Once Daily (Qd)		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S		20 Milligram, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17136163	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S		100 Milligram		Not Reported
	Apo-Leflunomide			S		20 Milligram, 1 Every 1 Hours		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S		300 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

			otherwise specified)	Intravenous	
	Risedronate Sodium	S		35 Milligram, Weekly (Qw)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Risedronate	C			Not Reported
	Hydroxychloroquine Sulfate	C		300 Milligram	Not Reported
	Xeljanz	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17137096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019531932		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Celebrex			S		200 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Simponi			S		50 Mg, Unk, [1 Every 2 Week(S)]		Not Reported
	Simponi			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Allopurinol			C		300 Mg, Unk		Not Reported
	Clomipramine			C		Unk		Not Reported
	Folic Acid			C		1 Mg, Unk, [5 Every 1 Week(S)]		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Zyloprim			C		Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	12814630	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016038001		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Physical Disability; Thrombocytosis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Unk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Naprosyn			S		500 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone			S		5 Mg		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw); Fomrulation: Solution		Not Reported
	Folic Acid			C		5 Mg, 4x/Week		Not Reported
	Gabapentin			C		Unk		Not Reported
	Lovastatin			C		Unk		Not Reported
	Metoprolol			C		50 Milligram		Not Reported
	Naproxen			C		1000 Milligram, Once Daily (Qd)		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Rosuvastatin Calcium			C		Unk		Not Reported
	Tofacitinib			C	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Ergocalciferol			C				Not Reported
	Vitamin D3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	12932139	EXPEDITED (15-DAY)		OT	CA-ROCHE-1851511		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Intra-arterial	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	00072602		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pregabalin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	14319105	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-113865			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Abatacept	S	Unknown		Bristol Myers Squibb
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Norvasc	S	Oral	5 Mg, Qd	Not Reported
	Norvasc	S	Oral	5 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Amlodipine Besilate	S	Oral	5.0 Mg, Qd	Not Reported
	Depo-Medrol	S	Intra-articular	Unk	Not Reported
	Depo-Medrol	S	Intramuscular	120 Mg, Unk	Not Reported
	Depo-Medrol	S	Intra-articular	80 Milligram	Not Reported
	Asacol	S	Oral	800 Mg, Tid	Not Reported
	Folic Acid	C	Oral	5 Mg, Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Omega Allergenic Extracts	C	Intradermal	1 Dosage Form, Qd	Not Reported
	Vitamin D3	C	Oral	1000 Iu, Qd	Not Reported
	Tylenol	C	Oral	500 Mg, Prn	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Atacand Plus	C	Oral	1 Df, Qd	Not Reported
	Cholecalciferol	C	Unknown	1 Dosage Form, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15719213	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-16351		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Clear Cell Renal Cell Carcinoma; Diarrhoea; Product Use In Unapproved Indication; Renal Mass; Vomiting	Etanercept	S	Unknown			Not Reported
	Infliximab	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Naprosyn	S	Unknown	Unknown		Not Reported
	Naprosyn	S				Not Reported
	Oxycodone	S	Unknown	Unknown		Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Medroxyprogesterone Acetate	S	Unknown	Unknown		Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Folic Acid	S	Unknown	Unknown		Not Reported
	Folic Acid	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Ciclosporin	S	Unknown	Unknown		Not Reported
	Ciclosporin	S				Not Reported
	Azathioprine	S	Unknown	Unknown		Not Reported
	Amitriptyline	S	Unknown	Unknown		Not Reported
	Elavil	S	Unknown	Unknown		Not Reported
	Cyclosporin	C	Unknown	Unknown		Not Reported
	Depo-Provera	C	Unknown	Unknown		Not Reported
	Cyclosporin A	C	Unknown	Unknown		Not Reported
	Cyclosporin A	C				Not Reported
	Anakinra	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15920485	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007765			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss; Tooth Loss	Methotrexate			S	Unknown		Barr
	Apo-Leflunomide			S	Unknown		Not Reported
	Enbrel			S	Unknown		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown		Not Reported
	Orencia			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine			S	Unknown		Not Reported
	Zostavax			S	Subcutaneous		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		Not Reported
	Desoximetasone			C	Oral		Not Reported
	Diclofenac			C	Unknown		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz			C	Oral	20 Milligram Daily;	Not Reported
	Cortisone Acetate			C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15923905	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007299		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral	3.2143 Milligram Daily;		Barr
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Apo-Sulfasalazine	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S			Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Infliximab	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Actemra	C	Unknown		Not Reported
Azathioprine	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Minocycline	C	Unknown		Not Reported
Penicillamine	C	Unknown		Not Reported
Prednisone	C	Unknown	12 Milligram Daily;	Not Reported
Penicillamine	C	Unknown		Not Reported
Tocilizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15942057	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007421		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Subcutaneous			Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported
	Dequalinium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16009026	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr

Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S				Barr
	Actemra	S	Unknown	162 Milligram.		Not Reported
	Actemra	S	Subcutaneous	162 Milligram, 2 Every 1 Week .		Not Reported
	Adalimumab	S	Unknown			Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram		Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram , 3 Every 1 Week .		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram , 2 Every 1 Week .		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Cyclical .		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Week .		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Prednisone	C	Unknown	20 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16050385	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020703		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16051218	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023427		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate Injection Bp			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16069928	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024282		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16073226	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021906		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Sulfasalazine		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil /00072602/		C	Unknown		Not Reported
	Celebrex		C	Unknown	400 Milligram Daily;	Not Reported
	Prednisone		C	Unknown		Not Reported
	Vitamin D /07503901/		C	Unknown	4000 Iu (International Unit) Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075928	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022589		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Lipitor			S	Unknown	40 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	300 Milligram Daily;		Not Reported
	Spiriva			S	Unknown	5 Milligram Daily;		Not Reported
	Zenhale			S	Unknown	200 Microgram Daily;		Not Reported
	Zenhale			S	Unknown	400 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Tiotropium Bromide Monohydrate			S	Unknown	5 Milligram Daily;		Not Reported
	Formoterol Fumarate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075930	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022340		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin	S	Unknown			Ivax
	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Oral			Barr
	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Oral	.		Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Hydroxychloroquine	S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/	S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/	S	Oral			Not Reported
	Neoral	S	Subcutaneous			Not Reported
	Neoral	S	Oral			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075960	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022719		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown			Barr
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown			Not Reported
	Cellcept	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine/00072603/	S	Unknown			Not Reported
	Lyrica	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075973	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16079654	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide	S	Unknown	10 Milligram Daily;		Barr
	Methotrexate	S	Unknown			Barr
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Simponi	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16079701	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1022656		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	Solution		Barr
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16079734	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Advil /00422701/			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16081557	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022935		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

	Rituxan		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown	400 Milligram Daily;	Not Reported
	Orencia		S	Unknown		Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram Daily;	Not Reported
	Humira		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Apo-Leflunomide		S	Oral	20 Milligram Daily;	Not Reported
	Actemra		S	Unknown		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Wellbutrin		C	Oral		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16081575	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024866		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Prevacid			C	Unknown	30 Milligram Daily;		Not Reported
	Folate			C	Unknown	1 Milligram Daily;		Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16081607	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022855		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16082735	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022799		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)			
			Simponi		S	Subcutaneous			Not Reported
			Sulfasalazine		S	Unknown			Not Reported
			Pantoprazole Magnesium		C	Unknown			Not Reported
			Folic Acid		C	Unknown			Not Reported
			Pantoprazole		C	Unknown			Not Reported
			Tenofovir Disoproxil		C	Unknown			Not Reported
			Tenofovir Disoproxil Fumarate		C	Unknown			Not Reported
			Xeljanz		C	Unknown			Not Reported
			Zopiclone		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16082874	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C	Unknown		Not Reported
	Celebrex	C			Not Reported
	Hydromorphone Hcl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16119843	EXPEDITED (15-DAY)		HO, OT	US-MALLINCKRODT-T201804234		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Cholesterol Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Cardiac Failure Congestive; Cataract; Catheterisation Cardiac; Chills; Coronary Artery Occlusion; Cough; Dementia; Diabetes Mellitus; Dizziness; Drug Ineffective; Dyspnoea; Eye	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Unknown	80 Units, Unk		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin			S	Subcutaneous	40 Units/0.5 Ml, 2 Times		Mallinckrodt

Laser Surgery; Feeling Abnormal; Gait Disturbance; Glaucoma; Hypoacusis; Influenza; Myalgia; Nasopharyngitis; Nausea; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Dose Omission; Proteinuria; Pruritus; Pyrexia; Rheumatoid Arthritis; Vertigo; Vomiting; Weight Decreased	Injection			Per Week (Wednesday, Saturday)		
	Repository Corticotropin Injection	S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	40 Units, Every 72 Hours		Mallinckrodt
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Tacrolimus	S	Unknown	1 Pill In Morning And Evening		Not Reported
	Meclizine Hcl	S	Unknown	Unk		Not Reported
	Mycophenolate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16194804	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633466-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Topicort	S	Cutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17137892	EXPEDITED (15-DAY)		OT	CA-ROCHE-1676974		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 11 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Xeljanz	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Acetaminophen	C		Not Reported
Ativan	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Codeine	C		Not Reported
Cortisone	C		Not Reported
Dexamethasone	C		Not Reported
Dilaudid	C	Unknown	Not Reported
Enablex [Darifenacin]	C	Unknown	Not Reported
Hydromorphone	C		Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
Kineret	C	Unknown	Not Reported
Lasix [Furosemide]	C		Not Reported
Loperamide	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C		Not Reported
Pantoprazole	C		Not Reported
Orphenadrine Citrate	C		Not Reported
Darifenacin	C		Not Reported
Rituxan	C	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17137916	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488168		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration 7.0 Year(S)		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration 3.0 Year(S)		Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration 3.0 Year(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489387		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Arthrotec		C	Unknown	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Gold		C		Not Reported
	Imuran [Azathioprine]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138057	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489415		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

		Voltaren [Diclofenac]			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported
		Zostavax			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138114	EXPEDITED (15-DAY)		HO	CA-ROCHE-2487386		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Month	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Rituxan	S	Unknown	184.0	Not Reported
	Codeine Sulfate	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 211.0 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	Therapy Duration: 4.0 Year	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown	Therapy Duration: 9.0 Month	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported

	Alendronate Sodium		S	Unknown			Not Reported
	Ciclosporin		C	Unknown			Not Reported
	Prednisone		C	Unknown	Therapy Duration: 11.0 Month		Not Reported
	Xeljanz		C	Unknown	Therapy Duration: 11.0 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489607		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown	3.0 Year(S)		Not Reported
	Enbrel			S	Unknown	260.0 Day(S)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	6.0 Year(S)		Not Reported
	Remicade			S	Unknown	426.0 Day(S)		Not Reported
	Methotrexate			C	Unknown	7.0 Year(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138217	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2489308			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported

Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported

		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S					Not Reported
		Xeljanz			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138225	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138274	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489545		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Increased; Urticaria	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Tocilizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138306	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145050		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular	Methotrexate			S	Oral			Barr

Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate	S	Parenteral			Barr
	Leflunomide	S	Unknown			Barr
	Adalimumab	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Infliximab	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Actemra	C	Unknown			Not Reported
	Azathioprine	C	Unknown			Not Reported
	Ciclosporin	C	Unknown			Not Reported
	Minocycline	C	Unknown			Not Reported
	Penicillamine	C	Unknown			Not Reported
	Prednisone	C	Unknown	12 Milligram Daily;		Not Reported
	Tocilizumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17139559	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703176		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Cimzia		C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17139821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488344		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140568	EXPEDITED (15-DAY)		OT	NVSC2019CA063112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine Phosphate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Novartis
	Plaquenil	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Arava	C	Unknown	20 Mg, Qd		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140743	EXPEDITED (15-DAY)		OT	BE-PFIZER INC-2019528534		24 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Salmonella Test Positive	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Ceftriaxone Sodium			S				Pfizer
	Ceftriaxone Sodium			S				Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Ampicillin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ampicillin			S				Not Reported
	Azathioprine			S		Unk		Not Reported
	Acyclovir [Aciclovir]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acyclovir [Aciclovir]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140779	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140945	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019051801		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Apo-Prednisone			S		3 Milligram, Once Daily (Qd)		Not Reported
	Apo-Prednisone			S		25 Milligram, Once Daily (Qd)		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; Unevaluable Event; Vomiting	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Indometacin	S		Unk	Not Reported
	Indomethacin [Indometacin]	S		Unk	Not Reported
	Methotrexate	S		25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	Unk Unk, Weekly (Qw)	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Prednisone	S	Oral	3 Milligram, Once Daily (Qd)	Not Reported
	Prednisone	S	Oral	25 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Apo-Prednisone	S		50 Milligram	Not Reported
	Prednisone	S		50 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Cymbalta	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141360	EXPEDITED (15-DAY)		OT	UA-SA-2019SA334205		30 YR	Female	UKR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Lymphadenitis; Lymphadenitis; Lymphadenopathy; Off Label Use; Unintentional Use For Unapproved Indication	Methotrexate			S	Intramuscular	Unk Unk, Qod (3 Injections)		Not Reported
	Methotrexate			S	Intramuscular	20 Mg, Qw		Not Reported
	Moxifloxacin Hydrochloride			S		400 Mg, Qd		Not Reported
	Enoxaparin Sodium			S		0.4 Ml		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Sildenafil Citrate			S		60 Mg, Qd		Not Reported
	Methylprednisolone			C		64 Mg, Qd		Not Reported
	Methylprednisolone			C		32 Mg, Qd		Not Reported
	Methylprednisolone			C		Gradual Decrease In The Dose By 4 Mg/10 Days		Not Reported
	Methylprednisolone			C		16 Mg, Qd		Not Reported
	Methylprednisolone			C		32 Mg, Qd		Not Reported
	Methylprednisolone			C		Gradual Decrease In The Dose By 2 Mg/10 Days Until Complete Withdrawal		Not Reported
	Methylprednisolone			C	Intravenous drip	125 Unk		Not Reported
	Methylprednisolone			C	Oral	125 Unk		Not Reported
	Oxygen			C		Unk Unk, Qmn (2-3 L/Min)		Not Reported
	Oxygen			C		30-40% Oxygen Through An Oxygen Concentrator In Case Of Saturation Reduction Of Less Than 88%		Not Reported
	Chloroquine			C		500 Mg, Qd		Not Reported
	Pantoprazole			C		40 Mg		Not Reported
	Folic Acid			C		5 Mg, Qw		Not Reported
	Rivaroxaban			C		20 Mg, Qd		Not Reported
	Iloprost			C	Respiratory (inhalation)	2.5 Mg, 6id		Not Reported
	Dabigatran			C		300 Mg, Qd		Not Reported

Warfarin	C	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141790	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1122658		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tadalafil			S	Unknown			Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141936	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5903		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141997	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5894		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Synovitis; Weight Increased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Clomipramine			C	Unknown			Not Reported
	Folic Acid			C	Unknown	5 Every 1 Week		Not Reported
	Pantoloc			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Zyloprim			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	11318943	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-050857		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Prescribed Underdose; Rheumatoid Arthritis;	Orencia			S	Subcutaneous	150 Mg, Qwk		Bristol Myers Squibb
	Rituxan			S	Unknown	1 G, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported

Synovitis; Vomiting	Xeljanz	S	Oral	5 Mg, Qd		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd		Not Reported
	Simponi	S	Unknown	50 Milligram, Qmo		Not Reported
	Simponi	S	Subcutaneous	50 Unk		Not Reported
	Naprosyn [Naproxen]	C	Unknown	500 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]	C	Unknown	50 Milligram		Not Reported
	Celebrex	C	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	12054230	NON-EXPEDITED			US-PFIZER INC-2016062022		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Vomiting	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Trileptal			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	12244691	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016041934		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergic Oedema; Arthrodesis; Drug Hypersensitivity;	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported

Drug Ineffective; Hospitalisation; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Methotrexate Sodium		S	Subcutaneous	25 Mg, Qwk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported
	Cimzia		S	Subcutaneous	Unk		Not Reported
	Remicade		S	Unknown	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan		S	Unknown	Unk		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide		S	Oral	10 Milligram		Not Reported
	Plaquenil		S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Leflunomide		S	Oral	10 Milligram		Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Bid		Not Reported
	Rituximab		S	Unknown	Unk		Not Reported
	Arava		C	Unknown	Unk		Not Reported
	Naproxen		C		500 Milligram, Bid		Not Reported
	Viread		C		Unk		Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	12330350	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054181		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased			otherwise specified)		
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Elavil	C	Unknown	Unk	Not Reported
	Hydrochlorothiazid	C		Unk	Not Reported
	Imitrex	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sumatriptan Succinate	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Sumatriptan	C		Unk	Not Reported

	Tofacitinib			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	13166337	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017014736		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qwk		Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Lyrica			C	Oral	50 Mg Am And 100 Mg Hs		Not Reported
	Lyrica			C		Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	13288085	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017030438		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel		S	Subcutaneous	Unk	Amgen
	Actemra		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Apo Hydroxyquine		S	Unknown	400 Milligram, Unk	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Oral	1 Gram, Qd	Not Reported
	Plaquenil		S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	14299032	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Leukopenia; Lower Respiratory Tract Infection; Musculoskeletal Stiffness; Pain; Palpitations; Pulmonary Mass; Rash; Rheumatoid Arthritis; Rheumatoid	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, Once In Every 2 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment			otherwise specified)		
	Orencia	S	Subcutaneous	125 Milligram, Weekly (Qw)	Not Reported
	Rituximab	S		Unk	Not Reported
	Gold	S		Unk	Not Reported
	Leflunomide	S		20 Milligram, Once Daily (Qd)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Vitamin D	C			Not Reported
	Arthrotec	C			Not Reported
	Imuran	C			Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C	Oral	1 Gram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	14645752	NON-EXPEDITED			US-AMGEN-USASP2018035507		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15377371	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018126860		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Gadolinium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram, Qd		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15728344	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-902500		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic	Risedronate Sodium Unk			S	Unknown			Teva
	Prednisolone			S	Unknown	7.5 Milligram Daily;		Actavis
	Domperidone Maleate			S	Unknown	30 Milligram Daily;		Not Reported
	Levothyroxine Sodium			S	Unknown	75 Microgram Daily;		Not Reported
	Carbocisteine			S	Unknown	1500 Milligram Daily;		Not Reported
	Itraconazole			S	Oral	100 Milligram Daily;		Not Reported

Hypotension	Lansoprazole	S	Unknown	30 Milligram Daily;	Teva
	Uniphyllin	S	Unknown	400 Milligram Daily;	Not Reported
	Lipase;Amylase;Protease	S	Unknown	30 Milligram Daily;	Not Reported
	Iviglob-Ex	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;	Not Reported
	Creon	C	Unknown		Not Reported
	Propranolol	C	Unknown		Not Reported
	Theophylline	C	Unknown		Not Reported
	Pancreatin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15801165	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15920482	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate Injection Bp			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15929030	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

		Tofacitinib Citrate			C	Unknown				Not Reported
		Leflunomide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15942258	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1010018			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15946512	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008103		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Ineffective;	Methotrexate			S	Unknown			Barr
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hypersensitivity; Ovarian Disorder; Ovarian Operation; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16000476	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016059		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16003920	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1017774		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Oral		Barr
	Minocycline	S	Unknown		Actavis
	Minocycline Hydrochloride	S	Unknown		Actavis
	Oxycodone	S	Unknown		Actavis
	Oxycodone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported

Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S			Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Marijuana	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S			Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Rituximab/Urelumab	C	Unknown		Not Reported

	Kineret			C	Unknown				Not Reported
	Lyrica			C	Oral				Not Reported
	Lyrica			C					Not Reported
	Prednisone			C	Unknown	7 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16045388	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020693		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Naprosyn			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16054827	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020353			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hip Surgery; Knee Arthroplasty; Osteoarthritis; Rheumatoid Arthritis; Sciatica; Unevaluable Event	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16060788	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16075847	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022465		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

						otherwise specified)	Intravenous			
		Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081495	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022795		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prolia Pre-Filled Syringe. Preservative-Free.			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Cymbalta			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081563	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022796		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug	Methotrexate			S	Oral			Barr
	Cimzia			S	Subcutaneous			Not Reported

Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine /00072603/		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Arava		C	Unknown		Not Reported
	Lyrica		C	Unknown		Not Reported
	Prednisone		C	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081565	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1022962		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligram Daily;		Not Reported

	Infliximab				C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081601	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022996		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081606	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023008		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C				Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C				Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Plantago Ovata			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16170322	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035598		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Asthenia; Contraindicated Product Administered; Depression; Drug	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Humira (Adalimumab)	S	Unknown			Not Reported
	Humira (Adalimumab)	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Infliximab	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Prednisone	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Reactine	C		10 Milligram Daily;		Not Reported
	Gabapentin	C	Unknown	1800 Milligram Daily;		Not Reported
	Acetaminophen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16188894	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035621		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Actemra		S	Unknown		Not Reported
	Humira (Adalimumab)		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Enbrel		S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
	Infliximab		S	Unknown		Not Reported
	Desoximetasone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16658095	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1085372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab Gp2013			S	Intravenous (not			Not Reported

Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased				otherwise specified)		
	Rituximab Gp2013		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16662553	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16693697	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Imuran		S	Unknown		Not Reported
					Infliximab		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16694530	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16827163	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2699437-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Device Issue; Discomfort; Gait	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported

Disturbance; Implantable Defibrillator Insertion; Joint Stiffness; Joint Swelling; Kidney Infection; Musculoskeletal Stiffness; Nasopharyngitis; Oral Mucosal Blistering; Pain; Pain In Extremity; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Pruritus; Retinal Detachment; Sinusitis; Wrong Technique In Product Usage Process	Humira 40mg/0.4ml	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16966267	NON-EXPEDITED		HO	US-PFIZER INC-2019463954		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Pneumonia Influenzal; Rash; Stomatitis	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			C		200 Mg, 2x/Day		Not Reported
	Forteo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17143352	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019530525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Mycophenolate Sodium			S	Unknown	1 Every 12 Hour(S)		Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk				Not Reported
		Prednisone		S	Unknown	Unk				Not Reported
		Remicade		S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17144818	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149327		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aspirin/00002701/			C	Unknown			Not Reported
	Atenolol			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Cyanocobalamin			C	Unknown			Not Reported
	Docusate Sodium			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Irbesartan Hct			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Myrbetriq			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported

	Venlafaxine Hydrochloride			C	Unknown					Not Reported
	Vesicare			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145176	EXPEDITED (15-DAY)		OT	GB-ABBVIE-19K-167-2955604-00		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Humira			S	Subcutaneous			Not Reported
	Metformin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145189	EXPEDITED (15-DAY)		DE, HO	GR-ROCHE-2490974		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Encephalitis Japanese B; Meningitis Bacterial; Speech Disorder	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145591	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1150008		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis;	Methotrexate			S	Unknown	Solution		Barr
	Celebrex			S	Unknown			Not Reported

Therapeutic Product Effect Decreased; Upper Limb Fracture	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Imuran		S	Unknown	Not Reported
	Neoral		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145593	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1149257			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Oral Herpes; Pain In Extremity; Rheumatoid Nodule; Skin Papilloma	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	2 Dosage Forms Daily;		Not Reported
	Myochrysine			S	Unknown	Solution Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145597	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1149234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell	Leflunomide			S	Unknown			Barr
	Methotrexate			S				Barr
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab Gp2013			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Infliximab			S	Unknown					Not Reported
	Humira (Adalimumab)			S	Subcutaneous					Not Reported
	Humira (Adalimumab)			S	Subcutaneous					Not Reported
	Etanercept			S	Subcutaneous					Not Reported
	Actemra			S	Unknown					Not Reported
	Actemra			S	Unknown					Not Reported
	Abatacept			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145602	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	Solution		Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145665	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2019051830			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			S		325 Milligram		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S				Not Reported
	Actemra			S				Not Reported
	Doxycycline			S		100 Milligram, 2x/Day (Bid)		Not Reported
	Enbrel			S		40 Milligram, Weekly (Qw)		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Milligram; Powder For Solution		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	200 Milligram, 2x/Day (Bid)		Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Acetaminophen			S				Not Reported
	Tylenol A			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported

Arava	S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
Celebrex	C				Not Reported
Celecoxib	C				Not Reported
Acetaminophen And Codeine Phosphate	C				Not Reported
Hydromorphone Hydrochloride	C				Not Reported
Meloxicam	C				Not Reported
Methotrexate	C				Not Reported
Synthroid	C				Not Reported
Tylenol W/Codeine No. 3	C				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145674	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149247		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Condition Aggravated; Diarrhoea; Dizziness; Fall; Fatigue; Feeding Disorder; Nausea; Pain; Sensitivity To Weather Change; Tooth Fracture; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145925	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146458	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Large Intestine Polyp	Methotrexate			S	Unknown			Barr

	Hydroxychloroquine Sulfate			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146609	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019536783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Celebrex			S	Unknown	200 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1500 Mg, 2x/Day		Pfizer
	Calcium Carbonate			S	Oral	3 Df, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	15 Mg, 1x/Day		Not Reported
	Relafen			S	Unknown	Unk		Not Reported
	Magnesium Aspartate			C	Oral	3 Df, 1x/Day		Not Reported
	Omega 3 [Fish Oil]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146691	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2019M1122117		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Azathioprine			S	Transplacental	150 [Mg/D]		Not Reported
	Quensyl			S	Transplacental	400 [Mg/D]		Mylan
	Calcium			C	Transplacental	Unk		Mylan
	Vomex A			C	Transplacental	150 [Mg/D (Bis 50)]		Mylan
	Influvac Tetra			C	Transplacental	Unk		Mylan
	Folsan			C	Transplacental	Unk		Mylan
	Buprenorphine			C	Transplacental	Unk		Mylan
	Budenofalk			C	Transplacental	6 [Mg/D]		Mylan

	Vitamin D Nos	C	Transplacental	2000 [Ie/D]		Mylan
	Prednisolon /00016201/	C	Transplacental	10 [Mg/D (Bis 3.5)]		Mylan
	Sumatriptan	C	Transplacental	100mg/D/3 Times 6th,9th Week		Mylan
	Ass	C	Transplacental	150 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146799	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146823	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149254		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Folic Acid			C	Oral				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146911	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147280	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191210823			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147310	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149249		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Eye Disorder; General Physical Health Deterioration; Gluten Sensitivity	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Hydroxychloroquinesulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147626	EXPEDITED (15-DAY)		HO	CA-ROCHE-2489623		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147630	EXPEDITED (15-DAY)		HO	CA-ROCHE-2487177		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration 153.0		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration 211.0 Day(S)	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral	Therapy Duration 4.0 Year(S)	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown	Therapy Duration 366.0	Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration 365.0		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ciclosporin	C				Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17151759	DIRECT		DS, LT, OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Depression; Hypoglycaemia; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Suicidal Ideation; Syncope	Hydroxychloroquine Sulfate Tabs			S	Oral	Quantity:1 Tablet(S);	9 YR	Zydus Pharm
	Vitamin D3 25mcg 1000iu			C				Not Reported
	Align Probiotics			C				Not Reported
	Biotin 5000 Mcg			C				Not Reported
	Move Free Joint Health Type 2 Collagen			C				Not Reported
	Boron			C				Not Reported
	Ha			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	9450917	EXPEDITED (15-DAY)		OT	FR-ZYDUS-001867		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Pyrexia; Scar; Skin	Omeprazole			S				Zydus Pharm
	Mycophenolic Acid			S				Not Reported
	Azathioprine/Azathioprine Sodium			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone/Prednisone Acetate			S				Not Reported
	Methotrexate/Methotrexate Sodium			S				Not Reported

Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	11745381	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015120647		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rocuronium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Sulfamethoxazole W/Trimethoprim	S	Unknown			Not Reported
	Penicillin	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Rocuronium Bromide	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	12340399	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016056038		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Amitriptyline			S	Unknown	Unk (Tablet)		Not Reported
	Amitriptyline			S	Unknown	Unk (Capsule)		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk (Capsule)		Not Reported
	Celebrex			S	Unknown	Unk (Capsule, Hard)		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Parenteral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

Prednisone	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Apo-Diclo	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Celecoxib	S	Unknown	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Elavil [Allopurinol]	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram 1 Every 2 Weeks	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, Qwk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Unknown	Unk	Not Reported
	Apo Pregabalin	S	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride;Perphenazine	S	Unknown	Unk	Not Reported
	Apo-Amitriptyline	S	Unknown	Unk	Not Reported
	Diclofenac Potassium	S	Unknown	Unk	Not Reported
	Winpred	S	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Tofacitinib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	12601635	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016096853			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 2 Times/Wk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram	Not Reported
	Plaquenil	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	13856318	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070219		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Orencia			S	Oral	200 Milligram, Bid		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported

Disturbance; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Hydroxychloroquine Phosphate	S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Phosphate	S	Oral	200 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20.0 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd	Not Reported
	Prednisone	C	Oral		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14182210	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017169862		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14186327	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170049		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Qd (1 Tablet Every 24 Hours)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate Sodium	S	Oral	Unk		Not Reported
	Prednisone	S	Unknown	Unk Unk, Qd		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone	S	Unknown	1 Tablet Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14222216	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actonel			C	Unknown	35.0 Mg, Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Risedronate Sodium			C	Unknown	35 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14233689	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021679		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate			S	Unknown	Unk		Apotex
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	6 Df, Qd		Not Reported
	Tacrolimus			S	Unknown	5 Df, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk Unk, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Oral	17 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14384355	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody	Mobicox			S	Oral			Boehringer Ingelheim

Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Alendronic Acid	S	Oral		Not Reported
	Amitriptyline [Amitriptyline Hydrochloride]	S	Oral		Not Reported
	Azathioprine	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Depo-Medrol	S	Intra-articular	Suspension Intra-Articular	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Dosage Form - Solution For Injection	Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Methotrexate [Methotrexate Sodium]	S	Oral		Not Reported
	Methotrexate [Methotrexate Sodium]	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Pantoloc [Pantoprazole]	S	Oral	Form Of Administration - Tablet (Enteric-Coated)	Not Reported
	Pantoloc [Pantoprazole]	S	Oral	Prolonged-Release Tablet	Not Reported
	Ratio-Oxycocet	S	Unknown		Not Reported
	Septra	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Alendronate	S	Unknown		Not Reported
	Apo Amitriptyline	S	Oral		Not Reported
	Apo-Alendronate	S	Unknown		Not Reported

Apo-Meloxicam	S	Unknown	Not Reported
Apo-Naproxen	S	Oral	Not Reported
Apo-Naproxen	S	Oral	Not Reported
Apo-Naproxen	S	Oral	Not Reported
Apo-Naproxen	S	Oral	Not Reported
Ranitidine	S	Oral	Not Reported
Ranitidine	S	Oral	Not Reported
Ranitidine	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Bactrim	S	Unknown	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Methylprednisolone [Methylprednisolone Sodium Succinate]	S	Intra-articular	Not Reported
Oxycocet	S	Oral	Not Reported
Oxycodone Hcl	S	Unknown	Not Reported
Vimovo	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Amitriptyline Pamoate	S	Oral	Not Reported
Esomeprazole Magnesium Trihydrate	S	Oral	Not Reported
Methylprednisolone Acetate	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo Ranitidine	S	Oral	Not Reported
Meloxicam	S	Unknown	Not Reported
Oxycocet	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported

		Celecoxib			C	Unknown				Not Reported
		Hydroxychloroquine Sulfate			C	Unknown				Not Reported
		Plaquenil			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14641000	NON-EXPEDITED			US-PFIZER INC-2018108094		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15630709	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15692314	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018171978		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15840630	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001098		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure Via Breast Milk; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15841614	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019007342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Enbrel			S	Unknown	Unk		Amgen

Ineffective; Off Label Use; Rheumatoid Arthritis	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram	Not Reported
	Leflunomide		S	Unknown	10 Milligram, Qd	Not Reported
	Methotrexate		S	Unknown	15 Milligram	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Simponi		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15952043	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010727		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15974567	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Orencia			S	Unknown			Bristol Myers Squibb

Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Mg, Unk	Not Reported
	Leflunomide		S	Unknown	10 Mg, Qd	Not Reported
	Methotrexate		S	Unknown	15 Mg, Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Simponi		C	Subcutaneous		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Arava		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15978383	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013841		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Orencia			S	Subcutaneous	150 Mg, Unk		Bristol Myers Squibb
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16057944	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020713		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Penicillin			S	Unknown			Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rocuronium			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16103785	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1026315			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16120602	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16161277	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034988		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Furosemide Sodium			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Nifedipine			C	Unknown			Not Reported
	Palafer			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Toloxin /00017701/			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

Xarelto	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Zinc Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16199983	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-036501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	5 Absent, Qd		Not Reported
	Intravenous Immune Globulin			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Sulfasalazine			S	Oral	250 Milligram, Qd				Not Reported
	Folic Acid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16393363	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019235708		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Off Label Use	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown			Pfizer
	Lyrica			S	Unknown	150 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Esomeprazole			C	Unknown	40 Mg, 1x/Day		Not Reported
	Lumigan Rc			C	Ophthalmic	Unk Unk, 1x/Day		Not Reported
	Nexium [Esomeprazole Sodium]			C	Unknown	Unk		Not Reported

	Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10 Mg, 1x/Day		Not Reported
	Trazodone	C	Unknown	200 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]	C	Unknown	3000 Mg, 1x/Day		Not Reported
	Valsartan	C	Unknown	Unk Unk, 1x/Day		Not Reported
	Valsartan	C	Unknown	Unk		Not Reported
	Wellbutrin Xl	C	Unknown	300 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16704222	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1090969		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis; Unevaluable Event	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16820129	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-201909000464			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerulosclerosis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Before Breakfast), Film-Coated Tablet		Concordia

Conjunctival Hyperaemia; Drug Eruption; Erythema; Erythema; Haemorrhage Subcutaneous; Lymphadenopathy; Malaise; Pyrexia; Toxic Skin Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	400 Mg, Freq: Unk X 1 Days		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg, Unk		Concordia
	Prednisolone	C		30 Mg, Qd		Not Reported
	Prednisolone	C		Dose Reduction		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17069596	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001903			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Cyst Rupture; Deep Vein Thrombosis; Fall; Ingrowing Nail; Malignant Melanoma; Malignant Melanoma In Situ; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nail Bed Bleeding; Nail Disorder; Nodule; Onychomadesis; Pain; Pain; Poor Peripheral Circulation; Post Procedural Complication; Postoperative Thrombosis; Pruritus; Rheumatoid Arthritis; Skin Discolouration; Skin Discolouration; Skin Fissures; Skin Haemorrhage; Upper Limb Fracture; Varicose Vein; Venous Operation; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk Unk, Bid		Concordia
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg; 1 In 2 Wk, 40mg/0.4ml		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg; 1 In 2 Wk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg; 1 In 2 Wk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	Unk		Not Reported
	Mobic			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Biotin			C		Unk		Not Reported
	Vitamin B			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17109186	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1144965		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17132909	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191208226		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding	Motrin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Asprin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting	Gold		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Naprosyn /00256201/		S	Unknown	Not Reported
	Plaquenil /00072602/		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim		S	Unknown	Not Reported
	Diclofenac		C	Unknown	Not Reported
	Tramadol Hydrochloride		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17148599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490210			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17148627	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149115	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram Daily;		Not Reported

							Solution			
	Prednisone			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149120	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150357		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Methotrexate			S	Unknown	Solution		Barr
	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149122	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150225		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Imuran		S	Unknown	450 Milligram Daily;	Not Reported
	Neoral		S	Unknown	250 Milligram Daily;	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown	200 Milligram Daily;	Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Citalopram Hydrobromide		C	Unknown		Not Reported
	Citalopram Hydrobromide		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149460	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Phthalylsulfathiazole			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149491	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain;	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

Pemphigus; Systemic Lupus Erythematosus			otherwise specified)	Intravenous	
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149553	NON-EXPEDITED			NVSC2019US067721			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149554	NON-EXPEDITED			NVSC2019US067728			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149558	NON-EXPEDITED			NVSC2019US067737			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149568	NON-EXPEDITED			NVSC2019US067723			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149666	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Glyburide			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported

		Metformin			C	Unknown				Not Reported
		Mycophenolate Mofetil			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149849	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191216105			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149990	EXPEDITED (15-DAY)		OT	FR-ACCORD-165350		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Off Label Use; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Methotrexate	S	Unknown		Accord
	Mycophenolic Acid	S			Accord
	Hydroxychloroquine	S			Not Reported
	Omeprazole	S			Not Reported
	Prednisone	S	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150008	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191217118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150034	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191215318		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150731	EXPEDITED (15-DAY)		LT	CA-ROCHE-2488223		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Film-Coated Tablet		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Ilaris	S	Subcutaneous	Single-Use Vial	Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Marijuana	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Lyrica	C	Unknown		Not Reported

	Rituxan			C	Unknown					Not Reported
	Hydroxychloroquine Sulfate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150878	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR207382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Ventolin Hfa			S	Respiratory (inhalation)	Unk Unk, Prn, (2-4 Puffs Q 4-6years)		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Breo Ellipta			S	Respiratory (inhalation)	Unk		Glaxosmithkline
	Colchicine			S		Unk		Glaxosmithkline
	Prednisone			S		50 Mg, Z, (Twice Week)		Not Reported
	Meloxicam			S		Unk Unk, Prn		Not Reported
	Celebrex			S		Unk Unk, Prn		Not Reported
	Estrogel			S	Topical	Unk Unk, Qd, (Apply Daily 1 Pump)		Not Reported
	Plaquenil			S		200 Mg, Bid		Not Reported
	Dexilant			S	Oral	60 Mg, Qd		Not Reported
	Rituximab			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151144	EXPEDITED (15-DAY)		HO	CA-ROCHE-2489617		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Anakinra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Naproxen Sodium	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Unknown			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Other			Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151591	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1149854		81 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dementia With Lewy Bodies; Fall; Hip Fracture; Movement Disorder; Parkinson'S Disease	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151592	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150037		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151603	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151635	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150338		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Methotrexate		S	Unknown	Barr
	Leflunomide		S	Unknown	Barr
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151637	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1149904		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151638	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149263			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate	S	Oral			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Lipitor	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151640	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151642	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate	S	Oral			Barr
	Methotrexate	S	Subcutaneous			Barr
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151643	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149841		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ear Pain; Facial Paralysis; Insomnia; Pain In Jaw	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151672	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150223		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

					Enbrel		S	Subcutaneous		Not Reported
					Humira		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Orencia		S	Unknown		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Plaquenil		S	Unknown		Not Reported
					Plaquenil		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151675	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151680	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150238		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Benadryl /00000402/			C	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Reactine /00884302/			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151719	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported

	Perindopril Erbumine			C	Oral	4 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151720	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150586		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Ciclosporin			S	Unknown			Ivax
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

		Sulfasalazine			S	Oral				Not Reported
		Sulfasalazine			S					Not Reported
		Xeljanz Xr			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151721	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Pseudoephedrine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17152058	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1122370			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Prednisone			S	Transplacental	Mother Dose 5 Mg		Not Reported
	Azathioprine			S	Transplacental	Mother Dose 2 Mg/Kg		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17152208	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027154			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache;	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	624 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Oxyneo			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Methylprednisolone			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported

Weight Increased	Oxycontin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153027	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150574		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153167	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150124		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153168	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150640		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Orencia			S	Intravenous (not otherwise specified)					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153171	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150228		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Reactine /00884302/			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported
	Cetirizine Hydrochloride			C	Unknown			Not Reported
	Benadryl /00000402/			C	Unknown			Not Reported
	Venlafaxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153172	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150645		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Methotrexate			S	Oral			Barr

Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Apo-Hydroxyquine			S	Unknown				Not Reported
	Apo-Hydroxyquine			S	Subcutaneous				Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Neoral			S	Unknown				Not Reported
	Neoral			S	Subcutaneous				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Remicade			S	Unknown				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153173	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1150610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Arava	C	Unknown			Not Reported
	Plaquenil/00072602/	C	Oral	400 Milligram Daily;		Not Reported
	Prednisone	C	Unknown			Not Reported
	Simponi	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153174	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150232		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	750 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydrochlorothiazide/Lisinopril Dihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz Xr			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153175	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150131		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Condition Aggravated; Contraindicated Product	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Parenteral			Not Reported

Administered; Drug Ineffective; Nodule; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153177	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150567		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Oral				Not Reported
		Xeljanz			C	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153219	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153220	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150655		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Naproxen			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153584	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hip Arthroplasty; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral	15 Milligram Daily;		Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153677	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150597		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153679	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150111			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Mirtazapine			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153698	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150722		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Anakinra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Desoximetasone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153735	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1150601			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153736	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150134			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Furuncle; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate		S	Unknown		Barr
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram Daily;	Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz Xr		S	Oral	11 Milligram Daily;	Not Reported
	Arava		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153737	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150606			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153773	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1150660		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Contraindicated Product Administered; Drug Ineffective; Hospitalisation; Meningitis	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150501		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153782	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17154048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17154156	NON-EXPEDITED			NVSC2019US067733			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457093		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154596	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191215082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

							otherwise specified)			
					Phthalylsulfathiazole	S	Unknown			Not Reported
					Plaquenil /00072602/	S	Unknown			Not Reported
					Prednisone	S	Unknown			Not Reported
					Rituxan	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456781		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solutiom		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154710	NON-EXPEDITED			NVSC2019US018133		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	15 Mg (Weekly)		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Topiramate			C	Unknown	25 Mg, Qd		Not Reported
	Topiramate			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155002	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150603		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155003	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150637		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate	S	Unknown			Barr
	Leflunomide	S	Unknown			Barr
	Arava	S	Unknown			Not Reported
	Certolizumab Pegol	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxyquinoline Sulfate	S	Unknown			Not Reported
	Neoral	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rapamune	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tacrolimus	S	Oral	6 Milligram Daily;		Not Reported
	Tacrolimus	S	Oral	4 Milligram Daily;		Not Reported
	Imuran	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155004	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150650		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats;	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Humira		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Arava		S	Oral	20 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Leucovorin /00566701/		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Coversyl /00790702/		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155008	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155011	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155012	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150588			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	28.5714 Milligram Daily;		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155149	NON-EXPEDITED			NVSC2019US017937		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2019	15668043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018167237			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	11326249	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015075697		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported

Stenosis; Synovitis; Vasculitic Rash	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	500 Milligram, Cyclical	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo	Not Reported
	Orencia	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	12.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Kineret	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	12232312	EXPEDITED (15-DAY)		CA	DE-TEVA-645985GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Atrial Septal Defect; Foetal Exposure During Pregnancy	Metoprolol	S	Transplacental	100 Milligram Daily;		Not Reported
	Lamotrigin	S	Transplacental	350 Milligram Daily;		Actavis
	Quensyl	S	Transplacental	200 Milligram Daily;		Not Reported
	Marcumar	C	Transplacental			Not Reported
	Clexane 40	C	Transplacental	80 Milligram Daily;		Not Reported
	Ass 100	C	Transplacental	100 Milligram Daily;		Not Reported
	Folsaeure	C	Transplacental	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	12356657	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016248801		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	1 Df, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arthrotec			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Parenteral	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown

Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk	Unknown
Celecoxib	S	Unknown	Unk	Pfizer
Celecoxib	S			Pfizer
Pregabalin	S	Unknown	Unk	Pfizer
Naprosyn	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Amitriptyline	S		Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Apo-Diclo	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Apo-Amitriptyline	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Elavil [Allopurinol]	S	Unknown	Unk	Not Reported

	Abatacept	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, Qwk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo Celecoxib	S		Unk	Not Reported
	Apo Pregabalin	S		Unk	Not Reported
	Amitriptyline Hydrochloride/Perphenazine	S	Unknown		Not Reported
	Winpred	S		Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	12611441	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016366150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Humira			S	Subcutaneous	40 Milligram, Every 2 Weeks		Not Reported

Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous	40 Milligram, Unk			Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Times/Wk			Not Reported
	Humira			S	Unknown	Unk			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	40 Mg, Unk			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Plaquenil			S	Oral	400 Milligram, Unk			Not Reported
	Plaquenil			S	Oral	400 Milligram			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Unk			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Unk			Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram, Unk			Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Unk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram			Not Reported
	Rituximab			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	13113122	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017001862		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase	Enbrel			S	Unknown	25 Milligram		Amgen
	Methotrexate			S	Subcutaneous	10 To 17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Neoplasm Excision; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Methotrexate	S	Unknown	10 To 12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 To 15 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Bid	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ciclosporin	C		150 Milligram, Qd	Not Reported
	Rituxan	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	14191119	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017489566		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	14200416	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491477		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	1 Tablet Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15563291	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245089		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Elavil			C	Unknown	Unk		Not Reported
	Hydrochlorothiazid			C		Unk		Not Reported
	Imitrex			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported

	Tenormin	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Sumatriptan Succinate	C		Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
	Hydrochlorothiazide	C	Unknown	Unk		Not Reported
	Amitriptyline	C	Unknown	Unk		Not Reported
	Sumatriptan	C		Unk		Not Reported
	Tofacitinib	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15580509	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017039792		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Actemra			S	Endocervical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day (Daily)		Not Reported
	Leflunomide			S		20 Mg, Daily		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qwk		Not Reported
	Lyrica			C		50 Mg Am And 100 Mg Hs		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Naproxen			C		500 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported

	Hydroxychloroquine Sulfate			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15671134	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018494371			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15883698	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004841			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Reactine [Cetirizine]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Cortisone Acetate		S	Unknown		Not Reported
					Cortisone Acetate		S	Topical		Not Reported
					Simponi		S	Subcutaneous		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
16-Dec-2019	15920479	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007312			Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr		
	Actemra			S	Subcutaneous			Not Reported		
	Apo-Leflunomide			S	Unknown			Not Reported		
	Enbrel			S	Subcutaneous			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Orencia			S	Unknown			Not Reported		
	Plaquenil			S	Unknown			Not Reported		
	Remicade			S	Intravenous (not otherwise specified)			Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
16-Dec-2019	15928985	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007291		50 YR	Female	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Unknown			Not Reported
	Zostavax			S				Not Reported
	Varicella-Zoster Immune Globulin (Human)			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15930826	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007315			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15934067	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007659			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15939917	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain;	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Rituxan		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tofacitinib		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Abatacept		S	Unknown		Not Reported
	Tylenol Arthritis Pain 8 Hour		C	Unknown		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Tylenol Arthritis		C		2600 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15942211	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007557		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15942232	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010017		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15959632	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012212		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Rheumatoid Arthritis; Skin	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Unknown			Not Reported

Reaction; Skin Swelling; Swelling	Enbrel		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/		S	Unknown	Not Reported
	Prednisone		S	Unknown	Actavis
	Cimzia		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15993953	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016226		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Sodium Aurothiomalate Injection Bp			S	Intramuscular			Not Reported

Xeljanz	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Benadryl	C	Unknown	Not Reported
Lasix	C	Unknown	Not Reported
Enablex	C	Unknown	Not Reported
Enablex	C	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Intra-arterial	Not Reported
Ativan	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Norflex	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Pantoloc	C		Not Reported
Synthroid	C		Not Reported
Vagifem	C	Vaginal	Not Reported
Hydromorphone	C		Not Reported
Anakinra	C		Not Reported
Codeine	C		Not Reported
Kenalog	C		Not Reported
Kadian	C		Not Reported
Oxyneo	C		Not Reported
Pantoloc	C		Not Reported
Restasis	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Acetaminophen	C		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Leflunomide	C		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

		Plantago Ovata			C	Unknown				Not Reported
		Plantago Ovata			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16009048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017285		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16009414	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017293			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram , 1 Every 1 Week .		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Unknown	12.5 Milligram		Barr
	Methotrexate			S	Subcutaneous			Barr

Methotrexate	S	Intramuscular		Barr
Methotrexate	S	Intramuscular		Barr
Arava	S	Oral	10 Milligram , 3 Every 1 Week .	Not Reported
Arava	S	Oral	10 Milligram .	Not Reported
Arava	S	Oral	200 Milligram , 2 Every 1 Week .	Not Reported
Arava	S	Oral	10 Milligram , 2 Every 1 Week .	Not Reported
Arava	S	Oral	10 Milligram Daily;	Not Reported
Arava	S	Oral	10 Milligram	Not Reported
Enbrel	S	Unknown	50 Milligram , 1 Every 1 Week	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous , 40 Milligram .	Not Reported
Hydroxychloroquine /00072603/	S	Unknown		Not Reported
Hydroxychloroquine /00072603/	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Milligram .	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Milligram, , Powder For Solution Intravenous .	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	S	Unknown	1000 Milligram, Solution Intravenous .	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16010282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016931		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr

Methotrexate	S		Barr
Leflunomide	S	Unknown	Barr
Leflunomide	S		Barr
Anakinra	S	Unknown	Not Reported
Anakinra	S		Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Azathioprine	S		Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Imuran	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16050520	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1020848		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder;	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Therapeutic Product Effect Decreased; Treatment Noncompliance					otherwise specified)				
	Sulfasalazine			S	Unknown				Not Reported
	Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156190	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034804		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Cholesterol Increased; Bone Erosion; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Hypertension; Joint Dislocation; Joint Stiffness; Non-Hodgkin'S Lymphoma; Osteoarthritis; Osteoporosis; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156201	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

					Plaquenil		S	Unknown				Not Reported
					Rituxan		S	Unknown				Not Reported
					Rituxan		S	Intravenous (not otherwise specified)				Not Reported
					Simponi		S	Unknown				Not Reported
					Simponi		S	Subcutaneous				Not Reported
					Sulfasalazine		S	Unknown				Not Reported
					Celebrex		C	Unknown				Not Reported
					Lyrica		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156222	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034332			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine 00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intraveous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156249	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034823		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Hypersensitivity; Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis	Methotrexate	S	Unknown			Barr
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156314	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034439		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Enbrel			S	Subcutaneous	50milligram		Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Subcutaneous	150gram		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous	50milligram, Solution Subcutaneous		Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400milligram		Not Reported
	Naprosyn			S	Unknown	50milligram		Not Reported
	Celebrex			C	Unknown	200milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161247	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034827		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161263	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1034991		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Viral Infection	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161270	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Methotrexate			S	Unknown			Barr

Enzyme Increased; Pneumonia	Actemra		S	Subcutaneous		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161272	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035389		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	1000 Milligram Daily;		Not Reported

	Naproxen	C	Oral	1000 Milligram Daily;		Not Reported
	Rosuvastatin Calcium	C	Oral			Not Reported
	Valtrex	C	Oral	2000 Milligram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034985		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161299	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161315	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035607		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16405014	EXPEDITED (15-DAY)		CA, DE, OT	FR-ASTRAZENECA-2019SE83158			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta;	Esomeprazole			S	Transplacental			Astrazeneca
	Esomeprazole			S	Transplacental			Astrazeneca
	Plaquenil			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Diffu K			S	Transplacental			Not Reported
	Diffu K			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported

Right-To-Left Cardiac Shunt	Cortancyl		S	Transplacental	Not Reported
	Imurel		S	Transplacental	Not Reported
	Imurel		S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16608051	EXPEDITED (15-DAY)		CA, DE, OT	FR-AUROBINDO-AUR-APL-2019-042768			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	20 Milligram, Once A Day		Aurobindo
	Cortancyl			S	Transplacental	1 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Transplacental	400 Milligram, Once A Day		Not Reported
	Diffu K			S	Transplacental	1 Dosage Form, Once A Day		Not Reported
	Imurel			S	Transplacental	150 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16701250	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-216066		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Maculopathy	Hydroxychloroquine			S	Unknown	Unk		Sun
	Chloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16708395	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-199337		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maculopathy; Retinal Depigmentation; Retinal Toxicity; Vision Blurred	Hydroxychloroquine			S	Unknown	200 Milligram, Bid			Sun	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16721927	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094587		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Morphine Sulfate			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16748627	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218134		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16748629	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218133		44 YR	Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acquired Pigmented Retinopathy; Retinal Toxicity	Hydroxychloroquine	S	Unknown		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16763267	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-198093		55 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Retinal Toxicity	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16784508	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201908000156			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Atrial Fibrillation; Coeliac Disease; Diarrhoea; Food Allergy; Gait Disturbance; Immobile; Injection Site Rash; Injection Site Urticaria; Peripheral Swelling; Rash; Spinal Osteoarthritis; Swelling; Urticaria	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous	40 Mg, 1 In 2 Wk, 40mg/0.8ml		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16940929	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019451116		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	500 Mg, For 2 Consecutive Days		Pfizer
	Methylprednisolone Sodium Succinate			S				Pfizer

	Prednisolone	S	Oral	Starting Dose Of 1 Mg/Kg Per Day		Not Reported
	Prednisolone	S				Not Reported
	Hydroxychloroquine	S	Oral	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17095420	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019196539		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Pantoprazole			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin Hcl			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Avelox			S	Unknown	Unk		Not Reported
	Keflex [Cefalexin]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hctz			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Losartan Potassium			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported

	Lopressor	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk		Not Reported
	Hydrochlorothiazide	S	Unknown	Unk		Not Reported
	Cipro [Ciprofloxacin]	S	Unknown	Unk		Not Reported
	Penicillin [Benzylpenicillin]	S	Unknown	Unk		Not Reported
	Isoniazid	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Iron Sucrose	C	Unknown	Unk		Not Reported
	Esomeprazole	C	Unknown	Unk		Not Reported
	Gold	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd		Not Reported
	Clindamycin	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17139304	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S		Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17149606	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191215091		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

					Orencia		S	Subcutaneous		Not Reported
					Methotrexate		S	Oral		Not Reported
					Hydroxychloroquine Sulfate		S	Urethral		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Fosamax		S	Unknown		Not Reported
					Folic Acid		S	Unknown		Not Reported
					Enbrel		S	Subcutaneous		Not Reported
					Desoximetasone		S	Oral		Not Reported
					Cimzia		S	Subcutaneous		Not Reported
					Arava		S	Oral		Not Reported
					Actemra		S	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156068	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019205807			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156093	NON-EXPEDITED			NVSC2019US016548		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Omalizumab	S	Unknown	Unk Ukn, Unknown		Not Reported
	Omalizumab	S				Not Reported
	Cyclosporine	S	Unknown	Unk Ukn, Unknown		Novartis
	Cyclosporine	S				Novartis
	Dapsone	S	Unknown	Unk Ukn, Unknown		Not Reported
	Dapsone	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk Ukn, Unknown		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156141	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156243	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156249	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Calcium Carbonate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

		Relafen			S	Unknown					Not Reported
		Omega 3 [Fish Oil]			C	Unknown					Not Reported
		Magnesium Aspartate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156274	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212796		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156349	EXPEDITED (15-DAY)		DE, HO	GR-ROCHE-2492148		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Confusional State; Encephalitis Japanese B; Mental Impairment; Speech Disorder	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156379	EXPEDITED (15-DAY)		OT	CA-SA-2019SA341973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Unknown	200 Mg, Bid		Sanofi
	Prednisone			S	Unknown	15 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	500 Mg		Not Reported
	Sulfasalazine			C	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156403	EXPEDITED (15-DAY)		OT	US-LAURUS LABS LIMITED-201900439		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Potentiating Drug Interaction; Vision Blurred	Hydroxychloroquine			S	Unknown	Mg/Day		Not Reported
	Docetaxel			S	Unknown			Not Reported
	Cyclophosphamide			C	Unknown			Not Reported
	Corticosteroids			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156420	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191210827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156773	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1150842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Methotrexate			S	Unknown	Solution		Barr
	Leflunomide			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156844	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20191213224		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling;	Reactine Unspecified (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Paracetamol			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound			otherwise specified)	
	Stelara	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo Prednison	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone	S	Oral	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide Sandoz	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil /00072603/	S	Oral	Not Reported
Plaquenil /00072603/	S	Unknown	Not Reported
Plaquenil /00072603/	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicort /00028604/	S	Subcutaneous	Not Reported
Topicort /00028604/	S	Unknown	Not Reported

	Topicort /00028604/	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S			Not Reported
	Paracetamol	C	Unknown		Not Reported
	Atasol /00020001/	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156860	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2019-08269		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Myopathy; Orthostatic Hypotension	Levothyroxine			S	Unknown	75 Microgram, Qd		Lupin
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Lupin
	Lansoprazole			S	Intracardiac	30 Mg, Qd		Not Reported
	Carbocisteine			S	Unknown	750 Milligram, Bid (Every 12 Hour)		Not Reported
	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisolone Acetate			S	Unknown	7.5 Mg, Qd		Not Reported
	Amylase/Lipase/Protease			S	Unknown	10 Mg, Tid (Every 8 Hour)		Not Reported
	Domperidone Maleate			S	Unknown	10 Mg, Tid (Every 8-Hour)		Not Reported
	Uniphyllin			S	Unknown	200 Milligram, Bid		Not Reported
	Risedronate Sodium			S	Unknown	35 Milligram, Unk		Not Reported
	Creon			S	Unknown	10 Mg, Tid (Every 8 Hour)		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156874	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150738		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156924	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156955	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate			S	Unknown			Barr

Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate Tab 25mg	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156957	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Oral			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Plaquenil	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17158908	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019534913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Sulfasalazine			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Codeine			S	Unknown	Unk		Not Reported
	Aclasta			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plantago Afra			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, 1x/Day		Not Reported
	Cannabis Sativa			C	Unknown	Unk Unk, 1x/Day		Not Reported
	Ergocalciferol			C	Unknown	2000 Iu, 1x/Day		Not Reported
	Folic Acid			C	Unknown	5 Mg, 1 Every 3 Week(S)		Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lipitor			C	Unknown	10 Mg, 1x/Day		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Weekly		Not Reported
	Tums [Calcium Carbonate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17159600	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019537144			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation;	Infliximab			S	Unknown	Unk		Not Reported

Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Advair	C		Unk	Not Reported
	Allopurinol	C		Unk	Not Reported
	Atrovent Hfa	C		Unk (Aerosol)	Not Reported
	Codeine	C		Unk	Not Reported
	Cyclobenzaprine Hydrochloride	C		Unk	Not Reported
	Dilaudid	C		Unk	Not Reported
	Hydromorphone Hydrochloride	C		Unk	Not Reported
	Ibuprofen	C		Unk	Not Reported
	Leucovorin Calcium	C		Unk	Not Reported
	Nexium Mups [Esomeprazole Magnesium]	C		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Ventolin Hfa	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17160239	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053731		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Not Reported

Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra	S		Unk	Not Reported
	Apo-Prednisone	S		5 Milligram	Not Reported
	Arava	S		Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		500 Milligram	Not Reported
	Fosamax	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Ucb
	Hydroxychloroquine	S			Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S		1 Gram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17160821	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1150908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Azathioprine		C	Subcutaneous	50 Milligram Daily;	Not Reported
	Azathioprine		C	Subcutaneous	50 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	12675144	NON-EXPEDITED		OT	CA-AMGEN-CANSL2015044183		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Aspirin	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	13121648	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017017327		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	10 To 12.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 To 17.5 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	10 To 15 Millgram, Qwk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day		Not Reported

Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Tocilizumab	S	Unknown	680 Mg, Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Ciclosporin	C		150 Mg, 1x/Day		Not Reported
	Rituxan	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	13458677	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP010091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Tramadol			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Diclofenac			S				Apotex
	Diclofenac			S				Apotex
	Diclofenac			S				Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S				Not Reported
	Naprosyn /00256201/			S				Not Reported
	Naprosyn /00256201/			S				Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Motrin			S				Not Reported

	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Voltaren /00372301/	S	Unknown	Unk	Not Reported
	Voltaren /00372301/	S			Not Reported
	Voltaren /00372301/	S			Not Reported
	Voltaren /00372301/	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	14226675	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017507862			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10.0 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750.0 Mg, Q4wk		Not Reported

Erythematosus Rash; Tooth Infection; Weight Decreased	Orencia		S	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Actonel		C	Unknown	35.0 Mg, Unk	Not Reported
	Esomeprazole Magnesium W/Naproxen		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Risedronate Sodium		C	Unknown	35 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	14705126	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018013813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported

	Plaquenil	S		400 Mg, Once Daily (Qd)	Not Reported
	Prednisone	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S		500 Milligram	Not Reported
	Sulfasalazine	S		1 G, 2x/Day (Bid)	Not Reported
	Xeljanz	S		Unk	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	14961363	NON-EXPEDITED			US-AMGEN-USASP2018072669		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15233081	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015249702		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Weekly (Qwk)	Pfizer
	Methotrexate Sodium	S	Unknown	20 Mg, Q2wk	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Qd	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Milligram	Pfizer
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qd	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Unknown
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic, Every 2 Weeks (Q2wk)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	12.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Kineret	S	Subcutaneous	100 Mg, 1x/Day	Not Reported
	Leflunomide	S	Oral	20 Mg, Daily	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported

	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclic, Every 4 Weeks (Q4wk)		Not Reported
	Orencia	S	Unknown	500 Mg, Cyclical		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Qmo		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Not Reported
	Orencia	S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, 1x/Day		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15250694	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015389147		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Pain; Peripheral Swelling; Rash; Swelling; Treatment Failure; Urticaria	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rocuronium Bromide			S	Unknown	Unk		Unknown
	Rocuronium Bromide			S	Unknown	Unk		Unknown
	Codeine			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Plaquenil	S		Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Gold	S		Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15539790	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-965471		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia;	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Tocilizumab	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Myochrysine	S	Parenteral			Not Reported
	Actemra	S	Unknown	12 Milligram Daily;		Not Reported
	Rituximab Gp2013	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	120 Milligram Daily;		Not Reported
	Prednisone	C		10 Milligram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15700579	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018504596		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15800352	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996062		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15800353	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996061		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Elavil (Amitriptyline Hydrchloride)	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15803209	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S				Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral	12.5 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15804321	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996072		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15923885	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007500		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15923903	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007428		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

	Plaquenil		S	Unknown			Not Reported
	Xeljanz		C	Unknown			Not Reported
	Xeljanz		C	Oral	100 Mbq Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15929035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007669		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15929277	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007482		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Arthralgia; Back Pain; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Hand Deformity;	Mycophenolate Mofetil			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Apo Diazepam			S	Unknown			Not Reported

Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15930776	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007481		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Abnormal; C-	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported

Reactive Protein Increased; Cataract; Cataract Operation; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Celebrex		S	Oral		Not Reported
	Enbrel		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Arava		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15930880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007678		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	2 Every 1 Week, 40 Milligram		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rho D Immune Globulin Human			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown	20 Milligram Daily;		Not Reported
	Tofacitinib			S	Subcutaneous	10 Milligram Daily;		Not Reported

	Celebrex	C	Oral	400 Milligram		Not Reported
	Ibuprofen	C	Oral			Not Reported
	Lipitor	C	Oral	1 Every 1 Week, 10 Milligram		Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15930882	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007878		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15934001	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007437		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme	Methotrexate			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Arava	S	Oral			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Prednisone	C	Oral	5 Milligram Daily;		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16008844	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016891		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Actemra	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
Apo-Leflunomide	S			Not Reported
Enbrel	S	Subcutaneous		Not Reported
Neoral	S	Subcutaneous		Not Reported
Neoral	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Plaquenil	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Leflunomide	S	Unknown		Barr
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Xeljanz	C	Oral		Not Reported
Hydroxychloroquine	C	Oral	400 Milligram Daily;	Not Reported
Arava	C	Oral	20 Milligram Daily;	Not Reported
Cimzia	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16044641	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020648		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced	Methotrexate			S	Unknown			Barr

Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Actemra		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown	1600 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown	8 Gram Daily;	Not Reported
	Leflunomide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16050620	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	200 Milligram Daily;		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16058829	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020766		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Celecoxib			C	Oral	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16058872	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			C	Unknown				Not Reported
		Wellbutrin			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16063272	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020731		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Prevacid			C	Unknown	60 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16069924	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021628		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16073261	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021935		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16075605	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1022469		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Therapy Non-Responder	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16075945	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022513		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral	1 Gram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1 Gram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported

	Lyrica	C	Oral			Not Reported
	Prednisone	C	Unknown	15 Milligram Daily;		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16124814	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16167656	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1035423		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170323	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034974		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Gbq Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate Injection Bp			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C				Not Reported
	Codeine			C				Not Reported
	Desoximetasone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog			C	Intra-articular			Not Reported
	Lasix			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C	Unknown			Not Reported
	Oxyneo			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported

	Restasis	C				Not Reported
	Rituxan	C	Intravenous (not otherwise specified)			Not Reported
	Synthroid	C				Not Reported
	Trimethoprim	C	Unknown			Not Reported
	Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170333	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035595		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Herpes Zoster; Myocardial Infarction; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	5 Milligram Daily;		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Prednisone Acetate			C	Unknown	5 Milligram Daily;		Not Reported
	Tylenol			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported

	Diphenhydramine	C				Not Reported
	Loperamide	C				Not Reported
	Norflex	C	Unknown			Not Reported
	Omnaris	C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous	C				Not Reported
	Plantago Ovata	C				Not Reported
	Synthroid	C	Unknown			Not Reported
	Vagifem	C	Vaginal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170354	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035366		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170367	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035488		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea;	Methotrexate			S	Subcutaneous			Barr

Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170405	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035480		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown	2.8571 Milligram Daily;		Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16172728	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035462		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Leflunomide			S	Unknown			Barr

Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Varenicline Tartrate	S	Oral	Varenicline Tartrate		Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Oxycodone Hydrochloride	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Unknown			Not Reported
	Valtrex	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16173663	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Mobicox			C	Unknown	15 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16174239	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035729		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16174398	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035689		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

		Restasis			C	Unknown				Not Reported
		Synthroid			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16174660	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035744			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous	Powder For Suspension Subcutaneous		Not Reported
	Leflunomide			S	Oral			Barr
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	20 Milligram Daily;		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

	Desoximetasone	C	Unknown	10 Milligram Daily;		Not Reported
	Desoximetasone	C	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone	C		10 Milligram Daily;		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Diclofenac	C		100 Milligram Daily;		Not Reported
	Diclofenac	C		100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16177336	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036891			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16178042	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Oral	1 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16183621	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037002		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16188233	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037040		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy;	Methotrexate			S	Unknown			Barr

Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Tramadol Hydrochloride	C	Oral			Not Reported
	Xeljanz	C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16188779	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036915		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Unknown	50 Milligram Daily;		Not Reported
	Zingiber Officinale			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16188798	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036993		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16193534	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037303		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16193606	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036935		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Abnormal	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16354698	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016190551		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Naproxen			C		500 Mg, 2x/Day		Not Reported
	Viread			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16904606	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201903-000501			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qod		Concordia

Erythematosus	(Authorized Generic),Plaquenil					
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qod		Concordia
	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd		Concordia
	(Authorized Generic),Plaquenil Prednisolone	C		50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17105596	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1010165		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17107655	EXPEDITED (15-DAY)		OT	US-INTERCEPT-PM2019002145		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Night Sweats; Sleep Disorder; Suicidal Ideation	Ocaliva			S	Oral	5 Mg, Qd		Intercept Pharmaceuticals
	Plaquenil			S		Unk Unk, Qd		Not Reported
	Alprazolam			C				Not Reported
	Amoxicillin			C				Not Reported
	Diclofenac			C				Not Reported
	Escitalopram			C				Not Reported
	Glimepiride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17149363	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191213587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S		Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazol	S	Unknown	Not Reported
	Plaquenil /00072603/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17159829	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053623		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfathalidine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Prednisone	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Phthalylsulfathiazole	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Humira	S	Subcutaneous	Ucb
	Fosamax	S		Not Reported
	Folic Acid	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Cortisone Acetate	S		Not Reported
	Arava	S		Not Reported
	Apo-Prednisone	S		Not Reported
	Tocilizumab	S		Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162070	NON-EXPEDITED			NVSC2019US069931		35 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162120	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Unk	Ucb
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Actemra	S		Unk	Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S		Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Ucb
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162515	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported

		Ibuprofen			C						Not Reported
		Morphine			C						Not Reported
		Pertussis Vaccine			C						Not Reported
		Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162517	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150977		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162519	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053742		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Folic Acid	S		Unk	Not Reported
Fosamax	S		Unk	Not Reported
Humira	S	Subcutaneous	Solution	Ucb
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S		Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Prednisone	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162522	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162635	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150972		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Celebrex	C	Unknown			Not Reported
	Ammonium Chloride/Guaifenesin/Sulfamethoxazole/Trimethoprim	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162813	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Ucb
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Phthalylsulfathiazole	S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported
	Prednisone	S		Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162930	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053759		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1 Gram, 2x/Day (Bid)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Urethral	400 Milligram, Once Daily (Qd)		Not Reported
	Adalimumab			S	Subcutaneous			Ucb
	Fosamax			S				Not Reported
	Folic Acid			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163393	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Tocilizumab			S				Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib Citrate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163394	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053440			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Solution		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution		Ucb
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163584	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Arava			S				Not Reported
	Diclofenac			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163995	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain;	Cimzia			S	Subcutaneous			Ucb
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S				Not Reported
	Apo-Folic Acid	S		Unk		Not Reported
	Folic Acid	S		5 Milligram		Not Reported
	Apo-Hydroxyquine	S				Not Reported
	Apo-Prednisone	S				Not Reported
	Arava	S	Oral			Not Reported
	Cortisone Acetate	S				Not Reported
	Cortisone Acetate	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Fosamax	S				Not Reported
	Humira	S	Subcutaneous			Ucb
	Hydroxychloroquine Sulfate	S				Not Reported
	Methotrexate Sodium	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazol	S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S				Not Reported
	Prednisone	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17164034	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported

	Phthalylsulfathiazole	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Humira	S	Subcutaneous		Ucb
	Fosamax	S			Not Reported
	Folic Acid	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Arava	S			Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17164175	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Prednisone			S				Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	Solution			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165446	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Ucb
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165447	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019053719		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		20 Milligram		Not Reported

Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported
	Pseudoephedrine Hydrochloride	S		25 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S			Not Reported
	Paracetamol	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Stelara	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Once Daily (Qd)	Not Reported
	Apo Prednison	S			Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported

Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Desoximetasone	S			Not Reported
Diclofenac Sodium	S			Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous	Solution For Injection	Ucb
Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Hydroxychloroquine	S		400 Milligram	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Leflunomide Sandoz	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S		Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Once Daily (Qd)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		40 Milligram, Once Daily (Qd)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported

	Prednisone	S			Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S			Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
	Sulfathalidine	S	Subcutaneous	Unk	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Subcutaneous		Not Reported
	Topicort [Hydrocortisone Acetate]	S		Unk	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
	Xeljanz	S			Not Reported
	Xeljanz	S			Not Reported
	Atasol [Paracetamol]	C			Not Reported
	Salazopyrin	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165775	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191210540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported

					Enbrel		S	Unknown		Not Reported
					Folic Acid		S	Unknown		Not Reported
					Fosamax		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Subcutaneous		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165856	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151419		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C		50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165876	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151424		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166303	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151423		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166318	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151532		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019542331			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	12085936	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015167344		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Unknown	50 Mg, Usual Dose Greater Than 3month		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Usual Dose Greater Than 3month		Pfizer
	Sulfasalazine			S	Unknown	Unk,Usual Dose Greater		Pfizer

Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting				Than 3month	
	Apo-Leflunomide	S	Unknown	Unk, Usual Dose Greater Than 3months	Not Reported
	Plaquenil	S	Unknown	Unk, Usual Dose Greater Than 3month	Not Reported
	Humira	S	Subcutaneous	Unk, Usual Dose Greater Than 3month	Not Reported
	Cimzia	S	Subcutaneous	Usual Dose Greater Than 3 Month	Not Reported
	Actemra	S	Unknown	Unk, Usual Dose Greater Than 3month	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Aspirin	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	13000890	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction;	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex

Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Trimethoprim/Sulfamethoxazole	S	Unknown	Unk		Apotex
	Hydroxychloroquine	S	Unknown	Unk		Apotex
	Tramadol	S	Unknown	Unk		Apotex
	Asa 81	S	Unknown			Not Reported
	Diclofenac Potassium	S	Unknown			Apotex
	Diclofenac Sodium	S	Unknown			Apotex
	Arava	S	Oral	Unk		Not Reported
	Aspirin /00002701/	S	Oral	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Voltaren /00372301/	S	Unknown			Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	13869128	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2456		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Humira	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported

	Tofacitinib			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	14198688	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3639		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Endocervical			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	14206887	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3739		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral				Not Reported
	Enbrel			S	Unknown				Not Reported
	Actemra			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Apo-Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15716314	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-987723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Teva
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral	7.5 Milligram Daily;		Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15799492	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996090		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Tremor; Vomiting	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Oral	Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown	Not Reported

	Tenofovir Disoproxil Fumaratae	C	Unknown			Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown			Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown			Not Reported
	Tenofovir Disoproxil Fumaratae	C	Oral			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Zopiclone	C	Unknown			Not Reported
	Methotrexate	C	Oral			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Estrogel	C	Unknown	1.8 Percent Daily;		Not Reported
	Gravol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15920391	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1007262		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis; Onychomycosis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Arava	C	Oral			Not Reported
	Arava	C				Not Reported
	Orencia	C	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	C				Not Reported
	Infliximab	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15944441	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA034910		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Clopidogrel Bisulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Furosemide			S	Unknown			Sanofi
	Famotidine			S	Unknown	Unk Unk, Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Doxycycline			S	Unknown	Unk Unk, Unk		Not Reported
	Trandolapril			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk Unk, Unk		Not Reported
	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Gabapentin			S	Unknown	Unk Unk, Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk Unk, Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk Unk, Unk		Not Reported
	Potassium			S	Unknown	Unk Unk, Unk		Not Reported

	Glyceryl Trinitrate	S	Unknown	Unk Unk, Unk		Sanofi
	Metoclopramide Hydrochloride	S		Unk Unk, Unk		Not Reported
	Trazodone Hydrochloride	S		Unk Unk, Unk		Not Reported
	Isosorbide Mononitrate	S		Unk Unk, Unk		Not Reported
	Victoza	S	Unknown	Unk Unk, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qod		Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira	S				Not Reported
	Flomax [Morniflumate]	S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16060843	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024073		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	8 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16079637	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cough;	Methotrexate			S	Unknown			Barr

Diabetes Mellitus; Drug Ineffective; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Enbrel	S	Unknown			Not Reported
	Gadolinium	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Celebrex	C				Not Reported
	Escitalopram Oxalate	C	Oral	10 Milligram Daily;		Not Reported
	Humira	C				Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram Daily;		Not Reported
	Plaquenil	C				Not Reported
	Prednisone	C		5 Milligram Daily;		Not Reported
	Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16098265	EXPEDITED (15-DAY)		OT	CA-009507513-1903CAN006963		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Remeron			S	Unknown	15 Milligram		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16193459	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036681		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	25 Milligram Daily;		Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16408267	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1743		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Product Use In Unapproved Indication; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown	Duration 366.0 (Unit Not Specified)		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported

Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Unknown	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Esomeprazole	C	Unknown	Not Reported
Lumigan	C	Ophthalmic	Not Reported
Nexium	C	Unknown	Not Reported
Suphedrine	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol Es	C	Unknown	Not Reported
Tylenol Es	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Wellbutrin Xl	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16721179	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094727		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Leukopenia; Retinopathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16733249	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1095473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	6 Milligram Daily;		Not Reported
	Apo-Triamcinolone Aq			S	Intra-articular			Not Reported
	Apo-Triamcinolone Aq			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira(Adalimumab)			S	Subcutaneous			Not Reported
	Humira(Adalimumab)			S	Unknown			Not Reported
	Immune Globulin Intravenous (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret 100mg Per Syringe			S	Subcutaneous	50 Milligram Daily;		Not Reported

	Single-Use,Preservative-Free Prefilled Syrin					
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;		Not Reported
	Hydroxychloroquine	S	Oral	5 Unknown Daily;		Not Reported
	Anakinra	S	Unknown			Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;		Not Reported
	Folic Acid(Natural Factors)	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16925606	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-057104		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisolone			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Imeth			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17088869	EXPEDITED (15-DAY)		HO	NVSC2019FR050298		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisone			S	Oral	5 Mg, Qd		Novartis
	Prednisone			S	Oral	5 Mg, Qd		Novartis
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Imeth			S	Subcutaneous	10 Mg, Qw		Not Reported

	Imeth			S	Subcutaneous	10 Mg, Qw				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17104025	EXPEDITED (15-DAY)		OT	GR-AUROBINDO-AUR-APL-2019-076286		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Aurobindo
	Belimumab			S	Unknown	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Dicoumarol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17167363	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010072		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pulmonary Toxicity; Therapy Non-Responder;	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported

Treatment Failure	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Ibuprofen	C	Oral			Not Reported
	Lipitor	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17167847	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1152238		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Treatment Failure; Tremor	Methotrexate			S	Oral	15 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole			C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral			Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C		7.5 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17167880	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5987			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Advair			C	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Atrovent Hfa			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Cyclobenzaprine Hydrochloride			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Leucovorin Calcium			C	Unknown			Not Reported
	Nexium Mups			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Ventolin Hfa			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17168052	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1152087		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17168112	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151616		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Aspirin			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

	Rosuvastatin			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17171046	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151612		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17171048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151709		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity;	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rabeprazole Sodium			C				Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

Rheumatoid Arthritis; Sleep Disorder; Swelling	Xeljanz	C	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17171075	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Naproxen			C		500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	13929686	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2700		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Cutaneous	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo Leflunomide	S	Oral		Not Reported
	Apo Leflunomide	S	Unknown		Not Reported
	Apo Leflunomide	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported

	Leflunomide	S	Unknown			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	14236360	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15259000	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1043		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Advil	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Mefenamic Acid	C	Unknown	Not Reported
	Dequalinium Chloride	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15320258	EXPEDITED (15-DAY)		OT	CA-ROCHE-2173456		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 5.0 Month(S)		Not Reported
	Arava			S	Unknown	Therapy Duration: 2.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	4.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]								
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15708014	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3644		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15798083	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995467		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Ineffective	Leflunomide		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Supeudol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15851412	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001570		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15860932	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0165			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Methotrexate (Trade Name			S	Unknown			Not Reported

Administered; Drug Ineffective; Rheumatoid Arthritis	Unknown)				
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15876664	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1004861		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Teva-Prednisone			S	Unknown			Actavis
	Teva-Prednisone			S	Unknown			Actavis
	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

	Folic Acid	C	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Plaquenil	C		Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15993834	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr

	Sarilumab			S	Unknown				Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram Daily;			Not Reported
	Methotrexate			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16000643	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016783		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Nodule; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16073209	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021788			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tramadol			C		100 Milligram Daily;		Not Reported

	Celebrex			C						Not Reported
	Tramacet			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16085248	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06871		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Subcutaneous	Unknown, Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported

	Infliximab			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16193552	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037286		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16198911	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1038628		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Anakinra	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
Cimzia Single-Use Prefilled Syringe	S			Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S			Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Cellcept	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Prednisone	C	Unknown	7 Milligram Daily;	Not Reported
Humira	C	Subcutaneous		Not Reported
Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16412489	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA021776			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Off Label Use	Inflectra	S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks	Not Reported
	Inflectra	S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks	Not Reported
	Inflectra	S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	150 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, 2x/Day	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Esomeprazole	C	Unknown	40 Mg, 1x/Day	Not Reported
	Lumigan Rc	C	Ophthalmic	Unk Unk, 1x/Day	Not Reported
	Nexium [Esomeprazole Sodium]	C	Unknown	Unk	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10 Mg, 1x/Day	Not Reported
	Trazodone	C	Unknown	200 Mg, 1x/Day	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	3000 Mg, 1x/Day	Not Reported
	Valsartan	C	Unknown	Unk Unk, 1x/Day	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported

	Wellbutrin Xl			C	Unknown	300 Mg, 1x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16679714	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1086659		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Aspirin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16902053	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-041960		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Immune System Disorder; Mass; Oropharyngeal Squamous Cell Carcinoma; Pain; Pyrexia; Throat Irritation	Bosentan			S	Oral			Zydus Pharm
	Apixaban			C	Unknown			Not Reported
	Nifedipine			C	Oral			Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported
	Tacrolimus			C	Unknown	2 Mg In Morning/ 3 Mg In Evening		Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Atovaquone			C	Oral			Not Reported
	Sildenafil			C	Oral			Not Reported
	Zoledronic Acid			C	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			C	Oral			Not Reported
	Cyanocobalamin			C	Oral			Not Reported
	Acetylsalicylic Acid			C	Oral			Not Reported
	Calcium Carbonate/Colecalciferol			C	Unknown	600 Mg/400 Iu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16932171	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1941614US			Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone Unk			S	Unknown	Unk		Allergan
	Thyroxine			S	Oral	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported

	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dicumarol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17042327	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP024673		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Q.12h (Therapy Duration: 731 Unit Unspecified)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported

	Meloxicam			C	Unknown	Unk				Not Reported
	Methotrexate			C	Unknown	Unk, Q.Wk.				Not Reported
	Synthroid			C	Unknown	Unk				Not Reported
	Tylenol /00020001/			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17117759	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1119294		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Kardegic			S	Oral	75 Milligram, Qd		Mylan
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd, 200 Mg Matin Et Soir		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17175621	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054444			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S				Not Reported
	Cortisone Acetate			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported

	Humira	S	Subcutaneous	Solution For Injection	Ucb
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17175715	EXPEDITED (15-DAY)		OT	NVSC2019US068527			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Inability; Paraesthesia	Triamcinolone Acetonide			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Aquaphor			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17176380	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153231			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Oedema; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown	2 Dosage Forms Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Nexium [Esomeprazole Sodium]			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Vitamins Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17176633	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054450		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17176736	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178069	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Muscle Strain; Nasopharyngitis; Nephrolithiasis; Urinary Tract Infection	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178079	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1153489		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility	Leflunomide			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Acetylsalicylic Acid	C	Unknown	81 Milligram Daily;	Not Reported
	Actonel	C	Unknown		Not Reported
	Advair	C	Unknown		Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram Daily;	Not Reported
	Fish Oil	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown	25 Milligram Daily;	Not Reported
	Magnesium Sulfate	C	Unknown		Not Reported
	Olmesartan Medoxomil	C	Unknown	40 Milligram Daily;	Not Reported
	Omega 3 /01333901/	C	Unknown		Not Reported
	Omega-3 Marine Triglycerides	C	Unknown		Not Reported
	Oxybutin	C	Unknown	2.5 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	9 Milligram Daily;	Not Reported
	Rabeprazole Sodium	C	Unknown	20 Milligram Daily;	Not Reported
	Rabeprazole Sodium	C	Oral	40 Milligram Daily;	Not Reported
	Spiriva	C	Unknown		Not Reported
	Tiotropium Bromide	C	Unknown	72 Microgram Daily;	Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported
	Vitamin B12 /00056201	C	Unknown	1500 Milligram Daily;	Not Reported
	Vitamin C /00008001/	C	Unknown		Not Reported
	Vitamin C Mse Matrix	C	Oral	1000 Milligram Daily;	Not Reported
	Zinc Gluconate	C	Unknown	25 Milligram Daily;	Not Reported
	Zopiclone	C	Unknown		Not Reported
	Folic Acid	C	Oral	5 Milligram Daily;	Not Reported
	Hydroxychloroquine	C	Oral	2 Dosage Forms Daily;	Not Reported
	Senna Alexandrina	C	Oral		Not Reported
	Amlodipine	C	Unknown	5 Milligram Daily;	Not Reported
	Ascorbic Acid	C	Oral	1000 Milligram Daily;	Not Reported
	Calcium	C	Unknown	1000 Milligram Daily;	Not Reported
	Citalopram	C	Unknown	30 Milligram Daily;	Not Reported

	Co-Enzyme Q10			C	Unknown	Not Reported
	Copper Sulfate			C	Unknown	Not Reported
	D-Alpha Tocopherol			C	Unknown	Not Reported
	D-Alpha Tocopherol/Fish Oil			C	Unknown	Not Reported
	Docosahexaenoic Acid			C	Unknown	Not Reported
	Docusate Sodium			C	Unknown	Not Reported
	Ergocalciferol			C	Unknown 3000 Dosage Forms Daily;	Not Reported
	Fatty Acids Nos			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178084	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1153497		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178944	EXPEDITED (15-DAY)		HO	US-ZYDUS-044647		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brudzinski'S Sign; Diarrhoea; Headache; Lethargy; Meningism; Mental Status Changes; Nausea; Pyrexia; Vomiting; West Nile Viral Infection	Hydroxychloroquine			S				Zydus Pharm
	Methotrexate			S				Not Reported
	Mycophenolic Acid			S				Not Reported
	Methylprednisolone			S				Not Reported
	Rituximab			S				Not Reported
	Prednisone/Prednisone Acetate			S				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179077	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1153329		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; Fall; Inflammatory Pain; Lumbar Vertebral Fracture; Pruritus; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Entocort			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179261	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153341		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr

Product Effect Decreased	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179602	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019230045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179611	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019229873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179748	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153475		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning	Leflunomide			S	Unknown			Barr

Sensation; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Adalimumab	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Tofacitinib	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Methotrexate	C	Subcutaneous			Not Reported
	Methotrexate	C	Oral			Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179968	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC-2019541123		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Sulfasalazine	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Actemra	S	Unknown	Unk		Not Reported
	Aurothiomalate De Sodium	S	Unknown	Unk		Not Reported
	Aurothiomalate De Sodium	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	40 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide	S	Unknown	10 Mg, 1x/Day		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab/Urelumab	C	Unknown	Unk		Not Reported
	Simponi	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17180880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153312			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Leflunomide			S	Unknown			Barr

Headache; Rheumatoid Arthritis; Tremor	Actemra	S	Unknown			Not Reported
	Adalimumab	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Oral	2.5 Milligram Daily;		Not Reported
	Methotrexate	C	Oral			Not Reported
	Pantoprazole	C				Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil	C				Not Reported
	Tenofovir Disoproxil Fumarate	C				Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown			Not Reported
	Xeljanz	C				Not Reported
	Zopiclone	C	Unknown	7.5 Milligram Daily;		Not Reported
	Zopiclone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17180885	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153512		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram Daily;		Barr

	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Unknown	100 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	1 Daily;		Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	11682807	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-09646		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Aurobindo
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	12696508	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1477		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea;	Methotrexate (Trade Name Unknown)			S	Unknown	Usual Dose > 3 Months		Not Reported
	Enbrel			S	Unknown	Usual Dose > 3 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Usual Dose > 3 Months		Not Reported
	Apo-Leflunomide			S	Unknown	Usual Dose > 3 Months		Not Reported

Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Therapeutic Response Decreased; Vomiting	Plaquenil	S	Unknown	Usual Dose > 3 Months	Not Reported
	Humira	S	Subcutaneous	Usual Dose > 3 Months	Not Reported
	Cimzia	S	Transmammary	Usual Dose >3 Month	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Actemra	S	Unknown	Usual Dose >3month	Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Tofacitinib Citrate	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Aspirin	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	13132615	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0240		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral	10 To 12.5 Milligram		Not Reported
	Methotrexate (Trade Name			S	Subcutaneous	10 To 17.5 Milligram		Not Reported

Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Neoplasm Excision; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Unknown)				
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	10 To 15 Millgram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Rituxan	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	14971016	NON-EXPEDITED			US-PFIZER INC-2018217549		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	15841112	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-999903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16043916	EXPEDITED (15-DAY)		HO	US-SA-2019SA060127		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Arthritis; Condition Aggravated; Depression; Fall; Joint Injury	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S				Sanofi
	Diclofenac Sodium			C				Not Reported
	Meloxicam			C				Not Reported
	Omeprazole			C				Not Reported
	Oxybutynin Chloride			C				Not Reported
	Prednisone			C				Not Reported
	Sertraline Hcl			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16088781	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-DE-1008137		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin	S	Unknown		Ivax
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Leflunomide	S	Unknown		Barr
	Methotrexate Sodium	S	Oral	20 Mg	Barr
	Methotrexate Sodium	S	Subcutaneous	20 Mg	Barr
	Methotrexate Sodium	S	Oral	20 Mg	Barr
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Hydroxychloroquine/00072603	S	Oral	Unk	Not Reported
	Hydroxychloroquine/00072603	S	Subcutaneous		Not Reported

	Hydroxychloroquine/00072603	S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603	S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603	S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603	S	Oral			Not Reported
	Rituxan	S	Unknown	Solution Intravenous		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous		Not Reported
	Orencia	S	Subcutaneous	125 Mg		Not Reported
	Orencia	S	Subcutaneous	125 Mg		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16201203	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16206600	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr

Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S	Unknown	200 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	S	Oral	5 Milligram Daily;		Not Reported
	Advil	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Ketorolac	C	Unknown			Not Reported
	Methotrexate	C	Unknown	20milligram, 1every 1weeks		Not Reported
	Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16206634	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038760		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Actemra			C	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported

	Celebrex	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16208604	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038709		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16410789	EXPEDITED (15-DAY)		OT	GB-JNJFOC-20180525818		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia;	Domperidone			S	Unknown			Not Reported
	Sporanox			S	Oral			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Uniphyllin			S	Unknown			Not Reported
	Creon			S	Unknown			Not Reported

Myopathy; Orthostatic Hypotension	Carbocisteine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Risedronate		S	Unknown	Not Reported
	Lansoprazole		S	Unknown	Not Reported
	Propanolol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17046877	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP024680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Doxycycline			S	Unknown	100 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	200 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
	Celebrex	C	Oral	200 Mg, Bid	Not Reported
	Celecoxib	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	C	Unknown	25 Mg, Q.Wk.	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Tylenol W/Codeine No. 3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17079726	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140518			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Joint Dislocation; Joint Stiffness; Osteoarthritis; Osteoporosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Methotrexate			S				Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

					Orencia	S	Unknown		Not Reported
					Otezla	S	Unknown		Not Reported
					Rituxan	S	Intravenous drip	Solution Intravenous	Not Reported
					Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
					Sirukumab	S	Unknown		Not Reported
					Stelara	S	Subcutaneous	Solution Subcutaneous	Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
					Cosentyx	S	Unknown		Not Reported
					Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17137775	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-104089		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Omeprazole			S	Unknown	Unk		Aurobindo
	Prednisone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17147537	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018240366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, We		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported

	Tofacitinib Citrate			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17164060	NON-EXPEDITED			NVSC2019US067437		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lichenoid Keratosis; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Oral	60 Mg		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Tacrolimus			C	Unknown	Unk		Not Reported
	Alprazolam			C	Unknown	Unk		Not Reported
	Metprolol			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Mirtazapine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17181841	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-201912002892			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Prescribed Underdose	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	100 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17182257	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported
	Rituximab			S	Unknown				Not Reported
	Simponi			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17182260	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154364		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183623	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1156663		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm; Pulmonary Mass	Ajovy			S	Unknown			Teva
	Stelara			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183683	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019545712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Sulfasalazine			S	Unknown			Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	1 Every 6 Weeks		Not Reported
	Folic Acid			C	Unknown	5 Mg, 1x/Day		Not Reported
	Pariet			C	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183721	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543836		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

		Orencia			S	Unknown	Unk			Not Reported
		Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
		Simponi			S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183725	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Cortisone			C	Intramuscular	Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183726	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543699		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Enbrel			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Df, 1x/Day		Not Reported
	Leflunomide			S	Unknown	1 Df, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown	35 Mg, Weekly		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183764	EXPEDITED (15-DAY)		DE	CA-DRREDDYS-USA/CAN/19/0117587		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atorvastatin			S	Oral			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Oral			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183825	EXPEDITED (15-DAY)		HO, OT	DK-APPCO PHARMA LLC-2078051		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Pneumonia Mycoplasmal	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Insulin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17184371	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019232012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclophenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Solution For Injection		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17184937	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154281			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Aspirin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Penicillin G Potassium	S	Unknown	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Pregabalin	C		Not Reported
	Penicillin G Procaine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17184969	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154333		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Hydroxychloroquine	S	Subcutaneous			Not Reported
	Neoral	S	Subcutaneous			Not Reported
	Neoral	S	Oral			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Plaquenil	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	5000 Milligram Daily;		Not Reported
	Cimzia	C	Subcutaneous			Not Reported
	Risedronate	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17185674	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121402			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Folic Acid			C	Unknown	Unk, Qid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186283	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186325	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186338	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154259		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Otezla			S	Oral	60 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186483	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Nausea; Oral Discomfort; Treatment Failure	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Adalimumab	S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Tofacitinib	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186484	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186485	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186504	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not			Not Reported

						otherwise specified)				
		Prednisone			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186506	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Unevaluable Event; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186534	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186681	EXPEDITED (15-DAY)		OT	NVSC2019CA075065			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Novartis
	Folic Acid	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Powder For Solution For Injection)	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186855	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154423			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Humira			S	Unknown	2.8571 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Oral	2.5 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186872	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154486		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Diovan			C				Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C				Not Reported
	Sertraline			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186895	NON-EXPEDITED			NVSC2019US074729			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg ((Second Dose Was Given 2 Weeks Later)		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg, Qd (For3 Days Followed By 1 Mg/Kg Daily)		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Heparin			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17187244	NON-EXPEDITED			NVSC2019US074521		66 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Xolair			S	Subcutaneous	600 Mg, Q2w		Not Reported
	Cyclosporine			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2019	17188270	EXPEDITED (15-DAY)		OT	NVSC2019CA076669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported

Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cortisone Acetate		S	Unknown	Unk		Not Reported
	Cimzia		S	Subcutaneous	Unk		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi		S	Subcutaneous	Unk		Not Reported
	Actemra		S	Unknown	Unk		Not Reported
	Apo-Prednisone		S	Unknown	Unk		Not Reported
	Arava		S	Unknown	Unk		Not Reported
	Enbrel		S	Subcutaneous	Unk		Not Reported
	Fosamax		S	Unknown	Unk		Not Reported
	Humira		S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Methotrexate		S	Unknown	Unk		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk		Not Reported
	Plaquenil		S	Unknown	Unk		Not Reported
	Prednisone		S	Unknown	Unk		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2019	17188271	EXPEDITED (15-DAY)		OT	NVSC2019CA075047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain;	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported

Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Fosamax	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	12806009	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016037867		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Plaquenil			S	Oral	300 Milligram, Once Daily		Not Reported

Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis				(Qd)	
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram Cyclical Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Gold	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	300 Milligram, Once Daily (Qd)	Not Reported
	Actonel	S	Oral	35 Milligram, Weekly (Qw)	Not Reported
	Xeljanz	S		Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram Cyclical	Not Reported
	Hydroxychloroquine	S		300 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		Unk, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		300 Milligram Cyclical	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Risedronate	S		35 Milligram, Weekly (Qw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	13766596	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015042698			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S		Unk, Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qw)		Not Reported

	Morphine Sulfate	S		Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
	Plaquenil	S		Unk	Not Reported
	Prednisone	C		Unk, 5 Mg	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	14299149	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050888		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Leflunomide			S		20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	7.5 Milligram		Not Reported
	Methotrexate			S		7.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Diclofenac Sodium And Misoprostol			S		50 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported

	Gold	C			Not Reported
	Imuran	C			Not Reported
	Arthrotec	C		50 Mg, 2x/Day (Bid)	Not Reported
	Vitamin D3	C			Not Reported
	Ergocalciferol	C			Not Reported
	Vitamin D Nos	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	14739451	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	15619990	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556541-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Pruritus; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	15949612	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000034			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Clopidogrel Bisulfate			S	Unknown	Unk		Not Reported
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Loperamide			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Potassium			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk		Not Reported
	Trazodone Hydrochloride			S	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qod		Not Reported

	Humira			S	Subcutaneous	40 Mg, Qow				Not Reported
	Humira			S						Not Reported
	Flomax /00889901/			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16365379	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-183675		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Myopathy; Orthostatic Hypotension	Lansoprazole			S	Unknown	30 Mg, Qd		Sun
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Lipase;Amylase;Protease Unk			S	Unknown	10 Mg, Tid		Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Uniphyllin			S	Unknown	200 Mg, Bid		Not Reported
	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Levothyroxine			S	Unknown	75 Microgram, Qd		Not Reported
	Domperidone Maleate			S	Unknown	10 Mg, Tid		Not Reported
	Carbocisteine			S	Unknown	750 Milligram, 1dose/12hour (750 Mg, Bid)		Not Reported
	Risedronate Sodium			S	Unknown	35 Milligram		Not Reported
	Creon			S	Unknown	10 Milligram, 1dose/8hr (10 Mg, Tid)		Not Reported
	Ivig			S	Unknown	Unk		Not Reported
	Propanolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16572858	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1075220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Aspirin			S	Oral			Not Reported

Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium	S	Unknown	Actavis
	Diclofenac Potassium	S	Unknown	Actavis
	Methotrexate	S	Unknown	Barr
	Ibuprofen	S	Unknown	Actavis
	Sulfamethoxazole And Trimethoprim	S	Unknown	Teva
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold Radioactive Colloidal	S	Other	Not Reported
	Gold Radioactive Colloidal	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Motrin	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Vitamin C	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Acetylsalicylic Acid/Vitamin C	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16583278	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2019-039093		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia; Toxicity To Various Agents; West Nile Viral Infection	Methylprednisolone			S	Unknown	Unk		Aurobindo
	Prednisone			S	Unknown	6 Milligram (Part Of A Regimen That Involved Tapering Of The Dose)		Not Reported

	Methotrexate			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Rituximab			S	Unknown	Unk			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk			Not Reported
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16748703	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-082588		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Eliquis			S	Unknown	Unk, Bid		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16908147	EXPEDITED (15-DAY)		CA, HO, OT	JP-ADVANZ PHARMA-201910001007			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Neonatal Asphyxia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	400 Mg, Qd		Concordia
	Magnesium Oxide			C		Unk		Not Reported
	Kefral			C		Unk		Not Reported
	Oxytocin			C		Unk		Not Reported

	Cefmetazole Sodium	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17046755	EXPEDITED (15-DAY)		DE, HO, LT, OT	JP-ADVANZ PHARMA-201911001684			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arrhythmia; Bone Marrow Failure; Breath Sounds Abnormal; Cardiac Failure; Cytomegalovirus Test Positive; Decreased Appetite; Diarrhoea; Face Oedema; General Physical Health Deterioration; Palpitations; Platelet Count Decreased; Stress Cardiomyopathy; Ventricular Extrasystoles; Ventricular Tachycardia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Valganciclovir Hydrochloride			S	Oral	1t/1x		Not Reported
	Valganciclovir Hydrochloride			S	Oral	2t/2x		Not Reported
	Mycophenolate Mofetil			C		2 Mg, Qd		Not Reported
	Takecab			C		Unk 20		Not Reported
	Predonine			C		Unk,5		Not Reported
	Predonine			C		Unk (Dose Reduced)		Not Reported
	Calonal			C		Unk, 200		Not Reported
	Baktar			C		Unknown		Not Reported
	Azosemide			C		Unk,30		Not Reported
	Bisoprolol Fumarate			C		Unk,2.5		Not Reported
	Torasemide			C		Unk,4		Not Reported
	Feburic			C		Unk,20		Not Reported
	Samsca			C		Unk,7.5		Not Reported
	Pursennid			C		Unk,12		Not Reported
	Mexitil			C		Unk,100		Not Reported
	Mercazole			C		Unk,5		Not Reported
	Lipovas			C		Unk,5		Not Reported
	Mevalotin			C		Unk,10		Not Reported
	Unisia			C		Unk		Not Reported
	Imidapril Hydrochloride			C		Unk,5		Not Reported
	Myslee			C		Unk,5		Not Reported
	Toyofarol			C		Unk,0.5		Not Reported

	Mycophenolate Mofetil	C	Unk	Not Reported
	Es Polytamin	C	Unk	Not Reported
	Bio-Three	C	Unk	Not Reported
	Hangeshashinto	C	Unk	Not Reported
	Albumin Tannate	C	Unk	Not Reported
	Nexium	C	Unk,20	Not Reported
	Polaprezinc	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17149900	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17189316	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17189592	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053899		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect	Cimzia			S	Subcutaneous	Unk		Not Reported

Decreased	Enbrel	S		1 Dosage Form, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Simponi	S			Not Reported
	Prednisone	C	Oral		Not Reported
	Lyrica	C			Not Reported
	Xeljanz	C	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190342	EXPEDITED (15-DAY)		DE, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6054		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Aurothiomalate De Sodium			S	Unknown			Not Reported
	Aurothiomalate De Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab;Urelumab	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190465	EXPEDITED (15-DAY)			AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2018-10002			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Pleural Effusion; Pleuritic Pain	Mycophenolate Mofetil			S	Unknown	Unknown		Alkem
	Cyclophosphamide			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methylprednisolone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190468	EXPEDITED (15-DAY)			AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2018-10009		26 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190490	EXPEDITED (15-DAY)		OT	AR-ALKEM LABORATORIES LIMITED-AR-ALKEM-2019-07459		32 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Granulomatous Dermatitis; Interstitial Lung Disease	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190673	EXPEDITED (15-DAY)			AR-ALKEM LABORATORIES LIMITED-AR-ALKEM-2018-11108		32 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Exposure During Pregnancy	Mycophenolate Mofetil	S	Unknown	Unk		Alkem
	Calcium Carbonate	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190918	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	300 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191255	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous			Unknown
	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191497	NON-EXPEDITED			US-PFIZER INC-2019551848		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea	Doxycycline Hyclate			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Hydroxychloroquine			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191748	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2019053613		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Cefazolin			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported
	Orencia			S		Unk		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	200 Milligram, Weekly (Qw)	Not Reported
Remicade	S	Powder For Solution Intravenous	Not Reported
Rituxan	S	Solution Intravenous	Not Reported
Amlodipine	C		Not Reported
Arava	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Methotrexate	C	Unk	Not Reported
Naproxen	C		Not Reported
Prednisone	C		Not Reported
Tofacitinib Citrate	C		Not Reported
Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191762	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer
	Actemra			S	Unknown	8.0 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191784	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Enbrel			S	Subcutaneous			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17193564	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1952077US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Prednisolone Unk			S	Unknown	Unk		Allergan
	Quensyl			S		5 Mg		Not Reported
	Benlysta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	15665897	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-05		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Mobicox			S	Unknown			Boehringer Ingelheim

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	15674128	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574075-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	15927623	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019003397		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder; Therapeutic Product Effect Decreased; Therapy Non-Responder	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Arava			S	Oral	200 Mg, Once Daily (Qd)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg Once Daily		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Monthly (Qm)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram		Not Reported
	Methotrexate			S	Oral	25 Mg, Monthly (Qm)		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Plaquenil			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once Daily (Qd)		Not Reported
	Prednisone			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	2 Gram Every 6 Months	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
	Risedronate Sodium	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16757033	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017396871		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Eliquis			S	Unknown	Unk, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16791977	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1105366		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Cardiac Arrest; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Pupil Fixed;	Hydroxychloroquine			S	Oral	Approximately 60 Tablets Of 200 Mg		Teva
	Naproxen			C	Oral	Several Amount Of 750mg Naproxen		Not Reported

Renal Failure; Toxicity To Various Agents; Unresponsive To Stimuli	Ibuprofen			C	Oral	Unknown Quantity Of 200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16820266	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2927400-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Hydroxychloroquine Sulfate Tablets, Usp		Not Reported
	Kineret			S	Subcutaneous	Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported

	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Naproxen	S	Unknown		Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)	S			Not Reported
	Gammagard	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intraarticular	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Solution Intramuscular	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498502		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration 731.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration 4.0 Year(S)		Not Reported
	Methotrexate			S	Unknown	Therapy Duration 10.0 Month(S)		Not Reported

	Methotrexate		S	Unknown	Therapy Duration 9.0 Year(S)	Not Reported
	Methotrexate		S	Subcutaneous	Therapy Duration 731.0	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Therapy Duration 10.0 Month(S)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Therapy Duration 4.0 Year(S), Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate		S	Unknown	Therapy Duration 4.0 Year(S)	Not Reported
	Xeljanz		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194679	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1155789		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194686	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194714	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201908-001780			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia
	Mycophenolate Mofetil			S	Oral	1000 Mg, Bid		Not Reported
	Prograf			S	Oral	0.5 Mg, Qd		Not Reported
	Losartan Potassium			S	Oral	50 Mg, Qd		Not Reported
	Itraconazole			S	Oral	200 Mg, Qd		Not Reported
	Nexium 1-2-3			S	Oral	20 Mg, Qd		Not Reported
	Predonine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194989	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hepatic Steatosis; Off Label Use; Synovitis	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195082	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201912002944			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Asthenia; Blood Glucose Increased; Contusion; Diarrhoea; Dizziness; Fall; Fall; Fatigue; Fatigue; Fungal Infection; Gait Disturbance; Gastric Disorder; Immunodeficiency; Joint Range Of Motion Decreased; Migraine; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Pain In Extremity; Pain In Extremity; Pneumonia; Rash Papular; Respiratory Disorder; Sensitivity To Weather Change; Stress; Therapeutic Response Shortened; Vaginal Haemorrhage; Viral Infection; Visual	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Humira			S	Subcutaneous	(1 In 1 Wk)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S		Unk		Not Reported

Impairment; Vomiting;
Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195088	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-201912003110			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia	Hydroxychloroquine			S	Unknown	200 Mg X2		Concordia
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195133	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195157	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195190	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1155815		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Exostosis; Osteoarthritis; Pain In Extremity; Pulmonary Thrombosis; Thrombosis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pantoprazole			C	Unknown	40 Milligram Daily;		Not Reported
	Pravastatin			C	Unknown	40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195191	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195442	EXPEDITED (15-DAY)		HO, OT	CN-ALKEM LABORATORIES LIMITED-CN-ALKEM-2019-05830		27 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Infection	Mycophenolate Mofetil			S	Unknown	Daily		Alkem
	Prednisolone			S	Oral	Daily		Not Reported
	Prednisolone			S	Oral	10 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Daily		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195657	NON-EXPEDITED		OT	NVSC2019US077986		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dose/Real Body Weight: 4.94 Mg/Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498563			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196257	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1155963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hepatitis Acute; Lymphoma	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196270	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156035		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Shoulder Operation; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196357	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196541	NON-EXPEDITED		OT	NVSC2019US077967		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	4.55 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196673	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019550573			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Fatigue; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Diclofenac			C		50 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			C	Oral	400 Mg, 1x/Day		Not Reported
	Indocid [Indometacin]			C		3 Every 1 Day(S)		Not Reported
	Leflunomide			C	Oral	Unk Unk, 1x/Day		Not Reported
	Naproxen			C		500 Mg, 1 Every 6 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196849	NON-EXPEDITED		OT	NVSC2019US077958		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	5.44 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197262	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155848			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Label Use; Pneumonia; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197272	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1155879		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)		Not Reported
	Aleve			C			Not Reported
	Arava			C	Unknown		Not Reported
	Prednisone			C	Unknown		Not Reported
	Simponi			C	Subcutaneous		Not Reported
	Simponi			C	Unknown		Not Reported
	Xeljanz			C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197273	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155849		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197281	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C				Not Reported
	Methotrexate			C	Parenteral			Not Reported
	Minocycline			C				Not Reported
	Penicillamine			C				Not Reported
	Phenylbutazone			C				Not Reported
	Prednisolone			C		6 Milligram Daily;		Not Reported
	Prednisone			C		12 Milligram Daily;		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197487	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156070		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197491	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155902		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Arthritis; Scar; Vomiting	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Aspirin/00002701/	C	Unknown			Not Reported
	Cymbalta	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197506	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155856			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197507	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Celebrex			S	Unknown			Not Reported

Non-Responder				Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;		Not Reported
				Toradol		S	Unknown			Not Reported
				Methotrexate		C				Not Reported
				Sulfasalazine		C		2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197509	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous	26 Milligram Daily;		Not Reported
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197529	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027524			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported

Advair	C	Unk	Not Reported
Allopurinol	C	Unk	Not Reported
Atrovent Hfa	C	Unk (Aerosol)	Not Reported
Codeine	C	Unk	Not Reported
Cyclobenzaprine Hydrochloride	C	Unk	Not Reported
Dilaudid	C	Unk	Not Reported
Hydromorphone Hydrochloride	C	Unk	Not Reported
Ibuprofen	C	Unk	Not Reported
Leucovorin Calcium	C	Unk	Not Reported
Nexium Mups [Esomeprazole Magnesium]	C	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unk	Not Reported
Sulfasalazine	C	Unk	Not Reported
Ventolin Hfa	C	Unk	Not Reported
Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197849	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3200633-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Quaternium-15			S	Unknown			Not Reported

	Lasix			C						Not Reported
	Synthroid			C						Not Reported
	Montelukast			C						Not Reported
	Bricanyl			C						Not Reported
	Enbrel			C						Not Reported
	Cetirizine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2019	15625545	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558391-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Duration 365.0		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2019	17198137	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-164980		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Reactivation; Ischaemic Stroke; Varicella Zoster Virus Infection; Vasculitis	Mycophenolic Acid			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2019	17198644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Therapy Duration:365.0		Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S				Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Folic Acid	S	Oral		Not Reported
Fosamax	S	Unknown		Not Reported
Fosamax	S	Oral		Not Reported
Golimumab	S	Unknown		Not Reported
Golimumab	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	Therapy Duration:11.0 Year(S)	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	Therapy Duration:365.0	Not Reported
Sulfasalazine	S	Unknown	Therapy Duration:365.0	Not Reported
Sulfathalidine	S	Unknown		Not Reported

	Topicort [Desoximetasone]	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
	Salazopyrina	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	14938512	NON-EXPEDITED			US-PFIZER INC-2018215382		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Lyrica			S	Oral	75 Mg, 3x/Day		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	16842391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2797897-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17041153	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201802-000660			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercholesterolaemia; Low Density Lipoprotein Increased; Platelet Count Decreased; Retinal Tear; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	50 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	35 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	27.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	22.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Oral	1 Dosage Form, Qd		Not Reported
	Amlodipine			S	Oral	10 Mg, Qd		Not Reported
	Cellcept			C		Unk		Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Bonalon			C		Unk		Not Reported
	Bonalon			C				Not Reported
	Calblock			C		Unk		Not Reported
	Avapro			C		Unk		Not Reported

	Carvedilol	C	Unk		Not Reported
	Natrix	C	Unk		Not Reported
	Nexium	C	Unk		Not Reported
	Nexium	C			Not Reported
	Famotidine	C	Unk		Not Reported
	Famotidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17124062	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1146237		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis; Urticaria	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Minocycline			S	Unknown			Actavis
	Minocycline			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S	Intravenous (not			Not Reported

		otherwise specified)	
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17177631	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019230172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)			
	Simponi	S	Subcutaneous	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Fosamax	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17194628	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498579		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199790	EXPEDITED (15-DAY)			GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2018-10791		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199807	EXPEDITED (15-DAY)		HO, OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2018-09566		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Glucose Tolerance Impaired; Maternal Exposure During Breast Feeding; Otitis Externa; Staphylococcal Infection; Therapy Partial Responder	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Alkem
	Mycophenolate Mofetil			S	Unknown	750 Mg, Bid		Alkem
	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Alkem
	Tacrolimus			S	Unknown	2 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	3 Mg, Bid		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg, Per Dose		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported

					Azathioprine		S	Unknown	50 Mg, Qd			Not Reported
					Azathioprine		S	Unknown	25 Mg, Qd			Not Reported
					Azathioprine		S	Unknown	50 Mg, Qd			Not Reported
					Gliclazide		S	Unknown	Unk			Not Reported
					Insulin		S	Unknown	Unk			Not Reported
					Rituximab		S	Intravenous (not otherwise specified)	1 G, Unk			Not Reported
					Hydroxychloroquine		S	Unknown	200 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199911	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156024			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported
	Allopurinol			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Plaquenil			C				Not Reported
	Sulfasalazine			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Xeljanz			C				Not Reported
	Codeine			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Dilaudid			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Ibuprofen			C				Not Reported

	Leucovorin Calcium			C					Not Reported
	Nexium Dr			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199926	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205492-00		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199963	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155835		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200584	EXPEDITED (15-DAY)		HO, LT, OT	US-ALKEM LABORATORIES		29 YR	Female	USA

LIMITED-US-ALKEM-2019-06269

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
West Nile Viral Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Trimethoprim–Sulfamethoxazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200606	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-07147			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia	Mycophenolate Mofetil			S	Oral	Unk		Alkem
	Tacrolimus			S	Topical	Unk		Not Reported
	Azathioprine			S	Oral	Unk		Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Thalidomide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200636	EXPEDITED (15-DAY)		HO, LT, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-07074		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure;	Mycophenolate Mofetil			S	Unknown	1000 Milligram		Alkem

Hypercalcaemia; Lymphoproliferative Disorder	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Once Weekly	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200771	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003102			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Disturbance; Paraesthesia; Skin Fissures	Hydroxychloroquine			S		Unk,Plaquenil		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200793	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019233563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Phthalylsulfathiazole			S	Unknown	Unk			Not Reported
	Plaquenil			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201567	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2019-066044		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Prednisolon			S	Unknown			Bausch And Lomb
	Quensyl			S	Unknown			Not Reported
	Benlysta Solution For Injection In Pre-Filled Pen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201727	NON-EXPEDITED		OT	NVSC2019US077983		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	6.07 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201728	NON-EXPEDITED		OT	NVSC2019US077969		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	8.25 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201878	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2019M1126876		1 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Synthroid		S		Unk	Mylan
	Cambia		S	Oral	75 Milligram, Bid	Mylan
	Cambia		S	Oral	1 Dosage Form	Mylan
	Cambia		S	Oral	2 Dosage Form, Qd	Mylan
	Diclofenac Potassium		S	Oral	Unk	Mylan
	Folic Acid		S		Unk	Mylan
	Hydroxychloroquine Sulfate		S	Oral	1 Dosage Form, Qd	Mylan
	Lisinopril		S		Unk	Mylan
	Lisinopril		S		Unk	Mylan
	Methotrexate		S	Subcutaneous	1 Dosage Form, Qw	Mylan
	Pantoprazole		S		Unk	Mylan
	Pantoprazole		S	Unknown	Unk	Mylan
	Sulfasalazine		S	Oral	1 Gram, Bid	Mylan
	Xeljanz		S	Oral	2 Dosage Form, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201920	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548402		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cimzia			S		200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Orencia			S		750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	50 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202788	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019550599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202838	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019550697			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Azithromycin			S				Pfizer
	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Azathioprine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Metoprolol			S				Not Reported
	Naproxen			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202839	NON-EXPEDITED			US-PFIZER INC-2019551329		76 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported

	Certolizumab	S	Unk		Not Reported
	Cefalexin	S	Unk		Not Reported
	Chlorphenamine	S	Unk		Not Reported
	Hydrocodone	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Leflunomide	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202841	NON-EXPEDITED			US-PFIZER INC-2019551452		65 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Nitrofurantoin			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17203089	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1126387			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Pneumonia; Sepsis; Splenomegaly; Systemic Lupus Erythematosus; Urinary Tract Infection	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Quensyl			S	Unknown	200 Milligram, Bid		Mylan
	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Mylan
	Tilidine Hydrochloride			C	Unknown	Unk, Qd		Mylan
	Pantozol /01263204/			C	Unknown	Unk, Qd		Mylan
	Cellcept /01275102/			C	Unknown	Unk		Mylan
	Decortin H			C	Unknown	40 Milligram		Mylan
	Torem /01036501/			C	Unknown	5 Milligram		Mylan
	Ibuprofen			C	Unknown	600 Milligram, Qd		Mylan

	Amlodipin /00972401/	C	Unknown	2.5 Milligram		Mylan
	Vigantoletten	C	Unknown	1000 International Unit		Mylan
	Clexane	C	Subcutaneous	0.4 Milliliter		Mylan
	Delix /00885601/	C	Unknown	2.5 Milligram		Mylan
	Prednisolon /00016201/	C	Unknown	75 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17203670	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155883		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17204380	NON-EXPEDITED		OT	NVSC2019US077964		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vitreous Floaters	Hydroxychloroquine			S	Unknown	5.33 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	13226892	EXPEDITED (15-DAY)		OT	CA-SA-2015SA125523		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	13362332	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk, Every 1 Day(S)		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Levothyroxine			S	Unknown	1 Df, Every 1 Day(S)		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Qd		Not Reported

	Tylenol /00020001/			S	Unknown	Unk				Not Reported
	Tocilizumab			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	15317340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2173448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 5.0 Month(S)		Not Reported
	Arava			S	Oral	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	15982533	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Systemic Lupus Erythematosus	Apo-Prednisone			S	Unknown	Unk			Not Reported
	Arava			S	Oral	Unk			Not Reported
	Cimzia			S	Subcutaneous	Unk			Not Reported
	Desoximetasone			S	Oral	Unk			Not Reported
	Enbrel			S	Unknown	Unk			Not Reported
	Folic Acid			S	Unknown	5 Milligram			Not Reported
	Fosamax			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous	40 Milligram			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16449542	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03336		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary	Etanercept			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported

Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Plaquenil			S	Unknown	Unknown	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine			S	Oral	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Unknown	Not Reported
	Enbrel			S	Unknown	Unknown	Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sodium Aurothiomalate			C	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate			C	Unknown		Not Reported
	Leflunomide			C	Unknown		Not Reported
	Xeljanz			C	Oral		Not Reported
	Xeljanz			C	Unknown	Unknown	Not Reported
	Arava			C	Unknown	Unknown	Not Reported
	Actemra			C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16475127	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15886		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported

Methotrexate	S	Parenteral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Rituxan	S	Subcutaneous	Unknown	Not Reported
Rituxan	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Enteric Coated	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported
Azathioprine	C	Unknown	Unknown	Not Reported
Ciclosporin/Cyclosporine	C	Unknown	Unknown	Not Reported
Minocycline	C	Unknown	Unknown	Not Reported

	Penicillamine			C	Unknown	Unknown		Not Reported
	Prednisolone			C	Unknown			Not Reported
	Actemra			C	Unknown	Unknown		Not Reported
	Tocilizumab			C	Unknown	Unknown		Not Reported
	D-Penicillamine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16514254	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1060441		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Restlessness	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Benepali			S	Unknown	50 Milligram, Qw		Mylan
	Benepali			S	Unknown	50 Milligram,		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram,		Mylan
	Chloroquine			C	Unknown	300 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17099186	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-112012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Cimzia	S	Subcutaneous			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Folic Acid	S	Unknown	1 Milligram		Not Reported
Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Apo Prednison	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Topicort [Hydrocortisone Acetate]	S	Topical			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17204990	NON-EXPEDITED		OT	NVSC2019US077985		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinopathy	Hydroxychloroquine			S	Unknown	6.77 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205318	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female;	Methotrexate (Trade Name			S	Unknown			Not Reported

Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Vomiting	Unknown)				
	Enbrel	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205327	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205338	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205339	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6078		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Leflunomide			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205341	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205396	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2019-6104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Fatigue; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Indocid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205713	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-201912003112			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Nausea; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		800 Mg, Qd, 2 400 Mg Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205722	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-201912003095			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Arthritis; Condition Aggravated; Depression; Fall; Joint Injury	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Kevzara			S	Subcutaneous	200 Mg, Qow (Strength-200mg/1.14ml)		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk (Autoinjector)		Not Reported
	Diclofenac Sodium			C		Unk Mg		Not Reported
	Meloxicam			C		15 Unk		Not Reported

	Omeprazole	C	Unk Mg	Not Reported
	Oxybutynin Chloride	C	5 Mg	Not Reported
	Prednisone	C	Unk Mg	Not Reported
	Sertraline Hcl	C	100 Unk	Not Reported
	Simponi	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205881	EXPEDITED (15-DAY)		OT	SE-ALKEM LABORATORIES LIMITED-SE-ALKEM-2019-01287		58 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Intravenous Immunoglobulin (Ivig)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205941	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-201912003094			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Prednisolone			S		Unk		Concordia
	Prednisolone			S		7.5 Mg, Qd		Concordia
	Prednisolone			S				Concordia
	Rituximab			S		375 Mg/M2,2 Doses 14 Days Apart		Not Reported
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Azathioprine	S	150 Mg	Not Reported
Azathioprine	S	Unk	Not Reported
Mycophenolate Mofetil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206018	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Flank Pain; Leukaemia; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206132	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201702-000881			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Hypersensitivity; Nausea; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Lasix			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206430	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6114		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Xeljanz	S	Oral		Not Reported
	Cimzia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206536	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-01939		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206542	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-01938		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Colchicines			S	Unknown	Unk		Not Reported
	Sodium Thiosulfate			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206617	EXPEDITED (15-DAY)			TW-ALKEM LABORATORIES LIMITED-TW-ALKEM-2018-10635		36 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Alkem
	Prednisolone			S	Unknown	30 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Felodipine			S	Unknown	5 Mg, Qd		Not Reported
	Irbesartan			S	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17207300	EXPEDITED (15-DAY)		DE	NVSC2019TN080180			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17207519	EXPEDITED (15-DAY)		OT	NVSC2019TN080175			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208104	NON-EXPEDITED			US-UCBSA-2017011447		58 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Zyrtec	S	Unknown Dose	Not Reported
	Certolizumab Pegol	S	Unknown Dose	Not Reported
	Acetaminophen	S	Unknown Dose	Not Reported
	Golimumab	S	Unknown Dose	Not Reported
	Levofloxacin	S	Unknown Dose	Not Reported
	Diphenhydramine Hcl	S	Unknown Dose	Not Reported
	Tramadol	S	Unknown Dose	Not Reported
	Hydromorphone	S	Unknown Dose	Not Reported
	Morphine	S	Unknown Dose	Not Reported
	Salicylate Sodium	S	Unknown Dose	Not Reported
	Diclofenac	S	Unknown Dose	Not Reported
	Oxycodone	S	Unknown Dose	Not Reported
	Hydrocodone	S	Unknown Dose	Not Reported
	Naproxen	S	Unknown Dose	Not Reported
	Clonidine	S	Unknown Dose	Not Reported
	Amlodipine	S	Unknown Dose	Not Reported
	Methylprednisolone	S	Unknown Dose	Not Reported
	Budesonide	S	Unknown Dose	Not Reported
	Nedocromil	S	Unknown Dose	Not Reported
	Cromolyn	S		Not Reported
	Montelukast	S	Unknown Dose	Not Reported
	Abatacept	S	Unknown Dose	Not Reported
	Adalimumab	S	Unknown Dose	Not Reported
	Methotrexate	S	Unknown Dose	Not Reported
	Dapsone	S	Unknown Dose	Not Reported
	Amoxicillin And Clavulanate Potassium	S	Unknown Dose	Not Reported
	Benzoic Acid	S	Unknown Dose	Not Reported
	Azithromycin	S	Unknown Dose	Not Reported
	Fluconazole	S	Unknown Dose	Not Reported

Clindamycin	S	Unknown Dose	Not Reported
Linezolid	S	Unknown Dose	Not Reported
Vancomycin	S	Unknown Dose	Not Reported
Ciprofloxacin	S	Unknown Dose	Not Reported
Cefdinir	S	Unknown Dose	Not Reported
Macrodantin	S	Unknown Dose	Not Reported
Heparin	S	Unknown Dose	Not Reported
Pantoprazole	S	Unknown Dose	Not Reported
Milk Of Magnesia	S	Unknown Dose	Not Reported
Fexofenadine	S	Unknown Dose	Not Reported
Sodium Hypochlorite	S	Unknown Dose	Not Reported
Prednisone	S	17 Mg Daily	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Sulindac	S		Not Reported
Albuterol	S		Not Reported
Gabapentin	S	Unk	Not Reported
Ramipril	S	Unk	Not Reported
Misoprostol	S	Unk	Not Reported
Rosuvastatin	S	Unknown Dose	Not Reported
Ranitidine	S	Unknown Dose	Not Reported
Teriparatide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208175	NON-EXPEDITED			US-UCBSA-2017031305			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall;	Cimzia			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported

Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Synovitis; Type V Hyperlipidaemia	Prolia	S		Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Tofacitinib Citrate	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Humira	S		40 Mg, Weekly (Qw)	Not Reported
	Humira	S			Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Arava	S	Oral	20 Mg Daily	Not Reported
	Aranesp	C			Not Reported
	Oxycodone	C			Not Reported
	Abilify	C		Unk	Not Reported
	Advair	C			Not Reported
	Atenolol	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Crestor	C			Not Reported
	Cytomel	C			Not Reported
	Dorzolamide Hcl	C		Unk	Not Reported
	Duloxetine Hydrochloride	C		Unk	Not Reported
	Duoneb	C			Not Reported
	Famotidine	C			Not Reported
	Finasteride	C			Not Reported
	Furosemide	C			Not Reported
	Gabapentin	C			Not Reported
	Leflunomide	C			Not Reported
	Lovaza	C			Not Reported
	Medrol	C			Not Reported
	Myrbetriq	C		Unk	Not Reported
	Nexium	C			Not Reported
	Fish Oil W/Tocopherol	C			Not Reported
	Oxycodone Hcl	C			Not Reported
	Prochlorperazine Maleate	C			Not Reported
	Relpax	C			Not Reported
	Singulair	C			Not Reported
	Soma	C			Not Reported

	Sulfazine Ec	C	Not Reported
	Synthroid	C	Not Reported
	Tamsulosin Hcl	C	Not Reported
	Topamax	C	Not Reported
	Topiramate	C	Not Reported
	Triamterene/Hctz	C	Not Reported
	Voltaren	C	Not Reported
	Xalatan	C	Not Reported
	Cymbalta	C	Not Reported
	Vicodin	C	Not Reported
	Vicodin	C	Not Reported
	Klonopin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208493	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-120960			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208514	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-120985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

	Rituxan	S	otherwise specified) Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209386	NON-EXPEDITED		OT	NVSC2019US077978		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	4.88 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209496	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209751	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019554720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Etanercept			S				Pfizer
	Actemra			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported

	Prednisone			S	Oral	10 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210008	NON-EXPEDITED		OT	NVSC2019US077973		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	6.06 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210106	EXPEDITED (15-DAY)		OT	FR-ANIPHARMA-2019-FR-000271		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Mg Daily		Ani
	Tahor			S	Oral	1 Df Daily 10 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Coumadine			S				Not Reported
	Kardegic			S		1 Df Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210369	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019554652			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Arava			C		20 Mg, 1x/Day		Not Reported
	Celebrex			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210372	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019554709		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Enbrel			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Actonel			S		35 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Plaquenil S			S		300 Mg, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			C		300 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210655	EXPEDITED (15-DAY)		OT	CA-SA-2019SA355019		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Ranitidine			S	Unknown	Unk Unk, Unk		Sanofi
	Acetazolamide			S	Unknown	Unk Unk, Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Amlodipine (Salt Not Specified)			S	Unknown	Unk Unk, Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk Unk, Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk, Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk Unk, Unk		Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk Unk, Unk		Not Reported

	Ferrous Fumarate	S	Unknown	Unk Unk, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Unk	Sanofi
	Insulin Human Nos	S	Unknown	Unk Unk, Unk	Sanofi
	Leflunomide	S	Unknown	Unk Unk, Unk	Sanofi
	Leflunomide	S			Sanofi
	Metformin Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Somatropine	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Prednisone	S	Unknown	Unk Unk, Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk Unk, Unk	Not Reported
	Testosterone	S	Unknown	Unk Unk, Unk	Not Reported
	Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
	Azathioprine	S			Not Reported
	Azathioprine	S			Not Reported
	Ciclosporin	S	Unknown	Unk Unk, Unk	Not Reported
	Ciclosporin	S			Not Reported
	Protropin	S	Intramuscular	Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
	Remicade	S			Not Reported
	Remicade	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulphathiazole	S	Unknown		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210999	NON-EXPEDITED		OT	NVSC2019US077977		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	730 G		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17211028	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505961		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Supeudol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	11437906	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056744		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Inflammation; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Rituximab			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12572852	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015113554		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12583397	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015363640		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Off Label Use; Pain; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, 4 Times/Wk		Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, 1x/Day		Unknown
	Sulfasalazine	S		1000 Mg, 2x/Day		Pfizer
	Humira	S	Subcutaneous	20 Mg, Daily		Not Reported
	Humira	S	Subcutaneous	Unk, 1x/Day		Not Reported
	Prednisone	S	Oral	5 Mg, Daily		Not Reported
	Arava	S		20 Mg, Daily		Not Reported
	Arava	S		20 Mg, Unk		Not Reported
	Plaquenil	S	Oral	200 Mg, 2x/Day		Not Reported
	Orencia	S		Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid		Not Reported
	Apo-Prednisone	S	Oral	5 Mg, Qd		Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12765196	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076380		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported

Asthenia; Bladder Catheterisation; Blood Calcium Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Iron Decreased; Blood Pressure Increased; Calcinosis; Cardiac Disorder; Cd4 Lymphocytes Decreased; Chest Pain; Condition Aggravated; Connective Tissue Inflammation; Diabetes Mellitus; Diarrhoea; Drug Monitoring Procedure Not Performed; Erythema; Fall; Fatigue; Gait Disturbance; Haemoglobin Decreased; Hand Fracture; Heart Rate Increased; Hyperparathyroidism Primary; Immunodeficiency; Infection; Joint Injury; Limb Injury; Loss Of Consciousness; Nephrolithiasis; Night Sweats; Optic Nerve Injury; Peripheral Swelling; Platelet Count Increased; Precancerous Cells Present; Pyrexia; Pyrexia; Renal Failure; Sinusitis; Skin Infection; Urinary Tract Infection; Visual Impairment; Weight Increased	Alemtuzumab	S	Intravenous drip	12 Mg, Qd	Sanofi
	Plaquenil	S	Unknown	Unk Unk,Unk	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	15625955	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557437-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16470270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone		S	Oral	Unk	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Subcutaneous	500 Milligram	Not Reported
	Sulfasalazine		S	Subcutaneous	1 Gram, Bid	Not Reported
	Certolizumab Pegol		S	Subcutaneous	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16537815	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017574		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Actemra			S	Unknown	64 Mg, Unk		Not Reported
	Actemra			S	Unknown	64 Mg, Q.Wk.		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Unk		Not Reported

Ciclosporin	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
Imuran /00001501/	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Piroxicam	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16657676	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084356			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported

Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Piroxicam	C			Not Reported
Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16867058	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201807-002707			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Mental Impairment; Overdose; Toxicity To Various Agents; Ventricular Tachycardia; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	36 G		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16964715	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201910001358			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Chills; Cushingoid; Decreased Appetite; Dehydration; Escherichia Urinary Tract Infection; Hypocalcaemia; Malaise; Nausea; Oedema Peripheral; Vomiting	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
	Avapro Hct			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg		Not Reported
	Prolia			S	Unknown	Unk; Single Dose Prefilled Syringe		Not Reported

Prolia	S	Unk, Recent Administration	Not Reported
Prednisolone	C	Unk	Not Reported
Prednisolone	C	25 Mg, Qd (Increased)	Not Reported
Prednisolone	C	15 Mg (Reducing Dose)	Not Reported
Prednisolone	C	10 Mg (Reducing Dose)	Not Reported
Prednisolone	C	5 Mg, Qd	Not Reported
Vitamin D	C	Unk	Not Reported
Calcium	C	Unk	Not Reported
Karvezide	C	Unk	Not Reported
Lyrica	C	Unk	Not Reported
Amlodipine	C	Unk	Not Reported
Amlodipine	C	10 Mg (Increased To 10 Milligram Mane)	Not Reported
Magnesium	C	Unk	Not Reported
Citracal Plus D	C	Unk	Not Reported
Panadol	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Hydralazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17166558	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1153033		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Humoral Immune Defect; Lupus Enteritis; Meningoencephalitis Viral; West Nile Viral Infection	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methylprednisolone			S	Unknown	High-Dose		Not Reported
	Prednisone			S	Unknown	6 Milligram Daily; As Part Of A Regimen That Involved Tapering Of The		Actavis

								Dose		
		Mycophenolate Mofetil			S	Unknown				Teva
		Rituximab			S	Unknown				Not Reported
		Trimethoprim/Sulfamethoxazole			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17199605	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205516-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17211738	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
					Simponi	S	Subcutaneous			Not Reported
					Sulfasalazine	S	Unknown			Not Reported
					Tocilizumab	S	Unknown			Not Reported
					Tofacitinib	S	Unknown			Not Reported
					Xeljanz	S	Unknown			Not Reported
					Methotrexate	S	Oral			Not Reported
					Methotrexate	S	Oral			Not Reported
					Cimzia	S	Unknown			Not Reported
					Rabeprazole Sodium	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508008		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil [Amitriptyline			C	Unknown			Not Reported

	Hydrochloride]			
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212163	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121431			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

		Phosphate]								
		Prednisone			S	Unknown	Unk			Not Reported
		Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
		Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
		Simponi			S	Subcutaneous	Unk			Not Reported
		Sulfasalazine			S	Oral	1 Gram, Bid			Not Reported
		Tofacitinib Citrate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212349	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1158545		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Esomeprazole			S	Unknown	40 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Apo-Prednisone			S	Unknown	5 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown	400 Milligram Daily;		Not Reported
	Folic Acid			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212721	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-08761		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Doxycycline			S	Unknown	Unk		Lupin
	Pentoxifylline			C	Oral	400 Milligram, Tid		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

	Rosuvastatin			C	Unknown	Unk			Not Reported
	Enalapril			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212843	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-03698		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Psoralen			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Immune Globulin (Iv)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212902	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-06160		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk, Titrated Up		Alkem
	Mycophenolate Mofetil			S	Unknown	1.5 Gram, Bid		Alkem
	Prednisone			S	Unknown	60 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

	Cilostazol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17213121	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6119			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17213603	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019555028		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Unknown	2 Df, Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported

	Cimzia		S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Folic Acid		S	Unknown	Unk Unk, Weekly	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17213794	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557047		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17214515	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091702		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Humira	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17214861	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-122427		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Citirizine [Cetirizine Hydrochloride]			S	Unknown	10 Milligram		Not Reported
	Citirizine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17215575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39441		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hyperhidrosis; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Product Use Issue; Rheumatoid Arthritis;	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Prednisone		S	Oral			Not Reported
	Xeljanz		S	Oral			Not Reported
	Apo-Prednisone		S	Unknown			Not Reported
	Enbrel		S	Subcutaneous			Not Reported
	Celebrex		C	Unknown	Unknown		Not Reported
	Ergocalciferol		C	Unknown	Unknown		Not Reported
	Folic Acid		C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17215819	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952910US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Actonel			S	Oral	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	Unk, Unknown		Allergan
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Novo-Rythro			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q Week		Not Reported
	Bupropion			C				Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Celebrex			C		200 Mg, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk Unk, Qd		Not Reported

		Ergocalciferol			C	Unknown	Unk, Qd			Not Reported
		Hydroxychloroquine			C	Oral	400 Mg, Qd			Not Reported
		Wellbutrin			C	Unknown	300 Mg, Qd			Not Reported
		Wellbutrin			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17215889	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1953219US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Risedronate Sodium Unk			S		5 Mg		Allergan
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Arava			S				Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q Week		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisone			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	500 Mg, Unk		Not Reported
	Cyclobenzaprine			C		10 Mg, Unk		Not Reported
	Desoximetasone			C		5 Mg, Qd		Not Reported
	Desoximetasone			C		5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone Acetate			C		5 Mg, Qd		Not Reported
	Tylenol /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17216507	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Celecoxib			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17216592	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-122317		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	0.6 Milliliter, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	13224711	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890699		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported

Synovitis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	14112535	EXPEDITED (15-DAY)		HO, OT	US-MALLINCKRODT-T201703249			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Anxiety; Aphonia; Arthralgia; Arthritis; Asthenia; Back Pain; Blister; Body Temperature Increased; Bone Pain; Bradykinesia; Bronchitis; Cataract; Chemical Burn; Condition Aggravated; Confusional State; Contusion; Disturbance In Attention; Dizziness; Drug Abuse; Dry Skin; Dyskinesia; Dysphagia; Dyspnoea; Fall; Fatigue; Feeling Abnormal; Folliculitis; Food Poisoning; Gait	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin			S	Subcutaneous	80 Units / 1 Ml, 2 Times		Mallinckrodt

Disturbance; Gastroenteritis Viral; Hair Texture Abnormal; Herpes Zoster; Hypersensitivity; Immunodeficiency; Incorrect Dose Administered; Influenza; Injection Site Haemorrhage; Injection Site Mass; Injection Site Pain; Insomnia; Kyphosis; Laryngeal Papilloma; Logorrhoea; Loss Of Consciousness; Malaise; Memory Impairment; Muscle Spasms; Muscular Weakness; Musculoskeletal Pain; Nasopharyngitis; Nervousness; Neuralgia; Pain In Extremity; Panic Attack; Peripheral Swelling; Pneumonia; Pollakiuria; Pruritus; Pulmonary Fibrosis; Pulmonary Oedema; Purpura; Pustule; Rash; Rectal Prolapse; Sarcoidosis; Scab; Skin Burning Sensation; Somnolence; Spinal Stenosis; Staphylococcal Infection; Toxic Encephalopathy; Tremor; Umbilical Haemorrhage; Urinary Tract Infection; Vein Disorder; Visual Impairment; Weight Decreased; Weight Increased; Wrong Technique In Product Usage Process	Injection			Per Week Wednesdays And Saturdays	
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week Wednesdays And Saturdays	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week (Wednesdays And Saturdays)	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week (Wednesdays And Saturdays)	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week (Wednesdays And Saturdays)	Mallinckrodt
	Morphine	S	Unknown	Unk	Mallinckrodt
	Prednisone	S	Unknown	20 Mg, One Week	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Levaquin	C	Unknown	For 14 Days	Not Reported
	Remeron	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	14778653	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018157950		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	15021181	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-031922		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Meperidine			S	Unknown	Unk		Not Reported

		Plaquenil			S	Oral	400 Milligram, Unk			Not Reported
		Prednisone			S	Unknown	Unk			Not Reported
		Sulfasalazine			S	Unknown	Unk			Not Reported
		Apo Leflunomida			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	15462312	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2017SE55839		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis;	Vimovo			S	Oral	Unknown Dose		Not Reported
	Esomeprazole Magnesium			S	Oral			Not Reported
	Esomeprazole Magnesium			S	Unknown	Esomeprazole Magnesium Trihydrate		Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral	250.0mg Unknown		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Pantoloc			S	Oral	Daily		Not Reported
	Pantoloc			S	Oral	Unk		Not Reported
	Pantoloc			S	Oral	Unk		Not Reported
	Pantoloc			S	Unknown			Not Reported

Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Pantoloc	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Alendronic Acid	S	Oral	Unknown Dose	Not Reported
	Amitriptyline	S	Oral		Not Reported
	Amitriptyline	S	Oral	Apo Amitriptyline	Not Reported
	Depo Medrol	S	Intra-articular	Daily	Not Reported
	Humira	S	Subcutaneous	40.0mg Unknown	Not Reported
	Imuran	S	Unknown	150.0mg Unknown	Not Reported
	Imuran	S	Unknown	150.0mg Unknown	Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Mobicox	S	Unknown		Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Apo-Meloxicam	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported

Ranitidine	S	Oral		Not Reported
Ranitidine	S	Oral		Not Reported
Septra	S	Unknown	Unknown Dose	Not Reported
Septra	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral	Tofacitinib Citrate, 10 Mg Daily	Not Reported
Xeljanz	S	Oral	Tofacitinib Citrate, 5 Mg Two Times Daily	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Apo Ranitidine	S	Oral		Not Reported
Apo Ranitidine	S	Oral	300 Mg, Weekly	Not Reported
Apo Ranitidine	S	Oral		Not Reported
Apo Ranitidine	S	Oral		Not Reported

Oxycocet	S	Unknown	Teva	Not Reported
Oxycocet	S	Unknown	Ratio	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Apo-Alendronate	S	Unknown	Fosamax	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Pregabalin	S	Oral		Not Reported
Pregabalin	S	Oral		Not Reported
Pregabalin	S	Oral		Not Reported
Azathioprine	S	Unknown		Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S		Unk	Not Reported
Elavil	S	Unknown		Not Reported
Adalimumab	S			Not Reported
Alendronate Sodium	S			Not Reported
Meloxicam	S			Not Reported
Pantoprazole	S			Not Reported
Sulfamethoxazole/Tri	S			Not Reported
Orencia	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Cannabis Sativa	C	Unknown		Not Reported
Cimzia	C			Not Reported
Codeine	C	Unknown	Unk Unk, Qd	Not Reported
Dexilant	C	Unknown		Not Reported
Eltroxin	C	Unknown		Not Reported

			Plaquenil		C	Unknown				Not Reported
			Plaquenil		C	Unknown				Not Reported
			Celebrex		C	Unknown				Not Reported
			Celebrex		C	Unknown				Not Reported
			Celebrex		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	16081534	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022817		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cellcept			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Imuran			S				Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S				Not Reported
	Hydroxychloroquine	S				Not Reported
	Doxycycline	C	Unknown			Not Reported
	Elavil /00002202/	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Tobramycin	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported
	Amitriptyline Hydrochloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	16739920	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-080375		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide An			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	16879556	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2946533-00		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Poor Venous Access; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous drip			Not Reported
	Orencia			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Immunoglobulin Human			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulin Human			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg		Not Reported

	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S			Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17216961	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-205628			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Pulmonary Fibrosis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Minocycline			S	Unknown	Unk		Ranbaxy
	Mycophenolate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	15 Milligram, Daily		Not Reported
	Prednisone			C	Unknown	5-7 Milligram Daily		Not Reported
	Prednisone			C		15 Milligram, Daily		Not Reported
	Prednisone			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17216992	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217255	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214787-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217356	EXPEDITED (15-DAY)		OT	IT-ALKEM LABORATORIES LIMITED-IT-ALKEM-2018-12210		3 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Partial Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217445	EXPEDITED (15-DAY)		DS, HO, OT	US-ADVANZ PHARMA-GSH201801-000272			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bladder Catheterisation; Blood Calcium Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Iron Decreased; Blood Pressure Increased; Calcinosis; Cardiac Disorder; Cd4 Lymphocytes Decreased; Chest Pain; Condition	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Alemtuzumab			S	Intravenous drip	Unk		Not Reported
	Alemtuzumab			S		Second Cycle		Not Reported

Aggravated; Connective Tissue Inflammation; Diabetes Mellitus; Diarrhoea; Drug Monitoring Procedure Not Performed; Erythema; Fall; Fatigue; Gait Disturbance; Haemoglobin Decreased; Hand Fracture; Heart Rate Increased; Hyperparathyroidism Primary; Immunodeficiency; Infection; Joint Injury; Limb Injury; Loss Of Consciousness; Nephrolithiasis; Night Sweats; Optic Nerve Injury; Peripheral Swelling; Platelet Count Increased; Precancerous Cells Present; Pyrexia; Pyrexia; Renal Failure; Sinusitis; Skin Infection; Urinary Tract Infection; Visual Impairment; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217547	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003116			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217554	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001086			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Hydroxychloroquine	S	Unknown	Unk		Concordia
	Enbrel	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217568	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-122817		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217895	EXPEDITED (15-DAY)		HO	CA-ROCHE-2505703		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue;	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218019	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-106735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo
	Losartan			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported

	Keflex		S	Unknown	Unk	Not Reported
	Levaquin		S	Unknown	Unk	Not Reported
	Lopresor		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	10 Milligram, Every Week	Not Reported
	Pariet		S	Unknown	Unk	Not Reported
	Penicillin		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Saccharated Iron Oxide		C	Unknown	Unk	Not Reported
	Esomeprazole		C	Unknown	Unk	Not Reported
	Cipro		C	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate		C	Unknown	Unk	Not Reported
	Gold		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218475	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2019SP013302		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Central Nervous System Lupus; Central Nervous System Vasculitis; Cerebral Ischaemia; Confusional State; Decorticate Posture; Depressed Level Of Consciousness; Headache; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Neck Pain; Off Label Use; Photophobia; Pyrexia; Speech Disorder; Viral Upper Respiratory Tract	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram Per Day		Not Reported
	Prednisolone			S	Oral	40 Milligram		Not Reported
	Prednisolone			S	Unknown	Weaned By 5 Mg Per Week To 5 Mg Daily		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Rituximab			S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 G Infusion In 2 Doses 14		Not Reported

Infection; Vomiting							Days Apart			
		Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218566	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-3212652-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218589	EXPEDITED (15-DAY)		OT	FR-ZYDUS-045120		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Atorvastatin			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Warfarin			S	Oral	()		Not Reported
	Anastrozole			S	Oral			Zydus Pharm
	Acetylsalicylate Lysine/Acetylsalicylic Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218937	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness;	Celecoxib			S	Oral	200.0 Mg, 2x/Day		Pfizer
	Enbrel			S		Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported

Pain	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218954	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557947		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Celebrex			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17219075	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39439		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug	Etanercept			S	Unknown	Unknown		Not Reported

Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Unknown	Not Reported
	Actemra	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17220178	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2019M1127044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness;	Synthroid			S		Unk		Mylan
	Cosentyx			S	Oral	300 Milligram, Monthly (1 Every 1 Months)		Mylan
	Diclofenac			S	Oral	Unk, Tid		Mylan
	Folic Acid			S	Unknown	Unk		Mylan

Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Golimumab	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Mylan
	Leucovorin Calcium	S	Oral	5 Milligram, Qw	Mylan
	Diltiazem Hydrochloride	S	Oral	240 Milligram	Mylan
	Meloxicam	S	Oral	7.5 Milligram, Qd	Mylan
	Methotrexate	S	Oral	25 Milligram, Qw	Mylan
	Methotrexate	S	Oral	4 Dosage Form, Qw	Mylan
	Methotrexate	S	Oral	10 Milligram, Qw	Mylan
	Otezla	S	Unknown	Unk	Mylan
	Pantoprazole	S	Oral	1 Dosage Form, Qd	Mylan
	Pantoprazole Magnesium	S	Unknown	Unk	Mylan
	Fluticasone Propionate	S		Unk	Mylan
	Mar-Pantoprazole	C	Unknown	Unk	Mylan
	Mometasone Furoate	C	Unknown	Unk	Mylan
	Premarin	C	Unknown	Unk	Mylan
	Salbutamol Sulfate	C		Unk	Mylan
	Tramadol Hydrochloride	C	Oral	Unk Unk, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17220384	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2019SF86740			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Nexium			S	Oral			Astrazeneca
	Folic Acid			S	Unknown			Not Reported
	Gabapentin			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17220463	EXPEDITED (15-DAY)		OT	NVSC2019CA082842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

					Humira		S	Subcutaneous	4 Mg		Not Reported
					Orencia		S	Unknown	Unk		Not Reported
					Plaquenil		S	Unknown	400 Mg, Qd		Not Reported
					Plaquenil		S	Unknown	400 Mg		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk		Not Reported
					Sarilumab		S	Unknown	Unk		Not Reported
					Sulfasalazine		S	Oral	1 G, Bid		Not Reported
					Phthalylsulfathiazole		S	Unknown	Unk		Not Reported
					Topicort		S	Subcutaneous	Unk		Not Reported
					Xeljanz		S	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17221310	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019217423		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	Unk		Amgen
	Eliquis			S	Unknown	Unk, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Weekly		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	12316845	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749593		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	Solution		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Simponi	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Celebrex	C	Unknown			Not Reported
	Cimzia	C	Subcutaneous	Solution		Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	15422962	EXPEDITED (15-DAY)		OT	DE-ROCHE-2186283		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Rituximab	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Xeljanz	C	Oral	5 Mg Bid	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	16210452	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020152			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Prednisone		S	Unknown	5 Milligram, Once A Day	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Tylenol		S	Unknown	Unk	Not Reported
	Acetaminophen		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17176795	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201912003001			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	20 Mg, Bid, 20mg Die		Not Reported
	Prednisone			S	Unknown	15 Mg, Bid, 15mg Die		Not Reported
	Methotrexate			C		Ad 20mg Q Week		Not Reported
	Sulfasalazine			C		500mg Ad 200 Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456973			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221584	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201812-004071			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Lansoprazole			C		Unk		Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221720	EXPEDITED (15-DAY)		HO	CA-ROCHE-2456725			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	Liquid Also Know As Immune Globulin (Human)		Not Reported
	Gammagard			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Synovitis; Vomiting			otherwise specified)	
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Other	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505965		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Baclofen			C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported

	Levaquin		C	Unknown			Not Reported
	Valsartan		C	Unknown			Not Reported
	Xalatan		C	Ophthalmic	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221795	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505959		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221820	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506832			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Varenicline Tartrate	S	Oral	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Valtrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221822	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201912003248			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Respiratory Tract Infection; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Simponi			S	Unknown	50 Mg/ Month		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505964		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]	C				Not Reported
	Cymbalta	C				Not Reported
	Hydromorphone	C				Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17222355	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214277-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17222535	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214541-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder;	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituximab		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Gold		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17292381	DIRECT	N				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Headache	Plaquenil Tab 200mg			S	Oral	Other Frequency:Other;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15527383	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2522789-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Motrin	S	Unknown		Not Reported
Naprosyn	S	Unknown		Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Asa	S	Unknown	Daily Low Dose	Not Reported
Gold	S	Unknown		Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Plaquenil	S	Unknown		Not Reported
Vitamin C	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Diclofenac	S			Not Reported
Diclofenac	S			Not Reported
Diclofenac	S			Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Ibuprofen	S	Unknown		Not Reported
Ibuprofen	S			Not Reported
Ibuprofen	S			Not Reported
Ibuprofen	S			Not Reported
Naproxen	S	Unknown		Not Reported
Tramadol Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15926362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653493-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Humira	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15948997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-049912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Milligram, Qwk, 7 Months		Bristol Myers Squibb
	Cyclosporine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported

Otezla	S	Oral	Unk	Not Reported
Rituxan	S	Parenteral	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sirukumab	S	Unknown		Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Minocin	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Apremilast	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Etanercept	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Prednisone	C	Unknown	5 Milligram	Not Reported
Methotrexate	C	Unknown	15 Mg, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Rheumatrex [Methotrexate Sodium]	C	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222690	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505958		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222813	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214942-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222829	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511779		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Actemra	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Arava	C	Unknown			Not Reported
	Cimzia	C	Subcutaneous	Solution		Not Reported
	Enbrel	C				Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Folic Acid	C	Oral			Not Reported
	Humira	C	Subcutaneous			Not Reported
	Indapamide	C	Oral			Not Reported
	Naprosyn [Naproxen]	C	Unknown			Not Reported
	Orencia	C	Intravenous (not otherwise specified)			Not Reported
	Pantoloc [Pantoprazole]	C	Oral			Not Reported
	Perindopril	C	Oral			Not Reported
	Tylenol	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222836	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Hydroxychloroquine			S	Unknown					Not Reported
	Xeljanz			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222934	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Month(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Month(S)		Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate Sodium		S	Oral		Not Reported
	Methotrexate Sodium		S	Subcutaneous		Not Reported
	Orencia		S	Subcutaneous	Therapy Duration: 3.0 Month(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Subcutaneous		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Year(S)	Not Reported
	Xeljanz		S	Oral		Not Reported
	Neoral		S	Oral		Not Reported
	Neoral		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Ciclosporin		S	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506870		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222973	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214948-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506875			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222998	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223023	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506979		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported

	Sulfasalazine			C	Oral					Not Reported
	Synthroid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223027	EXPEDITED (15-DAY)		DS	CA-ROCHE-2508060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223083	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-123529			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown	1 Every 1 Day		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223147	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6208		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223148	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6193		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Viral Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223152	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6196			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Depo-Medrol-Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Oral			Not Reported
	Ketoprofen			S	Topical			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2507989		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use, Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223242	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Loss Of Consciousness; Malaise; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

					Humira		S	Subcutaneous	Not Reported
					Humira		S	Subcutaneous	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Orencia		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223271	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506974		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Increased; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223307	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Cimzia	S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Azathioprine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223336	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan Hycela			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Acetaminophen;Codeine Phosphate		C			Not Reported
					Meloxicam		C			Not Reported
					Methotrexate		C	Unknown		Not Reported
					Synthroid		C			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
02-Jan-2020	17223430	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506830			Male	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported		
	Enbrel			S	Subcutaneous			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Hydroxychloroquine			S	Unknown			Not Reported		
	Leflunomide			S	Unknown			Not Reported		
	Methotrexate			S	Oral			Not Reported		
	Orencia			S	Unknown			Not Reported		
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported		
	Simponi			S	Subcutaneous			Not Reported		
	Sulfasalazine			S	Unknown			Not Reported		
	Folic Acid			C	Unknown			Not Reported		
	Pantoprazole Magnesium			C	Unknown			Not Reported		
	Tenofovir Disoproxil Fumarate			C				Not Reported		
	Xeljanz			C				Not Reported		
	Zopiclone			C	Unknown			Not Reported		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506983		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223445	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506833			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506837		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223670	EXPEDITED (15-DAY)		HO	CA-ROCHE-2506860		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223699	EXPEDITED (15-DAY)		OT	FR-ACCORD-168122		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral			Accord
	Tahor			S	Oral	Strength: 10 Mg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Caumadine			S	Oral			Not Reported
	Kardegic			S	Oral	Strength: 17 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223992	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224203	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557766			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Celebrex			S	Oral	200 Mg, 1x/Day		Pfizer
	Arthrotec			S	Unknown	Unk		Pfizer
	Arthrotec			S	Intracardiac	Unk		Pfizer
	Levofloxacin			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Meperidine Hcl			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Metronidazole			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Demerol			S	Unknown	Unk		Pfizer
	Erythromycin			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224256	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019559776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Lyrica			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Baclofen			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019560762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day (Every 24 Hours)		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day (Every 24 Hours)		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224321	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019560008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Joint Swelling; Pain	Lyrica	S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium	S		20 Mg, Weekly		Unknown
	Actemra	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224428	EXPEDITED (15-DAY)		OT	NVSC2019US082469		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Gait Disturbance; Herpes Zoster Disseminated; Rash	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224878	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-3214954-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Tramacet			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis	Plaquenil	S				Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S				Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Arava	S	Unknown			Not Reported
	Arava	S				Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Nortriptyline Hydrochloride	C				Not Reported
	Ergocalciferol	C				Not Reported
	Vagifem	C	Vaginal			Not Reported
	Tylenol	C				Not Reported
	Premarin	C		0.625 Milligram		Not Reported
	Nortriptyline	C				Not Reported
	Nortriptyline	C				Not Reported
	Methylprednisolone Acetate	C	Intramuscular			Not Reported
	Methylprednisolone Acetate	C				Not Reported
	Methylprednisolone Acetate	C				Not Reported
	Metformin	C				Not Reported
	Lyrica	C	Oral			Not Reported
	Lorazepam	C				Not Reported
	Calcium	C				Not Reported
	Risedronate Sodium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225487	EXPEDITED (15-DAY)		OT	NVSC2019CA083831		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use;	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound			otherwise specified)		
	Simponi	S	Subcutaneous	Unk, (Solution)	Not Reported
	Actemra	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk, (Via Int Corp Caver And Via Oral)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225491	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027777			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported

Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225567	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019561137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective For Unapproved Indication; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225955	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2019-066223		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Weaned By 5 Mg/Week Upto 5mg/Day		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Rituximab			S	Unknown	2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab	S	Unknown	2 Doses 14 Days Apart		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226021	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019561366		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Enbrel			S		50 Mg, Weekly		Pfizer
	Lyrica			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		640 Mg, (1 Every 4 Weeks)		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Certolizumab Pegol			S		200 Mg, (1 Every 2 Weeks)		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Weekly		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not	300 Mg, Weekly		Not Reported

						otherwise specified)			
			Rituximab		S		Unk		Not Reported
			Simponi		S	Subcutaneous	Unk		Not Reported
			Piroxicam		C		Unk		Not Reported
			Prednisone		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226419	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019561826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226648	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-109146		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Palpitations	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	2 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226826	EXPEDITED (15-DAY)		DS	SK-BEH-2019106701		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Product Use In Unapproved Indication; Uterine Hypotonus	Privigen			S	Intravenous (not otherwise specified)	60 Gram, Tot		Csl Behring
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring
	Bisulepin			S	Intravenous (not otherwise specified)	1 Milligram		Not Reported
	Albumin			S	Intravenous (not otherwise specified)	20 Gram, Qd		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	16 Milligram, Qd		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	4 Milligram, Qd		Not Reported
	Hydrocortisone			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Not Reported
	Prednisone			S	Oral	20-30 Mg/24 H		Not Reported
	Prednisone			S	Oral	20-30 Mg/24 H		Not Reported
	Penicillin G [Benzylpenicillin Sodium]			S	Intravenous (not otherwise specified)	5 Milliliter, Qid		Not Reported
	Vulmizolin			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported
	Cefixime			S	Oral	400 Milligram, Bid		Not Reported
	Ornidazole			S	Oral	500 Milligram, Bid		Not Reported
	Fluconazole			S	Oral	100 Milligram, Qd		Not Reported
	Fluconazole			S	Intravenous (not	100 Milligram, Qd		Not Reported

		otherwise specified)		
Cefotaxime	S	Intravenous (not otherwise specified)	1 Gram, Tid	Not Reported
Cefotaxime	S	Intravenous (not otherwise specified)	1 Gram, Tid	Not Reported
Metoprolol Tartrate	S	Oral	25 Milligram, Bid	Not Reported
Bisoprolol Fumarate	S	Oral	2.5 Milligram, Qd	Not Reported
Calcium Carbonate	S	Oral	500 Milligram, Bid	Not Reported
Folic Acid	S	Oral	10 Milligram, Bid	Not Reported
Potassium Chloride	S	Oral	600 Milligram, Tid	Not Reported
Vitamin D3	S	Oral	1500 International Unit, Qd	Not Reported
Vitamin B C Complex	S	Oral	Unk	Not Reported
Magnesium Lactate	S	Oral	500 Milligram, Bid	Not Reported
Vitamin K Nos	S	Intravenous (not otherwise specified)	10 Milligram, Tid	Not Reported
Etamsylate	S	Intravenous (not otherwise specified)	500 Milligram, Tid	Not Reported
Aminomethylbenzoic Acid	S	Intravenous (not otherwise specified)	50 Milligram, Tid	Not Reported
Flebogamma Dif [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	Unk	Not Reported
Nadroparine	S	Subcutaneous	0.3 Milliliter, Qd	Not Reported
Omeprazole	S	Oral	20 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram /12-24h	Not Reported
Paracetamol	S	Oral	500 Milligram, Prn	Not Reported
Paracetamol	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	13029297	EXPEDITED (15-DAY)		OT	CA-ROCHE-1867378		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Actemra			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Methotrexate			C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	13202187	EXPEDITED (15-DAY)		OT	CA-ROCHE-1891284		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	13280503	EXPEDITED (15-DAY)		HO	CA-ROCHE-1848397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported

Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate Sodium	S	Oral			Not Reported
	Cymbalta	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	14408416	NON-EXPEDITED			PR-AMGEN-USASP2018006037		71 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	14911755	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-045068		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Abatacept			S	Intravenous drip	250 Mg, Qmo; For 3 Months		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb

Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Poor Venous Access; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Subcutaneous	250 Milligram, Cyclical 6 Months	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd 3 Years	Not Reported
	Anakinra	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qd, 3 Years	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk, For 4 Months	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Qwk (2 Every 1 Week)	Not Reported
	Etanercept	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	For 3 Months	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram, Herbal Tea	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	For 3 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, 5 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk, For 9 Months	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk, For 10 Years	Not Reported

Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15411594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15415994	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186074		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension;	Rituxan			S	Intravenous drip			Not Reported

Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder	Actemra		S	Unknown		Not Reported
	Apremilast		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown	5 Months	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Minocin		S	Unknown		Not Reported
	Myochrysine		S	Unknown		Not Reported
	Stelara		S	Unknown		Not Reported
	Tofacitinib Citrate		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	4 Months	Not Reported
	Salazopyrin		S	Unknown	4 Months	Not Reported
	Simponi		S	Unknown	334	Not Reported
	Methotrexate		C	Unknown		Not Reported
	Orencia		C	Unknown	4 Years	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15842981	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151104439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint	Tramacet			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Operation; Spinal Stenosis; Treatment Failure	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Metformin	C	Unknown	Not Reported
	Lorazepam	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Methylprednisolone Acetate	C	Unknown	Not Reported
	Depomedrol	C	Intramuscular	Not Reported
	Lyrica	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15934150	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656844-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
			Rituxan		S		Intravenous (not otherwise specified)			Not Reported
			Apo-Leflunomide		S		Unknown			Not Reported
			Enbrel		S		Unknown			Not Reported
			Sulfasalazine		S		Unknown			Not Reported
			Rituximab		S		Intravenous (not otherwise specified)			Not Reported
			Hydroxychloroquine Sulfate		S		Unknown			Not Reported
			Desoximetasone		C		Unknown			Not Reported
			Diclofenac		C					Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
03-Jan-2020	16803329	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-BEH-2019106699			Female	SVK	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Privigen			S	Transplacental	Unk		Csl Behring		
	Privigen			S	Transplacental	Unk		Csl Behring		
	Bisulepin			S	Transplacental	Unk		Not Reported		
	Albumin			S	Transplacental	Unk		Not Reported		
	Dexamethasone			S	Transplacental	Unk		Not Reported		
	Dexamethasone			S	Transplacental	Unk		Not Reported		
	Hydrocortisone			S	Transplacental	Unk		Not Reported		
	Methylprednisolone			S	Transplacental	Unk		Not Reported		
	Methylprednisolone			S	Transplacental	Unk		Not Reported		
	Prednisone			S	Transplacental	Unk		Not Reported		
	Prednisone			S	Transplacental	Unk		Not Reported		
	Penicillin G [Benzylpenicillin Sodium]			S	Transplacental	Unk		Not Reported		
	Vulmizolin			S	Transplacental	Unk		Not Reported		
	Cefixime			S	Transplacental	Unk		Not Reported		

	Ornidazole	S	Transplacental	Unk	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Vitamin D [Colecalciferol]	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S		Unk	Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Omeprazole	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Paracetamol	S	Transplacental	Unk	Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	16826890	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109354		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil /00072602/	C	Unknown			Not Reported
	Depo-Medrol	C	Intra-articular			Not Reported
	Diclofenac	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17054505	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137954		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Eliquis Film Coated			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17175535	EXPEDITED (15-DAY)		OT	NVSC2018CA000536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Methotrexate			S	Intra-arterial	25 Mg, Qw (We)		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

	Tofacitinib Citrate			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17178820	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1153374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Off Label Use	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17202822	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019552521		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Arava			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227103	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027775			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227186	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0019		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227209	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0005			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S	Intracardiac			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hcl			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227368	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508664		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508668		63 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

					Leflunomide		S	Unknown	Not Reported
					Methotrexate		S	Oral	Not Reported
					Methotrexate		S	Subcutaneous	Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Not Reported
					Orencia		S	Unknown	Not Reported
					Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227524	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508670			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227655	EXPEDITED (15-DAY)		HO	CA-ROCHE-2508065			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227859	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227866	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypersensitivity Pneumonitis; Interstitial Lung Disease	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Doxycycline			C	Oral	50 Milligram Daily;		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227867	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162512		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis; Sinus Disorder; Sinusitis Noninfective	Methotrexate			S	Subcutaneous	12.5 Mg, 1 Every 1 Week		Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ergocalciferol/Riboflavin/Thiamine/Vitamin A			C	Unknown			Not Reported

		Esomeprazole Magnesium Trihydrate			C	Unknown				Not Reported
		Estradiol			C	Unknown				Not Reported
		Hydroxychloroquine Sulfate			C	Unknown				Not Reported
		L-Thyroxine /00068001/			C	Unknown				Not Reported
		Tylenol Arthritis Pain 8h			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227952	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162544			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Varilrix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227953	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162567		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227964	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019236411		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Headache	Benlysta			S	Intravenous drip	D1-D14-D28 Then Every 4 Weeks At 10 Mg / Kg		Glaxosmithkline
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Clareal			C	Unknown	Unk		Not Reported
	Cortancyl			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227991	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162555		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Synovitis; Weight Increased	Celebrex			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Clomipramine			C	Unknown	Not Reported
	Allopurinol			C		Not Reported
	Folic Acid			C		Not Reported
	Pantoloc			C	Unknown	Not Reported
	Plaquenil			C	Unknown	Not Reported
	Zyloprim			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512613		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228231	EXPEDITED (15-DAY)		HO	CA-ROCHE-2506976		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone	Actemra			S	Unknown			Not Reported

Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228584	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228792	EXPEDITED (15-DAY)		OT	FR-SA-2019SA325453		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S		1 Df, Qd		Sanofi
	Lovenox			S				Sanofi
	Doliprane			S				Not Reported
	Prednisone			S		1 Df, Qd		Not Reported
	Aspegic (Acetylsalicylate Lysine)			S				Not Reported
	Pentoxifylline			S		1 Df, Qd		Sanofi
	Kardegic			S				Not Reported
	Gestarelle G			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230242	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1125335		10 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; End Stage Renal Disease; Product Use In Unapproved Indication; Proteinuria	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230243	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164140			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug	Meloxicam			S	Oral			Teva

Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Oral			Barr
	Methotrexate	S	Oral			Barr
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Mobicox	S	Oral	7.5 Milligram Daily;		Not Reported
	Sulfasalazine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230289	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056807			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Cimzia			S		200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S		200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Sulfasalazine			S		500 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S		1000 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Oral	Dose: 5 (Unit Not Reported)		Not Reported
	Hydroxychloroquine			S		400 Unk		Not Reported
	Hydroxychloroquine			S		200 Milligram, Once Daily (Qd)		Not Reported
	Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Leflunomide			S		10 Milligram, Once Daily (Qd)		Not Reported

	Depo-Medrol	C	Unk	Not Reported
	Pantoprazole	C	40 Milligram, Once Daily (Qd)	Not Reported
	Arava	C	10 Mg Qd (1 Od Alternating With 2 Od)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163226			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	30 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230891	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1162628			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate		S	Subcutaneous	Barr
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	11456894	EXPEDITED (15-DAY)		OT	CA-ROCHE-1625944		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	13258161	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895864		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	14172505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2016940			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Qwk, Ongoing: Yes		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]				
	Folic Acid	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	14789014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	15048757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2141860		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity	Actemra			S	Unknown			Not Reported

Contracture; Nausea; Psoriasis; Pustular Psoriasis; Scar; Vomiting	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Cymbalta	C		Not Reported
	Hydromorphone	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17056992	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-074171		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Atorvastatin			S	Oral	40 Milligram, Once A Day		Not Reported
	Doxycycline			S	Oral	200 Milligram, Once A Day		Not Reported
	Metronidazole			S	Oral	1500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Tavanic			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Clopidogrel			C	Oral	75 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported

Fluconazole	C	Oral	200 Milligram, Once A Day	Not Reported
Lansoprazole	C	Oral	15 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233154	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511724		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511749			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Desoximetasone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233165	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509847		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233169	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown				Not Reported
	Rituxan			S	Intravenous drip				Not Reported
	Rituxan			S	Intravenous drip				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Arava			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Simponi			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233179	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509855		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Leflunomide		C	Unknown		Not Reported
					Methotrexate		C	Unknown		Not Reported
					Methotrexate		C	Subcutaneous		Not Reported
					Xeljanz		C	Oral		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**		**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
04-Jan-2020	17233191	EXPEDITED (15-DAY)		OT		CA-ROCHE-2508660		54 YR	Female	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**		**Duration**	**Mfr**	
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Somnolence; Visual Impairment	Actemra			S	Unknown				Not Reported	
	Rituxan			S	Intravenous drip				Not Reported	
	Acetaminophen			S	Unknown				Not Reported	
	Apo-Acetaminophen			S	Unknown				Not Reported	
	Apo-Leflunomide			S	Unknown				Not Reported	
	Arava			S	Oral				Not Reported	
	Cimzia			S	Subcutaneous				Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 823.0			Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 823.0			Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 823.0			Not Reported	
	Humira			S	Subcutaneous				Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported	
	Leflunomide			S	Oral	Therapy Duration:			Not Reported	
	Orencia			S	Unknown				Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)				Not Reported	
	Simponi			S	Subcutaneous				Not Reported	
	Sulfasalazine			S	Oral	Therapy Duration: 6.0			Not Reported	

							Months		
			Tylenol		S	Unknown			Not Reported
			Celebrex		C	Unknown			Not Reported
			Hydromorphone Hydrochloride		C	Unknown			Not Reported
			Meloxicam		C	Unknown			Not Reported
			Methotrexate		C	Unknown			Not Reported
			Synthroid		C	Unknown			Not Reported
			Tylenol W/Codeine No. 3		C	Unknown			Not Reported
			Xeljanz		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508100		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Erythematosus	Arava		S	Unknown		Not Reported
	Cetirizine		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

					Orencia	S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole	S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
					Prednisone	S	Unknown		Not Reported
					Prednisone	S	Unknown		Not Reported
					Remicade	S	Unknown		Not Reported
					Arava	S	Unknown		Not Reported
					Simponi	S	Subcutaneous		Not Reported
					Sulfasalazine	S	Oral		Not Reported
					Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511034			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

		Phthalylsulfathiazole			S	Unknown				Not Reported
		Prednisone			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512674		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Cimzia	C	Unknown	Single-Use Prefilled Syringe		Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233236	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Intracavernous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi				S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233326	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508699		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508709		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Phenylephrine Hcl			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown	Powder		Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Tofacitinib			S	Unknown	Not Reported
	Celebrex			C	Oral	Not Reported
	Ibuprofen			C	Oral	Not Reported
	Lipitor			C	Oral	Not Reported
	Prednisone			C		Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509589		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508677		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Leflunomide		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Remicade		S	Unknown		Not Reported
					Simponi		S	Unknown		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Folic Acid		C	Unknown		Not Reported
					Pantoprazole Magnesium		C	Unknown		Not Reported
					Tenofovir Disoproxil Fumarate		C	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported
					Zopiclone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233657	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163213		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Infection	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233658	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163218		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic;	Methotrexate			S	Unknown			Barr

Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Orencia	S	Unknown			Not Reported
	Ammonium Chloride/Guaifenesin/ Sulfamethoxazole/Tri Methoprim	C	Unknown			Not Reported
	Celebrex	C	Unknown	400 Milligram Daily;		Not Reported
	Septra	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233660	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163209		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Oral	20 Mg, 1 Every 2 Week		Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Haemophilus Influenzae Vaccine			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

	Prevnar 13		C	Intramuscular	Not Reported
	Tetanus Vaccine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233661	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163211		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown	15 Milligram Daily;		Not Reported
	Pregabalin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233662	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163222		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	12913291	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092198		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Oral	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	100 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	30 Milligram, Qd	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Cortisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	14702522	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012689		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Contraindicated Product Administered; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported

		Prednisone			C	Intravenous (not otherwise specified)	Unk			Not Reported
		Gold			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	14967529	EXPEDITED (15-DAY)		OT	PHHY2018ES012236		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	15879970	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019001966		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S		5 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S				Not Reported
	Myochrysine			S	Intramuscular	Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C		Solution		Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Otezla			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Salazopyrin			S				Not Reported

	Simponi	S		Solution Subcutaneous		Not Reported
	Sirukumab	S				Not Reported
	Sulfasalazine	S				Not Reported
	Ustekinumab	S				Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	15920789	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1007712			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17109182	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144885		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr

	Arava			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Allopurinol			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17180492	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1124088			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Nasopharyngitis; Oedema Peripheral; Pulmonary Hypertension	Ambrisentan			S	Unknown	Unk		Not Reported
	Ambrisentan			S	Unknown	30 Milligram, Qd		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Omeprazole			S	Oral	2 Df, Qd (1 Df, Bid, 1-0-1)		Not Reported
	Pregabalin			S	Unknown	3 Df, Qd (1 Df, Tid 1-1-1)		Not Reported
	Ramipril			S	Oral	2 Df, Qd (1 Df, Bid 1-0-1)		Mylan
	Eliquis			S	Unknown	2 Df, Qd (1 Df, Bid1-0-1)		Mylan
	Spasmolyt			S	Unknown	1 Df (15 Unknown Unit), Qd (1-0-0)		Mylan
	Spasmolyt			S	Unknown	30 Milligram, Qd(0-0-1)		Mylan
	Quensyl			S	Unknown	2 Df, Qd (1 Df, Bid)		Mylan
	Roactemra			S	Unknown	162 Milligram, Qw		Mylan
	Volibris			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17211642	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121744		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Meningioma	Coumadine			S	Oral	Unk		Bristol Myers Squibb

	Tahor	S	Oral	1 Dosage Form,Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram		Not Reported
	Anastrozole	S	Oral	1 Milligram, Daily		Not Reported
	Kardegic	S	Oral	1 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233785	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Oral			Not Reported
	Ramipril			S	Oral			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233788	EXPEDITED (15-DAY)		HO	FR-ACCORD-168358		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Palpitations	Escitalopram			S	Oral			Not Reported

	Plaquenil			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508676		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported

Visual Impairment	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen;Codeine Phosphate	C			Not Reported
	Celecoxib	C			Not Reported
	Hydromorphone Hcl	C			Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C			Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512608			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17234000	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508679		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

Peripheral Swelling	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Prednisone		S	Oral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511664		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509498			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235219	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235314	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235532	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506836		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Stenosis; Synovitis	Methotrexate			S	Oral	Not Reported
	Methotrexate			S	Oral	Not Reported
	Methotrexate			S	Oral	Not Reported
	Orencia			S	Unknown	Not Reported
	Actemra			S	Unknown	Not Reported
	Xeljanz			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508702		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235588	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508691		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

					Orencia		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Xeljanz		C	Oral		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
06-Jan-2020	17235892	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508007			Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Abdominal Discomfort; Alopecia; Glossodynia; Hand Deformity; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported		
	Rituxan			S	Intravenous drip			Not Reported		
	Arava			S	Unknown			Not Reported		
	Cimzia			S	Subcutaneous			Not Reported		
	Cortisone Acetate			S	Unknown			Not Reported		
	Enbrel			S	Subcutaneous			Not Reported		
	Folic Acid			S	Unknown			Not Reported		
	Fosamax			S	Unknown			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Hydroxychloroquine			S	Unknown			Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported		
	Methotrexate			S	Unknown			Not Reported		
	Orencia			S	Intravenous (not otherwise specified)			Not Reported		
	Phthalylsulfathiazole			S	Unknown			Not Reported		
	Prednisone			S	Unknown			Not Reported		
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported		
	Remicade			S	Intravenous (not otherwise specified)			Not Reported		
	Simponi			S	Subcutaneous			Not Reported		

	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236015	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2019-11056		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Rituximab			S	Unknown	375 Milligram/Sq. Meter		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236298	EXPEDITED (15-DAY)		HO	CA-ROCHE-2507985		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Myochrysine		S	Intramuscular	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous drip	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509500		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236356	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019562029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension; Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236467	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019563220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Impaired Work Ability; Nausea;	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Azathioprine		S	Unknown	Unk				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236760	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020001489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17237888	EXPEDITED (15-DAY)		CA, DE, OT	FR-MYLANLABS-2020M1001681			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	20 Milligram, Qd		Not Reported
	Imurel /00001501/			S	Transplacental	150 Milligram, Qd		Mylan
	Diffu K			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Mylan
	Plaquenil /00072603/			S	Transplacental	400 Milligram, Once Daily (Qd)		Mylan
	Cortancyl			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238309	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-40415		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unknown, Solution Subcutaneous		Not Reported
	Xeljanz	S	Unknown			Not Reported
	Lyrica	S	Unknown			Not Reported
	Nexium	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Suphedrine	C	Unknown			Not Reported
	Trazodone	C	Unknown			Not Reported
	Tylenol	C	Unknown			Not Reported
	Tylenol Extra Strength	C	Unknown	Unknown		Not Reported
	Valsartan	C	Unknown	Unknown		Not Reported
	Wellbutrin	C	Unknown	Extended Release		Not Reported
	Esomeprazole	C	Unknown			Not Reported
	Lumigan Rc	C	Ophthalmic	Solution Opthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238416	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported

Therapeutic Response Decreased	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;		Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238449	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163202			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Leflunomide			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238450	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163845			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown			Not Reported
	Acetaminophen	C	Oral			Not Reported
	Diphenhydramine	C	Oral			Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported
	Methylprednisolone	C	Unknown			Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238453	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163189		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Pain In Extremity; Peripheral Swelling; Psoriasis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238591	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S	Unknown	100 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not			Not Reported

				otherwise specified)		
	Plaquenil		S	Unknown	100 Milligram Daily;	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	66.6667 Milligram Daily;	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	66.6667 Milligram Daily;	Not Reported
	Glyburide		C		750 Milligram Daily;	Not Reported
	Infliximab		C			Not Reported
	Lipitor		C		10 Milligram Daily;	Not Reported
	Metformin		C	Oral		Not Reported
	Mycophenolate Mofetil		C	Oral	1500 Milligram Daily;	Not Reported
	Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238593	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1163798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238598	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1163175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Oral			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238601	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162744		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238639	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1163342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Disability; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C		25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238646	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163849			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17239456	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163976		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Low Density Lipoprotein Decreased	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17239457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163894		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease; Off Label Use	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown	2000 Milligram Daily;		Not Reported
Xeljanz	S	Unknown			Not Reported
Acetaminophen	C	Unknown			Not Reported
Acetaminophen	C	Unknown	3000 Milligram Daily;		Not Reported
Esomeprazole	C	Unknown	40 Milligram Daily;		Not Reported
Esomeprazole	C	Unknown			Not Reported
Lumigan Rc	C	Ophthalmic			Not Reported
Suphedrine [Pseudoephedrine Hydrochlroiide]	C	Unknown	10 Milligram Daily;		Not Reported
Trazodone	C	Unknown	200 Milligram Daily;		Not Reported
Valsartan	C	Unknown			Not Reported
Valsartan	C	Unknown			Not Reported
Wellbutrin Xl	C	Unknown	300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17239894	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-000573		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	13965727	EXPEDITED (15-DAY)		OT	CA-SA-2017SA153945		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Spinal Column Injury; Treatment Failure	Arava	S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil	S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate	S		25 Mg		Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel	S	Unknown	Unk Unk,Unk		Not Reported
	Actemra	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Unknown	Unk Unk,Unk		Not Reported
	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan	S	Unknown	Unk Unk,Unk		Not Reported
	Mobicox	C	Unknown	15 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	15044843	EXPEDITED (15-DAY)		DS	CA-ROCHE-2141913		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	15411424	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186685		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Knee Arthroplasty; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	16044441	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1019965		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst;	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr

Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous	1 Every 1 Week .	Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Apo-Gabapentin	S	Oral	200 Milligram Daily;	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	D-Alpha Tocopherol	C	Unknown	2400 Milligram Daily;	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	80 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C		80 Milligram Daily;	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram Daily;	Not Reported
	Nasonex	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Oral		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported

	Trazodone Hydrochloride	C		50 Milligram Daily;	Not Reported
	Tylenol	C	Oral	1000 Milligram Daily;	Not Reported
	Acetaminophen/Oxycodone Hydrochloride	C	Unknown		Not Reported
	Nexium	C	Unknown	80 Milligram Daily;	Not Reported
	Acetaminophen	C		1000 Milligram Daily;	Not Reported
	Cholecalciferol	C			Not Reported
	Ergocalciferol	C			Not Reported
	Loperamide Hydrochloride	C			Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C		40 Milligram Daily;	Not Reported
	Perphenazine	C			Not Reported
	Vitamin A Nos	C			Not Reported
	Vitamin B12 [Vitamin B12 Nos]	C			Not Reported
	Xeljanz	C			Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Biotin	C	Unknown		Not Reported
	Nicotinamide	C	Unknown		Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	2400 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	16905796	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1119247		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Ibuprofen			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported

	Orencia	S	Unknown			Not Reported
	Plaquenil	S	Oral	200 Milligram Daily;		Not Reported
	Apo-Ibuprofen	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17113218	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2019-07084		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17169953	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018240373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Methotrexate			S	Intra-arterial	25 Mg, We		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Orencia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
	Simponi	S	Subcutaneous	Unk, (Solution Subcutaneous)	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510350		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240062	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510377		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240102	EXPEDITED (15-DAY)		OT	GB-ROCHE-2508910		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Rituximab			S	Unknown	2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240244	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510375		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Cephalexin [Cefalexin]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240263	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514006		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Surgical Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Mobicox	C	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240300	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511123		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510457		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Pain; Pruritus; Rash; Swelling	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240306	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510878		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240490	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511744			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511665		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509567			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Enbrel		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0050		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Piroxicam	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240543	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0030			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240552	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Lyrica			S	Oral	Strength: 150 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510400		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240620	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510405		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240631	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509940		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Rituxan			S	Intravenous drip				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240721	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510456		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C				Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240743	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510832		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240989	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Hydroxychloroquine		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Prednisone		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514037		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241073	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510474			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241149	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Neoplasm Malignant;	Leflunomide			S	Oral	Unk		Apotex

Pneumonia; Rheumatoid Arthritis	Plaquenil /00072602/		S	Oral	Unk			Not Reported
	Methotrexate		C	Unknown	Unk			Not Reported
	Ramipril		C	Unknown	Unk			Not Reported
	Sulfasalazine		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241338	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241353	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1163471		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Mg 1 Days		Teva
	Tahor 10 Mg, Comprimé Pelliculé			S	Oral	1 Dosage Forms 1 Days		Not Reported

	Plaquenil	S	Oral	400 Mg		Not Reported
	Coumadine	S	Oral			Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	S	Oral	1 Dosage Forms 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241408	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Malaise; Nausea; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241549	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026898			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241602	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748892		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

			Hydroxychloroquine		S	Unknown				Not Reported
			Hydroxychloroquine		S	Unknown				Not Reported
			Celebrex		C	Unknown				Not Reported
			Cimzia		C	Subcutaneous				Not Reported
			Folic Acid		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241664	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510470		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241691	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241712	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020001495		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Actemra			S	Unknown	776 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	400 Mg, Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	775 Mg, Monthly		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510455		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510421		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported

Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Arava	S	Oral			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	5.0 Years		Not Reported
	Tylenol	S	Unknown			Not Reported
	Acetaminophen	S	Unknown			Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Celebrex	C	Oral			Not Reported
	Codeine Phosphate	C				Not Reported
	Hydromorph	C				Not Reported
	Meloxicam	C				Not Reported
	Methotrexate	C	Unknown			Not Reported
	Synthroid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510911		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity;	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Treatment Failure	Methotrexate			S	Oral	Not Reported
	Prednisone			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511098		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17242165	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511669		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Desoximetasone		C		Not Reported
	Orencia		C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17242283	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1001068		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Pericarditis; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243342	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509949		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511074		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

		Rosuvastatin Calcium			C	Unknown				Not Reported
		Asa			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243406	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1164535			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243494	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020US001592		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Ventricular Tachyarrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	36 G		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243976	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17244090	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000011			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Pentoxifylline			S	Unknown	1 Df, Qd		Validus
	Plaquenil /00072603/			S	Unknown	1 Df, Qd		Not Reported
	Lovenox			S	Unknown	Unk		Not Reported
	Doliprane			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	1 Df, Qd		Not Reported
	Aspegic /00002703/			S	Unknown	Unk		Not Reported
	Kardegic			S	Unknown	Unk		Not Reported
	Gestarelle G			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	11964612	EXPEDITED (15-DAY)		HO	CA-ROCHE-1700523		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Abnormal; Liver Function Test Increased; Pharyngeal Oedema; Rash; Rheumatoid Arthritis; Swelling; Wheezing	Rituxan	S	Intravenous (not otherwise specified)	Dose: Single		Not Reported
	Arava	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Dose: Single		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 3 Months		Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 2 Months		Not Reported
	Xeljanz	C	Unknown			Not Reported
	Simponi	C				Not Reported
	Enbrel	C				Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	13457469	EXPEDITED (15-DAY)		OT	CA-SA-2017SA067786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonitis; Pneumothorax	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Naproxen			C	Oral	500 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	13851389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	14501692	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased; Treatment Failure; Weight Decreased	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Codeine	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Milligram,2every One Days		Not Reported
	Rituximab	S	Endocervical			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	14827888	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2110529		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Month(S)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	6.0 Months		Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duaration: 3months		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other		Not Reported
	Adalimumab	S	Subcutaneous	Therapy Duration: 3.0 Months	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	15251729	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1059141		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conduction Disorder; Electrocardiogram Qt Prolonged; Hyperkalaemia; Hypokalaemia; Mental Status Changes; Overdose; Qrs Axis Abnormal; Sinus Tachycardia; Toxicity To Various Agents; Ventricular Tachyarrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	36 Gram, Total		Not Reported
	Potassium Chloride			S	Unknown	Total 200meq In First 12h...		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	15942221	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010010		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	16742586	EXPEDITED (15-DAY)		HO, LT, OT	CA-SHIRE-CA201927387			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea;	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, 2x/Day:Bid		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 1x/Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Obesity; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Hydroxychloroquine		S	Oral	5 Dosage Form, 1x/Day:Qd	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, 1x/Week	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone		S	Intra-articular	Unk	Not Reported
	Triamcinolone		S	Unknown	Unk	Not Reported
	Folic Acid		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17003781	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported

Therapy Non-Responder; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Phenylephrine Hydrochloride	S	Unknown		Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Borate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram, 2 Times/Wk	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5 Milligram, 2 Times/Wk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Celebrex	C	Oral	400 Milligram	Not Reported
	Ibuprofen	C	Oral	400 Milligram	Not Reported
	Lipitor	C	Oral	10 Milligram, Qd	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17202372	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis; Therapeutic Response	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk [15-25 Mg Unknown]		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

Decreased	Sulfasalazine	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk		Sanofi
	Prednisone	C	Unknown	Unk [7 To 20 Mg Unknown]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17219859	NON-EXPEDITED			US-SA-2019SA359498		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypersensitivity	Arava			S		Unk		Sanofi
	Zolpidem Tartrate			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510478		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 411.0		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)				
	Prednisone			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244870	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-201912003259			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	1 Dosage Form, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Unknown	Unk		Not Reported
	Doliprane			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	1 Dosage Form, Qd		Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Unknown	Unk		Not Reported
	Pentoxifylline			S	Unknown	1 Dosage Form, Qd		Not Reported
	Kardegic			S	Unknown	Unk		Not Reported
	Gestarelle G			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244984	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension; Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Plaquenil		S	Unknown		Not Reported
	Desoximetasone		C	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244990	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0113			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Impaired Work Ability; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245044	EXPEDITED (15-DAY)		LT	CA-ROCHE-2514896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Sarilumab		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Rabeprazole Sodium		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245069	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511680		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511722		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511755		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245189	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2509930		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245190	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511768		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245434	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000172		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac Sodium;Misoprostol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Misoprostol			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Two Times		Not Reported

							A Day			
		Etanercept		S	Unknown	Unk				Not Reported
		Amitriptyline		S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245449	EXPEDITED (15-DAY)		HO	CA-ROCHE-2512660			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245485	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000462		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Pregabalin	S	Unknown	Unk	Not Reported
	Pregabalin Capsules	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Aurobindo
	Celecoxib Capsules	S	Unknown	Unk	Aurobindo
	Actemra	S	Unknown	Unk	Not Reported
	Allopurinol	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
	Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Diclo	S	Unknown	Unk	Not Reported
	Apo-Diclofenac	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported

Etanercept	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750.0 Milligram, Every Week	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tofacitinib	C	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5.0 Milligram, Two Times A Day	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported

	Methotrexate			S	Oral	Unk			Not Reported
	Methotrexate			S	Parenteral	Unk			Not Reported
	Methotrexate			S	Parenteral	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245509	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Large Intestine Infection	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245516	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pneumonia	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245517	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1165138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245541	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164973		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512065		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245628	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512043		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
		Remicade			S	Unknown				Not Reported
		Mobicox			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245650	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512672			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Mobicox			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512708		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513979		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245713	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

Abnormal; C-Reactive Protein Increased; Colitis; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Baclofen	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	1.0 Dosage Forms	Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Zingiber Officinale	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512027		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure	Rituxan	S	Intravenous drip	Solution Intravenous		Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous		Not Reported
	Mobicox	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245972	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246044	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512673		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel		S	Subcutaneous	Not Reported
	Methotrexate		S	Intramuscular	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Naprosyn [Naproxen]		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512664		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246300	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020004661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246348	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020005080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly (1 Every 1 Week)		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (1 Every 12 Hours)		Pfizer
	Arava			S	Oral	10 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Naproxen			S	Oral	500 Mg, 2x/Day (1 Every 12 Hours)		Not Reported
	Prednisone			S	Oral	Unk Unk, 1x/Day (1 Every 1 Day)		Not Reported
	Prednisone			S	Subcutaneous	1.5 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly (1 Every 1 Month)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246360	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020006788			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Ibuprofen			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246564	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511565		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246962	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514284		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Nasonex	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Zoledronic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17247295	EXPEDITED (15-DAY)		OT	CA-SA-2020SA001532			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Bisoprolol Sandoz			C		Unk		Not Reported
	Jamp Calcium			C		Unk		Not Reported
	Teva Risedronate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17247679	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248175	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alopecia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Retinopathy; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prolia Pre-Filled Syringe. Preservative-Free			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248198	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165208		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248417	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-001028		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported

	Sulfasalazine			S	Unknown	500 Milligram	Not Reported
	Sulfasalazine			S	Unknown		Not Reported
	Xeljanz			S	Oral	1 Dosage Form, Q12h	Not Reported
	Lyrica			C	Unknown		Not Reported
	Rituximab			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248461	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163861		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported

Desoximetasone	C	Oral	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc[Pantoprazole]	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Rituximab	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248462	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164590		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported

Stiffness; Therapeutic Product Effect Incomplete	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164432		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease; Off Label Use	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Enbrel			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248472	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164434		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Off Label Use; Rheumatoid Arthritis; Synovitis; Underdose; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165217		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248791	EXPEDITED (15-DAY)		OT	CA-SA-2019SA355104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S		15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Sanofi
	Humira			S		Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17249211	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020004595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1 Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	13519793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038272		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Not Reported
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Mg, Unk		Not Reported

						Methotrexate		S	Intravenous (not otherwise specified)	Not Reported
						Acetylsalicylic Acid		C	Unknown	Not Reported
						Lantus		C	Subcutaneous	Not Reported
						Lozide [Indapamide]		C	Unknown	Not Reported
						Metformin		C	Unknown	Not Reported
						Naproxen		C	Unknown	Not Reported
						Prednisone		C	Unknown	Not Reported
						Ramipril		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	15651367	NON-EXPEDITED		OT	US-SA-2018SA038094			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Paraesthesia; Rash; Rash; Rheumatoid Arthritis; Swelling Of Eyelid	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S				Not Reported
	Actemra			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Xeljanz			C	Oral	11 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	16185568	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine	S	Unknown	Unk, Unknown	Apotex
	Azathioprine	S	Unknown	Unk Unk, Unknown	Apotex
	Cyclosporine	S	Unknown	Unk	Apotex
	Cyclosporine	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk, Unknown	Apotex
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Apotex
	Esomeprazole	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Sarilumab	S	Subcutaneous	20 Mg, One Every Two Weeks	Not Reported
	Sarilumab	S	Unknown	20 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Nicotinamide	S	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	0.5 Mg, Bid	Not Reported
	Esomeprazole Sodium	S	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	400 Mg, Qd	Not Reported
	Magnesium	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Nexium /01479302/	C	Unknown	Unk	Not Reported

				Dexpanthenol		C	Unknown	Unk		Not Reported
				Riboflavin		C	Unknown	Unk		Not Reported
				Vitamin A /00056001/		C	Unknown	Unk		Not Reported
				Vitamin C /00008001/		C	Unknown	Unk		Not Reported
				Adalimumab		C				Not Reported
				Xeljanz		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	16671603	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077101		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris			S	Unknown			Not Reported

Ilaris	S	Subcutaneous		Not Reported
Ilaris	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Rituximab	C	Unknown		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	16835922	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110159		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Cephalexin			S	Unknown			Not Reported
	Cephalexin			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Teva
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin Hydrochloride			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Teva
	Hctz			S	Unknown			Ivax
	Hctz			S	Unknown			Ivax
	Losartan Potassium			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Metoprolol Tartrate			S	Unknown			Not Reported
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Penicillin G			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Biaxin			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydralazine Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Pariet			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Phosphate	S	Unknown			Not Reported
	Cipro[Ciprofloxacin]	C				Not Reported
	Esomeprazole	C				Not Reported
	Gold	C				Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported
	Iron Sucrose	C				Not Reported
	Prednisone	C	Unknown	8.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17075620	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025078			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk (1 Every 4 Weeks)		Not Reported
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Oral	Unk, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Infliximab			S	Intravenous (not	300 Mg, Q.Wk.		Not Reported

				otherwise specified)		
	Lyrica		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Piroxicam		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Rabeprazole Sodium		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250084	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250121	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516277		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250254	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020004653		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate Sodium			S	Unknown			Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250391	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP026966		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Prednisone			S	Unknown	95 Mg, Qd		Not Reported
	Prednisone			S	Unknown	85 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd, 9 To 10 Mg		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd, 10 To 12 Mg		Not Reported
	Prednisone			S	Unknown	13 Mg, Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Apotex
	Lithium Carbonate			S	Unknown	Unk		Apotex
	Memantine			S	Unknown	Unk		Apotex
	Clonidine			S	Unknown	Unk		Apotex
	Mycophenolate			S	Unknown	Unk		Apotex
	Montelukast			S	Unknown	Unk		Apotex
	Cimetidine			S	Unknown	Unk		Apotex
	Amlodipine			S	Unknown	Unk		Apotex
	Pregabalin			S	Unknown	Unk		Apotex
	Diltiazem			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Naltrexone			S	Unknown	4.5 Mg, Qd		Apotex
	Pentoxifylline			S	Unknown	Unk		Apotex
	Calcitonin			C	Unknown	Unk		Not Reported
	Ketamine			S	Oral	Unk		Not Reported
	Ketamine			S	Topical	Unk		Not Reported
	Ketamine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lidocaine			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Lidocaine	S	Topical	Unk	Not Reported
	Apremilast	S	Unknown	Unk	Not Reported
	Ibudilast	S	Unknown	Unk	Not Reported
	Mexiletine	S	Unknown	Unk	Not Reported
	Metprolol	S	Unknown	Unk	Not Reported
	Magnesium	S	Unknown	Unk	Not Reported
	Magnesium	S			Not Reported
	Vitamin B2 /00154901/	S	Unknown	Unk	Not Reported
	Vitamin B2 /00154901/	S			Not Reported
	Capsaicin	S	Topical	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Palmitoylethanolamide	S	Unknown	Unk	Not Reported
	Spironolactone	S	Unknown	Unk	Not Reported
	Vitamin C /00008001/	S	Unknown	Unk (High Dose)	Not Reported
	N-Acetylcysteine	S	Unknown	Unk	Not Reported
	Bumetanide	S	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Ezetimibe	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514003		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Potassium Chloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250524	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514001		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis	Methotrexate		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Arava		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514002		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251488	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511663		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Arava	C	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251490	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514005		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Tongue Ulceration; Tooth Infection	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Indometacin			C		Not Reported
	Prednisone			C		Not Reported
	Tramadol			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251781	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165582		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Oxyneo			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported

	Synthroid	C	Unknown		Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251783	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512563		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Gabapentin		C	Oral	Not Reported
	Tylenol		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251931	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512671		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Duration 3 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Duration 2 Months		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Duration 9 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Duration 3.0 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous Duration 12.0		Not Reported

				Months	
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Duration 3.0 Years	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral	Duration 3.0 Months	Not Reported
	Xeljanz	S	Oral	Duration 2.0 Months	Not Reported
	Acetaminophen	C			Not Reported
	Cortisone	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251936	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512675		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Baclofen			C				Not Reported

	Dorzolamide Hydrochloride/Timolol Maleate	C				Not Reported
	Estradiol	C				Not Reported
	Furosemide	C				Not Reported
	Levaquin	C				Not Reported
	Valsartan	C				Not Reported
	Xalatan	C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513965		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17252075	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling;	Mobicox			S	Oral			Boehringer Ingelheim
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous	Not Reported
	Arava			S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Not Reported
	Sulfasalazine			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17252322	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17252555	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020003020		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia;	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported

Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium	S	Unknown	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, Daily	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	9 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil S	S	Unknown	200 Mg, Daily	Not Reported
	Prednisone	S	Unknown	9 Mg, Daily	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Acetaminophen	C			Not Reported
	Cortisone [Hydrocortisone]	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253190	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253512	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165601		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253532	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2020-CA-1165259			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253796	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165576		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17255036	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-000256		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Leflunomide	S	Unknown	1 Dosage Form, Qd	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram, Qd	Not Reported
	Tramacet	S	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
	Lyrica	C	Oral	150 Milligram, Bid	Not Reported
	Metformin	C	Unknown	500 Milligram, Bid	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17255133	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-40661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown	Unknown		Not Reported
	Cimzia			C	Subcutaneous	Unknown, Solution Single Use Pre-Filled Syringe		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	13246787	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895135		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling;	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Year(S)		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported

Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Methotrexate	S	Unknown	Therapy Duration: 4.0 Month(S)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Month(S)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Month(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	16387997	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029784		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Celecoxib Capsules			S	Oral	200 Milligram, Once A Day		Aurobindo
	Levofloxacin Tablet			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Intravenous (not otherwise specified)	5 Milligram		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide Sandoz			S	Unknown	Unk		Not Reported

	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Every Week	Not Reported
	Norfloxacin	S	Unknown	400 Milligram	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Erythro Base	S	Unknown	Unk	Not Reported
	Act Diclo Miso	S	Unknown	Unk	Not Reported
	Apo-Bisoprolol	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17249853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511614		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Lyrica	C			Not Reported
Marijuana	C			Not Reported
Orencia	C	Intravenous (not otherwise specified)		Not Reported
Oxycodone	C			Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255236	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Spinal Column Injury; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Mobicox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255240	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Aluminum Acetate	C	Unknown	Not Reported
	Atacand	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Neurontin	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Benzethonium Chloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255276	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511650		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral	11.0 Years		Not Reported

Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	11.0 Months	Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	365.0	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Other		Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported

		Hydroxychloroquine Sulfate			S	Oral				Not Reported
		Naproxen			S	Oral				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Prednisone			S	Oral				Not Reported
		Prednisone			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255586	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255899	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17256065	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512850		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17256371	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Mobicox			S	Unknown			Boehringer Ingelheim
	Desoximetasone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Rabeprazole			S	Unknown				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17256772	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA006430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Plaquenil			S	Unknown	400.0 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown	2.0 G, Qd		Not Reported
	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17257640	EXPEDITED (15-DAY)		DE, HO	CN-PFIZER INC-2019529537		10 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Emphysema; Pneumothorax; Respiratory Failure	Methylprednisolone			S		20 Mg/Kg, Daily		Pfizer
	Methylprednisolone			S	Oral	1.5 Mg/Kg, Daily		Pfizer
	Methylprednisolone			S		20 Mg/Kg, Daily		Pfizer
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Unk(1.5 G/Kg)		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Unk(1.5 G/Kg), Given Again		Not Reported
	Cyclophosphamide			S		800 Mg/M2, Unk(Once As Pulse Therapy)		Not Reported
	Cyclophosphamide			S		800 Mg/M2, Unk(Once As		Not Reported

				Pulse Therapy)Given Again	
	Cyclophosphamide	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17258069	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020006663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17258667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513921			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17258769	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514032		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Hexacetonide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259010	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514924		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259029	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514965		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

		Remicade			S	Unknown				Not Reported
		Sulfasalazine			S	Oral				Not Reported
		Varicella-Zoster Immune Globulin			S	Intramuscular	Liquid Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259035	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514945		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259074	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516351			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514951		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Oral	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Oral	Not Reported
	Rho D Immune Globulin			S	Unknown	Not Reported
	Celebrex			C	Oral	Not Reported
	Ibuprofen			C		Not Reported
	Lipitor			C	Oral	Not Reported
	Prednisone			C	Oral	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259084	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516522			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516344		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Vaginal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259114	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516942		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259151	EXPEDITED (15-DAY)		HO	CA-ROCHE-2517059		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Oxycontin			S	Unknown	Tablet (Extended Release)		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actonel			C	Unknown			Not Reported
	Diphenoxylate Hcl			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517578		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517516		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517598		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Vomiting	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Anakinra		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259408	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518767		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Lyrica		C	Oral	Not Reported
	Marijuana		C	Unknown	Not Reported
	Orencia		C	Unknown	Not Reported
	Oxycodone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	14467684	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous	50 Mg, One Every One Month		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	15433577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189361			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514963		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Prednisone			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513906		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259841	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2514039		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Actemra			S	Unknown			Not Reported

Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Rituxan	S	Intravenous (not otherwise specified)	Solution For Infusion	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Ilaris	S	Subcutaneous	Single Use Vial: Powder For Solution Subcutaneous	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Unknown	Solution For Infusion	Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259873	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516209			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporosis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259883	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518729		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Acetaminophen		C	Unknown	Not Reported
	Gabapentin		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260299	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

						Prednisone		S	Unknown	Not Reported
						Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
						Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
						Remicade		S	Intravenous bolus	Not Reported
						Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260300	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516095			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260301	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516323		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
		Orencia			C	Intravenous (not otherwise specified)				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517545		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260314	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518102		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516342		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance;	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Prednisolone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	12321013	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745426		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Knee	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound			otherwise specified)	
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	13133034	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882218		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	15719920	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-05			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	16213099	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019155494		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	2 G, Daily		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily (Die)		Not Reported

Hydroxychloroquine	S	400 Mg, Daily (Die)	Not Reported
Actemra	S	Unk	Not Reported
Orencia	S	125 Mg, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	16341561	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-027460		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Pantoprazole			S	Oral	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril			S	Unknown	Unk		Aurobindo
	Lisinopril			S	Unknown	Unk		Aurobindo
	Tecta			S	Oral	Unk		Not Reported
	Diclofenac			S	Oral	75 Milligram, As Required		Not Reported
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	1 Dosage Form		Not Reported
	Diclofenac			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	200 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported

Sulfasalazine	S	Unknown	500 Milligram, Once A Day	Not Reported
Sulfasalazine	S	Oral	2 Gram, Once A Day	Not Reported
Synthroid	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	2 Dosage Form, Once A Day	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Voltaren Sr	S	Oral	75 Milligram, Two Times A Day	Not Reported
Voltaren Sr	S	Oral	Unk	Not Reported
Voltaren Sr	S	Unknown	Unk	Not Reported
Cambia	S	Oral	2 Dosage Form, Once A Day	Not Reported
Cambia	S	Oral	1 Dosage Form	Not Reported
Cambia	S	Oral	75 Milligram, Two Times A Day	Not Reported
Plaquenil	S	Oral	1 Dosage Form, Once A Day	Not Reported
Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	1 Dosage Form, Every Week	Not Reported
Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
Apo-Lisinopril	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	16437198	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-031295		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aortic Aneurysm; Drug Ineffective; Drug Resistance; Hiccups; Retinal Toxicity	Amoxicillin	S	Unknown	3 Gram, Once A Day		Aurobindo
	Amoxicillin	S				Aurobindo
	Clarithromycin	S	Unknown	1 Gram, Once A Day		Aurobindo
	Doxycycline	S	Unknown	200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine	S	Unknown	600 Milligram, Once A Day		Not Reported
	Levofloxacin	S	Unknown	500 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260543	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000130			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Osteoporosis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260565	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Oral	Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qow		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Sanofi
	Methotrexate			C	Oral	20 Mg, Qw		Not Reported
	Tocilizumab			C	Subcutaneous	162 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512569		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	4.0 Years		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	4.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Intravenous (not otherwise specified)	Not Reported
	Imuran [Azathioprine]	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515349		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260663	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006346			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk, Unk		Sanofi
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260698	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Codeine			C				Not Reported

		Meloxicam			C					Not Reported
		Methotrexate			C	Unknown				Not Reported
		Synthroid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260722	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260783	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514954		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C				Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Plantago Ovata			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C	Unknown	Vaginal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260826	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0247			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260830	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260875	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Treatment Failure; Vasculitis; Vomiting	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Cimzia			S	Subcutaneous	Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260877	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Doxycycline			S	Unknown	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261050	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514891		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514953		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Penicillin G [Benzylpenicillin]			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Calcium			C		Not Reported
	Hydroxychloroquine			C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported
	Tylenol			C	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261070	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513945		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

Product Effect Decreased	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Tiaprofenic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262523	EXPEDITED (15-DAY)		DE, HO, OT	US-BAYER-2020-004172		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Dyspnoea; Hypotension; Mouth Haemorrhage; Oral Mucosal Discolouration; Oxygen Saturation Decreased; Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral	Unk		Bayer
	Hydroxychloroquine			S		6 G, Once		Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262769	EXPEDITED (15-DAY)		OT	NVSC2020DE004106			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral;	Ramipril			S	Oral	2 Df, Qd (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	3 Df, Qd (1 - 1- 1)		Not Reported

Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole		S	Oral	2 Df, Qd (1 - 0 - 1)	Novartis
	Omeprazole		S	Unknown	40 Mg, Qd	Novartis
	Sildenafil		S	Unknown	60 Mg, Qd	Not Reported
	Spasmolyt		S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt		S	Unknown	1 Df, Qd	Not Reported
	Spasmolyt		S	Unknown	15 Mg, Qd	Not Reported
	Tocilizumab		S	Subcutaneous	162 Mg, Qw	Not Reported
	Tocilizumab		S	Subcutaneous	162 Mg, Qw	Not Reported
	Ambrisentan		S	Unknown	Unk	Not Reported
	Quensyl		S	Unknown	40 Mg, Qd (1 Df, Bid (1 - 0 - 1))	Not Reported
	Quensyl		S	Unknown	40 Mg, Qd (20 Mg Bid)	Not Reported
	Volibris		S	Unknown	Unk	Not Reported
	Volibris		S			Not Reported
	Eliquis		S	Unknown	2 Df, Qd	Not Reported
	Eliquis		S	Unknown	2 Df, Qd	Not Reported
	Lyrica		C	Unknown	300 Mg, Qd (100 Mg, Tid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262892	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral			Not Reported

		Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown				Not Reported
		Sulfasalazine			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516580		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263462	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516617			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263578	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516715		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518053		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	600mg		Not Reported
	Codeine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Methylprednisolone			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen;Caffeine			C				Not Reported

	Caffeine;Codeine;Paracetamol	C		Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263658	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Pain	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263674	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2516064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17264176	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Otezla			S				Not Reported
	Simponi			S				Not Reported
	Stelara			S				Not Reported
	Xeljanz			S				Not Reported
	Cosentyx			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17264709	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020010755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Salazopyrin			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265129	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-20K-028-3223218-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Drug Reaction; Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Humira	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515435		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515486		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Actemra	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Therapy Duration: 9.0 Months	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 4.0 Years	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 4.0 Years	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Lyrica	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

	Arava	S	Oral	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265190	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00119		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Ocular Toxicity	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	12689305	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1444		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Apo Celecoxib	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	12911732	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2016GSK144075		45 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Arthropathy; Asthenia; Circumstance Or Information Capable Of Leading To Medication Error; Inappropriate Schedule Of Product Administration; Malaise; Metabolic Surgery; Nausea; Overdose; Product Dose Omission; Pyelonephritis; Sinusitis; Somnolence; Tachycardia; Tendon Rupture; Weight Decreased; Weight Loss Poor	Benlysta			S		Unk Unk, Cyc		Glaxosmithkline
	Benlysta			S		Unk, Cyc		Glaxosmithkline
	Benlysta			S		Unk, Cyc		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		820 Mg, Unk		Glaxosmithkline
	Benlysta			S		930 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline

	Benlysta	S	Unk	Glaxosmithkline
	Prednisone	S	Unk	Not Reported
	Reuquinol	S	Unk	Not Reported
	Azathioprine	C	Unk	Glaxosmithkline
	Ketoprofen Lysine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	15630696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105381		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Indometacin			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	16387992	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029849		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Subcutaneous	20 Milligram, Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	20.0 Milligram, 4 Every 1 Week		Not Reported
	Plaquenil			S	Oral	200.0 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Voltaren			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	75.0 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17050039	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137045		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Pain; Therapeutic Product Effect Decreased; Treatment Failure	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil			S	Unknown					Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17227609	EXPEDITED (15-DAY)		HO	CA-ROCHE-2415329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17258422	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-ASTRAZENECA-2020SE03451			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During	Metoprolol Tartrate			S	Transplacental	Unk		Not Reported

Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Omeprazole	S	Transplacental	Unk	Not Reported
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Bisulepin	S	Transplacental	Unk	Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S	Unknown	Unk	Not Reported
	Albumin	S	Transplacental	Unk	Not Reported
	Paracetamol	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Ornidazole	S	Transplacental	Unk	Not Reported
	Cefixime	S	Transplacental	Unk	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Vulmizolin	S	Transplacental	Unk	Not Reported

	Penicillin G [Benzylpenicillin Sodium]			S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid			S	Transplacental	Unk		Not Reported
	Vitamin D [Colecalciferol]			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516327		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515630			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265486	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000189			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Humira			S	Unknown	Unk		Not Reported

	Orencia			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265634	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0208		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil S	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Reactine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265740	EXPEDITED (15-DAY)		HO	CA-ROCHE-2518159		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Warfarin		S	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266000	EXPEDITED (15-DAY)		DS	CA-ROCHE-2516492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	365		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	365	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Prednisone	S	Oral	365.0	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Salazopyrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266020	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000206			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266022	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2020AP005966		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cyclobenzaprine			S	Oral	Unk, Unknown		Apotex
	Esomeprazole			S	Oral	Unk, Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unk, Unknown		Not Reported
	Clindamycin			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266167	NON-EXPEDITED			US-CELGENEUS-USA-20200103523		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspepsia; Eczema; Nodule; Psoriatic Arthropathy; Weight Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266374	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000210			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Methotrexate			S	Oral	25 Mg, Weekly (12.5 Mg, Two Doses In One Day, Weekly)		Not Reported
	Methotrexate			S	Unknown	Increased To 20 Mg		Not Reported
	Prevnar 13			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266811	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020010649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		10 Mg, 1x/Day		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266914	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020012778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug	Methotrexate Sodium			S	Unknown			Pfizer

Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	1 G, 2x/Day	Pfizer
	Humira		S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266960	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020013075			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Pamidronate Disodium			S	Unknown	Unk		Unknown
	Azathioprine			S	Unknown	150 Mg, 1x/Day		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Dilaudid			C		Unk		Not Reported
	Mercaptopurine			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Tenoxicam			C		Unk		Not Reported
	Ustekinumab			C	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266977	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020012790		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267074	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020015344		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Tahor			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil S			S	Oral	400 Mg, Unk		Not Reported
	Coumadine			S	Oral	Unk		Not Reported
	Anastrozole			S	Oral	1 Mg, 1x/Day		Not Reported
	Kardegic			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517549		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Imitrex [Sumatriptan]	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Sumatriptan	C	Unknown		Not Reported
	Tenormin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267572	EXPEDITED (15-DAY)		OT	NVSC2020US006167		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Dyspnoea Exertional; Orthopnoea	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17268186	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515549		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Cimzia	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17269607	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Diphenhydramine Hydrochloride			S	Unknown	Unk Unk, Unk		Sanofi
	Celecoxib			S	Oral	Unk Unk, Unk		Not Reported
	Demerol			S	Unknown	Unk Unk, Unk		Sanofi
	Levofloxacin			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S				Sanofi
	Azithromycin			S	Unknown	250 Mg		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Ezetrol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17269873	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020013014			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	15887212	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0806		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Intolerance; Synovitis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Received 3 Doses		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	16479864	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Triamcinolone Aq			S	Intra-articular	Spray, Metered Dose		Not Reported
	Apo-Triamcinolone Aq			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin Intravenous (Human)			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported

	Triamcinolone			S	Intra-articular	Unknown		Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid (Natural Factors)			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	16940157	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001250			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Certolizumab Pegol			C	Subcutaneous	200 Mg, Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17047581	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491577		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17134934	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019530204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, 1 Every 8 Week (S)		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 1 Every 2 Week(S)		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	100 Mg, 1 Every 1 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 1 Every 2 Day(S)		Not Reported
	Glyburide			C		750 Mg, 1x/Day		Not Reported
	Infliximab			C		Unk		Not Reported
	Lipitor			C		10 Mg, 1x/Day		Not Reported
	Metformin			C	Oral	Unk, 2x/Day		Not Reported
	Mycophenolate Mofetil			C	Oral	750 Mg, 2x/Day		Not Reported
	Prednisone			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17186676	EXPEDITED (15-DAY)		OT	NVSC2019CA075072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Fosamax	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17211778	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201912003172			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Unknown	15-25 Mg Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270824	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00077		24 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Dry Skin; Oral Discomfort; Pruritus; Type Iv Hypersensitivity Reaction; Urticaria	Hydroxychloroquine Sulfate	S	Unknown	0.2 Milligram In A Solution Of 0.4 Ml	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	0.4 Milligram In A Solution Of 0.8 Ml, (0.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	0.8 Milligram In A Solution Of 1.6 Ml (1 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	1.6 Milligram In A Solution Of 3.1 Ml (1.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	3.1 Milligram In A Solution Of 6.3 Ml (2.0 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	6.3 Milligram In A Solution Of 12.5 Ml (2.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	12.5 Milligram In A Solution Of 25.0 Ml (3.0 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	25.0 Milligram In A Solution Of 50 Ml (3.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	50 Milligram In A Solution Of 100 Ml (4.0 Hours)	Lupin
	Hydroxychloroquine Sulfate Tablets	S	Unknown	100 Milligram, Unk (4.5 Hours)	Lupin
	Hydroxychloroquine Sulfate Tablets	S	Unknown	100 Milligram, Unk (5 Hours)	Lupin
	Hydroxychloroquine Sulfate Tablets	S	Unknown	100 Milligram, Qd (Maintained As A Daily Medication)	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270841	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000193			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; Dyspnoea Exertional;	Hydroxychloroquine			S	Unknown	Unk		Concordia

Heart Rate Increased; Orthopnoea; Oxygen Saturation Decreased; Rales; Respiratory Rate Increased; Restrictive Cardiomyopathy; Systolic Dysfunction; Ventricular Dysfunction

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270846	EXPEDITED (15-DAY)		CA	DE-ADVANZ PHARMA-202001000236			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Timing Unspecified; Trisomy 18	Hydroxychloroquine			S	Transplacental	Unk (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270854	EXPEDITED (15-DAY)		OT	JP-LUPIN PHARMACEUTICALS INC.-2020-00131		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Methylprednisolone			S	Intravenous (not otherwise specified)	1 Gram, Qd For 3 Day		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Prednisolone			S	Oral	40 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	8 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271142	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0313			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Salazopyrin			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271143	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271230	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201705-002832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonitis; Pneumothorax	Hydroxychloroquine			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, Injection For Solution		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk,Capsule, Hard		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517547		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518112		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Product Use In Unapproved Indication; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported

					Methotrexate		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518757		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex [Darifenacin]			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271879	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516082		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Not Reported
	Dexamethasone	C	Intramuscular	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported

	Loperamide	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Triamcinolone Acetonide	C	Intra-articular	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272044	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020012847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S	Oral	7.5 Mg, Unk		Pfizer
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272058	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020010657		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Adalimumab			S	Unknown	40 Mg, 2x/Day			Not Reported
	Ciclosporin			S		Unk			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	125 Mg, Weekly			Not Reported
	Rituxan			S	Unknown	Unk			Not Reported
	Rituximab			S	Unknown	Unk			Not Reported
	Tocilizumab			S	Unknown	Unk			Not Reported
	Gabapentin			C	Oral	400 Mg, 3x/Day			Not Reported
	Tylenol Arthritis			C		650 Mg, 4x/Day			Not Reported
	Xeljanz			C	Oral	5 Mg, Daily			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272121	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020016060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272585	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-BAUSCH-BL-2020-000639			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Hydrocortisone			S	Transplacental			Not Reported
	Dexamethasone			S	Transplacental			Bausch And Lomb
	Dexamethasone			S	Transplacental			Bausch And Lomb
	Bisoprolol Fumarate			S	Transplacental			Not Reported
	Vitamin K Nos			S	Transplacental			Not Reported

Bisulepin	S	Transplacental	Not Reported
Nadroparine	S	Transplacental	Not Reported
Etamsylate	S	Transplacental	Not Reported
Privigen	S	Transplacental	Not Reported
Privigen	S	Transplacental	Not Reported
Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Not Reported
Metoprolol Tartrate	S	Transplacental	Not Reported
Potassium Chloride	S	Transplacental	Not Reported
Prednisone	S	Transplacental	Not Reported
Prednisone	S	Transplacental	Not Reported
Vitamin B Complex	S	Unknown	Not Reported
Albumin	S	Transplacental	Not Reported
Paracetamol	S	Transplacental	Not Reported
Calcium Carbonate	S	Transplacental	Not Reported
Ornidazole	S	Transplacental	Not Reported
Cefixime	S	Transplacental	Not Reported
Fluconazole	S	Transplacental	Not Reported
Magnesium Lactate	S	Transplacental	Not Reported
Methylprednisolone	S	Transplacental	Not Reported
Methylprednisolone	S	Transplacental	Not Reported
Folic Acid	S	Transplacental	Not Reported
Omeprazole	S	Unknown	Not Reported
Cefotaxime	S	Transplacental	Not Reported
Cefotaxime	S	Transplacental	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Vulmizolin	S	Transplacental	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Not Reported

	Vitamin D [Colecalciferol]	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17274758	EXPEDITED (15-DAY)		DE, OT	US-BEH-2020111543		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Product Use In Unapproved Indication; Stillbirth	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)			Csl Behring
	Methylprednisolone			S	Unknown			Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Etoposide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	8644662	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-16703324		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling;	Abatacept			S	Unknown	Inf:8,Last Infusion On 24-May-2012 Last Infusion On 15-Jan-2014. 3j75953-Exp Date:Jul-2016.		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	1 Df, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported

Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Mg, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, A Day	Not Reported
	Tramadol Hydrochloride And Acetaminophen	S	Unknown		Not Reported
	Tramacet	S	Unknown	Unk	Not Reported
	Tramacet	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Prednisone	C	Unknown		Not Reported
	Oxycocet	C	Unknown		Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown	2 Tab, Unk	Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Depo-Medrol	C	Subcutaneous	Unk, Qmo	Not Reported
	Depo-Medrol	C	Intramuscular	Unk, Qmo	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Actonel	C	Unknown	35 Milligram, Qwk	Not Reported

	Methylprednisolone Acetate	C	Unknown			Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	40 Milligram, Qmo		Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo		Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Nortriptylin	C	Unknown	20 Milligram, Qd		Not Reported
	Nortriptylin	C	Unknown			Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	15663618	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2018-CA-980916		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia; Fatigue; Gastric Disorder; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Leflunomide			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported

	Sirukumab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram Daily;	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apremilast	S	Unknown		Not Reported
	Minocin	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Orencia	C	Unknown		Not Reported
	Orencia	C			Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	16226755	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1145		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Compression	Sulfasalazine	S	Unknown	Die		Not Reported
	Hydroxychloroquine	S	Unknown	Die		Not Reported
	Hydroxychloroquine	S	Unknown	Die		Not Reported
	Actemra	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	16821832	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019397200		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Naprosyn [Naproxen Sodium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17274874	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-002161			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Pantoprazole			S	Unknown	Unk		Aurobindo
	Aleve			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17274895	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201802-000579			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Paraesthesia; Rash; Rash; Rheumatoid Arthritis; Swelling Of Eyelid	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275168	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-233249		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Milligram, Daily		Sun
	Tahor 10 Mg, Comprime Pellicule			S	Oral	1 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	400 Milligrams, Unk		Not Reported
	Coumadine			S	Oral	Unk		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275252	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518338			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported

					Enbrel		S	Subcutaneous		Not Reported
					Folic Acid		S	Unknown		Not Reported
					Fosamax		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Methotrexate		S	Unknown		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Prednisone		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275291	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275294	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275296	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275422	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000260			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dermatitis Allergic; Drug Ineffective; Lower Limb Fracture; Pain; Skin Lesion; Spinal Fracture; Weight Increased; Wrist Fracture	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17277879	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020016043			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pancytopenia; Rash	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Asaphen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17277884	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020016034		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate Sodium			S				Unknown
	Sulfasalazine			S				Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C		7.5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17277886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020015828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin	Methotrexate Sodium			S		Unk		Unknown
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S		Unk		Not Reported

Irritation; Weight Increased	Plaquenil S	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Ibuprofen	C	600 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17278312	EXPEDITED (15-DAY)		OT	NVSC2019CA086423		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cetrizine			S	Unknown	10 Mg		Not Reported
	Cetrizine			S	Unknown	25 Mg		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S				Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Oral	400 Mg, Qd	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Subcutaneous	1 G, Qd	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Topicort	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Atasol	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17278675	EXPEDITED (15-DAY)		OT	NVSC2019CA062116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	Unk		Novartis
	Methotrexate Sodium			S	Unknown	25 Mg, Every 6-8 Weeks		Novartis
	Cortisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17278853	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-00516			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

	Plaquenil	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown		Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279247	NON-EXPEDITED			NVSC2020US008095		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Prednisone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279325	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020018918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Enbrel			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279336	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2517211		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported

Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Nasonex	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Oxycodone Terephthalate	C		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279781	NON-EXPEDITED			NVSC2020US008032		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropsychiatric Symptoms; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279805	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA017708			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported

Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Etanercept	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	S	Oral	5 Mg, Daily	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	9 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil S	S	Unknown	200 Mg, Daily	Not Reported
	Prednisone	S	Unknown	9 Mg, Daily	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Acetaminophen	C			Not Reported
	Cortisone [Hydrocortisone]	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	10977909	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015025803		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Daily		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Monthly		Not Reported
	Simponi			S	Subcutaneous	50 Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Remicade			S	Unknown	3 Milligram/Kilogram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Milligram, Daily		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	200 Mg, (Every 4 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	12990786	EXPEDITED (15-DAY)			US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL002141			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Furosemide			S	Intravenous drip	80 Mg, Qd		Validus
	Furosemide			S				Validus
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	100 Mg, Qd		Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Unknown	250 Mg, Q6h		Not Reported
	Methylprednisolone			S				Not Reported

	Hydroxychloroquine			S	Unknown	200 Mg, Bid	Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk	Not Reported
	Carvedilol			S	Oral	12.5 Mg, Tid	Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Cyclophosphamide			S			Not Reported
	Azathioprine			S	Unknown	50 Mg, Tid	Not Reported
	Hydralazine			S	Unknown	25 Mg, Tid	Not Reported
	Nitroglycerine			S	Intravenous (not otherwise specified)	60 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	13519807	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038321		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Liver Function Test Increased; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	14295590	NON-EXPEDITED		OT	US-PFIZER INC-2017538711		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rash	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Hydroxychloroquine	S	Oral	Unk		Not Reported
	Plaquenil	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	14815472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110703		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 12.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade			S	Unknown					Not Reported
	Infliximab			C	Unknown					Not Reported
	Desoximetasone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	16298203	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121443			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg 40mg/0.8ml		Not Reported
	Xeljanz			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	16300431	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121442		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Oral	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	16965363	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019457898		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported
	Prednisone			S		Unk		Not Reported
	Naprosyn [Naproxen]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17149061	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191206550		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use;	Motrin			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported

Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported

Plaquenil /00072602/	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Vitamin C /00008001/	S	Unknown	Not Reported
Apo Hydroxychloroquine	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Voltaren /00372301/	S	Unknown	Not Reported
Sulfametoxazol/Trimetoprim	S	Unknown	Not Reported
Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17223339	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-109009		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Ramipril			S	Oral	Unk		Aurobindo
	Esomeprazole			S	Unknown	Unk		Not Reported
	Boswellia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17280132	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-087058		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Naproxen			S	Oral	100 Milligram, Once A Day		Not Reported
	Naproxen			S	Oral	500 Milligram, Two Times		Not Reported

Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis				A Day	
	Naproxen	S	Oral	1000 Milligram, Once A Day	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Twice In A Week	Not Reported
	Folic Acid	S	Unknown	400 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Two Times A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Atenolol	S	Unknown	25 Milligram, Once A Day	Not Reported
	Sulfasalazin	S	Oral	500 Milligram, Two Times A Day	Not Reported
	Sulfasalazin	S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Once A Day	Not Reported
	Co Atenolol	S	Unknown	20 Milligram, Once A Day	Not Reported
	Methotrexate Sodium	S	Unknown	20 Milligram, Every Week	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Every Week	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1 Every 2 Weeks	Not Reported
	Palafer Cf	S	Unknown	Unk Unk, Once A Day	Not Reported
	Pantoloc	S	Unknown	40 Milligram, Once A Day	Not Reported
	Arava	S	Unknown	20 Milligram, Once A Day	Not Reported
	Naprosyn	S	Oral	500 Milligram, Two Times	Not Reported

			A Day	
Naprosyn	S	Oral	1000 Milligram, Once A Day	Not Reported
Naprosyn	S	Oral	100 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	40 Milligram, Once A Day	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Once A Day	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk Unk, Once A Day	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk, Once A Day	Not Reported
Humira	S	Subcutaneous		Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Naproxen Sodium	S	Oral	100 Milligram, Two Times A Day	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, Two Times A Day	Not Reported
Naproxen Sodium	S	Oral	500 Milligram, Two Times A Day	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, Once A Day	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram, 2 In Week	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Celebrex	C	Oral	200 Milligram, Once A Day	Not Reported

	Celecoxib			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17280820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0388		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17280830	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0413		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Gabapentin			C	Unknown				Not Reported
	Tylenol Arthritis			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281759	EXPEDITED (15-DAY)		HO	CA-ROCHE-2520587		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281792	EXPEDITED (15-DAY)		OT	CA-ROCHE-2520386		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported

Fracture	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	Solution		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tylenol Arthritis Pain	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281795	EXPEDITED (15-DAY)		LT	CA-ROCHE-2521035		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Dyspnoea; Odynophagia; Rheumatoid Arthritis; Stridor	Rituxan			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17282315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2520406		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin Hydrobromide			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Dilaudid	C	Unknown	Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283057	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020020262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported

			Plaquenil		S	Unknown	Unk			Not Reported
			Remicade		S	Intravenous (not otherwise specified)	Unk			Not Reported
			Simponi		S	Subcutaneous	Unk			Not Reported
			Stelara		S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020020653		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283466	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Liquid Intramuscular		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	14066264	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017151683		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	25 Milligram, Qd		Not Reported
	Simponi			C		Unk		Not Reported
	Atenolol			C	Oral	50 Milligram, Qd		Not Reported
	Inflectra			C	Intravenous (not otherwise specified)	300 Milligram,(Q0, 2,6, Week Then Every 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285802	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523752		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285810	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523787		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Methotrexate			S	Oral	Not Reported
	Methotrexate			S	Intramuscular	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Not Reported
	Asa			C	Unknown	Not Reported
	Ergocalciferol			C	Unknown	Not Reported
	Lantus			C	Subcutaneous	Not Reported
	Lozide [Indapamide]			C	Unknown	Not Reported
	Naprosyn [Naproxen]			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported
	Ramipril			C	Unknown	Not Reported
	Metformin			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285884	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00693			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Infliximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

In Daily Activities; Obesity;
Off Label Use;
Polyarthritis; Psoriasis;
Red Blood Cell
Sedimentation Rate
Increased; Septic Shock;
Synovitis; Underdose;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17286046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521067		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17286091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521085		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17256046	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3220051-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dermatitis Allergic; Drug Ineffective; Lower Limb Fracture; Pain; Skin Lesion; Spinal Fracture; Weight Increased; Wrist Fracture	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Methotrexate			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Simponi			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286597	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00680			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab	S	Unknown			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab	S	Subcutaneous	Unknown		Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286603	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-00685			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286607	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00738			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Prednisone	S	Oral			Not Reported
	Prednisone	S				Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	12386748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015095675		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine			S		300 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg, Daily		Not Reported
	Remicade			S		3 Mg/Kg, (Received 3 Doses)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	200 Mg, (Every 4 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	12676434	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016108897		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celebrex	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydromorphone	C		Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	2 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	14013022	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017408867		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonitis; Pulmonary Toxicity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	14921463	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043742		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Oral	4.0 Mg/Kg, Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prevacid			C	Unknown	30 Milligram, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	15560134	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018048332		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Cetirizine Hydrochloride			S		Dosage Form: Unspecified		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Actemra			S		Dosage Form: Unspecified		Not Reported
	Apo-Prednisone			S		5 Mg, Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Dosage Form: Unspecified		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Folic Acid			S		500 Mg, Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Fosamax			S		Intracorpus Route		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Dosage Form: Unspecified		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Dosage Form: Unspecified		Not Reported
	Phthalylsulfathiazole			S		Dosage Form: Unspecified		Not Reported
	Plaquenil			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Sulfasalazine			S	Oral	1 G Two Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cortisone Acetate			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	15560216	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181030392		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Intracavernous			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Diclofenac Sodium		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	16298219	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121389			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Q4w		Not Reported
	Certolizumab Pegol			S	Unknown	400 Mg, Qow		Not Reported
	Infliximab			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17090074	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025456		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In	Metformin			S	Unknown	500 Mg, Bid		Apotex
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Remicade	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Altace	C	Unknown	5 Mg, Qd		Not Reported
	Asa	C	Unknown	81 Mg, Qd		Not Reported
	Folic Acid	C	Unknown	Unk (6 Every 1 Week)		Not Reported
	Methotrexate	C	Oral	15 Mg, Qd		Not Reported
	Omega 3 /01333901/	C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium	C	Unknown	20 Mg, Qd		Not Reported
	Vitamin D /00107901/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17250549	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007215		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Off Label Use; Toxicity To Various Agents	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	Unk, 3 Every 1 Day		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287208	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00689			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Triamcinolone Acetonide			S	Unknown	Unknown		Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Triamcinolone Acetonide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287257	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2520375		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Amitriptyline	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287417	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518697			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Gabapentin			C	Unknown	Not Reported
	Xeljanz			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287533	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518271		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous drip	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288021	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-002228		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily	Pantoprazole			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported

Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Plaquenil		S	Unknown	Unk	Not Reported
	Prinivil		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Oral	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine		S	Oral	500 Milligram, Once A Day	Not Reported
	Synthroid		S	Unknown	Unk	Not Reported
	Voltaren Sr		S	Oral	Unk	Not Reported
	Voltaren Sr		S	Oral	75 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288398	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA013858		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Qw (1 Every 1 Weeks)		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288659	EXPEDITED (15-DAY)		HO, LT	NVSC2020GB011027		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Panic Attack; Psychotic Disorder; Self-Injurious Ideation; Suicidal Ideation	Methotrexate			S	Oral	25 Mg, Qw		Novartis
	Hydroxychloroquine Sulphate			S	Oral	400 Mg, Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported

	Folic Acid			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288976	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020023022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown			Pfizer
	Tofacitinib Citrate			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288985	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020022973		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Subcutaneous	1 Df, Weekly		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased	Glumetza	S	Unknown	500 Mg, 2x/Day	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Altace	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Asa	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289048	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN006467		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Zenhale			S	Unknown	200 Microgram, Qd (1 Every 1 Days), Dosage Form: Metered Dose Aerosol		Merck
	Zenhale			S	Unknown	200 Milligram, Bid (2 Every		Merck

				1 Days)	
	Spiriva	S	Unknown	2.5 Milligram, Bid (2 Every 1 Days)	Not Reported
	Plaquenil	S	Oral	300 Milligram, Qd (1 Every 1 Days)	Not Reported
	Methotrexate	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
	Lipitor	S	Unknown	40 Milligram, Qd (1 Every 1 Days); Dosage Form: Not Specified	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qd (1 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289327	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524706		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289374	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524633		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)		Not Reported
	Enbrel			S	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		Not Reported
	Methotrexate			S	Unknown		Not Reported
	Simponi			S	Subcutaneous		Not Reported
	Ergocalciferol			C	Unknown		Not Reported
	Leucovorin [Folinic Acid]			C	Unknown		Not Reported
	Prednisone			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-00612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Glyburide			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Metformin			C	Oral	Unknown		Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289758	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1004729			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Spasmolyt			S	Unknown	30 Milligram, Qd(30 Mg, Qd)		Mylan
	Spasmolyt			S	Unknown	1 Dosage Form, Qd (1 Df, Qd)		Mylan
	Ambrisentan			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	3 Dosage Form, Qd(1 Df, 3x/Day (1 - 1- 1))		Not Reported
	Sildenafil			S	Unknown	60 Milligram, Qd		Not Reported
	Omeprazole			S	Oral	2 Dosage Form, Qd (1 Df, 2x/Day (1 - 0 - 1))		Not Reported
	Quensyl			S	Unknown	40 Milligram, Qd (1 Df, Bid (1 - 0 - 1))		Mylan
	Eliquis			S	Unknown	2 Dosage Form, Qd		Mylan
	Volibris			S		Unk		Mylan
	Volibris			S	Oral	Unk		Mylan
	Tocilizumab			S	Subcutaneous	162 Milligram, Qw		Mylan
	Tocilizumab			S	Subcutaneous	162 Milligram, Qw		Mylan
	Ramipril			S	Oral	2 Dosage Form, Qd (1 Df,2x/Day(1 - 0 - 1))		Mylan
	Eliquis			C	Unknown	5 Milligram, Qd(2.5 Mg Bid)		Mylan
	Ramipril			C	Unknown	5 Milligram, Qd		Mylan
	Spasmolyt			C	Unknown	15 Milligram, Qd		Mylan
	Quensyl			C	Unknown	40 Milligram, Qd(20 Mg Bid)		Mylan
	Lyrica			C	Unknown	300 Milligram, Qd(100 Mg, Tid)		Mylan

	Omeprazole			C	Unknown	40 Milligram, Qd (20 Mg, Bid)				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289815	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2020-0010523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Morphine Sulfate			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Daily		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289906	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2020-001503		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Pentoxifylline			S	Unknown			Not Reported
	Aspegic (Acetylsalicylic Acid)			S	Unknown			Not Reported
	Kardegic			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Lovenox			S	Unknown			Not Reported

	Gestarelle G	S	Unknown		Not Reported
	Doliprane	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17290228	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1171101		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Form Strength : Unknown		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	14921644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044730		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Off Label Use; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Ciprofloxacin Hydrochloride	S	Unknown			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	200 Milligram, Bid		Not Reported
	Prednisone	C	Unknown	7.5 Milligram, Qd		Not Reported
	Tridural	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Cimetidine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	16676089	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2877461-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Ciclosporin			S	Oral			Not Reported

					Actemra	S	Unknown		Not Reported
					Mycophenolate Mofetil	S	Unknown		Not Reported
					Hydroxychloroquine Sulfate	S	Unknown		Not Reported
					Pregabalin	S	Unknown		Not Reported
					Plaquenil	S	Oral		Not Reported
					Sodium Aurothiomalate	S	Unknown		Not Reported
					Arava	S	Oral		Not Reported
					Imuran	S	Unknown		Not Reported
					Hydroxychloroquine	S	Unknown		Not Reported
					Lyrica	S	Unknown		Not Reported
					Prednisone	C	Unknown		Not Reported
					Piroxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	16831207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3535		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17168676	EXPEDITED (15-DAY)		OT	CA-ROCHE-1632257		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Abdominal Pain; Abdominal Pain Lower; Abscess Oral; Arthralgia; Asthenia; Barium Enema Abnormal; Blood Pressure Diastolic Abnormal; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Body Temperature Decreased; Bursitis; Disease Susceptibility; Dry Throat; Dry Throat; Eye Disorder; Fatigue; Fatigue; Heart Rate Decreased; Hypoaesthesia; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Oedema Peripheral; Palpitations; Polyp; Sinusitis; Tooth Disorder; Tooth Fracture	Rituxan	S	Intravenous (not otherwise specified)	Last Rituximab Dose: 08/Mar/2016		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Diphenhydramine Hydrochloride	C	Oral			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	C	Oral			Not Reported
	Celebrex	C				Not Reported
	Pantoloc [Pantoprazole]	C				Not Reported
	Ativan	C				Not Reported
	Norvasc	C				Not Reported
	Folic Acid	C				Not Reported
	Methotrexate	C				Not Reported
	Diltiazem	C				Not Reported
	Celebrex	C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17221812	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003220			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypersensitivity	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Zolpidem Tartrate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17257120	EXPEDITED (15-DAY)		DE, HO	CA-PFIZER INC-2020009000		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Bacteraemia; Body Temperature Increased; Central Nervous System Infection; Clostridium Difficile Infection; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Escherichia Infection; Headache; Nausea; Nervous System Disorder; Seizure; Somnolence; Stress Ulcer; Strongyloidiasis; Thrombosis; Upper Gastrointestinal Haemorrhage; Vomiting; Weight Decreased	Methotrexate Sodium	S	Unknown	Unknown
	Prednisone	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17265975	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000204			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Hydroxychloroquine			S	Unknown	200 Mg, Qod		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Bisoprolol Sandoz			C		Unk		Not Reported
	Jamp Calcium			C		Unk		Not Reported
	Teva Risedronate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertensive Urgency; Presyncope	Rituximab			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration:- 7.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Methotrexate			S	Oral	Therapy Duration:- 7.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration:- 7.0 Years		Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290456	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528022		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290482	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0450			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290592	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Stelara			S	Subcutaneous				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Otezla			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290601	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0449		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290629	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528043		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported

					Mycophenolate Mofetil		S	Unknown		Not Reported
					Azathioprine		S	Unknown		Not Reported
					Cyclophosphamide		S	Unknown		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Methotrexate Sodium		S	Unknown		Not Reported
					Prednisone Acetate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17291357	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3240682-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17291376	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0448		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Xeljanz	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Glumetza	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	C	Unknown	Not Reported
	Altace	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Asa (Acetylsalicylic Acid)	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17293254	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08483		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram,		Lupin

Unapproved Indication; Retinopathy	Qd, (Total Dose: 876 Grams)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295082	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1005757		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisynthetase Syndrome; Rebound Effect	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295425	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020027208		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Methotrexate Sodium			S	Oral	30 Mg, Weekly(1 Every 1 Weeks)		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day(1 Every 1 Days)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown	30 Mg, 2x/Day(2 Every 1 Days)		Not Reported
	Prednisone			C	Unknown	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295898	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020027399		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia ; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17296317	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1004929		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Hepatocellular Injury; Weight Loss Poor	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17297064	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00711			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523802		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299166	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Ciclosporin		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524271		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299224	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524708		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Psoriasis; Pustular Psoriasis;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Rheumatoid Arthritis; Scar	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299249	EXPEDITED (15-DAY)		HO	CA-ROCHE-2524262		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Oxycontin		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524986		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525016		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depomedrol			C	Other			Not Reported
	Depomedrol			C	Other	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299298	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525970			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Nephrolithiasis; Product Dose Omission; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527290		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299342	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299373	EXPEDITED (15-DAY)		HO	CA-ROCHE-2527572		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Actemra			S	Intravenous (not			Not Reported

Increased			otherwise specified)		
	Apo-Gabapentin	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fentanyl	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Solution	Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown	Tablet (Extendedrelease)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Actonel	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown		Not Reported
	Ergocalciferol	C	Intravenous (not otherwise specified)		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C	Unknown	Spray, Metered Dose	Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C	Unknown	Tablet (Entericcoated)	Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Tylenol	C	Oral		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527568		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527965		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299443	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527587		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	12681997	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016400589		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5.0 Milligram, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	Unk (Solution)	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	10 Mg/Kg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk (Powder For Solution)	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo Celecoxib	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	2 Mg, 1x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	13188251	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2017GMK026180			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Arthralgia; Asthenia; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Glenmark
	Esomeprazole Magnesium			S	Oral	40 Mg, Od (1 Every 1 Day)		Not Reported
	Folic Acid			S	Unknown	1 Df, 2 Every 1 Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid (2 Every 1 Day)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qw (1 Every 1 Week)		Not Reported

	Prednisone	S	Unknown	5 Mg, Od (1 Every 1 Day)	Not Reported
	Xeljanz	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qw (1 Every 1 Week)	Not Reported
	Plaquenil /00072603/	S	Unknown	200 Mg, Bid (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	13852885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Intra-arterial	25 Mg, Qwk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Sulfate]					
	Prednisone	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	1 G, Bid		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Diclofenac Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	14507104	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1805859US			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Asacol 800			S	Oral	800 Mg, Tid		Allergan
	Amlodipine Besylate			S	Oral	5 Mg, Qd		Not Reported
	Amlodipine Besylate			S	Oral	5 Mg, Unknown		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unknown		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unknown		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unknown		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Bi-Weekly		Not Reported
	Methotrexate Sodium			S	Subcutaneous	50 Mg, Q Week		Not Reported
	Plaquenil			S	Unknown	Unk, Unknown		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Orencia			S				Not Reported
	Atacand Plus			C	Oral	Unk		Not Reported
	Bisoprolol Fumarate			C	Oral	2.5 Mg, Unknown		Not Reported

	Depo-Medrol	C	Intra-articular	120 Mg, Unknown		Not Reported
	Depo-Medrol	C	Intramuscular	120 Mg, Unknown		Not Reported
	Depo-Medrol	C	Unknown	Unk		Not Reported
	Ferrous Gluconate	C	Oral	300 Mg, Unknown		Not Reported
	Folic Acid	C	Oral	5 Mg, Unknown		Not Reported
	Tylenol	C	Unknown	500 Mg, Unknown		Not Reported
	Vitamin D3	C	Unknown	1000 Iu, Qd		Not Reported
	Amlodipine Besilate	C	Oral	5 Mg, Unk		Not Reported
	Omega Allergenic Extracts	C		1 Df, Qd Intradermal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	14678468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2089917		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	15980424	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017430169		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	25 Milligram, Qd		Not Reported
	Atenolol			C	Oral	50 Mg, 1x/Day		Not Reported
	Simponi			C		Unk		Not Reported
	Inflectra [Infliximab]			C	Intravenous (not otherwise specified)	300 Milligram,(Q0, 2,6, Week Then Every 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	16083042	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2706659-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

	Methotrexate Sodium		S	Unknown	Not Reported
	Neoral		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine		S	Oral	Not Reported
	Celecoxib		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	16981320	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1128206		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Clavulin			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported

	Prednisone	C		705 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	7.5 Milligram Daily;		Not Reported
	Tridural	C	Unknown			Not Reported
	Tylenol[Paracetamol]	C	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]	C		400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17282858	EXPEDITED (15-DAY)		OT	NVSC2020US008551			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Dermatitis	Hydroxychloroquine Sulfate			S	Oral	2 Df, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17288297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2522989		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cyclosporin A			S	Unknown			Not Reported
	Depo-Provera			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Naprosyn [Naproxen]			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17295895	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524847		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Arava			S	Oral			Not Reported
	Benzylpenicillin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Infusion		Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17295928	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202001000290			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Rash Erythematous; Skin Burning Sensation; Skin Exfoliation	Hydroxychloroquine			S		Unk		Concordia
	Dupixent			C		600 Mg (Loading Dose)		Not Reported
	Dupixent			C		300 Mg, (Every 2 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17296360	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527559		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17296373	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524696			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled		Not Reported

Erythematosus; Wound				Syringe	
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297000	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202001000297			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Hydroxychloroquine			S		200 Mg, Qd		Concordia
	Citracal Max			S		315 Mg + 250iu, Tid		Not Reported
	Cephalexin			S		250 Mg, Qid		Not Reported
	Diltiazem			S		120 Mg, Qd		Not Reported
	Diltiazem			S		300 Mg, Qd		Not Reported
	Furosemide			S		60 Mg, Qd (Morning)		Not Reported
	Furosemide			S		40 Mg, Qd (Afternoon)		Not Reported
	Esopmeprazole			S		40 Mg, Bid		Not Reported
	Potassium Chloride Er			S		10 Meq, Bid		Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Dofetilide			S		0.25 Mg, Bid		Not Reported

	Dofetilide	S			Not Reported
	Trazodone	S		375 Mg, Qd (Bedtime)	Not Reported
	Warfarin	S		5 Mg, Qd	Not Reported
	Warfarin	S		2.5 Mg, (Monday, Wednesday, And Friday)	Not Reported
	Alendronate	S		70 Mg, Weekly	Not Reported
	Diphenoxylate-Atrop	S		10 Mg, Prn, Daily	Not Reported
	Tracleer	S	Oral	125 Mg, Bid	Not Reported
	Zydus Bosentan	S	Oral	125 Mg, Qd	Not Reported
	Finasteride	S		5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523731		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297592	EXPEDITED (15-DAY)		HO	CN-ROCHE-2525198		24 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Intentional Product Use Issue;	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported

Myocardial Necrosis Marker Increased; Off Label Use	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Methylprednisolone			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297685	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00237		43 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Cephalexin			S	Unknown	Unk		Lupin
	Erythromycin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk (Solution Subcutaneous)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17298570	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-06970			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Muscle Spasms; Pruritus; Urticaria	Duloxetine			S	Unknown	Unk		Lupin
	Sertraline			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Oxycodone			S	Unknown	Unk		Novel Labs

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17298582	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08449		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1952 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17299424	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020027146		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinitis	Triatec (Ramipril)			S	Oral	1 Df, Qd		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1tab 2/2d + 2tab 2/2d		Not Reported
	Cortancyl			S	Oral	1 Df, Qd		Not Reported
	Uvedose			S	Oral	1 Df, Q3m		Not Reported
	Dafalgan Codeine			S	Oral	4 Df, Qd		Not Reported
	Calcidose [Calcium Carbonate]			S	Oral	2 Df, Qd		Not Reported
	Advagraf			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17301049	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020027578			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (2 Every 1 Days)		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17301248	EXPEDITED (15-DAY)		OT	NVSC2020CA013507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis; Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection	Azithromycin			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Depomedrol			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk (200 Mg Od)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302257	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014160		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Arthralgia; Diarrhoea	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qod		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	15 Mg, Qw		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported

	Methotrexate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302262	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Plaquenil			S		2 Df, Qd; 200 Mg		Sanofi
	Paracetamol			S				Not Reported
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		2 Df, Qd (200 Mg)		Sanofi
	Sulfasalazine			S				Not Reported
	Paracetamol			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		1 Df, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Leflunomide			C	Oral			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported
	Synthroid			C				Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302264	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Unk		Sanofi
	Diclofenac Sodium	S	Unknown	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Sanofi
	Methotrexate	S	Unknown	Unk		Not Reported
	Alendronate Sodium	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Sanofi
	Prednisone	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302271	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302275	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302291	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2020M1007334			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisolone			S	Oral	20 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	60 Milligram, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown			Mylan
	Cyclophosphamide			S	Unknown	Pulse Therapy		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302530	EXPEDITED (15-DAY)		OT	RU-ASTRAZENECA-2019SF30946			Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Omeprazole			S	Oral			Not Reported
	Acyclovir			S	Unknown			Not Reported
	Chloropyramine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Igg			S	Intravenous (not			Not Reported

					otherwise specified)				
	Nadroparin			S	Unknown				Not Reported
	Acetaminophen			S	Unknown				Not Reported
	Rituximab			S	Unknown	2 Infusions 14-21 Days Apart Of 1000mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302578	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1006250		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Silodyx			S	Oral	Unk		Mylan
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17303675	EXPEDITED (15-DAY)		DE	CA-009507513-2001CAN007751		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown	70 Milligram, Qw		Merck
	Flovent			S	Unknown			Not Reported
	Albuterol Sulfate (+) Ipratropium Bromide			S	Unknown			Not Reported
	Lasix (Furosemide Sodium)			S	Unknown	40 Milligram		Not Reported
	Lipitor			S	Unknown	10 Milligram		Not Reported
	Losec (Omeprazole Magnesium)			S	Oral	20 Milligram		Not Reported
	Metformin			S	Unknown	500 Milligram, Bid		Not Reported
	Nitrazadon			S	Unknown	10 Milligram		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Qd		Not Reported
	Prednisone			S		5 Milligram, Qd		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported

	Tylenol			S	Unknown	500 Milligram				Not Reported
	Atorvastatin Calcium			S	Unknown	10 Milligram				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17304866	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole]			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17305041	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA017795			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

Pulmonary Sarcoidosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	14849864	EXPEDITED (15-DAY)		CA, OT	CA-ROCHE-2114741		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	15263337	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-021076		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Conduction Disorder;	Hydroxychloroquine			S	Oral			Zydus Pharm

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Mental Status Changes; Overdose; Sinus Tachycardia; Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	16167858	NON-EXPEDITED			US-AMGEN-USASP2019053482		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Allopurinol			S	Unknown	Unk		Not Reported
	Macrobid [Clarithromycin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	16468077	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-211285		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis; Parkinsonism; Seizure	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	10 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	16607608	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040844		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Cephalexin Tablets			S	Unknown	Unk		Aurobindo

Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin	S	Unknown	Unk	Aurobindo
	Clindamycin	S	Unknown	Unk	Aurobindo
	Losartan	S	Unknown	Unk	Aurobindo
	Pantoprazole	S	Unknown	Unk	Aurobindo
	Arava	S	Unknown	Unk	Not Reported
	Avelox	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Intracardiac	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17002086	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091594		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	300 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17097307	NON-EXPEDITED		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2019-07074		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dizziness; Overdose	Hydroxychloroquine Sulfate Tablets			S	Oral	20 Dosage Form, Single		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17133380	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025719		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Rabeprazole			S	Unknown	20 Mg, Unk		Apotex
	Prednisone			S	Unknown	15 Mg, Unk		Not Reported
	Meloxicam			S	Unknown	15 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Desoximetasone			S	Unknown	13 Mg, Unk		Not Reported

	Methotrexate			S	Unknown	12.5 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17157820	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025989		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin			S	Unknown	Unk		Apotex
	Metformin			S				Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Imuran /00001501/			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17161620	NON-EXPEDITED		OT	TN-LUPIN PHARMACEUTICALS INC.-2019-06882		50 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd (Daily Dose Of 3 Mg/Kg/Day With A Cumulative Dose Of 730 Gram)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17241172	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-201912003257			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lower Respiratory Tract Infection; Oropharyngeal Pain; Wheezing	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Kevzara			S	Subcutaneous	200 Mg Qow, Every Other Week		Not Reported
	Sarilumab Pre-Filled Syringe			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305033	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Plaquenil			S		400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Oral	20 Mg		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305038	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee	Arava			S				Sanofi
	Celecoxib			S		Unk		Not Reported
	Diclofenac Sodium			S				Not Reported
	Plaquenil			S				Sanofi

Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist Deformity	Sulfasalazine	S				Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Methotrexate	C	Subcutaneous	5 Mg, Qw		Not Reported
	Xeljanz	C		5 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305039	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA013785		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown	15 Mg/M2, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	4 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Qm		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown	42 Mg		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305448	NON-EXPEDITED			US-AMCO LTD-GSH201611-005903			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydralazine			S	Unknown	25 Mg, Tid		Not Reported
	Azathioprine			S	Unknown	50 Mg, Tid		Not Reported
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported

Prednisone	S	Unknown	100 Mg, Qd		Not Reported
Prednisone	S				Not Reported
Furosemide	S	Intravenous drip	80 Mg, Qd		Not Reported
Furosemide	S	Unknown	80 Mg, Freq: Unk X 1 Days		Not Reported
Carvedilol	S	Oral	12.5 Mg, Tid		Not Reported
Isosorbide Mononitrate	S	Unknown	Unk		Not Reported
Nitroglycerine	S	Intravenous (not otherwise specified)	60 Mg, Qd		Not Reported
Methylprednisolone	S	Unknown	250 Mg, Qid (Q6h)		Not Reported
Methylprednisolone	S				Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	500 Mg		Not Reported
Cyclophosphamide	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305695	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08485		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 730 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305711	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08484		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1314 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305748	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0480		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17306364	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003471		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported
	Calcium			S	Unknown	Unk		Not Reported
	Fosinopril			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Vitamin D			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17306510	EXPEDITED (15-DAY)		DE	US-PERRIGO-20US000826		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Clindamycin Palmitate Hydrochloride			S	Oral	Unknown, Unknown		Perrigo
	Esomeprazole Magnesium			S	Oral	Unknown, Unknown		Perrigo
	Hydroxychloroquine			S	Oral	Unknown, Unknown		Not Reported
	Cyclobenzaprine			S	Oral	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17306659	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004089		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Erythematosus; Wound	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Q12h	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, Q12h	Not Reported
	Topicort [Desoximetasone]	S	Cutaneous	Unk	Not Reported
	Atasol [Paracetamol]	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307005	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2020-003529		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo

Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hcl / Pseudoephedrine Hcl	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400.0 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported

				otherwise specified)		
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine		S	Oral	500 Milligram	Not Reported
	Sulfathalidine		S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Sulfathalidine		S	Oral	500 Milligram	Not Reported
	Tofacitinib		S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Tofacitinib Citrate		S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Topicort		S	Cutaneous	Unk	Not Reported
	Atasol		C	Unknown	Unk	Not Reported
	Salazopyrin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307010	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Topical	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1.0 Milligram		Not Reported

	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Topicort	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307033	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08488		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose:1752 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307035	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08481		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1022 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307037	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1168 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307039	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08487		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 3796 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307242	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	7.0 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307244	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd (Tablet)		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Acetaminophen			C				Not Reported
	Acetaminophen			C		Unk		Not Reported
	Desoximetasone			C				Not Reported
	Desoximetasone			C		Unk		Not Reported
	Naproxen			C				Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Rabeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307257	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA013864		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Bacitracin/ Neomycin/ Polymyxin B			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Intramuscular	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307308	EXPEDITED (15-DAY)		LT	CA-ROCHE-2527074			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307513	EXPEDITED (15-DAY)		OT	IT-LAURUS LABS LIMITED-201900430		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Malaise; Off Label Use; Pain; Papule; Pyrexia; Skin Lesion	Hydroxychloroquine Sulfate			S	Unknown	Two Daily Doses		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amlodipine			C	Unknown	Daily		Not Reported
	Acetylsalicylic Acid			C	Unknown	Lunchtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307544	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08489		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1460 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307546	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08482		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 2044 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307555	NON-EXPEDITED		OT	TR-LUPIN PHARMACEUTICALS INC.-2019-08628		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Generalised Exanthematous Pustulosis; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	40 Milligram, Qd		Lupin
	Methylprednisolone			S	Unknown	120 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307572	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524920			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Naprosyn [Naproxen]			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307577	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1171473		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Doxycycline			S	Oral	200 Mg		Actavis
	Silodyx			S	Oral			Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307918	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014608		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Hydroxychloroquine			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi

Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S		Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qw	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown	50 Mg	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Qw	Not Reported
	Humira	S	Unknown	0.8 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Rituximab	S			Not Reported
	Rituximab;Urelumab	C			Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Arava	S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine	S	Unknown	400 Mg		Sanofi
	Methotrexate	S	Unknown	17.5 Mg, Qw		Not Reported
	Actemra	S	Subcutaneous	162 Mg		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituximab	S	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307951	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-233921		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Stillbirth	Dexamethasone			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Etoposide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307955	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-233323		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; Restrictive	Hydroxychloroquine			S	Unknown	Unk		Sun

Cardiomyopathy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17308071	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17309844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise;	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Humira			C	Unknown	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17309928	EXPEDITED (15-DAY)		HO	CA-ROCHE-2527599		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Atenolol			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17309967	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527606		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Codeine			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Methotrexate			S	Oral	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527625		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310041	EXPEDITED (15-DAY)			US-ROCHE-2271070			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Rituxan			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Humira			S	Unknown				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310170	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527907		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Secretion Discharge; Spinal Stenosis; Synovitis	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528070		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Myochrysine		S	Intramuscular	Not Reported
	Orencia		S	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported
	Septra		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310227	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528362			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Not Reported
	Methotrexate			S	Oral	Not Reported
	Orencia			S	Unknown	Not Reported
	Folic Acid			C	Oral	Not Reported
	Leflunomide			C	Unknown	Not Reported
	Prednisone			C	Oral	Not Reported
	Xeljanz			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310466	EXPEDITED (15-DAY)		HO	CA-ROCHE-2528420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528462		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310532	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529940		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310558	EXPEDITED (15-DAY)		HO	US-ROCHE-2281337		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Gastroenteritis Salmonella; Post Procedural Infection	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310583	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530230		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Solution Subcutaneous Single Use		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310605	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN007489		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Fosamax			S	Unknown	Unk		Merck
	Golimumab			S	Unknown	Unk		Merck
	Prednisone			S	Unknown	Unk		Merck
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported

Cimzia	S	Subcutaneous	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	5.0 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Formulation: Solution Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	20.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Oral	25 Milligram; Solution	Not Reported
Methotrexate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1000.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310626	EXPEDITED (15-DAY)		HO	US-ROCHE-2460671		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310662	EXPEDITED (15-DAY)			US-ROCHE-2288732			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310755	EXPEDITED (15-DAY)			US-ROCHE-2260871			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported

	Methotrexate			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Humira			S	Unknown				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310797	EXPEDITED (15-DAY)			US-ROCHE-2262800			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310926	EXPEDITED (15-DAY)		HO	US-ROCHE-2344654		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningoencephalitis Viral; West Nile Viral Infection	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfamethoxazole/Trimethoprim			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311279	EXPEDITED (15-DAY)			US-ROCHE-2253451			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral	30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311283	EXPEDITED (15-DAY)		HO	US-ROCHE-2249579		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Mycobacterial Infection; Pneumocystis Jirovecii Pneumonia	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			C	Oral	As Prophylaxis		Not Reported
	Sulfamethoxazole/Trimethoprim			C	Oral	High Dose As 21-Day Treatment Course For P. Jirovecii Pneumonia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311445	EXPEDITED (15-DAY)			US-ROCHE-2317551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311504	EXPEDITED (15-DAY)		OT	US-ROCHE-2329821		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Rituximab			S	Intravenous drip	Single Dose		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	For 5 Days		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cyclophosphamide			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Enoxaparin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311593	EXPEDITED (15-DAY)			US-ROCHE-2247406			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Vomiting	Rituximab			S	Unknown	4 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown	10 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	30 Days, 11 Refills		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311655	EXPEDITED (15-DAY)			US-ROCHE-2269536			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17312691	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported

Flovent	S	Unknown	Not Reported
Lasix [Furosemide]	S	Unknown	Not Reported
Lipitor	S	Unknown	Not Reported
Losec [Omeprazole]	S	Oral	Not Reported
Metformin	S	Unknown	Not Reported
Nitrazadon	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Salmeterol Xinafoate	S	Unknown	Not Reported
Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	12913307	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091228		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Gram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	2000 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Other	Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	15705980	EXPEDITED (15-DAY)		OT	CA-009507513-1812CAN000060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic	Fosamax			S	Unknown	Unk Unk, Unknown		Merck
	Cozaar			S	Unknown	Unk Unk, Unknown		Merck
	Cozaar			S	Unknown	Unk Unk, Unknown		Merck
	Vasotec			S	Unknown	Unk		Merck
	Vasotec			S		Unk		Merck
	Methotrexate			S	Subcutaneous	10 Milligram, Qw (Qwk)		Not Reported
	Methotrexate			S	Subcutaneous	10 Miligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qd		Not Reported

Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Biaxin	S	Unknown	Unk, Unknown	Not Reported
	Celebrex	S	Unknown	Unk, Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Unk Unk, Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk, Unknown	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qw	Not Reported
	Enbrel	S		Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk Unk, Unknown	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk Unk, Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk Unk, Unknown	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk Unk, Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk Unk, Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk, Unknown	Not Reported
	Penicillin (Unspecified)	S	Unknown	Unk Unk, Unknown	Not Reported
	Plaquenil	S	Unknown	Unk, Unknown	Not Reported
	Cephalexin	S	Unknown		Not Reported
	Diazide (Gliclazide)	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Isoniazid	S	Unknown		Not Reported
	Lopressor	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Penicillin G	S	Unknown		Not Reported
	Tecta	S	Unknown		Not Reported

	Xeljanz	S		50 Milligram, 2 Every 1 Day(S)	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Every Day	Not Reported
	Venofer	C		Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C		Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Cipro (Ciprofloxacin)	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown		Not Reported
	Atenolol	C			Not Reported
	Colchicine	C			Not Reported
	Coversyl (Perindopril Erbumine)	C			Not Reported
	Leucovorin	C			Not Reported
	Levothyroxine Sodium	C			Not Reported
	Ranitidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	15978307	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013831		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk Unk, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported

	Hydroxychloroquine	S	Oral	400 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, Unk		Not Reported
	Asa	C	Unknown	81 Mg, Unk		Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Lantus	C	Subcutaneous			Not Reported
	Lozide [Indapamide]	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Naprosyn [Naproxen]	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16199338	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006094		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain;	Fosamax			S	Unknown	Unk		Merck
	Acetaminophen			S	Unknown	Dosage Form: Not Specified		Not Reported
	Acetaminophen (+) Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Alendronic Acid			S	Unknown	Unk		Not Reported
	Amitriptyline Pamoate			S	Oral	75.0 Milligram, 1 Every 1 Day (S)		Not Reported
	Amitriptyline Pamoate			S	Oral	75 Milligram, 1 Every 24 Hours		Not Reported
	Apo Amitriptyline			S	Oral	75 Milligram, 1 Every 1 Days		Not Reported
	Apo Amitriptyline			S	Unknown	Unk		Not Reported
	Apo Amitriptyline			S	Oral	75 Milligram, 1 Every 1 Day (S)		Not Reported

Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 24 Hours	Not Reported
	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo-Meloxicam	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Meloxicam	S	Unknown	Unk	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	250 Milligram, 2 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	1000.0 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	250 Milligram, 2 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	1000 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
	Apo Naproxen	S	Oral	1000 Milligram, 1 Every 24 Hours	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 1 Every 24 Hours	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 1 Every 12 Hours	Not Reported
	Apo Prednisone	S	Unknown	15 Milligram, 1 Every 1 Day	Not Reported
	Apo Prednisone	S	Unknown	Unk	Not Reported
	Apo Prednisone	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported

Apo Prednisone	S	Unknown	15 Milligram, 1 Every 24 Hours	Not Reported
Apo Prednisone	S		Unk	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 1 Day (S)	Not Reported
Apo Ranitidine	S	Oral	150 Milligram, 2 Every 1 Day (S)	Not Reported
Apo Ranitidine	S	Unknown	150 Milligram, 2 Every 1 Days	Not Reported
Apo Ranitidine	S	Unknown	Unk	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 1 Week	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Apo Ranitidine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Bactrim	S	Unknown	Dosage Form: Not Specified	Not Reported
Depo-Medrol	S	Intra-articular	Suspension Intra-Articular	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Weeks	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every Weeks	Not Reported
Enbrel	S	Subcutaneous	50 Milligram 1 Every 1 Week	Not Reported
Enbrel	S	Subcutaneous	50 Milligram	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Enbrel	S		Unk	Not Reported
Esomeprazole Magnesium (+) Naproxen	S	Oral	Unk	Not Reported
Esomeprazole Magnesium (+) Naproxen	S	Unknown	Unk	Not Reported

Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40.0 Milligram, Dosage Form: Solution Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Imuran (Azathioprine Sodium)	S	Unknown	150 Milligram, 2 Every 1 Day	Not Reported
Imuran (Azathioprine Sodium)	S	Unknown	150 Milligram, Dosage Form: Not Specified	Not Reported
Lyrica	S	Oral	150 Milligram, 2 Every 1 Day(S)	Not Reported
Lyrica	S		300 Milligram, 1 Every 1 Days	Not Reported
Lyrica	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Methotrexate	S	Oral	20 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methylprednisolone Acetate	S	Intra-articular	Unk	Not Reported
Methylprednisolone Acetate	S	Unknown	Unk	Not Reported
Mobicox	S	Oral	Unk	Not Reported
Pantoloc	S	Oral	Dosage Form: Tablet (Enteric Coated)	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pregabalin	S	Oral	300 Milligram, 1 Every 1 Day(S)	Not Reported

Pregabalin	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Pregabalin	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Septra	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Day(S), Dosage Form: Not Specified	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Days	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, 1 Every 1 Week	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 24 Hours	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 24 Hours	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	15.0 Milligram, 1 Every 1 Day	Not Reported
Prednisone	S	Unknown	150 Milligram, 1 Every 1 Days	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	15 Milligram, 1 Every 24 Hours	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 1 Day	Not Reported
Ranitidine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 1 Week	Not Reported
Ranitidine	S		300 Milligram, 1 Every 1 Days	Not Reported
Ranitidine	S	Oral	150 Milligram, 1 Every 12 Hours	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 24	Not Reported

			Hours	
Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram, 1 Every 1 Day(S)	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Every 24 Hours	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Every 24 Hours	Not Reported
Etanercept	S	Subcutaneous	50 Milligram	Not Reported
Azathioprine	S	Unknown	150 Milligram	Not Reported
Azathioprine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	150 Milligram	Not Reported
Amitriptyline Hydrochloride	S	Oral	75.0 Milligram, 1 Every 1 Day	Not Reported
Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Days	Not Reported
Meloxicam	S	Unknown	Unk	Not Reported
Meloxicam	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported
Trimethoprim	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	2 Dosage Form, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	2 Milligram, 1 Every 1 Days	Not Reported

Xeljanz	S	Oral	2 Milligram, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	2 Dosage Form, 1 Every 24 Hours	Not Reported
Xeljanz	S	Oral	10 Milligram, 1 Every 24 Hours	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Apo Naproxen	S	Unknown	250 Milligram, Bid, Dosage Form: Tablet (Enteric Coated)	Not Reported
Apo Naproxen	S	Unknown	1000 Milligram, 1 Every 1 Days, Dosage Form: Tablet (Enteric Coated)	Not Reported
Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days, Dosage Form: Tablet (Enteric Oated)	Not Reported
Elavil Pamoate	S	Oral	75 Milligram, 1 Every 1 Days	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Weeks, Solution	Not Reported
Methylprednisolone Sodium Succinate	S	Unknown		Not Reported
Methylprednisolone Sodium Succinate	S			Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days, Tablet (Enteric Coated)	Not Reported
Naproxen	S	Oral	250 Milligram, 2 Every 1 Days, Tablet (Enteric Coated)	Not Reported
Naproxen	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Naproxen	S	Oral	1 Every 1 Days	Not Reported

Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Ratio Oxycocet	S	Unknown	Unk	Not Reported
Sulfamethoxazole (+) Trimethoprim	S	Unknown	Unk	Not Reported
Vimovo	S	Unknown	Tablet (Delayed And Immediate Release)	Not Reported
Amitriptyline Hydrochloride	S		75 Milligram, 1 Every 1 Days	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	250 Milligram, 2 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	1000 Milligram, 2 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, 1 Every 1 Days	Not Reported
Pantoloc	S	Unknown	Unk	Not Reported
Pantoloc	S	Oral	Unk	Not Reported
Ranitidine Hydrochloride	S	Oral	300 Milligram, 1 Every 1 Days	Not Reported
Vimovo	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Pantoprazole Sodium	S	Oral	Unk	Not Reported

Methotrexate Sodium	S	Oral	20 Milligram, 1 Every 1 Week		Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
Methotrexate Sodium	S		Unk		Not Reported
Pantoloc	S	Unknown	Caoted Tablet		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Dosage Form: Not Specified		Not Reported
Celecoxib	C				Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Plaquenil	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16199931	EXPEDITED (15-DAY)		DS, HO, OT	CA-009507513-1904CAN006502		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Erythema; Granuloma	Fosamax			S	Unknown	Unk		Merck
	Fosamax			S	Unknown	70 Milligram; 1 Every 1 Week		Merck
	Fosamax			S	Unknown	70 Milligram, 4 Every 1 Week		Merck
	Fosamax			S	Unknown	70 Milligram		Merck
	Actemra			S	Unknown	360.0 Mg, 1 Every Month		Not Reported
	Actemra			S	Unknown	680.0 Mg, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	2.68 Mg, 1 Every 4 Weeks, Dosage Form Reported As Not Specified		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Week		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram, 1 In Every 1 Week	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, Dosage Form Repoted As Subcutaneous Solution	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, Dosage Form Repoted As Subcutaneous Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	70 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported

Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week, Dosage Form Reported As Not Specified	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported

Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week, Dosage Form Reported As Not Specified	Not Reported
Methotrexate	S	Unknown	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	70 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Myochrysine	S	Parenteral	50 Milligram, 1 Every 1 Month	Not Reported

Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Weeks, Dosage Form Reported As Solution Intramuscular	Not Reported
Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Orencia	S	Unknown	780 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 (Units Not Provided)	Not Reported
Remicade	S	Unknown	Unk, Dosage Form Reported As Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Dosage Form Reported As Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligrams, 1 Every 12 Hours	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day, Dosage Form Reported As Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Dosage Form Reported As Not Specified	Not Reported

Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Endocervical	Unk, Dosage Form Reported As Not Specified	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Apremilast	S	Unknown	60 Milligram, 2 Every 1 Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram	Not Reported
Cimzia	S	Subcutaneous	Unk, Single-Use Pre-Filled Syringe, Dosage Form Reported As Solution Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram, Dosage Form Reported As Not Specified	Not Reported
Ibuprofen	S	Oral	Unk	Not Reported
Infliximab	S	Oral	Unk, Dosage Form Reported As Not Specified	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin (Ibuprofen)	S	Oral	600 Milligram, 1 Every 1 Day	Not Reported
Motrin (Ibuprofen)	S	Oral	Unk, 1 Every 1 Day,	Not Reported

			Dosage Form Reported As Not Specified	
Otezla	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk, Dosage Form Reported As Solution Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo Ibuprofen	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cyclosporine	S	Unknown	Not Specified	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported

	Nitrazepam	C	Unknown	5 Milligram		Not Reported
	Nitrazepam	C	Unknown	5 Milligram		Not Reported
	Oxycodone	C	Unknown	Unk		Not Reported
	Uloric	C	Unknown	80 Milligram, 2 Every 1 Day		Not Reported
	Uloric	C	Unknown	80 Milligram		Not Reported
	Colchicine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16267235	EXPEDITED (15-DAY)		HO	US-BIOGEN-2019BI00729804		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Cardiac Disorder; Cognitive Disorder; Dyspnoea; Gout; Localised Infection; Malaise; Multiple Sclerosis Relapse; Pain; Seizure; Skin Discolouration; Sleep Disorder; Speech Disorder; Stress; Systemic Lupus Erythematosus	Plegridy			S	Subcutaneous			Biogen
	Plegridy			S	Subcutaneous			Biogen
	Plegridy			S	Subcutaneous			Biogen
	Plegridy			S	Subcutaneous			Biogen
	Hydroxychloroquine			S	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Cyanocobalamin			C	Unknown			Not Reported
	Fluticasone			C	Unknown			Not Reported
	Hctz			C	Unknown			Not Reported
	Levetiracetam			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Kcl			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Temazepam			C	Unknown			Not Reported
	Fluoxetine			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Memantine			C	Unknown			Not Reported

	Diltiazem			C	Unknown				Not Reported
	Fluticasone			C	Unknown				Not Reported
	Warfarin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16497851	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019265512		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection; Weight Increased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, Cyclic (1 On Odd Days, 2 On Even Days)		Not Reported
	Doxazosin Mesylate			C		1 Mg, Daily		Not Reported
	Metoprolol			C		25 Mg, Daily		Not Reported
	Diltiazem			C		120 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16694396	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-076882		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn E			S	Unknown	500 Milligram, Bid		Not Reported

Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Plaquenil S	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Folic Acid	C	Unknown	5 Milligram		Not Reported
	Gabapentin	C	Unknown			Not Reported
	Lovastatin	C	Unknown			Not Reported
	Metoprolol	C	Unknown	50 Milligram		Not Reported
	Naproxen	C	Unknown			Not Reported
	Naproxen Sodium	C	Unknown	1000 Milligram		Not Reported
	Pantoprazole	C	Unknown			Not Reported
	Rosuvastatin	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Unknown			Not Reported
	Tramadol Hydrochloride	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17275429	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000230			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	0.5 Mg, Bid		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17312883	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00272		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Loss Of Employment; Off Label Use; Product Use Issue	Cephalexin			S	Unknown	Unk		Lupin
	Losartan Potassium			S	Unknown	Unk		Lupin
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram Every Week		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram Every Weeks		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin Sodium]			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Leucovorin [Folinic Acid]			C	Unknown	Unk		Not Reported
	Coversyl [Perindopril Erbumine]			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown	Unk		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Ranitidine			C	Unknown	Unk		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17312891	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527359			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17312901	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00278		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Rash; Therapeutic Product Effect Decreased	Losartan Potassium Tablet			S	Unknown	Unk		Lupin
	Losartan Potassium Tablet			S	Unknown	Unk		Lupin
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Gliclazide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported

Codeine	S	Unknown	Unk	Not Reported
Enalapril	S	Unknown	Unk	Not Reported
Enalapril	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram Every Week	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Lopressor	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram Every Week	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Tecta	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	50 Milligram, Bid (2 Every 1 Day)	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Atenolol	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported

	Coversyl [Perindopril Erbumine]			C	Unknown	Unk			Not Reported
	Esomeprazole			C	Unknown	Unk			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown	Unk			Not Reported
	Levothyroxine Sodium			C	Unknown	Unk			Not Reported
	Ranitidine			C	Unknown	Unk			Not Reported
	Venofer			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17313070	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Omeprazole Magnesium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17313873	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Cetirizine		S	Unknown	Not Reported
	Cortisone Acetate		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314401	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528461		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

		Ergocalciferol			C	Unknown				Not Reported
		Leucovorin [Folinic Acid]			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314616	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA013890		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125.0 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Meloxicam			C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314624	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Arava			S	Unknown	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported

Erythematosus	Folic Acid	S	Unknown	5 Mg		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Sanofi
	Methotrexate	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314628	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013892		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning Sensation; Drug Ineffective; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Kevzara			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported

	Rituximab	S	Unknown	1 G		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Tofacitinib	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Methotrexate	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314645	EXPEDITED (15-DAY)		DS	CA-ROCHE-2531124		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315416	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018196569		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S	Unknown	Dosage Form: Unspecified	Glaxosmithkline
	Cetirizine Hydrochloride	S			Glaxosmithkline
	Desoximetasone	S	Oral	Dosage Form: Unspecified	Glaxosmithkline
	Folic Acid	S	Unknown	500 Mg, Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Dosage Form: Unspecified	Not Reported
	Actemra	S	Unknown	Dosage Form: Unspecified	Not Reported
	Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Dosage Form: Unspecified	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Intracorpus Route	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Dosage Form: Unspecified	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Dosage Form: Unspecified	Not Reported
	Phthalylsulfathiazole	S	Unknown	Dosage Form: Unspecified	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous	Not Reported
	Sulfasalazine	S	Oral	1 G Two Every 1 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315444	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315445	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013887		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	1.0 G		Not Reported

	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	0.8 Ml, Qd		Not Reported
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315448	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315449	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	1 Every 1		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

					otherwise specified)					
	Rituxan			S	Unknown	1000 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315450	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014603		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Celecoxib			S	Oral	200 Mg		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Qow		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	5 Mg, Qow		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Methotrexate			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Unknown	7.5 Mg		Not Reported
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qow		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qow		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	500 Mg		Not Reported

Enbrel	S	Unknown	50 Mg	Not Reported
Enbrel	S	Unknown	25 Mg, Qow	Not Reported
Enbrel	S	Unknown	25 Mg	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	1 Ml, Qw	Not Reported
Enbrel	S			Not Reported
Humira	S	Unknown	40 Mg	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Humira	S	Unknown	50 Mg	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	125 Mg, Qw	Not Reported
Orencia	S	Unknown	12.5 Mg	Not Reported
Orencia	S	Unknown	12.5 Mg, Qow	Not Reported
Acetaminophen;Codeine Phosphate	C		Unk	Not Reported
Altace	C	Unknown	10 Mg	Not Reported
Altace	C	Unknown	5 Mg	Not Reported
Apo-Gabapentin	C	Unknown	300 Mg	Not Reported
Apo-Gabapentin	C	Oral	100 Mg	Not Reported
Apo-Prednisone	C	Oral	15 Mg, Qd	Not Reported
Apo-Prednisone	C	Unknown	5 Mg	Not Reported
Atorvastatin Calcium	C	Oral	40 Mg, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, Qow	Not Reported
Cipralex [Escitalopram]	C	Unknown	10 Mg	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Mg	Not Reported
Conjugated Estrogens	C	Oral	0.625 Mg	Not Reported
Cymbalta	C	Unknown	60 Mg	Not Reported
Cymbalta	C	Unknown	120 Mg, Qd	Not Reported
Cymbalta	C	Unknown	30 Mg, Qid	Not Reported
Escitalopram	C	Unknown	10 Mg	Not Reported

	Estrace	C	Unknown	0.5 Mg		Not Reported
	Gabapentin	C	Oral	100 Mg		Not Reported
	Gabapentin	C	Unknown	300 Mg		Not Reported
	Hydrochlorothiazide	C	Subcutaneous	12.5 Mg		Not Reported
	Hydromorphone Hydrochloride	C	Oral	3 Mg, Bid		Not Reported
	Hydromorphone Hydrochloride	C	Oral	30 Mg, Bid		Not Reported
	Mupirocin	C	Topical	Unk		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	20 Mg, Qd		Not Reported
	Prednisone	C	Unknown	15 Mg, Qd		Not Reported
	Prednisone	C	Oral	5 Mg		Not Reported
	Prednisone	C	Oral	5 Mg, Tid		Not Reported
	Shark Liver Oil	C	Unknown	Unk		Not Reported
	Tapentadol Hydrochloride	C	Unknown	50 Mg		Not Reported
	Taro-Mupirocin	C	Topical	Unk		Not Reported
	Tramacet	C	Oral	Unk		Not Reported
	Tramadol Hydrochloride	C	Oral	50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315591	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020031847		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S				Pfizer
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Atenolol			C	Oral	50 Mg, 1x/Day		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527934		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013861		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

					otherwise specified)				
	Rituximab			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315939	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013872		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Arava			S	Oral			Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S		Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Pregabalin			S				Not Reported
	Sulfasalazine			S				Not Reported
	Plaquenil			S				Sanofi
	Actemra			S		640 Mg, Q4w		Not Reported
	Azathioprine			S				Not Reported
	Certolizumab Pegol			S		200 Mg, Qow		Not Reported
	Certolizumab Pegol			S		200 Mg, Qow		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Qw		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Enbrel			S		50 Ng, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	400 Mg, Qw		Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Orencia			S				Not Reported

	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Qw		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Unk		Not Reported
	Rituxan	S		Solution Intravenous		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Piroxicam	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17316269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17317853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529157		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Premarin			C				Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318042	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529273		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Advil [Ibuprofen]	C				Not Reported
	Folic Acid	C				Not Reported
	Ketorolac	C				Not Reported
	Methotrexate	C				Not Reported
	Naproxen	C				Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529977		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318153	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530659		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness;	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318167	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2020SE10997		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Esomeprazole			S	Oral			Astrazeneca
	Cyclobenzaprine			S	Oral			Not Reported
	Clindamycin			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318170	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530746		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Methotrexate			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530791			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown				Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Meloxicam			C					Not Reported
	Sulfasalazine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527613		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Anakinra			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Warfarin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528091			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2020	16199830	EXPEDITED (15-DAY)		HO, OT	CA-009507513-1904CAN006247		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia;	Fosamax			S	Unknown	70.0 Milligram,Qw (1 Every 1 Week)		Merck

Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Fosamax	S	Unknown	70 Milligram, 1 Every 1 Week	Merck
	Fosamax	S	Unknown	Unk	Merck
	Actemra	S	Unknown	360.0 Milligram,Qm (1every 1 Month) (Also Reported As Every 4 Weeks)	Not Reported
	Actemra	S	Unknown	680.0 Milligram, 1 Every 1 Month(Also Reported As Every 4 Weeks)	Not Reported
	Actemra	S	Unknown	680.0 Milligram	Not Reported
	Actemra	S	Unknown	2.68 Milligram, 1 Every 4 Weeks	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qw (1 Every 1 Week)	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, 1 Every 1 Week	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram,Biw (2 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	25 Milligram , (1 Every 2 Weeks)	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, Qw(1 Every 1 Week)	Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram,Biw (1 Every 2 Weeks)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	20.0 Milligram	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Unknown	12.0 Milligram, Every 4 Weeks(1every4week)	Not Reported
Methotrexate	S	Unknown	15.0 Milligram, (1every 4week)	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, (1 Every 4	Not Reported

			Weeks)	
Methotrexate	S	Unknown	12 Milligram, (1 Every 1 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	10.0 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Intramuscular	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Intramuscular	50.0 Milligram	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	780.0 Milligram, Qw(1every1week)	Not Reported
Orencia	S	Unknown	760 Milligram, Qw (1 Every 1 Week)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every1 Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000.0 Milligram (2 Every 1 Day)	Not Reported
Sulfasalazine	S	Unknown	500.0 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	360.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Simponi	S	Subcutaneous	680.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Q24h(1every24 Hours) (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h (1 Every 2 Hours)	Not Reported
Prednisone	C	Unknown	10.0 Milligram	Not Reported
Prednisone	C	Unknown	20.0 Milligram	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Cyclosporine	C	Unknown	150.0 Milligram, Q24h (1every24hours) (1 Every 1 Day)	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported

		Xeljanz			C	Oral	5.0 Milligram, Bid (2 Every 1 Day)			Not Reported
		Prednisolone			C	Unknown	Unk			Not Reported
		Prednisolone			C	Unknown	10.0 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2020	14925926	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-009461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times A Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	25 Milligram,Two Every 1 Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk, 5 Years		Not Reported
	Methotrexate Sodium			S	Unknown	200 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd For 2 Years		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram,1 Every One Day,		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk, For 4 Months		Not Reported
	Humira			S	Unknown	15 Milligram, 1 Every 1 Week		Not Reported

Humira	S	Subcutaneous	40 Milligram,1 Every Two Week	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk For 8 Months	Not Reported
Apo-Hydroxyquine	S	Oral	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk, For 2 Months	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Week	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram,2 Every One Day	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Wellbutrin	C	Oral	Unk	Not Reported
Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
Bupropion	C	Oral	Unk	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	12676043	EXPEDITED (15-DAY)		DS, OT	CA-SA-2015SA146389		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia;	Arava			S	Oral	20 Mg, Unk		Sanofi

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Leflunomide	S	Oral	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Plaquenil	S	Oral	400 Mg,Qd	Sanofi
	Plaquenil	S	Oral	1 Df, Qd	Sanofi
	Methotrexate	S	Oral	25 Mg,Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	1 Df, Qd	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	4000 Mg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Desoximetasone	S	Cutaneous	Unk	Sanofi
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S		Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Sanofi
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Sanofi
	Hydrocortisone Acetate	S	Unknown	Unk	Sanofi
	Prednisone	S	Unknown	Unk	Not Reported

Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G,Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S		1 G, 1 In 12 Hours	Not Reported
Sulfasalazine	S	Oral	2 Df, Qd	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Sanofi
Hydroxychloroquine	S	Oral	Unk	Sanofi
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg	Not Reported
Folic Acid	S	Unknown	25 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Cortisone	S	Oral	Unk Unk,Prn		Not Reported
Cortisone	S	Oral	Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Enbrel	S	Subcutaneous	Unk, Prn		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Stelara	S	Unknown	Unk		Not Reported
Sulfathalidine	S	Unknown	Unk		Not Reported
Golimumab	S	Subcutaneous	Unk		Not Reported
Golimumab	S	Unknown	Unk		Not Reported
Xeljanz	S		Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Atasol [Paracetamol]	C	Unknown	Unk		Not Reported
Salazopyrin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	12913703	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092859		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	13516439	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Tofacitinib			S	Unknown	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	14823743	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111554		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Duration 1460 Days		Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tofacitinib	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Anti-D Immunoglobulin	S	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Lipitor	C	Oral			Not Reported
	Celebrex	C	Oral			Not Reported
	Ibuprofen	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	15399856	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Tofacitinib			S	Unknown				Not Reported
		Acetaminophen			C	Unknown				Not Reported
		Gabapentin			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	15999216	EXPEDITED (15-DAY)		OT	CA-ROCHE-2268510		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16071582	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05854		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Infliximab	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous, Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S			Not Reported
	Arava	C	Unknown	Unknown	Not Reported

	Arava			C	Oral	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Unknown			Not Reported
	Orencia			C	Unknown	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16126100	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027156		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Voltaren [Diclofenac]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16440009	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2019DEP000563		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound; Wound	Diclofenac Potassium			S	Unknown	Unk		Assertio Therapeutics
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg, Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Weekly		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	Unk, Once Ever 24 Hours		Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Unknown	Unk, Qd	Not Reported
Methotrexate Sodium	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfathalidine	S	Unknown	1000 Mg, Bid	Not Reported
Sulfathalidine	S	Unknown	500 Mg, Unk	Not Reported

	Topicort /00028604/	S	Subcutaneous	Unk		Not Reported
	Topicort /00028604/	S	Other	Unk		Not Reported
	Xeljanz	S	Unknown	Unk, Bid		Not Reported
	Atasol /00020001/	C		Unk		Not Reported
	Salazopyrin	C		Unk		Not Reported
	Tofacitinib Citrate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16842013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27234		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown Duration: 579.0		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Unknown	Unknown		Not Reported
	Acidophilus			C	Unknown	Unknown		Not Reported

Aspirin	C	Unknown	Unknown	Not Reported
Calcium	C	Unknown	Unknown	Not Reported
Crestor	C	Unknown	Unknown	Not Reported
Deflazacort	C	Unknown		Not Reported
Dilaudid	C	Unknown	Unknown	Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Hydromorph	C	Unknown	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Januvia	C	Unknown	Unknown	Not Reported
Kenalog	C	Unknown	Unknown	Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C	Unknown	Unknown	Not Reported
Lidocaine	C	Unknown	Unknown	Not Reported
Lidocaine	C	Topical	Unknown	Not Reported
Lidocaine	C	Topical		Not Reported
Nitroglycerin	C	Unknown	Unknown	Not Reported
Pantoprazole	C	Unknown	Unknown	Not Reported
Pregabalin	C	Unknown	Unknown	Not Reported
Pregabalin	C	Unknown		Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported
Risedronate	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported
Salbutamol	C	Unknown	Unknown	Not Reported
Metronidazole	C	Unknown	Unknown	Not Reported
Triamcinolone	C	Unknown	Unknown	Not Reported

	Triamcinolone	C	Unknown			Not Reported
	Xeljanz	C	Unknown	Unknown		Not Reported
	Xeljanz	C	Oral			Not Reported
	Pantoloc	C	Unknown			Not Reported
	Pantoloc	C	Unknown	Unknown		Not Reported
	Tylenol	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17217695	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201912003223			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Localised Infection; Peripheral Swelling	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Predonine			C		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17219722	EXPEDITED (15-DAY)		OT	NVSC2019FR081048		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Acneiform	Trametinib			S	Oral	2 Mg, Qd		Novartis
	Trametinib			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Oral	800 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17322814	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527604			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Systemic Lupus Erythematosus	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17323511	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Sulfasalazine			S	Unknown	1000 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported

		Humira			S	Unknown	20 Mg			Not Reported
		Orencia			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17323862	EXPEDITED (15-DAY)		HO	CA-ROCHE-2523785		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			C	Subcutaneous			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17323924	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004134		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk, Qwk, Therapeutic Duartion: 8 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram (Iv)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram (Iv)		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk, Therapeutic Duration: 8 Years		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral	7.5 Milligram		Not Reported
	Prednisolone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324042	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-003851			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324252	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202001000338			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Prescribed 1.5 Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527620		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen;Caffeine			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Tylenol No.2			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324312	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528161		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324328	EXPEDITED (15-DAY)		OT	MQ-ALKEM LABORATORIES LIMITED-MQ-ALKEM-2020-00067		53 YR	Female	MTQ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Hyperkeratosis	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324844	EXPEDITED (15-DAY)		HO	CA-ROCHE-2524075		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524693		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Cimzia	C	Unknown	Not Reported
Perindopril	C	Oral	Not Reported
Enbrel	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Oral	Not Reported
Humira	C	Unknown	Not Reported
Indapamide	C	Oral	Not Reported
Naprosyn [Naproxen]	C	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported
Pantoloc [Pantoprazole]	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported
Rituxan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17325431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, 1x/Day		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

	Xeljanz			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17325515	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Off Label Use; Product Use Issue; Treatment Failure	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Enbrel			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326045	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034333			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326048	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium	S		20 Mg, Weekly		Unknown
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S		300 Mg, 1x/Day		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032247		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Benadryl			C	Unknown	Unk		Not Reported
	Naproxen Sodium			C	Unknown	Unk		Not Reported
	Plaquenil S			C	Unknown	Unk		Not Reported
	Reactine [Cetirizine			C	Unknown	Unk		Not Reported

	Hydrochloride]									
	Venlafaxine Hydrochloride			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326065	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034081		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Unknown
	Sulfasalazine			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326128	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		200 Mg, Weekly		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, 1x/Day		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020034101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Unknown
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	200 Mg, 2x/Day		Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326226	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034073		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Mouth Ulceration; Nausea;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, 1x/Day		Pfizer
	Humira			S	Unknown	Unk		Not Reported

Pneumonia; Rectal Ulcer; Therapeutic Product Effect Decreased; Ulcer	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	5 Mg, 1x/Day	Not Reported
	Betaloc [Metoprolol Tartrate]		C	Unknown	Unk	Not Reported
	Desoximetasone		C	Unknown	Unk	Not Reported
	Losec [Omeprazole]		C	Unknown	Unk	Not Reported
	Synthroid		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326571	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1008225		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Atorvastatin			S	Oral	40 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	3 Dosage Form, Qd		Mylan
	Levofloxacin Hemihydrate			S	Oral	1 Dosage Form, Qd		Mylan
	Metronidazole			S	Oral	1500 Milligram, Qd		Mylan
	Lansoprazole			C	Oral	15 Milligram, Qd		Mylan
	Clopidogrel			C	Oral	75 Milligram, Qd		Mylan
	Fluconazole			C	Oral	200 Milligram, Qd		Mylan
	Ceftriaxone			C	Intravenous (not otherwise specified)	Inconnue		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326638	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032464			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Leflunomide			S	Unknown	0.5 Df, Unk		Not Reported

	Leflunomide			S	Oral	20 Mg, Every Day			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Sarilumab			S	Unknown	Unk			Not Reported
	Meloxicam			C	Unknown	Unk			Not Reported
	Sulfasalazine			C	Oral	3 G, 1x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326664	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2020031610		74 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dyspnoea; Nausea; Vomiting	Sulfasalazine			S	Oral	2000 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17328976	EXPEDITED (15-DAY)		OT	NVSC2020FR013954		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Hepatocellular Injury; Weight Loss Poor	Doxycycline			S	Oral	200 Mg, Qd		Novartis
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17330350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019189		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion;	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Leflunomide			S		5 Mg		Sanofi

Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Certolizumab Pegol	S	Subcutaneous	200 Mg		Not Reported
	Enbrel	S	Unknown	50 Mg		Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Methotrexate	S	Unknown	5 Mg		Not Reported
	Orencia	S	Unknown	750 Mg		Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Prednisone	C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17330368	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019246			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Plaquenil			S		400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Sulfasalazine			S		500 Mg		Not Reported
	Xeljanz			S	Oral	2 Df, Qd (50 Mg)		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Atenolol			C				Not Reported
	Celebrex			C				Not Reported
	Colchicine			C				Not Reported
	Coversyl [Perindopril Arginine]			C		Unk		Not Reported
	Hctz			C				Not Reported
	Leucovorin [Folinic Acid]			C	Oral	5 Mg, Qw		Not Reported
	Levothyroxine Sodium			C				Not Reported
	Methotrexate			C	Intramuscular	12.5 Mg, Qw		Not Reported
	Ranitidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	13676137	EXPEDITED (15-DAY)		OT	CA-ROCHE-1952678		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C				Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tenormin			C				Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	14702662	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012999		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		Unk		Not Reported

Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Arava	S	Oral	Unk		Not Reported
	Enbrel	S		Unk		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia	S		Unk		Not Reported
	Plaquenil	S	Oral	Unk		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Weekly (Qw) Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	15691852	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181138322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Benadryl			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pms Azithromycin			S	Unknown			Not Reported
	Procytox			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Levofloxacin			S	Unknown			Not Reported

	Ezetrol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	15790320	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018149717		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Immunosuppression; Infection; Influenza; Pyrexia; Rhinorrhoea; Tachycardia; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16252388	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039387		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis; Sinus Disorder; Sinusitis Noninfective	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Microgram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Ergocalciferol;Retinol;Riboflavin; Thiamine			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	L-Thyroxine [Levothyroxine]			C	Unknown	Unk		Not Reported
	Tylenol Arthritis Pain			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16814622	EXPEDITED (15-DAY)		OT	PT-CELLTRION INC.-2019PT024898			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gastrointestinal Disorder; Interstitial Lung Disease; Product Use In Unapproved Indication; Pulmonary Embolism	Rituximab (Unknown)			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Not Reported
	Rituximab (Unknown)			S				Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16830284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2644831-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16907860	EXPEDITED (15-DAY)		OT	GR-ADVANZ PHARMA-201908000655			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Thyroxine			S	Oral	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17180364	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027355			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	200 Mg, 1 Every 8 Week (S)		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 1 Every 2 Week(S)		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	100 Mg, 1 Every 1 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 1 Every 2 Day(S)		Not Reported
	Glyburide			C		750 Mg, 1x/Day		Not Reported

	Infliximab	C		Unk		Not Reported
	Lipitor	C		10 Milligram, 1x/Day		Not Reported
	Metformin	C	Oral	Unk, 2x/Day		Not Reported
	Mycophenolate Mofetil	C	Oral	750 Mg, 2x/Day		Not Reported
	Prednisone	C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17242306	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP026893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Disability; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, (Therapy Duration: 365 (Unspecified Unit))		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Leucovorin /00566701/			S	Oral	5 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk, Qd		Not Reported
	Naproxen			C	Oral	250 Mg, Unk		Not Reported
	Calcium Citrate W/Magnesium Citrate			C	Unknown	Unk		Not Reported
	Citalopram Hydrobromide			C	Unknown	10 Mg, Unk		Not Reported
	Clobetasol Propionate			C	Topical			Not Reported
	Escitalopram Oxalate			C	Unknown	10 Mg, Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17242377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018036		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine	S	Oral	Unk		Apotex
	Leflunomide	S	Oral	Unk		Apotex
	Arava	S	Oral			Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Coversyl /00790702/	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17329962	EXPEDITED (15-DAY)		DE	US-PERRIGO-20US000827		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulmonary Oedema; Toxicity To Various Agents	Ibuprofen			S	Oral	Unknown, Single		Perrigo
	Hydroxychloroquine			S	Oral	Unknown, Single		Not Reported
	Naproxen			S	Oral	Unknown, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17330008	EXPEDITED (15-DAY)		HO, OT	DK-MYLANLABS-2020M1009652		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Product Use In Unapproved Indication; Weight Decreased	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	250 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17330010	EXPEDITED (15-DAY)		DE, HO	GR-MYLANLABS-2020M1009661		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Encephalitis Japanese B; Meningitis Bacterial; Product Use In Unapproved Indication; Speech Disorder; Treatment Failure	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Unknown	Unk		Mylan
	Rituximab			S				Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S				Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Prednisolone			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17330516	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17332132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530671		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Actemra			S	Unknown			Not Reported

Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Oral				Not Reported
	Methotrexate			S	Oral				Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Restasis			C	Unknown				Not Reported
	Synthroid			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333374	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituximab		S	Intravenous drip		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Topicort [Desoximetasone]		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333428	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531417		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333490	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529931		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333511	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-00322		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Placenta Accreta; Placenta Praevia; Procedural Haemorrhage	Methylprednisolone			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Calcium & Vitamin D [Calcium;Colecalciferol]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333558	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333560	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown				Not Reported
		Remicade		S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333621	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530460			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530416			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Failure	Kineret	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530860		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333695	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526069		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333991	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2530768		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

				Enbrel	S	Subcutaneous		Not Reported
				Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
				Hydroxychloroquine	S	Oral		Not Reported
				Methotrexate	S	Oral	Solution	Not Reported
				Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
				Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
				Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334133	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Xeljanz			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	650 Milligram, Bid		Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Kevzara			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, Tid		Not Reported
	Premarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334437	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530467		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Risedronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530491		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334691	EXPEDITED (15-DAY)		OT	GR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-234388		55 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334999	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2019-110099			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Peripheral Swelling	Rheumatrex			S	Unknown	5 Tablets Once Weekly		Dava
	Folic Acid			S	Unknown	1 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335204	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019212		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Eye Disorder; General Physical Health Deterioration; Gluten Sensitivity	Arava			S		Unk		Sanofi
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi

	Methotrexate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335211	EXPEDITED (15-DAY)		DS	CA-SA-2020SA019258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Arava			S	Unknown	Unk		Sanofi
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335346	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2019-102670			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Rheumatrex			S	Unknown	Unk Unknown, Unknown		Dava
	Hydroxychloroquine			S	Unknown	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335696	EXPEDITED (15-DAY)		OT	US-CELLTRION INC.-2020US018195			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Alveolar Haemorrhage	Infliximab (Unknown)			S		Unk		Not Reported
	Infliximab (Unknown)			S				Not Reported
	Hydroxychloroquine			S				Not Reported

	Hydroxychloroquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335970	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034096			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Unknown
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335984	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2020034296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335997	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective	Methotrexate Sodium			S	Oral	9 Df, Unk		Unknown

	Sulfasalazine	S		Unk	Pfizer
	Apo-Leflunomide	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
	Remicade	S		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Prednisone	C	Oral	5 Mg, 1x/Day	Not Reported
	Prednisone	C		10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531402		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Ustekinumab			S	Unknown	Not Reported
	Xeljanz			S	Oral	Not Reported
	Orencia			C	Intravenous (not otherwise specified)	Not Reported
	Methotrexate			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530627			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530870		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous drip	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Dyclonine Hydrochloride	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Morphine Sulfate	C	Unknown	Not Reported

	Omnaris	C	Unknown	Not Reported
	Orphenadrine Citrate	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Intramuscular	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	11565068	EXPEDITED (15-DAY)		OT	CA-009507513-1509CAN012569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip	Fosamax			S	Oral	Unk		Merck
	Fosamax			S		Route: Intra Corpus Cavernosum		Merck
	Fosamax			S	Subcutaneous	Unk		Merck
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo Prednisone			S	Unknown	5 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qw		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Arava	S	Oral	20 Milligram, Unknown	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg/0.8 Ml, Solution For Injection In Prefilled Syringe	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day(S)	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unknown	Not Reported
	Apo Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Apo Folic Acid	S	Unknown	1, Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Zyrtec	S	Unknown	25 Milligram	Not Reported
	Cortisone	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	400 Mg, Q24h	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Cetrizine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
	Cetrizine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported

Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S		Unk, Other	Not Reported
Folic Acid	S	Oral	500 Milligram Per Litre, Unknown	Not Reported
Folic Acid	S		Unk, Unknown	Not Reported
Folic Acid	S	Unknown	5.0 Unk	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk, Unknown	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Qd	Not Reported
Prednisone	S	Unknown		Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Acetaminophen	S	Unknown	Unk, Unknown	Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Atasol	C	Unknown		Not Reported
Tofacitinib Citrate	C			Not Reported
Ibuprofen	C			Not Reported
Prinivil	C	Unknown		Merck
Cholecalciferol	C	Unknown		Not Reported
Xeljanz	C			Not Reported
Zyrtec	C			Not Reported
Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	12816635	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Cimzia	S		200 Mg, Ev 2 Weeks(Qow)	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Weekly (Qw) Solution Subcutaneous	Not Reported
	Actemra	S		640 Mg, Ev 4 Weeks	Not Reported
	Actemra	S		640 Milligram, Weekly (Qw)	Not Reported
	Arava	S	Oral	1 Dosage Form, Weekly (Qw)	Not Reported
	Cyclosporine	S	Oral	Unk	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly (Qw) Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S		300 Milligram, Weekly (Qw)	Not Reported
	Imuran	S		Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Apo-Azathioprine	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)	Not Reported
	Lyrica	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Orencia	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Hydroxychloroquine	S		Unk	Not Reported

	Piroxicam			C						Not Reported
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	12817973	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037705		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Cimzia			S	Subcutaneous	Unk, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) (Kit)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk, Powder For Solution Intravenous		Not Reported
	Plaquenil			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Asa			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Formulation: Solution Subcutaneous		Not Reported
	Calcite D			C		1500 Milligram, Once Daily (Qd)		Not Reported
	Citalopram			C		Unk		Not Reported
	Domperidone			C		Unk		Not Reported
	Folic Acid			C		Unk, 50 Mg		Not Reported
	Gabapentin			C		Unk		Not Reported
	Gliclazide			C		Unk		Not Reported
	Lipitor			C		Unk		Not Reported
	Nifedipine			C		Unk		Not Reported
	Pantoloc			C				Not Reported
	Pantoprazole Sodium			C				Not Reported

	Risedronate	C			Not Reported
	Risedronate Sodium	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Tylenol Regular	C		650 Mg, 2x/Day (Bid) (Strength :325)	Not Reported
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	14307925	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		5 Mg, Unk		Not Reported
	Fosamax			S		Unk Milligram		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S		500 Mg, Unk		Not Reported

	Apo-Prednisone			S		Unk			Not Reported
	Desoximetasone			S	Oral				Not Reported
	Hydroxychloroquine Sulfate			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	15714888	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-113697		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Drug Ineffective; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Disorder; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Gadolinium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, 1every 1day		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram, Qd		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	15832234	EXPEDITED (15-DAY)		DS	CA-ROCHE-1893094		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondropathy; Disability;	Actemra			S	Unknown			Not Reported

Drug Ineffective; Headache; Malaise; Sarcoidosis; Tooth Extraction; Tooth Fracture; Weight Increased	Arava		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Imuran [Azathioprine]		S	Unknown	Not Reported
	Methotrexate Sodium		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Humira		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	15865926	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram; Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S		20 Mg, Unk		Not Reported
	Methotrexate			S		20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	17 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Ev 4 Weeks		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S		1 G, 2x/Day (Bid)		Not Reported
	Enbrel			S		25 Milligram, 2x/Day (Bid)		Not Reported
	Tofacitinib Citrate			C	Oral	5 Mg, 2x/Day (Bid)		Not Reported

	Prednisone			C					Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day (Bid)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	16002106	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	16443886	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033243		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Amlodipine			S	Oral	5 Milligram		Aurobindo
	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Asacol			S	Oral	800 Milligram,3 Every 1 Days		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Methotrexate	S	Subcutaneous	25 Milligram,1 Every 2 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	2.5 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Atacand Plus	C	Oral	Unk, Once A Day	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Depo-Medrol	C	Intra-articular	120 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120 Milligram	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	500 Milligram	Not Reported
	Vitamin D3	C	Unknown	1000 International Unit, Once A Day	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	16889211	EXPEDITED (15-DAY)		OT	GR-GLAXOSMITHKLINE-GR2019178532		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Lansoprazole			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Ramipril			S	Unknown	Unk		Glaxosmithkline
	Thyroxine			S	Oral	Unk		Glaxosmithkline
	Thyroxine			S	Unknown	Unk		Glaxosmithkline
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17004837	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	1 Every 1 Week		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk,1every1week		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Leflunomide	S	Unknown	20 Milligram		Not Reported
	Meloxicam	C	Oral	7.5 Milligram, Prn		Not Reported
	Prednisolone	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram,2every1day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17005829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103681		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17221372	NON-EXPEDITED		OT	BR-AMGEN-BRASP2019214635		59 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient; Conjunctivitis; Product Use Issue	Enbrel			S	Unknown	25 Milligram, 2x/Week		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Weekly, Once Per Week		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Reuquinol			S	Unknown	400 Mg, 1x/Day		Not Reported
	Methotrexate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17242162	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Drug Ineffective; Duodenal Ulcer	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1000 Mg, Bid		Not Reported
	Zantac			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17242744	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026838		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Leflunomide		S	Unknown	Unk	Apotex
	Leflunomide		S	Unknown	Unk	Apotex
	Hydroxychloroquine		S	Unknown	Unk	Apotex
	Actemra		S	Subcutaneous	162 Mg, Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Q.Wk.	Not Reported
	Methotrexate		S	Oral	10 Mg, Unk	Not Reported
	Orencia		S	Subcutaneous	125 Mg, Q.Wk.	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17246104	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026844		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17335940	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-098241			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 2 Weeks		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Asacol	S	Oral	800 Milligram, 3 Times A Day	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Depo-Medrol	S	Intramuscular	120 Milligram	Not Reported
	Depo-Medrol	S	Intra-articular	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk Unk, Once A Day	Not Reported
	Tylenol	C	Oral	500 Milligram	Not Reported
	Vitamin D3	C	Oral	Unk Unk, Once A Day	Not Reported
	Cholecalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336140	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527623		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Sumatriptan Succinate	C			Not Reported
	Tenormin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336204	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0537		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Benadryl		C	Unknown	Not Reported
	Naproxen Sodium		C	Unknown	Not Reported
	Plaquenil S		C	Unknown	Not Reported
	Reactine		C	Unknown	Not Reported
	Venlafaxine Hydrochloride		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336278	EXPEDITED (15-DAY)		DS	CA-ROCHE-2527578		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Not Reported
	Acetaminophen;Caffeine	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Tylenol With Codeine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Caffeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336330	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-00439			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Methylprednisolone			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Prednisone			S	Transplacental	Unk		Not Reported
	Alfacalcidol			S	Transplacental	Unk		Not Reported
	Calcium & Vitamin D [Calcium;Colecalciferol]			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531552			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532604		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

					Orencia	S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
					Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
					Bupropion	C	Oral		Not Reported
					Sulfasalazine	C	Unknown		Not Reported
					Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532608			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Arthritis	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338085	EXPEDITED (15-DAY)		OT	CA-SA-2020SA018845		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Subcutaneous	750.0 Mg, Qw		Not Reported

	Rituxan			S	Intravenous (not otherwise specified)	2000.0 Mg		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338086	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019339		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methyl Salicylate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019215		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition	Arava			S	Unknown	20 Mg		Sanofi

Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Sulfasalazine	S	Unknown	1 G	Not Reported
	Plaquenil	S	Unknown		Sanofi
	Leflunomide	S	Unknown	20 Mg	Sanofi
	Methotrexate	S	Unknown	20 Mg (Solution)	Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown		Not Reported
	Neoral	S	Unknown		Not Reported
	Rapamune	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Tacrolimus	S	Oral	2.0 Mg, 2 Every 1 Days	Not Reported
	Tacrolimus	S	Oral	3 Mg 2 Every 1 Days	Not Reported
	Imuran [Azathioprine]	C	Unknown	25 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338104	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Arava			S	Unknown	Unk		Sanofi
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

						otherwise specified)				
		Xeljanz			S	Oral	5 Mg, 2 Every 1 Days			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338108	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg [2 Every 1 Day]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338110	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid, 2 Every 1 Days		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Oral	25 Mg		Not Reported

		Methotrexate			C		25 Mg			Not Reported
		Methotrexate			C	Subcutaneous	25 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338129	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2020011898		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Ocular Toxicity	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530847		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338198	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019474			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Mg		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Xeljanz			S	Unknown	5 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338202	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

						otherwise specified)				
		Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338216	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019534		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	15 Mg		Not Reported
	Methylprednisolone			S	Unknown	80 Mg		Not Reported
	Actemra			S				Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338217	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA018854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea;	Arava			S	Oral	20 Mg, Qd		Sanofi
	Celecoxib			S	Other	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Oral	100 Mg, Bid		Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q3w	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Sanofi
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Qm	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q3w	Not Reported
	Vitamin B1 Nos	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Fumarate	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Retinol Palmitate	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported

	Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
	Trazodone	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown			Not Reported
	Vitamin A [Retinol]	C	Unknown			Not Reported
	Vitamin B3	C	Unknown	Unk		Not Reported
	Vitamin B1 Nos	C	Unknown	Unk		Not Reported
	Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk		Not Reported
	Vitamin B6	C	Unknown	Unk		Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk		Not Reported
	Vitamin E Nos	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338465	EXPEDITED (15-DAY)		DS, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000190			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Skin Exfoliation; Swelling Face	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338550	EXPEDITED (15-DAY)		OT	CA-ROCHE-2224086		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Arthropathy; Bursitis; Joint Contracture; Joint Effusion; Joint Swelling; Malaise; Ocular Toxicity; Rheumatoid Nodule; Synovial Disorder; Synovitis	Rituxan			S	Intravenous (not otherwise specified)	Previous Rituximab Infusion: 21/Mar/2019		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Hydroxychloroquine			C	Oral	Alternating With 200 Mg Oral Once Daily		Not Reported

	Levothyroxine	C	Unknown			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C				Not Reported
	Spiriva	C	Nasal			Not Reported
	Tylenol	C				Not Reported
	Voltaren [Diclofenac]	C	Unknown	Gel		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338577	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017021010		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 10 Days		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S				Not Reported
	Xeljanz			S				Not Reported
	Leflunomide			S				Not Reported
	Sarilumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Prednisone			C	Oral	5 Mg, Once Daily (Qd)		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Unk		Not Reported
	Actemra			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338625	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017039111		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Cimzia			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram		Not Reported
	Apo-Leflunomide			S		20 Mg, Once Daily (Qd)		Not Reported
	Otezla			S		Unk		Not Reported
	Simponi			S		Solution Subcutaneous		Not Reported
	Enbrel			S		Unk		Not Reported
	Tofacitinib			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338816	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530918		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Simponi			S	Subcutaneous					Not Reported
		Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531400		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338921	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020033666		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Eye Pain; Hallucination, Visual; Lacrimation Increased; Vision Blurred; Visual Impairment	Methotrexate Sodium			S		20 Mg, 1x/Day		Pfizer
	Plaquenil			S		2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338944	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034846		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression;	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (1 Every 1 Weeks)		Pfizer

Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations	Sulfasalazine	S	Oral	Unk	Pfizer
	Enbrel	S		50 Mg, Weekly (1 Every 1 Weeks)	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Leucovorin Calcium	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	24 Hr		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338973	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020034888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced	Methotrexate Sodium			S		Unk		Unknown
	Xeljanz			S		Unk		Pfizer

Liver Injury	Cosentyx			S		Unk			Not Reported
	Hydroxychloroquine			S		Unk			Not Reported
	Leflunomide			S		Unk			Not Reported
	Orencia			S		Unk			Not Reported
	Otezla			S	Oral	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Stelara			S	Subcutaneous	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17339225	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17339503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019159		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Arava			S	Unknown	Unk		Sanofi

Administered; Drug Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like Illness; Insomnia; Nasopharyngitis; Pain In Jaw; Pelvic Prolapse; Post Procedural Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide	S	Oral	20 Mg, Qd	Sanofi
	Methotrexate	S	Oral	12.5 Mg, Qw	Not Reported
	Hydroxychloroquine	S	Unknown		Sanofi
	Prednisone	S	Oral	5 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	S	Oral	5 Mg, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral		Not Reported
	Desoximetasone	C			Not Reported
	Celebrex	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Fentanyl	C	Unknown	1 Df	Not Reported
	Gabapentin	C	Oral	400 Mg, Bid	Not Reported
	Metformin;Sitagliptin	C	Oral	Unk Unk, Bid	Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, Qd	Not Reported
	Rabeprazole	C	Oral	180 Mg (1 Every 1 Days)	Not Reported
	Ranitidine	C	Oral	150 Mg (1 Every 1 Days)	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg (2 Every 1 Days)	Not Reported
	Synthroid	C	Oral	1 Df (1 Every 1 Days)	Not Reported
	Vitamin B 12	C	Oral	Unk Unk, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Zopiclone	C		7.5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17339722	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034852			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate Sodium	S	Oral	20 Mg, 1x/Day		Pfizer
	Enbrel	S	Subcutaneous			Pfizer
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral	200 Mg, 1x/Day		Not Reported
	Cimzia	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia	S	Unknown			Not Reported
	Folic Acid	C	Oral	5 Mg, Unk		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Prednisone	C	Oral			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17343625	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20200134706		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Increased; Blood Glucose Increased; Blood Potassium Decreased; Blood Sodium Increased; Cardiac Arrest; Haematocrit Decreased; Haemoglobin Decreased; Haemoptysis; Hypotension; Oxygen Saturation Decreased; Pulmonary Oedema; Toxicity To Various Agents; White Blood Cell Count Increased	Ibuprofen			S	Oral	200 Mg Tablet		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Naproxen			S	Oral	750mg Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17344841	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020038746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral			Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17345715	EXPEDITED (15-DAY)		OT	NVSC2018CA000600		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Dihydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	500 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Intracorpus Route		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
Sulfasalazine	S	Oral	1 G, Bid		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Cortisone Acetate	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17413249	DIRECT	Y	RI			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	11579040	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015030469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue;	Cimzia			S	Subcutaneous			Ucb
	Reactine [Cetirizine Hydrochloride]			S		10 Mg		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Apo-Folic Acid			S		5mg		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported

Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine	S		10mg	Not Reported
	Prednisone	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk, Weekly (Qw)	Not Reported
	Sulfasalazine	S	Oral	1 G, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S		Unk, Once Daily (Qd)	Not Reported
	Cortisone	S	Oral		Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	Unk, Once Daily (Qd)	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Not Reported

	Diclofenac Sodium	S		Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S		10 Milligram	Not Reported
	Apo-Prednisone	S		Unk	Not Reported
	Atasol	C			Not Reported
	Cortisone Acetate	S			Not Reported
	Golimumab	S		Unk	Not Reported
	Stelara	S			Not Reported
	Leflunomide	S	Oral		Not Reported
	Paracetamol	S			Not Reported
	Sarilumab	S			Not Reported
	Topicort [Hydrocortisone Acetate]	S	Subcutaneous		Not Reported
	Topicort [Hydrocortisone Acetate]	S			Not Reported
	Xeljanz	S		2 Every 1 Days	Not Reported
	Salazopyrin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	12907801	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-089303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported

	Sulfasalazine	S	Unk		Not Reported
	Tocilizumab	C			Not Reported
	Azathioprine	C	Unk, Once Daily (Qd)		Not Reported
	Ciclosporin	C			Not Reported
	Minocycline	C	Unk		Not Reported
	Prednisolone	C	6 Mg, Once Daily (Qd)		Not Reported
	Prednisone	C	6 Mg, 2x/Day (Bid)		Not Reported
	Actemra	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14630074	EXPEDITED (15-DAY)		HO, OT	RO-AUROBINDO-AUR-APL-2018-013972		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Intentional Product Misuse; Rheumatoid Arthritis; Thrombosis In Device; Treatment Noncompliance; Vascular Stent Thrombosis	Clopidogrel			S	Unknown	Unk		Aurobindo
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	30 Milligram (1 Per Week)		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Prednisone			S	Unknown	20 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	150 Mg, Daily		Not Reported
	Diclofenac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14695624	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012651		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic;	Cimzia			S	Subcutaneous	2 Df, Once Daily (Qd)		Not Reported
	Actemra			S		Unk		Not Reported

Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel	S		50 Mg, Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S			Not Reported
	Arava	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C		Unk, 2x/Day (Bid)	Not Reported
	Ergocalciferol	C		Unk, Weekly (Qw)	Not Reported
	Estrogel	C		0.6 %, 3x/Day (Tid)	Not Reported
	Furosemide	C		40 Mg, Once Daily (Qd)	Not Reported
	Potassium Chloride	C		1500 Mg, Once Daily (Qd)	Not Reported
	Valsartan	C		320 Mg, Once Daily (Qd)	Not Reported
	Xalatan	C	Ophthalmic	50 Mg, Once Daily (Qd)	Not Reported
	Tofacitinib Citrate	C			Not Reported
	Morphine	C			Not Reported
	Zingiber Officinale	C		500 Mg, Unk	Not Reported
	Atasol	C		Unk	Not Reported
	Baclofen	C		Unk	Not Reported
	Levaquin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14911461	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2018020605			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported

Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Tooth Disorder; Tooth Infection; Weight Decreased	Arava	S		10 Mg, Once Daily (Qd)	Not Reported
	Enbrel	S		Unk	Not Reported
	Hydroxychloroquine	S		400 Mg, Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Ev 4 Weeks	Not Reported
	Prednisone	S		Unk	Not Reported
	Etanercept	S			Not Reported
	Actonel	C		35 Milligram	Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	15620559	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556552-00		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

Synovitis; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	15801002	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-1098		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema; Herpes Zoster; Hypoaesthesia; Immunosuppression; Infection; Influenza; Mouth Ulceration; Pyrexia; Rheumatoid Arthritis; Rhinorrhoea; Tachycardia; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	16075574	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012936			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Asacol			S	Oral	800 Milligram, 3 Every 1 Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported

	Depo-Medrol			C	Intra-articular	Unk			Not Reported
	Omega Allergenic Extracts			C	Intradermal				Not Reported
	Tylenol			C	Unknown	Unk			Not Reported
	Vitamin D3			C	Unknown	Unk			Not Reported
	Ferrous Gluconate			C	Unknown	Unk			Not Reported
	Folic Acid			C	Unknown	Unk			Not Reported
	Amlodipine Besilate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	16845009	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019397838		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17002627	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989507-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Pulmonary Oedema	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17235490	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026896			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex

Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Leflunomide		S	Unknown	20 Mg, Qd	Apotex
	Methotrexate		S	Unknown	25 Mg, Q.Wk.	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17241012	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP026871		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Red Cell	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.O.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	200 Mg, Q.M.T.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	200 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported

Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17243300	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020001164		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction	Ramipril			S	Oral	Unk		Pfizer
	Esomeprazole Sodium			S	Unknown	Unk		Unknown
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Boswellia Serrata;Colecalciferol;Curcuma Longa Rhizome;Glucosamine Sul			S	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17271509	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00154		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Exposure During Pregnancy; Off Label Use; Stillbirth	Methylprednisolone			S	Unknown	Unk		Lupin
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported

		Azathioprine			S	Unknown	Unk			Not Reported
		Dexamethasone			S	Unknown	Unk			Not Reported
		Etoposide			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17345761	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026416			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi Aria			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17346862	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202001000446			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prozac			S	Unknown	1 Dosage Form, Qd,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17346976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Azathioprine		S	Unknown		Not Reported
	Certolizumab Pegol		S	Unknown		Not Reported
	Ciclosporin		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Imuran [Azathioprine]		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533719		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347258	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533785		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529944		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347506	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020038795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Unknown
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Sulfasalazine			C	Unknown	2 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347548	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020038770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347626	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-2535227		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Gastroenteritis Cryptosporidial; Neutropenia; Secondary Immunodeficiency	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347797	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2020M1010333		30 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Haemorrhage; Adrenal Insufficiency; Anticoagulation Drug Level Above Therapeutic; Drug Ineffective	Warfarin			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Low-Dose		Mylan
	Aspirin /00002701/			S	Unknown	100 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Enoxaparin			S	Unknown	During Attempts To Conceive (Unknown Dose)		Mylan
	Enoxaparin			S	Unknown	After Discontinuation Of Warfarin (Unknown Dose)		Mylan
	Enoxaparin			S	Unknown	120 Milligram		Mylan
	Rituximab			S	Unknown	Two Doses		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347877	EXPEDITED (15-DAY)		OT	MY-GLAXOSMITHKLINE-MY2020GSK014259		37 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Condition Aggravated; Cutaneous Vasculitis; Dermatitis Psoriasiform; Drug Intolerance; Erythrodermic Psoriasis; Herpes Zoster;	Prednisolone			S		7.5 Mg, Qd		Glaxosmithkline
	Prednisolone			S		30 Mg, Qd		Glaxosmithkline
	Cyclosporine			S		25 Mg, Qd		Glaxosmithkline
	Cyclosporine			S		75 Mg, Qd		Glaxosmithkline

Hypersensitivity Vasculitis; Lupus Nephritis; Musculoskeletal Disorder; Psoriasis; Psoriasis Area Severity Index Increased; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus Disease Activity Index Decreased; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Azathioprine	S	100 Mg, Qd	Glaxosmithkline
	Acitretin	S	Unk	Glaxosmithkline
	Hydroxychloroquine	S	200 Mg, Qd	Not Reported
	Methotrexate	S	15 Mg, We (Weekly)	Not Reported
	Methotrexate	S	3.5 G	Not Reported
	Ustekinumab	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17348449	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3257305-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17349316	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003177		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported

	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Infliximab	S			Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Remicade	S			Not Reported
	Rituximab	S			Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Cephalexin [Cefalexin]	C		500 Milligram, 3x/Day (Tid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17349695	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350084	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202001000180			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Exposure	Hydroxychloroquine			S	Unknown	Unk		Concordia

During Pregnancy; Haemophagocytic Lymphohistiocytosis; Ischaemic Stroke; Respiratory Failure; Stillbirth	Prednisone	S	Unknown	Unk		Not Reported
	Azathioprine	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350323	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020039232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Actemra			S				Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported
	Folic Acid			C		1 Df, Weekly		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350401	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003189		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Cimzia			S		Solution Subcutaneous		Not Reported
	Actemra			S		50 Milligram, Weekly (Qw)		Not Reported
	Actemra			S		4.0 Mg/Kg		Not Reported
	Actemra			S		Unk		Not Reported
	Adalimumab			S				Not Reported

Arava	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		200 Milligram, Once Daily (Qd)	Not Reported
Leflunomide	S		20 Milligram, Once Daily (Qd)	Not Reported
Lyrica	C			Not Reported
Methotrexate	C	Oral	Unk, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous	0.8 Milliliter, Weekly (Qw)	Not Reported
Diclofenac	C			Not Reported
Celebrex	C			Not Reported
Orencia	S		1 Dosage Form, Monthly (Qm)	Not Reported
Orencia	S		750 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S		1.0 Gram	Not Reported
Rituximab	S		1.0 Gram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1.0 Gram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	C			Not Reported
Tocilizumab	C	Endocervical		Not Reported
Valsartan	C			Not Reported

Xeljanz	C	Oral	5.0 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350475	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mitral Valve Disease; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine Sodium			S	Unknown			Not Reported
	Bactrim			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350794	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1176371		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic	Cephalexin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin Phosphate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Actavis
	Hctz			S	Unknown			Ivax
	Losartan			S	Unknown			Teva

Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate	S	Subcutaneous	1.4286 Milligram Daily;	Barr
	Metoprolol Tartrate	S	Unknown		Actavis
	Moxifloxacin Hydrochloride	S	Unknown		Teva
	Pantoprazole Magnesium	S	Unknown		Teva
	Arava	S	Unknown		Not Reported
	Biaxin	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydralazine Hydrochloride	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Pariet	S	Unknown		Not Reported
	Penicillin G 2-Amino-4- Methoxy-6-Methylpyrim	S	Unknown		Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Iron Sucrose	C	Unknown		Not Reported
	Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350874	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tofacitinib		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Rabeprazole Sodium		C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350897	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atrovent			S	Unknown			Not Reported
	Alendronate Sodium Hydrate			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Albuterol Sulfate And Ipratropium Bromide			S	Unknown			Not Reported
	Lasix [Furosemide Sodium]			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole Magnesium]			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

		Prednisone			S	Unknown				Not Reported
		Salmeterol Xinafoate			S	Unknown				Not Reported
		Tylenol			S	Unknown				Not Reported
		Atorvastatin Calcium			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350898	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2020-0556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350899	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

	Ibuprofen	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Methotrexate	C	Oral	25 Milligram		Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram		Not Reported
	Methotrexate	C	Unknown	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350975	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		567 Milligram, Ev 4 Weeks		Not Reported
	Arava			S		20 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S		15 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Rituximab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531131		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Lyrica	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530650		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin;Clavulanate			S	Unknown			Not Reported

Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Potassium				
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tridural		C	Unknown	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351260	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530445		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Prednisone			S	Oral				Not Reported
	Prednisone			S	Unknown				Not Reported
	Prednisone			S	Oral				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Triamcinolone Hexacetonide			S	Unknown				Not Reported
	Triamcinolone Hexacetonide			S	Other				Not Reported
	Vaccinia Immunoglobulins			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351316	EXPEDITED (15-DAY)		LT	CA-ROCHE-2532218			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

	Orencia		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S			Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351465	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Actemra			S				Not Reported
	Arava			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Oral	20 Milligram, Weekly (Qw)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Orencia			S				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351893	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-002237		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Metronidazole			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Bausch And Lomb
	Erythromycin			S	Unknown			Bausch And Lomb
	Erythromycin Estolate			S	Unknown			Not Reported
	Meperidine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Daily		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Apo-Bisoprolol			S	Unknown			Not Reported
	Apo-Norflox			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Meperidine Hcl	S	Unknown	Not Reported
	Bisoprolol Fumarate	S	Unknown	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
	Celecoxib	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17352117	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020044776			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Premature Baby	Methylprednisolone			S		Unk		Pfizer
	Methylprednisolone			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Alfacalcidol			S		Unk		Not Reported
	Vitamin D2 And Calcium Hydrogen Phosphate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12331166	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054169		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	0.8 Milligram/Kilogram		Not Reported

Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Unknown	40 Milligram Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	300 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported

Anakinra	S	Subcutaneous	100 Milligram, Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Actonel	S	Oral	35 Milligram, Qwk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Mg, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qh	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk Unk, Qd	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	300 Milligram, Qh	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk Unk, Qwk	Not Reported
Risedronate	C	Unknown	35 Milligram, Qwk	Not Reported
Prednisone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12335415	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055292		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Enbrel	S	Unknown	50 Milligram	Amgen
	Actemra	S	Subcutaneous	162 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Fosamax	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vit D3	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Mtx [Methotrexate]	C		Unk	Not Reported
	Fosavance	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12572488	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016092115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 4 Times/Wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12901948	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016150079		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Intolerance; Dyspepsia; Fatigue; Gastrointestinal Disorder; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

			Methotrexate		C	Unknown	20 Milligram		Not Reported
			Sulfasalazine		C	Unknown	1 Gram, 2 Every 1 Day		Not Reported
			Sulfasalazine		C	Unknown	1000 Milligram		Not Reported
			Sulfasalazine		C		500 Milligram		Not Reported
			Trazodone		C		Unk Unk, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	14311120	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050847		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Prednisone			C		5 Mg, Once Daily (Qd)		Not Reported
	Methotrexate			C				Not Reported
	Aspirin			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	14311497	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2017051050		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Cimzia	S	Subcutaneous		Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder And Solvent For Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S		500 Milligram	Not Reported
	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Arava	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15289757	EXPEDITED (15-DAY)		HO, LT, OT	US-APPCO PHARMA LLC-2053873		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conduction Disorder; Hypokalaemia; Mental Status Changes; Overdose; Sinus	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma

Tachycardia; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Tachycardia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15389922	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018041562		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unknown Dose		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unknown Dose		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine			S		Unknown Dose		Not Reported
	Leflunomide			S		Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Orencia			S		750 Milligram, Ev 4 Weeks		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Ev 4 Weeks		Not Reported
	Sulfasalazine			S		Unknown		Not Reported
	Tocilizumab			S		Unknown Dose		Not Reported
	Tofacitinib			S		Unknown Dose		Not Reported
	Tofacitinib Citrate			S		Unknown Dose		Not Reported
	Apo-Leflunomide			S				Not Reported
	Kevzara			S				Not Reported
	Rituximab			S				Not Reported
	Xeljanz			S	Oral	50 Milligram, 2x/Day (Bid)		Not Reported
	Rabeprazole Sodium			C		Unknown		Not Reported
	Methotrexate			C	Oral	20 Milligram, Weekly (Qw)		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, 2x/Day (Bid)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15748179	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2239		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Magnesium			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15865362	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002159		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S		1 Df, Weekly (Qw)	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S		Unk	Not Reported
	Plaquenil		S		Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Arava		C		Unk	Not Reported
	Codeine		C		Unk	Not Reported
	Lyrica		C	Oral		Not Reported
	Tylenol		C		Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15878928	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002242		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S		5 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Leflunomide			S		20 Milligram		Not Reported
	Methotrexate			S		5 Mg, Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

Test Positive	Orencia	S		750 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Apo-Leflunomide	S		20 Milligram	Not Reported
	Apo-Leflunomide	S		5 Milligram	Not Reported
	Gold	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Arava	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16108289	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709179-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Eye Disorder; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Humira			S	Subcutaneous			Not Reported
	Bactrim			S	Oral	160/800 Mg		Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Azathioprine Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16178863	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738275-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16858861	EXPEDITED (15-DAY)		OT	GR-TAKEDA-2019TEU011003		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Lansoprazole			S	Unknown	Unk		Takeda
	Prednisolone			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Thyroxin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Dicumarol			C	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16897978	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019430021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Actemra			S		567 Mg, Monthly		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Rituxan			S		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16994165	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019045197		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Weekly (Qw)		Not Reported
	Certolizumab Pegol			S		200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol			S		200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Weekly (Qw)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Monthly (Qm)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Ev 4 Weeks		Not Reported

Actemra	S		640 Milligram, Weekly (Qw)	Not Reported
Apo-Azathioprine	S			Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Arava	S	Oral	Unk, Weekly (Qw)	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Azathioprine	S			Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Oral		Not Reported
Enbrel	S		50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S		50 Milligram	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	40 Milligram, Weekly (Qw)	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S		400 Milligram, Weekly (Qw)	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Imuran [Azathioprine]	S			Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Lyrica	S			Not Reported
Methotrexate	S		20 Milligram	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Mycophenolate Mofetil	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, 2x/Day (Bid)	Not Reported

	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S		500 Milligram	Not Reported
	Prednisone	C			Not Reported
	Piroxicam	C			Not Reported
	Arava	S		20 Milligram	Not Reported
	Folic Acid	C			Not Reported
	Leflunomide	C			Not Reported
	Pregabalin	S			Not Reported
	Rituximab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Tofacitinib Citrate	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16997288	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17240944	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Leflunomide			S	Oral	20.0 Mg, Qd		Apotex
	Leflunomide			S	Unknown	0.5 Df, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	3.0 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17242057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026849		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arrhythmia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Swelling; Swollen Joint Count Increased; Urticaria	Leflunomide			S	Oral	20 Mg, Every 1 Day		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sarilumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352474	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1175997		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine Besilate	S	Oral		Teva
	Amlodipine Besilate	S	Oral	5 Milligram Daily;	Teva
	Mesalazine	S	Oral	2400 Milligram Daily;	Actavis
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Amlodipine Besilate	C	Oral	5 Milligram Daily;	Not Reported
	Atacand Plus	C	Oral		Not Reported
	Bisoprolol Fumarate	C	Oral		Not Reported
	Vitamin D3	C	Unknown	1000 Iu (International Unit) Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Folic Acid	C	Oral		Not Reported
	Ferrous Gluconate	C	Oral		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Depo-Medrol	C	Intramuscular		Not Reported
	Depo-Medrol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352565	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003253		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S		300 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)	200 Milligram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Methotrexate	S	Subcutaneous	65 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	65 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S		25 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352650	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3257168-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ramipril			C				Not Reported
	Oxycodone Hydrochloride			C				Not Reported
	Acetaminophen			C				Not Reported

		Oxycodone Terephthalate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352739	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529217		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Biotin			C				Not Reported
	Cholecalciferolum			C				Not Reported
	Diphenoxylate Hcl			C				Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Ferrous Fumarate			C				Not Reported
	Loperamide			C	Unknown			Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Oxycodone Terephthalate			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Percocet [Oxycodone			C	Unknown			Not Reported

	Hydrochloride;Paracetamol]			
	Perphenazine	C		Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C	Unknown	Not Reported
	Retinol Palmitate	C	Unknown	Not Reported
	Riboflavin	C		Not Reported
	Thiamine Hcl	C		Not Reported
	Thiamine Mononitrate	C		Not Reported
	Trazodone	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin A [Retinol]	C	Unknown	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352819	EXPEDITED (15-DAY)		HO	CA-ROCHE-2525929		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352877	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0568		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Coversyl		C	Unknown	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Leucovorin Calcium		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz			S	Oral	Not Reported
	Arava			S	Oral	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Plaquenil			S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352966	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3257136-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Eye Disorder; Headache; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Skin Erosion	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353101	EXPEDITED (15-DAY)		OT	US-ZYDUS-046904		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rebound Effect	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353157	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530892		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Actemra			S	Unknown			Not Reported

Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Rituxan	S	Intravenous drip	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Ramipril	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen;Codeine	C	Unknown	Not Reported
	Caffeine;Dihydrocodeine Bitartrate;Paracetamol	C	Unknown	Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate	C	Ophthalmic	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353165	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531106		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353208	EXPEDITED (15-DAY)		DE, HO	US-ALVOGEN-2020-ALVOGEN-102618		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clindamycin			S				Not Reported
	Cyclobenzaprine Hydrochloride			S				Not Reported
	Esomeprazole			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353473	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000447			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression;	Hydroxychloroquine			S	Unknown	Unk		Concordia

Drug Resistance; Off Label Use	Trametinib			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533975		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353593	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530486		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral; Prerenal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported

Failure; Renal Disorder; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353655	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535837		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530581		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353907	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR-1177738		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol (Chlorhydrate De)			S	Oral	80 Mg		Teva
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17355394	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020040977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate Sodium			S	Oral	4 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Leucovorin Calcium			S	Oral	5 Mg, Weekly		Pfizer
	Cosentyx			S	Oral	300 Mg, Monthly		Not Reported
	Diclofenac			S	Oral	Unk, (3 Every 1 Day)		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Meloxicam			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Oral	1 Df, 1x/Day		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported

	Diltiazem Hydrochloride			C	Oral	240 Mg, Unk			Not Reported
	Fluticasone Propionate			C	Respiratory (inhalation)	Unk			Not Reported
	Mar-Pantoprazole			C	Unknown	Unk			Not Reported
	Mometasone Furoate			C	Unknown	Unk			Not Reported
	Premarin			C	Unknown	Unk			Not Reported
	Salbutamol Sulfate			C	Respiratory (inhalation)	Unk			Not Reported
	Tramadol Hydrochloride			C	Oral	Unk Unk, 1x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17355493	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020039223		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17355826	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-02709		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haemorrhage; Drug	Infliximab			S	Intravenous (not			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Haemorrhage; Infection; Influenza Like Illness; Malaise; Nausea; Rheumatoid Arthritis; Urinary Tract Infection			otherwise specified)			
	Celebrex	S	Unknown	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Unknown Solution Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported
	Plaquenil	C	Oral			Not Reported
	Sulfasalazine	C	Unknown	Unknown		Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	15854681	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633525-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Tocilizumab			S	Unknown	Not Reported
	Tofacitinib			S	Unknown	Not Reported
	Xeljanz			S	Unknown	Not Reported
	Adalimumab			S	Subcutaneous	Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Not Reported
	Rabeprazole Sodium			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	16851800	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2937832-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rapamune			S	Unknown			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxyquinoline Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported

	Imuran			C	Unknown					Not Reported
	Azathioprine			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358261	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3256489-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Retinopathy	Humira			S	Subcutaneous	10 Months		Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531525		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)		
					Simponi	S	Subcutaneous		Not Reported
					Sulfasalazine	S	Oral		Not Reported
					Desoximetasone	C			Not Reported
					Methotrexate	C			Not Reported
					Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531538		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

	Infliximab			S	Intravenous (not otherwise specified)				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530929			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported

	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530347		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Nortriptyline			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Nasonex	C	Unknown	Not Reported
	Aclasta	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Ascorbic Acid	C		Not Reported
	Biotin	C		Not Reported
	Calcium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C		Not Reported
	Fentanyl	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Loperamide	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Omega 3-6-9 [Fish Oil]	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C		Not Reported
	Sodium	C		Not Reported
	Thiamine Hcl	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin A [Retinol]	C		Not Reported
	Vitamin B3	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358674	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358677	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]								
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Desoximetasone			C					Not Reported
	Methotrexate			C					Not Reported
	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358682	EXPEDITED (15-DAY)		OT	CA-ROCHE-2534194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Actemra			S	Intratumor			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17376781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	11310374	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015073223		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Acetaminophen			S	Oral	65 Milligram		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Oral	65 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Milligram		Not Reported

Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Dilaudid	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, 4 Times/Wk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Prednisone	S	Unknown	7.5 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Apo Hydromorphone	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydromorphone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	15.5 Unk	Not Reported
	Hydromorphone Hydrochloride	S	Unknown	Unk	Not Reported
	Calcium Folinate	S	Unknown	5 Milligram	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Humira	C	Unknown	Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	C	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Oral	50 Milligram	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Fosavance	C		Unk Unk, Qwk	Not Reported
Hydrocortisone	C	Intravenous (not otherwise specified)	250 Milligram	Not Reported
Hydrocortisone	C	Unknown	Unk	Not Reported
Hyzaar	C		12.5 Milligram, Qd	Not Reported
Hyzaar	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Alendronate Sodium;Colecalciferol	C		Unk Unk, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	11490879	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2015093585		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, 4		Amgen

Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User				Times/Wk	
	Enbrel	S	Subcutaneous	25 Milligram, Bid	Amgen
	Enbrel	S	Unknown	25 Milligram	Amgen
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Cyclical	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Immune Globulin Intravenous (Human)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not	1 Dosage Form, Qwk	Not Reported

		otherwise specified)		
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S			Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Orencia	S		250 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported

Anakinra	S	Unknown	Unk, Qd	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S	Unknown	Unk	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Abatacept	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk, Qwk	Not Reported
Methotrexate Sodium	S			Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Apo Triamcinolone Aq	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
Triamcinolone Acetonide	S			Not Reported
Triamcinolone Acetonide	S			Not Reported

	Hydroxychloroquine Sulfate		S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	1 Dosage Form, Qd	Not Reported
	Gammagard		S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Naproxen Sodium		S	Unknown	Unk	Not Reported
	Folic Acid		C		Unk	Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unk	Not Reported
	Triamcinolone Hexacetonide		C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	12635667	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016101720		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported

	Toradol			S	Unknown	Unk			Not Reported
	Prednisone			C	Unknown	7-10 Milligram, Unk			Not Reported
	Tramadol			C	Unknown	100 Milligram, As Necessary			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	14321179	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017110785		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	16120605	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044829			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk Unk, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	17358981	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020015573		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	12302836	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016051354		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Off Label Use; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Rheumatoid Factor Positive; Synovitis	Plaquenil		S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide		S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	13908882	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2017127671		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

				Sulfasalazine		S	Unknown	500 Milligram	Not Reported
				Methotrexate		S	Unknown	Unk	Not Reported
				Methotrexate		S			Not Reported
				Gold		S	Unknown	Unk	Not Reported
				Apo-Leflunomide		S	Unknown	Unk	Not Reported
				Apo-Leflunomide		S			Not Reported
				Ilaris		S	Intravenous (not otherwise specified)	Unk	Not Reported
				Ilaris		S	Subcutaneous	Unk	Not Reported
				Ilaris		S	Unknown	Unk	Not Reported
				Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
				Plaquenil [Hydroxychloroquine Sulfate]		S			Not Reported
				Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
				Sodium Aurothiomalate		S			Not Reported
				Rituximab		S	Unknown	Unk	Not Reported
				Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
03-Feb-2020	14421683	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018006742		34 YR	Female	CAN
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**	
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Enbrel			S	Unknown	Unk		Amgen	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	

		Leflunomide			S	Unknown	Unk			Not Reported
		Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid			Not Reported
		Bactrim			S	Unknown				Not Reported
		Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	14868417	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2018061435		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Miliaria; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	11:1 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	200 Milligram, Q12h		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Citalopram			C		10 Milligram, Qd		Not Reported
	Pantoloc			C		40 Milligram, Bid		Not Reported
	Pantoloc			C				Not Reported

		Prednisone		C	Unknown	10 Milligram, Qd			Not Reported
		Celebrex		C	Unknown	200 Milligram, Bid			Not Reported
		Lorazepam		C	Unknown	1 Milligram, Qhs (At Bedtime)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16055007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2277556		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16084291	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022664		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral	2 Gram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Paracetamol			S	Unknown			Not Reported

Intolerance; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pain; Pemphigus; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus; Wound	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Apo-Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil/00072603/	S	Oral		Not Reported

	Plaquenil/00072603/	S			Not Reported
	Reactine//Cetirizine Hydrochloride	S	Unknown		Not Reported
	Reactine//Cetirizine Hydrochloride	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S			Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Topicort	S	Subcutaneous		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16129066	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027216		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Oral	800 Milligram, Tid		Not Reported

Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Mesalazine	S	Oral	800 Milligram, Tid	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Amlodipine Besilate	C	Oral	5 Milligram, Qd	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Depo-Medrol	C	Intra-articular	120 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120 Milligram	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Omega Allergenic Extracts	C	Unknown		Not Reported
	Tylenol	C	Unknown	500 Milligram	Not Reported
	Vitamin D3	C	Unknown	1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16201898	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019058114			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Naproxen		C		500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16443920	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033823		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Altace			C	Unknown	5 Milligram, Once A Day		Not Reported
	Asa			C	Unknown	81 Milligram, Once A Day		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	1 Dosage Form, 6 Every 1 Week		Not Reported
	Methotrexate			C	Oral	15 Milligram, Once A Day		Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Milligram, Once A Day		Not Reported

	Vitamin D			C	Unknown	Unk			Not Reported
	Omega 3			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16521599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346118		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16829773	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1109222		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown			Duramed
	Bisoprolol			S	Unknown			Duramed
	Celecoxib			S	Oral	200 Milligram Daily;		Teva
	Diclofenac W/Misoprostol			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Methotrexate			S				Barr

Methotrexate	S	Unknown		Barr
Methotrexate	S	Unknown		Barr
Prednisone	S	Unknown		Actavis
Norfloxacin	S	Unknown		Not Reported
Bisoprolol Fumurate	S	Unknown		Duramed
Levofloxacin Hemihydrate	S	Unknown		Teva
Methotrexate Sodium	S	Unknown		Barr
Apo-Bisoprolol	S	Unknown		Not Reported
Apo-Norflox	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arthrotec	S	Unknown		Not Reported
Ceclor	S	Unknown		Not Reported
Celebrex	S	Oral		Not Reported
Celebrex	S	Oral		Not Reported
Demerol	S	Unknown		Not Reported
Erythro Base	S	Unknown		Not Reported
Erythromycin	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Lyrica	S	Unknown		Not Reported
Meperidine	S	Unknown		Not Reported
Meperidine Hcl	S	Unknown		Not Reported
Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
Plaquenil	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Erythromycin	S	Unknown		Not Reported
Metronidazole	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17261096	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200.0 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q.M.T.		Not Reported
	Prednisone			C	Unknown	10.0 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17270951	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unknown		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

	Rituximab	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	10.0 Mg, Qd		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Simponi	C	Subcutaneous	Unk		Not Reported
	Xeljanz	C	Unknown	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359168	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported
	Loperamide			C	Oral	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359226	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533869		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Kineret	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Other	Not Reported
	Triamcinolone Hexacetonide	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533849		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

					Methotrexate		S	Oral	Not Reported
					Methotrexate		S	Oral	Not Reported
					Methotrexate		S	Oral	Not Reported
					Methotrexate		S	Unknown	Not Reported
					Methotrexate		S	Oral	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Desoximetasone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359279	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533864			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100 Mg Per Syringe Single Use, Preservative- Pre Filled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported

					Orencia	S	Intravenous (not otherwise specified)		Not Reported
					Prednisone	S	Oral		Not Reported
					Prednisone	S	Oral		Not Reported
					Sulfasalazine	S	Oral		Not Reported
					Triamcinolone	S	Subcutaneous		Not Reported
					Triamcinolone Acetonide	S	Unknown		Not Reported
					Triamcinolone Acetonide	S			Not Reported
					Triamcinolone Acetonide	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359286	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533836			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous,		Not Reported

				100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359348	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532707			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User					otherwise specified)				
	Sulfasalazine			S	Oral				Not Reported
	Triamcinolone Acetonide			S	Intra-articular				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359365	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532680			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359389	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Gp2013	S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Months		Not Reported
	Gp2013	S	Unknown			Not Reported
	Abatacept	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 610.0 Days		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 4.0 Years		Not Reported
	Humira	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months		Not Reported
	Infliximab	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359475	EXPEDITED (15-DAY)		HO	CA-ROCHE-2531147		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing			Not Reported

Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure			technique	
	Enbrel	S	Unknown	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Gabapentin	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C		Not Reported
	Vitamin C [Ascorbic Acid]	C		Not Reported
	Biotin	C		Not Reported
	D-Alpha Tocopherol	C		Not Reported
	Ergocalciferol	C		Not Reported
	Esomeprazole	C		Not Reported
	Ferrous Fumarate	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Loperamide	C		Not Reported
	Nasonex	C		Not Reported
	Nicotinamide	C		Not Reported
	Nortriptyline	C		Not Reported
	Pantoprazole	C		Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C		Not Reported
	Retinol Palmitate	C		Not Reported
	Riboflavin	C		Not Reported
	Sodium Ascorbate	C		Not Reported
	Thiamine	C		Not Reported
	Thiamine Hydrochloride	C		Not Reported

	Trazodone			C						Not Reported
	Tylenol			C						Not Reported
	Vitamin A [Retinol]			C						Not Reported
	Vitamin B12 [Cyanocobalamin]			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359490	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201904-001246			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Meningitis Aseptic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Daily Administration)		Concordia
	Micardis			C		Unk		Not Reported
	Thyradin S			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Baktar			C				Not Reported
	Takepron			C		Unk		Not Reported
	Takepron			C				Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Bonalon			C		Unk		Not Reported
	Bonalon			C				Not Reported
	Persantin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359581	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2543863-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Pruritus; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Ibuprofen			S	Unknown			Not Reported

		Sulfasalazine			S	Unknown			Not Reported
		Plaquenil			S	Unknown			Not Reported
		Leflunomide			S	Unknown			Not Reported
		Hydroxychloroquine Sulfate			S	Unknown			Not Reported
		Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359641	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531537		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359679	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359682	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0585			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Simponi		C	Subcutaneous	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359689	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359691	EXPEDITED (15-DAY)		HO	CA-ROCHE-2531148		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported

Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Gabapentin	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Actonel	C		Not Reported
	Aclasta	C		Not Reported
	Esomeprazole	C		Not Reported
	Ferrous Gluconate	C		Not Reported
	Genteal [Carmellose Sodium;Hypromellose]	C		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Nasonex	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359693	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000512			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359849	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532669			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359891	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532661			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359996	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533770		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Calcium	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Oral	Not Reported
	Omega-3 Fatty Acids	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Aclasta	C		Not Reported
	Actonel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533775		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Sunconjunctival	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360147	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-092402		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D	Amlodipine			S	Oral	5 Milligram		Aurobindo
	Methotrexate			S	Subcutaneous	25 Milligram, One Every 2 Weeks		Not Reported
	Asacol			S	Oral	800 Milligram, 3 Times A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported

Deficiency	Enbrel	S	Subcutaneous	50 Milligram		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Amlodipine Besilate	C	Unknown	Unk		Not Reported
	Atacand Plus	C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk		Not Reported
	Depo-Medrol	C	Unknown	Unk		Not Reported
	Ferrous Gluconate	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

							otherwise specified)			
			Phthalylsulfathiazole		S		Unknown			Not Reported
			Prednisone		S		Unknown			Not Reported
			Reactine [Cetirizine Hydrochloride]		S		Unknown			Not Reported
			Remicade		S		Intravenous (not otherwise specified)			Not Reported
			Rituxan		S		Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360276	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Acetaminophen And Codeine		C	Unknown	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Synthroid		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360307	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533782		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Hydroxychloroquine		S	Unknown		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533784		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Ciclosporin		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Imuran [Azathioprine]		S	Unknown	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360506	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531843		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531687		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Naproxen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17361304	EXPEDITED (15-DAY)		DE	US-GLENMARK PHARMACEUTICALS-2020GMK045822		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide	Naproxen			S	Oral	Unk		Glenmark
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362077	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362094	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532892			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User				otherwise specified)		
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone Acetonide		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362159	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532688		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C	Intra-articular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362187	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020041070		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Subcutaneous	50 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Enalapril			S	Unknown			Actavis
	Hydrochlorothiazide			S	Unknown			Ivax
	Losartan			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Pantoprazole Magnesium			S	Unknown			Teva
	Codeine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Isoniazid	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Levaquin	S	Unknown	Not Reported
	Lopresor	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Penicillin	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Cipro	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Saccharated Iron Oxide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362927	EXPEDITED (15-DAY)		OT	CA-SA-2020SA003084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy; Treatment Failure	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Myochrysine			S		Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q4w		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Qw		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Sarilumab			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1.0 G		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Tofacitinib			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Qd		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363123	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023722			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-	Plaquenil			S		400 Mg		Sanofi
	Arava			S				Sanofi

Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride	S				Not Reported
	Sulfasalazine	S				Not Reported
	Azathioprine	S		100 Mg		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Xeljanz	S		5 Mg, Qd (2 Every 1 Days)		Not Reported
	Hydroxychloroquine	C				Not Reported
	Leflunomide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Sublingual			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363250	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533735		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Product Use In Unapproved Indication; Product Use Issue; Septic Shock; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported

		Sulfasalazine			S	Oral				Not Reported
		Triamcinolone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532637			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous	Therapy Duration:- 404.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration:- 5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533753		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C	Unknown	Tablet (Extendedrelease)		Not Reported
	Oxyneo			C	Unknown	Tablet (Extendedrelease)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363386	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005934		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363643	EXPEDITED (15-DAY)		DS	CA-SA-2020SA024097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Infection; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		10 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1500 Mg, Bid		Not Reported
	Levothyroxine Sodium			S				Not Reported
	Leflunomide			S				Sanofi
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Etanercept			S		1 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005936			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	10 Milligram		Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363959	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1500 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	10677800	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014100610		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Sulfasalazine			S	Oral	2 Gram, Qd		Not Reported
	Tramacet			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	17.5 Mg - 25mg Every Week		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form, Qd		Not Reported
	Tramadol/Acetaminophen			S	Oral	Unk		Not Reported
	Metformin			C	Unknown	5 Milligram, Qd		Not Reported
	Metformin			C	Unknown	500 Milligram, Bid		Not Reported
	Lorazepam			C		1 Milligram, Once Nightly		Not Reported

Lorazepam	C		1 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Premarin	C	Unknown	0.625 Milligram	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Tylenol Arthritis Pain	C		Unk	Not Reported
Actonel	C		35 Milligram, Qwk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
Methylprednisolone Acetate	C			Not Reported
Depomedrol	C	Intramuscular	40 Mg, Qmo	Not Reported
Depomedrol	C	Subcutaneous	Unk Unk, Qmo	Not Reported
Depomedrol	C			Not Reported
Lyrica	C	Oral	150 Milligram, Bid	Not Reported
Nortriptyline	C	Unknown	Unk (Tablet And Capsule)	Not Reported
Nortriptyline	C			Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	11231394	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015064666		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue;	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Humira	S	Subcutaneous	Unk		Not Reported
	Zostavax	S	Subcutaneous	Unk (Powder For Suspension)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium	S	Oral	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	11515749	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2015293060		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension;	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Every Two Week		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram		Pfizer
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	12.5 Mg, 4times/Wk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Bid		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)		Not Reported

Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Infliximab Hospira	S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)	Not Reported
	Infliximab Hospira	S	Unknown	Unk	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))	Not Reported
	Infliximab Hospira	S	Unknown	3 Mg, Weekly	Not Reported
	Infliximab Hospira	S		5 Mg, Unk	Not Reported
	Methotrexate Sodium	S		15 Mg/M2, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Unknown
	Methotrexate Sodium	S		15 Mg, 2x/Week	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Unknown
	Methotrexate Sodium	S		Unk	Unknown
	Methotrexate Sodium	S	Unknown	1 Dosage Form, Qwk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Unknown
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Pfizer
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Pfizer
	Triamcinolone	S	Unknown	Unk	Unknown
	Triamcinolone	S		Unk	Unknown
	Triamcinolone	S		Unk	Unknown
	Infliximab	S	Unknown	3 Mg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Infliximab	S	Intravenous (not otherwise specified)	3 Unk	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Pfizer
Triamcinolone Acetonide	S	Unknown	Unk	Pfizer
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Pfizer
Triamcinolone Acetonide	S			Pfizer
Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1 Every 24 Hour(S))	Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg, Daily	Not Reported
Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S))	Not Reported

Anakinra	S	Unknown	50 Mg, Weekly	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Mg, 1x/Day Qd	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S))	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S))	Not Reported
Orencia	S	Unknown	250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S		280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not	280 Mg, 1x/Day Qd	Not Reported

		otherwise specified)		
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Gammagard	S			Not Reported
Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, 1x/Day	Not Reported
Gamastan	S	Intramuscular	70 G, Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12304669	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015013797		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milliliter, Bid		Not Reported
	Xeljanz			S	Oral	10 Milliliter, Bid		Not Reported
	Xeljanz			S	Oral	Unk, Bid		Not Reported
	Xeljanz			S	Oral	10 Milliliter		Not Reported
	Xeljanz			S	Oral	5 Milliliter		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Vioxx			S	Oral	Unk		Not Reported
	Vioxx			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	200 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

	Leflunomide	S	Unknown	Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Wellbutrin	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12343875	NON-EXPEDITED		OT	CA-AMGEN-CANSL2016055527		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

				Rituxan		S	Unknown	Unk	Not Reported
				Simponi		S	Subcutaneous	Unk	Not Reported
				Sulfasalazine		S	Unknown	Unk	Not Reported
				Apo Hydroxychloroquine		S	Unknown	Unk	Not Reported
				Hydroxychloroquine		S	Unknown	Unk	Not Reported
				Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
				Rituximab		S	Unknown	Unk	Not Reported
				Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12695500	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245898		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	Unk		Not Reported
	Fosamax	C		Unk		Not Reported
	Ibuprofen	C	Unknown	Unk		Not Reported
	Lisinopril	C	Unknown	Unk		Not Reported
	Vit D3	C	Unknown	Unk		Not Reported
	Alendronate Sodium	C	Unknown	Unk		Not Reported
	Mtx [Methotrexate]	C		Unk		Not Reported
	Fosavance	C		Unk		Not Reported
	Synthroid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13299527	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016375688		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Unknown	Unk		Pfizer
	Celecoxib			S	Oral	200 Mg, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo Celecoxib			S	Oral	200 Mg, Bid		Not Reported

	Toradol	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	7-10 Mg, Unk		Not Reported
	Tramadol	C	Unknown	100 Mg, As Necessary		Not Reported
	Prednisone	C		7-10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13330098	EXPEDITED (15-DAY)		OT	CA-ROCHE-1693450			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13917842	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2017371881		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram		Pfizer

Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Apo Sulfasalazine	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

	Rituximab			S	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14328853	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017297972		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14639970	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0752		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Overdose; Product Use Issue; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Leflunomide			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14817954	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018054977		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	25 Milligram, Unk		Not Reported
	Orencia			S	Subcutaneous	250 Milligram, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported

					Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
					Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
					Hydroxychloroquine Sulfate	S	Unknown	20 Milligram, Bid	Not Reported
					Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
					Rituximab	S	Unknown	Unk	Not Reported
					Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Hydroxychloroquine	S	Unknown	200 Milligram, Unk	Not Reported
					Hydroxychloroquine	S	Unknown	300 Milligram, Unk	Not Reported
					Actemra	S	Unknown	Unk	Not Reported
					Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
					Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
					Prednisone	C		40 Milligram, Unk	Not Reported
					Prednisone	C		250 Milligram, Unk	Not Reported
					Sulfasalazine	C	Unknown	Unk	Not Reported
					Xeljanz	C	Oral	5 Milligram, Unk	Not Reported
					Xeljanz	C	Unknown	Unk	Not Reported
					Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
					Celebrex	C	Unknown	Unk	Not Reported
					Arava	C	Oral	10 Milligram, Unk	Not Reported
					Loperamide	C	Unknown	Unk	Not Reported
					Wellbutrin	C	Unknown	Unk	Not Reported
					Pantoprazole	C	Unknown	Unk	Not Reported
					Simponi	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15278631	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018110461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Enbrel	S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Morphine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15348973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175923		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15348992	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175991		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15436734	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190086		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15638561	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-978039		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Ineffective; Fungal Infection; Off Label Use; Osteomyelitis; Systemic Infection; Systemic Mycosis	Voriconazole			S	Unknown			Teva
	Voriconazole			S	Oral			Teva
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Amphotericin B			S	Unknown			Not Reported
	Amphotericin B			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported

		Amphotericin B			S	Intravenous (not otherwise specified)				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15683328	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2018CA024265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk;		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	3 Mg, Weekly		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Day		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Not Reported

Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Short Stature; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Milligram, Bid	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S		15 Mg, 2x/Week	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Methotrexate Sodium	S	Unknown	1 Dosage Form, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Not Reported
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	3 Mg, Weekly,Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Unk	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
	Triamcinolone Acetonide	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1	Not Reported

			Every 24 Hour(S))	
Hydroxychloroquine	S	Oral	5 Mg/Kg,	Not Reported
Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S)),	Not Reported
Anakinra	S	Unknown	50 Mg, Weekly	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Mg, 1x/Day Qd	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported

Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S)),	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S)	Not Reported
Orencia	S		250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S	Unknown	280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported

	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S		Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
	Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk,	Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
	Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Gammagard	S		Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
	Gamastan	S	Intramuscular	70 G, Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15710539	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018303849		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer

Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	300 Milligram, Qd	Pfizer
	Sulfasalazine	S	Unknown	500 Milligram	Pfizer
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo Leflunomida	S	Unknown	20 Milligram	Not Reported
	Apo Leflunomida	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Magnesium	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Mtx	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15719053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245381		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day, (Bid)		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported

Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S		0.8 Mg/Kg, Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg, 1x/Day, (Qd)	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic, (Q2wk)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S	Unknown	300 Mg, Daily ((200mg:1 And A Half Pill), Qd)	Not Reported
	Plaquenil	S	Oral	300 Mg, 1x/Day, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic: On Day 0 And Day 15	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S		1 G, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S		Unk	Not Reported
Gold	S		Unk	Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Anakinra	S		Unk	Not Reported
Apo-Hydroxyquine	S	Oral	20 Mg, Unk, (Every Hour)	Not Reported
Apo-Hydroxyquine	S		20 Mg, Daily, (Every Hour)	Not Reported
Actonel	S	Oral	35 Mg, Weekly, Qwk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Mg, Cyclic, Qh	Not Reported
Apo-Leflunomide	S		20 Mg, Daily (Qd (1 Every 24 Hour(S))	Not Reported
Apo-Leflunomide	S		Unk, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		Unk, 1x/Day, Once Every 24 Hours	Not Reported
Risedronate	S		35 Mg, Weekly	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Hydroxychloroquine	S		Unk Unk, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, Unk	Not Reported
Risedronate	C		35 Mg, Weekly, Qwk	Not Reported
Hydroxychloroquine Sulfate	C		300 Mg, Cyclic, Qh	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	200 Mg, 2x/Day, Bid	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk, Weekly, Qwk	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15867790	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16092462	EXPEDITED (15-DAY)		OT	PHHY2019CA057177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx	S	Unknown			Novartis
	Methotrexate	S	Unknown	Unk Unk, Unknown		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Enbrel	S	Unknown	Unk Unk, Unknown		Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Otezla	S	Oral	Unk Unk, Unknown		Not Reported
	Plaquenil	S	Unknown	Unk Unk, Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Stelara	S	Subcutaneous	Unk Unk, Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16454389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk Unk, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16831220	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3552		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown	Strength: 500 Mg		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16891747	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-28949		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Prednisone	S	Oral		Not Reported

	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16912193	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201910001021			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Of Conjunctiva	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Unk, Qd		Concordia
	Mizoribine			C	Unknown	Unk		Not Reported
	Tacrolimus Monohydrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17030148	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001623			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Pulmonary Oedema	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	40 Mg, 1 In 2 Wk (40mg/0.4ml(40 Milligram, Solution For Injection In Pre-Filled Pen)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17273061	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC-2020016994		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide	Clindamycin Hcl			S	Oral	Unk		Pfizer
	Esomeprazole Magnesium			S	Oral	Unk		Unknown
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17274911	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005784		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	4 Df, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported

	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	50 Mg, Q.M.T.	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Unk, Prn	Not Reported
	Prednisone	C	Unknown	24 Mg, Qd	Not Reported
	Prednisone	C	Unknown	23 Mg, Qd	Not Reported
	Prednisone	C	Unknown	25 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531428		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine			S	Unknown			Not Reported

Systemic Lupus Erythematosus; Treatment Failure	Hydrochloride			
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364072	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537099			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown	Single-Use Vial		Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537110			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2534200		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364139	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534304		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Actonel			C				Not Reported
	Ergocalciferol			C				Not Reported
	Esomeprazole			C				Not Reported

	Ferrous Gluconate	C	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Not Reported
	Loperamide	C	Not Reported
	Nasonex	C	Not Reported
	Pantoprazole Magnesium	C	Not Reported
	Prednisone	C	Not Reported
	Trazodone	C	Not Reported
	Tylenol	C	Not Reported
	Oxycodone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364143	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534269			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100 Mg Per Syringe Single Use		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

		Triamcinolone Hexacetonide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364184	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533950		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Nortriptyline			S	Oral			Not Reported
	Orencia			S	Vaginal			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Nasonex			C	Unknown	Metered Dose		Not Reported

	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C			Not Reported
	Perphenazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone	C			Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364199	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533938		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364233	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364361	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530616			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364637	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Meloxicam		S	Oral		Not Reported
					Otezla		S	Unknown		Not Reported
					Pantoprazole		S	Oral		Not Reported
					Pantoprazole Magnesium		S	Unknown		Not Reported
					Synthroid		S	Unknown		Not Reported
					Diltiazem Hydrochloride		C	Unknown		Not Reported
					Fluticasone Propionate		C	Unknown		Not Reported
					Mar-Pantoprazole		C	Unknown		Not Reported
					Mometasone Furoate		C	Unknown		Not Reported
					Premarin		C	Unknown		Not Reported
					Salbutamol Sulfate		C	Unknown		Not Reported
					Tramadol Hydrochloride		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364672	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0601		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365137	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365159	NON-EXPEDITED			NVSC2020US027808			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Trametinib			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365204	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0625			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Lyrica		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365355	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537118			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

			Sulfate]							
			Prednisone		S	Oral				Not Reported
			Cetirizine Hydrochloride		S	Unknown				Not Reported
			Remicade		S	Intravenous (not otherwise specified)				Not Reported
			Simponi		S	Subcutaneous				Not Reported
			Sulfasalazine		S	Subcutaneous				Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
04-Feb-2020	17365439	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537126			Male	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported		
	Actemra			S				Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported		
	Rituxan			S				Not Reported		
	Anakinra			S	Unknown			Not Reported		
	Anakinra			S				Not Reported		
	Apo-Leflunomide			S	Oral			Not Reported		
	Apo-Leflunomide			S				Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Enbrel			S				Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Humira			S				Not Reported		
	Hydroxychloroquine			S	Unknown			Not Reported		
	Hydroxychloroquine			S				Not Reported		
	Ilaris			S	Unknown			Not Reported		
	Ilaris			S				Not Reported		
	Methotrexate			S	Unknown			Not Reported		
	Methotrexate			S				Not Reported		
	Orencia			S	Unknown			Not Reported		
	Orencia			S				Not Reported		

		Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
		Plaquenil [Hydroxychloroquine Sulfate]			S					Not Reported
		Remicade			S	Unknown				Not Reported
		Remicade			S					Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365468	NON-EXPEDITED		HO, OT	US-APOTEX-2020AP007164		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Cryptosporidial; Neutropenia	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365620	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024416		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Parenteral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	22 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Adalimumab			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)		
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Tocilizumab		C			Not Reported
	Prednisone		C		6 Mg, Bid	Not Reported
	Minocycline		C			Not Reported
	Penicillamine		C			Not Reported
	Ciclosporin		C			Not Reported
	Azathioprine		C		Unk Unk, Qd	Not Reported
	Actemra		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365621	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA023724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Hydroxychloroquine Sulfate			S				Sanofi
	Paracetamol			S				Not Reported
	Arava			S				Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Indometacin			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S		12.5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Morphine Salt Not Specified			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365622	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Hydroxychloroquine			S	Unknown			Sanofi
	Plaquenil			S	Oral			Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral			Sanofi
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365623	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease;	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Diphenhydramine Hydrochloride			S				Sanofi
	Celecoxib			S	Oral			Not Reported

Rheumatoid Arthritis; Treatment Failure	Demerol	S			Sanofi
	Levofloxacin	S			Not Reported
	Methotrexate	S			Not Reported
	Azithromycin	S		250 Mg, Qd	Not Reported
	Cyclophosphamide	S		2000 Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Imuran [Azathioprine]	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Ezetrol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365628	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023804			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365629	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S		8 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365630	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA024044			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Acetylsalicylic Acid			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Benzylpenicillin			S		Unk		Not Reported

	Enbrel			S		Unk				Not Reported
	Humira			S	Subcutaneous	Unk				Not Reported
	Acetaminophen			C		Unk				Not Reported
	Pregabalin			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365632	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S				Not Reported
	Tocilizumab			S				Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Orencia			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Solution)		Not Reported
	Enbrel			S				Not Reported
	Cimzia			C	Subcutaneous	Solution		Not Reported
	Prednisone			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365633	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023682		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S		25 Mg 4 Every 1 Week		Not Reported

				Plaquenil	S				Sanofi
				Sulfasalazine	S	Oral			Not Reported
				Actemra	S		162 Mg, Qw		Not Reported
				Simponi	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365634	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA023772			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365635	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi

	Xeljanz			C	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365636	EXPEDITED (15-DAY)		CA, OT	CA-SA-2020SA025775			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S		Unk Unk, Biw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Oral	500 Mg, Qd		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Vioxx			S				Not Reported
	Leflunomide			C		10 Mg		Not Reported
	Xeljanz			C	Oral	2 Df, Qd, 5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365637	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023805		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Condition Aggravated; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness	Plaquenil			S	Unknown			Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Celebrex			C	Unknown					Not Reported
	Tramacet			C						Not Reported
	Tramadol			C		100 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365638	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported
	Arava			S		20 Mg		Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S		567 Mg, Qm		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365639	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA024490		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported

	Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365641	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024414		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Hydroxychloroquine			S		300 Mg		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		10 Mg		Sanofi
	Celecoxib			S		50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Plaquenil			S		300 Mg		Sanofi
	Prednisone			S				Not Reported
	Sulfasalazine			S		2 G		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365642	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024413		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

					Enbrel	S	Subcutaneous		Not Reported
					Orencia	S	Unknown		Not Reported
					Simponi	S	Subcutaneous	Solution	Not Reported
					Acetaminophen	C			Not Reported
					Cyclobenzaprine	C	Unknown	10 Mg	Not Reported
					Cyclobenzaprine	C	Unknown	10 Mg	Not Reported
					Desoximetasone	C	Unknown	5 Mg, Qd	Not Reported
					Desoximetasone	C	Unknown	5 Mg, Qd	Not Reported
					Leflunomide	C	Unknown		Not Reported
					Prednisone	C	Unknown	5 Mg, Qd	Not Reported
					Prednisone Acetate	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365643	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024411		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365644	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Plaquenil			S		200 Mg, Qd (2 Every 1 Day)		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Sulfasalazine			S		1 G, Qd (2 Every 1 Day)		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Qd(2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365645	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365647	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025492			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Qd		Sanofi
	Sulfasalazine			S		500 Mg, 4 Every 1 Days		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetaminophen			C		500 Mg		Not Reported
	Hydrocortisone Valerate			C				Not Reported
	Hydromorphone			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Lyderm [Fluocinonide]			C				Not Reported
	Naproxen			C		Unk		Not Reported
	Naproxen			C		250 Mg, Qd		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Sodium Aurothiomalate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365649	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024106		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365650	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365651	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025786			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Plaquenil			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S				Sanofi
	Prednisone			S		6 Mg, Qd		Not Reported
	Pregabalin			S		150 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Trazodone Hydrochloride			S		25 Mg, Qd		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Imuran [Azathioprine Sodium]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365652	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA023870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Indometacin			S	Oral	50 Mg, Qid		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Q4w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Q8w		Not Reported
	Indomethacin [Indometacin]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365653	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Orencia			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365654	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023792		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Subcutaneous			Sanofi
	Arava			S	Unknown	10 Mg		Sanofi
	Actemra			S	Unknown	650 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg, Qm		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Rituxan			S	Subcutaneous	1000 Mg		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Prednisone			C		250 Mg		Not Reported
	Prednisone			C		40 Mg		Not Reported
	Sulfasalazine			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365655	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S		50 Mg		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Methotrexate			C		25 Mg		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous	50 Mg, Qm		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365656	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023721			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Aspirine			S				Not Reported
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Procaine Benzylpenicillin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Pregabalin			C				Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365658	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024419		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S				Sanofi
	Amlodipine Besilate			S	Oral	5 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk Unk, Qd		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Asacol			S	Unknown	800 Mg, Tid		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Enbrel			S		50 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Diphenhydramine	C	Oral	50 Mg	Not Reported
	Ebastine	C			Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365659	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solutions)		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365660	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutanoeus		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365661	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		300 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S		200 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg; Qw		Not Reported
	Methotrexate			S		20 Mg; Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not	300 Mg, Q6w		Not Reported

				otherwise specified)		
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C			Not Reported
	Wellbutrin		C	Oral		Not Reported
	Xeljanz		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365662	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023786		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg		Sanofi
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Methotrexate			S	Oral	200 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	200 Mg		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365663	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm;	Hydroxychloroquine			S		Unk		Sanofi

Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Pregabalin	S	Unk	Not Reported
	Leflunomide	S	Unk	Sanofi
	Methotrexate	S	25 Mg	Not Reported
	Mirtazapine	S	15 Mg	Not Reported
	Sulfasalazine	S	Unk	Not Reported
	Actemra	S	Unk	Not Reported
	Enbrel	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365664	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Pregabalin			S				Not Reported
	Actemra			S				Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S				Not Reported
	Prednisone			C				Not Reported
	Piroxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365665	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365666	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA024082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Plaquenil			S		200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cefazolin			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)		
	Humira		S	Subcutaneous		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S			Not Reported
	Naproxen		C		500 Mg	Not Reported
	Viread		C			Not Reported
	Xeljanz		C	Oral	5 Mg	Not Reported
	Arava		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365667	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA023793			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Alendronate Sodium			S	Unknown	70 Mg, Qw		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S		360 Mg, Qm		Not Reported
	Enbrel			S		25 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Ciclosporin			C		150 Mg, Qd		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365668	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Plaquenil Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4w		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024036		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365680	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown	Tablets		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Cosentyx			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365681	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Mg		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Leflunomide			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Df		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

		Pantoprazole			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365682	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Arava			S		10 Mg, Qd		Sanofi
	Paracetamol			S	Endocervical			Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Prednisone			S	Oral	20 Ng		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C		20 Mg, Qw Solution		Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported
	Methotrexate			C		Unk, Q4w		Not Reported
	Meloxicam			C				Not Reported
	Synthroid			C				Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported

	Actemra			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365683	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA024415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Hydroxychloroquine			S		400 Mg		Sanofi
	Actemra			S	Unknown			Not Reported
	Leflunomide			S		10 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q4w		Not Reported
	Prednisone			S	Unknown			Not Reported
	Risedronate Sodium			C		35 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17366989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043725		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Mg, Unk		Not Reported

Leflunomide	S	Oral	20 Mg, Unk		Not Reported
Otezla	S	Oral	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17366993	EXPEDITED (15-DAY)		HO, LT	FR-ELI_LILLY_AND_COMPANY-FR202001013747		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Palpitations; Reading Disorder	Fluoxetine Hydrochloride			S	Unknown	1 Df, Qd, Tablet		Eli Lilly And Co
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367375	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020048559		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

		Remicade			S		Unk			Not Reported
		Simponi			S	Unknown	Unk			Not Reported
		Simponi			S	Subcutaneous	Unk			Not Reported
		Desoximetasone			C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367657	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367697	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178528		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

					otherwise specified)				
	Sulfasalazine			S	Unknown				Not Reported
	Tacrolimus			S	Unknown				Not Reported
	Prednisone			C	Oral	17 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367722	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179082		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S	Unknown			Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Calcium Carbonate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367888	NON-EXPEDITED			US-PFIZER INC-2020044225		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer

	Codeine Sulfate	S	Unk	Not Reported
	Yodoxin	S	Unk	Not Reported
	Augmentin	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17369219	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016056029		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	0.8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported

	Orencia		S	Unknown	750 Mg, Q4wk	Not Reported
	Orencia		S	Unknown	750 Milligram	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	5 Mg, Q8wk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Certolizumab Pegol		C	Unknown	Unk	Not Reported
	Tofacitinib		C		Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Simponi		C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12538837	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016070695		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Milligram, Bid		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported

Arava	S	Oral	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Oral	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	Unk, Q2wk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
Hydroxychloroquine	C	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qwk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Folic Acid	C	Oral	5 Milligram, Qd (6 Days Per Week)	Not Reported
Folic Acid	C	Oral	5 Milligram	Not Reported
Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12705597	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1521		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vit D3			C	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosavance			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

	Mtx			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12774372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076813		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5.0 Milligram		Not Reported
	Fosamax			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported
	Lisinopril			C	Unknown	Unk		Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported

	Fosavance			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	13162393	EXPEDITED (15-DAY)		OT	CA-ROCHE-1884997		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 976.0		Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 9.0 Year(S)		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 10.0 Year(S)		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	13923554	EXPEDITED (15-DAY)		HO, LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2654		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Apo-Sulfasalazine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15272092	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-943473		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypokalaemia; Overdose	Hydroxychloroquine			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15400613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15470065	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1073020		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Risedronate			S	Unknown	35 Mg, Unk		Not Reported
	Theophylline			S	Unknown	200 Milligram, Bid		Not Reported
	Levothyroxine			S	Unknown	75 Microgram, Qd		Not Reported

Hypotension	Prednisolone	S	Unknown	7.5 Milligram, Qd	Not Reported
	Domperidone	S	Unknown	10 Milligram, Q8h,30 Mg, Qd (10 Mg, Tid)	Mylan
	Amylase/Lipase/Protease	S	Unknown	10 Milligram, Tid	Mylan
	Carbocisteine	S	Unknown	750 Milligram, Bid,750 Milligram (750mg 2 Tds)	Mylan
	Immunoglobulins Nos	S	Unknown	Unk	Mylan
	Creon	S	Unknown	10 Milligram, Q8h, (30 Milligram, Qd, 10 Mg, Tid)	Mylan
	Uniphyllin	S	Unknown	400 Milligram, Qd (200 Mg, Bid)	Mylan
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Mylan
	Propanolol /00030001/	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15500678	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018024121		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15582761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times A Week		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16088849	EXPEDITED (15-DAY)		OT	PHHY2019CA056635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Stelara			S	Subcutaneous	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Methotrexate			C	Unknown	Unk			Not Reported
	Arava			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16783313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-084437		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16863631	EXPEDITED (15-DAY)		OT	PT-JNJFOC-20190929486		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Interstitial Lung Disease; Off Label Use; Product Use In Unapproved Indication; Pulmonary Embolism; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Twice 2 Weeks Apart, Cyclic (9 Cycles)		Not Reported
	Rituximab			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17245651	EXPEDITED (15-DAY)		OT	FR-ROCHE-2513203		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Hyperkeratosis; Ocular Toxicity	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17263011	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1001517		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	5 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan
	Imeth /00113801/			S	Subcutaneous	10 Milligram, Qw		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296572	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079273			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296604	EXPEDITED (15-DAY)		DE, OT	TN-APPCO PHARMA LLC-2079274			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Haemophagocytic Lymphohistiocytosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296702	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-PFIZER INC-2020025201			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Fluconazole			S	Transplacental	Unk		Pfizer
	Methylprednisolone			S	Transplacental	Unk		Pfizer
	Methylprednisolone			S	Transplacental	Unk		Pfizer
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Nadroparine			S	Transplacental	Unk		Not Reported
	Etamsylate			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Flebogamma Dif			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Metoprolol Tartrate			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Vitamin B Complex			S	Transplacental	Unk		Not Reported
	Albumin			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported

	Ornidazole	S	Transplacental	Unk		Not Reported
	Cefixime	S	Transplacental	Unk		Not Reported
	Magnesium Lactate	S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk		Not Reported
	Folic Acid	S	Transplacental	Unk		Not Reported
	Omeprazole	S	Transplacental	Unk		Not Reported
	Cefotaxime	S	Transplacental	Unk		Not Reported
	Cefotaxime	S	Transplacental	Unk		Not Reported
	Hydroxychloroquine	S	Transplacental	Unk		Not Reported
	Hydrocortisone	S	Transplacental	Unk		Not Reported
	Vulmizolin	S	Transplacental	Unk		Not Reported
	Penicillin G	S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk		Not Reported
	Vitamin D	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17363211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

						Methotrexate		S	Oral	Not Reported
						Methotrexate		S	Intramuscular	Not Reported
						Naproxen		S	Unknown	Not Reported
						Orencia		S	Intravenous (not otherwise specified)	Not Reported
						Lozide [Indapamide]		C	Unknown	Not Reported
						Metformin		C	Oral	Not Reported
						Prednisone		C	Unknown	Not Reported
						Ramipril		C	Unknown	Not Reported
						Vitamin D3		C	Unknown	Not Reported
						Xeljanz		C	Oral	Not Reported
						Acetylsalicylic Acid		C	Unknown	Not Reported
						Calcium		C	Unknown	Not Reported
						Ergocalciferol		C	Unknown	Not Reported
						Lantus		C	Unknown	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
05-Feb-2020	17370217	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179028			Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Azathioprine			S	Unknown			Not Reported		
	Methotrexate			S	Unknown			Barr		
	Mycophenolate Mofetil			S	Unknown			Teva		
	Prednisone			S	Unknown			Actavis		
	Anakinra			S	Unknown			Not Reported		
	Hydroxychloroquine			S	Unknown			Not Reported		
	Orencia			S	Unknown			Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
05-Feb-2020	17370247	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179012		73 YR	Female	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370250	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370276	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210851		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun

	Ramipril			S	Unknown	Unk				Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370297	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047519		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Daily		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370526	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179284			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance;	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported

Hepatotoxicity; Liver Function Test Increased	Ciclosporin		S	Unknown		Actavis
	Leflunomide		S	Unknown	20 Milligram Daily;	Barr
	Doxycycline Hyclate		S	Unknown		Actavis
	Mercaptopurine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Barr
	Methylprednisolone		S	Unknown		Actavis
	Bromocriptine		S	Unknown		Not Reported
	Colchicine		S	Unknown		Not Reported
	Dilaudid		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Pamidronate Disodium		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tenoxicam		S	Unknown		Not Reported
	Ustekinumab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370549	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370571	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2533713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370736	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000023			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported

Onealfa	C	Unk		Not Reported
Onealfa	C			Not Reported
Takepron	C	Unk		Not Reported
Takepron	C			Not Reported
Persantin	C	Unk		Not Reported
Epadel T	C	Unk		Not Reported
Bonalon	C	Unk		Not Reported
Bonalon	C			Not Reported
Loxonin	C	Unk		Not Reported
Selbex	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533766		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported

Erythematosus; Wound	Humira	S	Sunconjunctival	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371199	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US049131		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Ineffective; Fungal Infection; Nodule; Osteomyelitis; Rash; Systemic Infection; Systemic Mycosis	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Astellas
	Voriconazole			S	Oral			Not Reported
	Voriconazole			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unknown Freq.		Not Reported

	Prednisone			S	Unknown	40 Mg, Once			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531864		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371763	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372026	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Mycophenolate Mofetil			S	Unknown	2 Gram Daily;		Teva
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine			S	Oral	200 Milligram Daily;		Not Reported
	Myfortic			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372069	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179359		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown	6 Dosage Forms Daily;		Not Reported
	Tacrolimus			S	Unknown	5 Dosage Forms Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372076	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179282		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia	Azathioprine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Barr
	Leflunomide			S	Unknown				Barr
	Actemra			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Intravenous drip				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372079	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372123	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Plaquenil	S				Sanofi
	Methotrexate	S	Subcutaneous	25 Mg, Qw, Solution		Not Reported
	Arava	S		Tablet		Sanofi
	Enbrel	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372133	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023785		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	300 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qw		Sanofi
	Actemra			S		50 Mg, Qw		Not Reported
	Actemra			S		4.0 Mg/Kg		Not Reported
	Adalimumab			S		Unk		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S		40 Mg		Not Reported
	Orencia			S		Unk Unk, Qm		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S		1 G		Not Reported
	Rituximab			S		1 G		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Simponi		S			Not Reported
	Celebrex		C			Not Reported
	Diclofenac		C			Not Reported
	Lyrica		C			Not Reported
	Methotrexate		C	Subcutaneous	20 Mg, Qw	Not Reported
	Methotrexate		C		0.8 Ml, Qw	Not Reported
	Sulfasalazine		C			Not Reported
	Tocilizumab		C	Endocervical		Not Reported
	Valsartan		C			Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Methotrexate		C	Oral	Unk Unk, Qw	Not Reported
	Methotrexate		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372135	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA025298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S		5 Mg, 2 Every 1 Day		Not Reported
	Orencia			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C		Form: Solution		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372138	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024488		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Hydroxychloroquine			S		300 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Arava			S				Sanofi
	Sulfasalazine			S		2 Mg		Not Reported
	Celecoxib			S				Not Reported
	Leflunomide			S		10 Mg		Sanofi
	Prednisone			S				Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, 1 Every 1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372139	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Doxycycline			S		50 Mg		Not Reported
	Leflunomide			S		20 Mg, Qd (1 Every 1 Day)		Sanofi
	Plaquenil			S		Unk		Sanofi
	Doxycycline Hyclate			S		50 Mg		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

	Rituximab	S	Unk	Not Reported
	Methotrexate	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Simponi	C	Unk	Not Reported
	Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372147	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025784		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Hydroxychloroquine			S		300 Mg		Sanofi
	Arava			S				Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Celecoxib			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		2 Mg		Not Reported
	Folic Acid			C		10 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Plaquenil			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Acetaminophen			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		50 Mg, Qiw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen;Codeine			C				Not Reported

		Phosphate								
		Meloxicam			C					Not Reported
		Methotrexate			C		25 Mg, Qw			Not Reported
		Synthroid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372164	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S		400 Mg		Sanofi
	Hydroxychloroquine			S		200 Mg, 2 Every 1 Weeks		Sanofi
	Hydroxychloroquine			S		200 Mg		Sanofi
	Hydroxychloroquine			S		400 Mg		Sanofi
	Hydroxychloroquine			S		200 Mg 2 Every 1week		Sanofi
	Hydroxychloroquine			S		400 Mg, 3 Every 1 Weeks		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S				Not Reported
	Orencia			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Adalimumab			S		40 Mg, 1 Every 2 Weeks		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Actemra			S	Subcutaneous	162 Mg 2 Every 1 Weeks		Not Reported
	Actemra			S		162 Mg		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported
	Xeljanz			C		5 Mg, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372171	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530390		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Vaginal			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Aclasta			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Esomeprazole			C				Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Nasonex			C				Not Reported
	Nortriptyline			C	Unknown			Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			C				Not Reported
	Oxycodone Terephthalate			C				Not Reported
	Perphenazine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Trazodone Hydrochloride			C	Unknown			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372473	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179363		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372538	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1013147		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Weight Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17373082	EXPEDITED (15-DAY)		OT	NVSC2020US027795			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Malignant Neoplasm	Hydroxychloroquine			S	Unknown	Unk		Novartis

Progression; Pancreatic Carcinoma; Product Use In Unapproved Indication	Trametinib	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17373885	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079842			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374167	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079843			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374926	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020047444		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid	Methotrexate Sodium			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Unk		Not Reported
	Isoniazid			S	Unknown			Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	500 Mg, 1 Every 2 Weeks		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Azathioprine			C				Not Reported

Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Diphenhydramine Hydrochloride	C			Not Reported
	Folic Acid	C			Not Reported
	Glyburide	C			Not Reported
	Glyburide	C		Unk	Not Reported
	Metformin	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Pariet	C			Not Reported
	Ramipril	C			Not Reported
	Synthroid	C			Not Reported
	Trajenta	C			Not Reported
	Vitamin B6	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538100		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Solutiuon		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration- 730.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	11761994	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015241187		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Cyclic: 4 Times/Week		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Unknown
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Hydromorphone Hydrochloride			S		Unk		Unknown
	Folic Acid			S		5 Mg, Unk		Not Reported
	Folic Acid			S		15.5 Unk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Mg, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	520 Milligram		Not Reported
	Acetaminophen			S	Oral	65 Mg, Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Mg, Unk		Not Reported
	Fosavance			C		Unk Unk, Qwk		Not Reported

	Hydrocortisone	C	Intravenous (not otherwise specified)	250 Mg, Unk		Not Reported
	Hyzaar	C		12.5 Mg, Qd		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12327018	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2013020048		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Physical Disability; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	500 Milligram, Bid		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Milligram		Not Reported
	Prednisone			S	Unknown	20 Milligram A Day		Not Reported
	Prednisone			S	Unknown	2.5 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naprelan	C		1000 Milligram, Qd	Not Reported
	Folic Acid	C		5 Milligram, 4 Times/Wk	Not Reported
	Crestor	C		Unk	Not Reported
	Metoprolol	C		50 Milligram	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Lovastatin	C	Unknown	Unk	Not Reported
	Vitamin D	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Naproxen	C	Unknown	500 Milligram, Bid	Not Reported
	Naproxen Sodium	C	Unknown	1000 Milligram, Qd	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Rosuvastatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12480786	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016249481		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Incorrect Route Of Product Administration; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Off Label Use; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Apo Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12908779	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAXALTA-2016BLT007821			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life;	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Abatacept			S	Intravenous (not otherwise specified)	200 Mg, 1x A Month		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	50 Milligram, Unknown		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported

Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Anakinra	S	Subcutaneous	50 Milligram, 1x/Week	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	1 Dosage Form, 1x/Day:Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Unknown	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, 2x A Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Unknown	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 1x A Week	Not Reported
	Enbrel	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, 1x/Day:Qd	Not Reported
	Hydroxychloroquine	S	Oral	1 Dosage Form, 1x/Day:Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg/Kg, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, Unknown	Not Reported
	Infliximab	S	Unknown	1 Dosage Form, 1x/Day:Qd	Not Reported
	Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1x/2wks	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
	Methotrexate	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported

Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral	50 Mg, Tablet	Not Reported
Apo-Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
Sulfasalazine	S	Oral	250 Mg, 1x A Day	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, 2x A Week	Not Reported
Tocilizumab	S			Not Reported
Triamcinolone	S	Unknown	Spray Metered Dose	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x/2wks	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1 Every 2 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x A Month	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported

Prednisone	S	Oral	50 Milligram, 2x/Day:Bid		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid		Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid		Not Reported
Prednisone	S	Oral	3 Milligram, 2x/Day:Bid		Not Reported
Prednisone	S	Oral	2 Dosage Form, 1x/Day:Qd		Not Reported
Triamcinolone Acetonide	S	Unknown	Unk		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk		Not Reported
Triamcinolone Hexacetonide	S	Other	Unk		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk		Not Reported
Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13107350	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	For 8 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Minocycline Hydrochloride	S	Unknown		Not Reported
	Oxycodone Hydrochloride	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13113133	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0862		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Plaquenil	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13114444	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105843		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Ankylosing Spondylitis; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Test Abnormal; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Increased; Cataract; Chest Pain; Chills; Contraindicated Product Administered;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 5th Of Unspecified Month		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 1st Of		Not Reported

Contusion; Deep Vein Thrombosis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Erythema; Fall; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin; Heart Rate Increased; Hepatic Enzyme Abnormal; Hypercalcaemia; Infection; Inflammation; Influenza; Infusion Related Reaction; Lethargy; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Morton'S Neuralgia; Muscular Weakness; Musculoskeletal Disorder; Musculoskeletal Stiffness; Mycotic Allergy; Nausea; Neuropathy Peripheral; Oral Discomfort; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling; Product Use Issue; Productive Cough; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid				Unspecified Month	
	Methotrexate Sodium	S	Subcutaneous	Start Date: 8th Of Unspecified Month	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	Start Date: On 10th Of Unspecified Month In 2011.	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	4 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituxan	S	Intravenous (not		Not Reported

Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer; Speech Disorder; Ulcer			otherwise specified)		
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Codeine	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Rituximab	S	Unknown		Not Reported

	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Alendronic Acid	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Ergocalciferol	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisolone	C		Not Reported
	Desoximetasone	C		Not Reported
	Naproxen	C		Not Reported
	Plaquenil /00072602/	C		Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Sulfasalazine	C		Not Reported
	Symbicort	C		Not Reported
	Tramadol Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13136489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882213		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Pain; Pain In Extremity; Peripheral Swelling; Swelling	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13224604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890646		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

		Prednisone Acetate			C	Unknown					Not Reported
		Hydroxychloroquine Sulfate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13231930	NON-EXPEDITED		OT	US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL000196			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Hypersensitivity; Nausea; Vomiting	Lasix			S	Unknown	Unk		Validus
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	14335835	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2163		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	14746831	EXPEDITED (15-DAY)		HO	CA-ROCHE-2104630		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Oral			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15227435	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016285040		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer

Incomplete; Treatment Failure	Methotrexate Sodium	S	Oral	20 Mg, Weekly	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S	Oral	200 Mg, 1x/Day	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, 1x/Day	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, 1x/Day (200 Mg 2 Tablet)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Oral	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Folic Acid	C	Oral	5 Mg, 1x/Day (6 Days Per Week)	Not Reported
	Folic Acid	C	Oral	5 Mg, 1x/Day	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Leflunomide	C	Oral	20 Mg, 1x/Day	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Oral	200 Mg, Bid	Not Reported

Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Otezla	S	Oral			Celgene
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide	S	Oral	20 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15395851	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186085		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported
	Wellbutrin			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15448137	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189248		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15517815	NON-EXPEDITED		OT	CA-AMGEN-CANSL2017166286		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen

Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Enbrel	S	Unknown	50 Milligram	Amgen
	Enbrel	S	Subcutaneous	200 Milligram, Q2wk	Amgen
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Q2wk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Cyclical	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	5 Milligram	Not Reported
	Leflunomide	S	Oral	5 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	5 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	5 Milligram	Not Reported
	Prednisone	C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15668198	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570721-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated;	Humira			S	Subcutaneous			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Oral			Not Reported

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Amlodipine	S	Oral	Not Reported
	Depo-Medrol	S	Intra-articular	Not Reported
	Depo-Medrol	S		Not Reported
	Mesalazine	S	Oral	Not Reported
	Atacand Plus	C	Oral	Not Reported
	Bisoprolol Fumarate	C	Oral	Not Reported
	Ferrous Gluconate	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Omega Allergenic Extracts	C	Intradermal	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15675190	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573931-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthritis Bacterial; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Gastric Disorder; Mobility Decreased; Nerve Injury; Neurological Procedural Complication; Pain; Post Procedural Complication;	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Plaquenil			C				Not Reported

Procedural Complication; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15712231	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US052428		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Azathioprine			S	Unknown	Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown Freq.		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Gold			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15912115	NON-EXPEDITED			US-ABBVIE-18K-163-2484812-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15914265	NON-EXPEDITED			US-ABBVIE-18K-163-2476752-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15915352	NON-EXPEDITED			US-ABBVIE-18K-163-2607470-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16048932	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018185639		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Arthropathy; Arthropathy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Unknown
	Celecoxib			S	Unknown	200 Milligram, Q12h		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk, 11:1 Mg		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown

Gastric Disorder; Groin Pain; Joint Swelling; Miliaria; Miliaria; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Citalopram	C	Unknown	10 Mg, 1x/Day	Not Reported
	Citalopram	C		Unk	Not Reported
	Celebrex	C		200 Mg, 2x/Day	Not Reported
	Celebrex	C		Unk	Not Reported
	Lorazepam	C		1 Mg, 1x/ Day (At Bedtime)	Not Reported
	Lorazepam	C		Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	C		Unk	Not Reported
	Pantoloc	C		40 Mg, 2x/Week	Not Reported
	Pantoloc	C	Unknown	40 Mg, 2x/Day	Not Reported
	Pantoloc	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16122586	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018175541		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Enbrel			S	Unknown	50 Milligram, Unk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Pfizer

Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel	S	Unknown	25 Mg, Qwk	Pfizer
	Salazopyrin	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Qwk	Unknown
	Methotrexate Sodium	S	Unknown	20 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	25 Milligram	Not Reported
	Orencia	S	Subcutaneous	250 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Gold	S	Subcutaneous	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Unk	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	20 Mg, 2x/Day	Not Reported
	Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	C	Oral	10 Milligram	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	40 Milligram	Not Reported
	Prednisone	C		250 Milligram	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16133266	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16189081	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011205		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Apotex
	Azathioprine			S	Unknown			Apotex
	Cyclosporine			S	Unknown			Apotex
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Medroxyprogesterone			S	Unknown	Unk		Not Reported
	Depo-Provera			S	Unknown			Not Reported
	Etanercept			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	400 Mg, Total		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown	Unk		Not Reported
	Cyclosporine			C	Unknown	Unk		Not Reported
	Depo-Provera			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16207344	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167550			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Naproxen			C		500 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16234392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-036882		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Off Label Use; Rash; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Arava		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Simponi		C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Leflunomide		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16722029	EXPEDITED (15-DAY)		DS, OT	CA-CELGENEUS-CAN-20190805428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16817760	EXPEDITED (15-DAY)			CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000509			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Buprenorphine			C		Unk		Not Reported
	Xarelto			C		Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Lasix /00032602/			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported
	Vitamin B12 Nos			C		Unk		Not Reported
	Vitamin B6			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17021208	EXPEDITED (15-DAY)		CA, DE, OT	FR-MYLANLABS-2019M1106907			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	Maternal Dose: 20 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Transplacental	Maternal Dose: 400 Mg Qd		Mylan
	Diffu K			S	Transplacental	1 Dosage Form, Qd		Mylan
	Cortancyl			S	Transplacental	Maternal Dose:1 Df, Qd		Mylan
	Imurel /00001501/			S	Transplacental	150 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17147710	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019205773		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17242739	NON-EXPEDITED			NVSC2020US000828		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk				Novartis
	Methotrexate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17251356	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2020SE00846		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Inexium			S	Oral			Astrazeneca
	Tardyferon			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Levothyrox			S	Oral	100ug/Inhal Daily		Not Reported
	Imurel			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17278596	EXPEDITED (15-DAY)		DE, HO, OT	US-ASTRAZENECA-2020SE07371		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide	Esomeprazole Magnesium			S	Oral	Unk		Not Reported
	Clindamycin Hcl			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17316856	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Unknown

Arthritis	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide	S	Unknown	10 Mg, Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Simponi	C	Subcutaneous	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17333011	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3253493-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17370427	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Kineret		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Naproxen		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373500	EXPEDITED (15-DAY)		DS	CA-ROCHE-2531906		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539457		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373911	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374219	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Vitamin B1 [Thiamine]			S	Unknown			Not Reported
	Aclasta			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

Ascorbic Acid	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Nortriptyline	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Thiamine Hydrochloride	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Vitamin A [Retinol]	C	Unknown	Not Reported
Vitamin B3	C	Unknown	Not Reported
Vitamin B6	C	Unknown	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
Nasonex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374397	EXPEDITED (15-DAY)		DE, HO	US-ALVOGEN-2020-ALVOGEN-102684		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To	Naproxen			S	Oral			Not Reported

Various Agents	Ibuprofen		S	Oral	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374779	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023720		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Plaquenil			S		Unk		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg Qw		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Solution)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374782	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025870			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported

	Humira		S	Subcutaneous		Not Reported
	Orencia		S			Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S			Not Reported
	Prednisone		C		2 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375092	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375337	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0655		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375889	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported

Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375961	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537152			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

	Enbrel			S	Unknown	Not Reported
	Enbrel			S		Not Reported
	Humira			S	Subcutaneous	Not Reported
	Humira			S		Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Hydroxychloroquine			S		Not Reported
	Ilaris			S	Subcutaneous	Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide			S	Oral	Not Reported
	Leflunomide			S		Not Reported
	Methotrexate			S	Unknown	Not Reported
	Methotrexate			S		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Orencia			S		Not Reported
	Remicade			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Sulfasalazine			S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535459			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Cetirizine Hydrochloride		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

		Cetirizine Hydrochloride			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533781		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377492	NON-EXPEDITED			US-ABBVIE-19K-163-2658597-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377497	EXPEDITED (15-DAY)		HO	CN-IPCA LABORATORIES LIMITED-IPC-2020-CN-000399			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377511	NON-EXPEDITED			US-ABBVIE-19K-163-2660980-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Diarrhoea; Drug Hypersensitivity; Hepatic Function Abnormal; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Glimepiride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377526	NON-EXPEDITED			US-ABBVIE-19K-163-2658649-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance	Methotrexate			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Cimzia			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377532	NON-EXPEDITED			US-ABBVIE-19K-163-2618887-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377651	NON-EXPEDITED			US-ABBVIE-19K-163-2663000-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377848	NON-EXPEDITED			US-ABBVIE-19K-163-2663033-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Methotrexate				S	Oral			Not Reported
	Enbrel				S	Unknown			Not Reported
	Plaquenil				S	Unknown			Not Reported
	Leflunomide				S	Unknown			Not Reported
	Sulfasalazine				S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377864	NON-EXPEDITED			US-ABBVIE-19K-163-2663035-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Sinusitis; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377887	NON-EXPEDITED			US-ABBVIE-19K-163-2662918-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377912	NON-EXPEDITED			US-ABBVIE-19K-163-2628453-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Nausea; Therapeutic Product Effect Decreased; Vomiting	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz Xr		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377922	NON-EXPEDITED			US-ABBVIE-19K-163-2666857-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Migraine	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377937	NON-EXPEDITED			US-ABBVIE-19K-163-2665118-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Eruption; Drug Intolerance; Necrosis; Nephrotic Syndrome; Oedema	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Arava			S	Unknown					Not Reported
	Gold			S	Unknown					Not Reported
	Methotrexate			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377951	NON-EXPEDITED			US-ABBVIE-19K-163-2636615-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377967	NON-EXPEDITED			US-ABBVIE-19K-163-2665116-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Pruritus; Rash; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377980	NON-EXPEDITED			US-ABBVIE-19K-163-2665109-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective	Humira	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Xeljanz Xr	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377984	NON-EXPEDITED			US-ABBVIE-19K-163-2662926-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Eye Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377988	NON-EXPEDITED			US-ABBVIE-19K-163-2667995-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378056	NON-EXPEDITED			US-ABBVIE-19K-163-2666891-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective	Methotrexate		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378076	NON-EXPEDITED			US-ABBVIE-19K-163-2666894-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hand Deformity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378141	NON-EXPEDITED			US-ABBVIE-19K-163-2666886-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous	12 Years		Not Reported
	Methotrexate			S	Oral	10 Years		Not Reported
	Hydroxychloroquine			S	Unknown	10 Years		Not Reported
	Sulfasalazine			S	Unknown	For 10 Years		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378142	NON-EXPEDITED			US-ABBVIE-19K-163-2666914-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported

Incomplete		Methotrexate			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378152	NON-EXPEDITED			US-ABBVIE-19K-163-2666769-00		54 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fatigue; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold Injections			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378188	NON-EXPEDITED			US-ABBVIE-19K-163-2666788-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Exposure During Pregnancy; Injection Site Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378200	NON-EXPEDITED			US-ABBVIE-19K-163-2666879-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Prior To May 2018 For		Not Reported

Gastrointestinal Disorder				Two Years	
	Enbrel		S	Unknown	Not Reported
	Rituxan		S	Oral	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Leflunomide		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378202	NON-EXPEDITED			US-ABBVIE-19K-163-2665120-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378220	NON-EXPEDITED			US-ABBVIE-19K-163-2666656-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378235	NON-EXPEDITED			US-ABBVIE-19K-163-2666632-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported

	Enbrel			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Methotrexate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378245	NON-EXPEDITED			US-ABBVIE-19K-163-2666741-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378252	NON-EXPEDITED			US-ABBVIE-19K-163-2668063-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378260	NON-EXPEDITED			US-ABBVIE-19K-163-2666774-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Ineffective; Drug Ineffective	Orencia				S	Unknown				Not Reported
	Plaquenil				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378289	NON-EXPEDITED			US-ABBVIE-19K-163-2667013-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dizziness; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Headache; Herpes Zoster; Neuropathy Peripheral; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378291	NON-EXPEDITED			US-ABBVIE-19K-163-2671146-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Colchicine			C				Not Reported
	Motrin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378292	NON-EXPEDITED			US-ABBVIE-19K-163-2643787-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378310	NON-EXPEDITED			US-ABBVIE-19K-163-2671152-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378330	NON-EXPEDITED			US-ABBVIE-19K-163-2666975-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378352	NON-EXPEDITED			US-ABBVIE-19K-163-2666927-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Failure; Drug Ineffective	Humira			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Arava			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378373	NON-EXPEDITED			US-ABBVIE-19K-163-2666719-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Remicade			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378379	NON-EXPEDITED			US-ABBVIE-19K-163-2666659-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other	Usp		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378384	NON-EXPEDITED			US-ABBVIE-19K-163-2666660-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Drug Ineffective; Psoriasis	Humira			S	Subcutaneous	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378410	NON-EXPEDITED			US-ABBVIE-19K-163-2670791-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Ineffective; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378418	NON-EXPEDITED			US-ABBVIE-19K-163-2666952-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Memory Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378441	NON-EXPEDITED			US-ABBVIE-19K-163-2670727-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported
	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378464	NON-EXPEDITED			US-ABBVIE-19K-163-2670911-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378472	NON-EXPEDITED			US-ABBVIE-19K-163-2670898-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378475	NON-EXPEDITED			US-ABBVIE-19K-163-2667035-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Intolerance; Nausea; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Therapeutic Product Effect Decreased	Enbrel				S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378501	NON-EXPEDITED			US-ABBVIE-19K-163-2667990-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378513	NON-EXPEDITED			US-ABBVIE-19K-163-2671178-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cognitive Disorder; Contusion; Depression; Fatigue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378529	NON-EXPEDITED			US-ABBVIE-19K-163-2646176-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378540	NON-EXPEDITED			US-ABBVIE-19K-163-2670962-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378545	NON-EXPEDITED			US-ABBVIE-19K-163-2667056-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378565	NON-EXPEDITED			US-ABBVIE-19K-163-2647284-00		35 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378572	NON-EXPEDITED			US-ABBVIE-19K-163-2667992-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378573	NON-EXPEDITED			US-ABBVIE-19K-163-2667989-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Injection Site Rash; Injection Site Rash; Pain; Pain; Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378578	NON-EXPEDITED			US-ABBVIE-19K-163-2667062-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Primary Biliary Cholangitis; Therapeutic Product Effect Incomplete; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378602	NON-EXPEDITED			US-ABBVIE-19K-163-2671180-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378612	NON-EXPEDITED			US-ABBVIE-19K-163-2647659-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378635	NON-EXPEDITED			US-ABBVIE-19K-163-2671247-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378637	NON-EXPEDITED			US-ABBVIE-19K-163-2653591-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378668	NON-EXPEDITED			US-ABBVIE-19K-163-2653576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378671	NON-EXPEDITED			US-ABBVIE-19K-163-2676244-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Infection; Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cefuroxime			C				Not Reported
	Flagyl			C				Not Reported
	Topiramate			C				Not Reported
	Percocet			C				Not Reported
	Darvocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378673	NON-EXPEDITED			US-ABBVIE-19K-163-2653480-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Doxycyclin			S	Unknown			Not Reported
	Macrobid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Triamterene			S	Unknown			Not Reported
	Proair			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378678	NON-EXPEDITED			US-ABBVIE-19K-163-2671251-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Metotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378683	NON-EXPEDITED			US-ABBVIE-19K-163-2673925-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

		Methotrexate			C	Oral				Not Reported
		Hydroxychloroquine			C	Oral				Not Reported
		Hydroxychloroquine			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378687	NON-EXPEDITED			US-ABBVIE-19K-163-2654903-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378701	NON-EXPEDITED			US-ABBVIE-19K-163-2654855-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378704	NON-EXPEDITED			US-ABBVIE-19K-163-2654915-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Therapeutic	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Product Effect Decreased	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378753	NON-EXPEDITED			US-ABBVIE-19K-163-2657336-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear; Liver Function Test Abnormal; Malaise; Skin Toxicity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378764	NON-EXPEDITED			US-ABBVIE-19K-163-2654916-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378772	NON-EXPEDITED			US-ABBVIE-19K-163-2657293-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Imuran			S	Unknown					Not Reported
	Plaquenil			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378776	NON-EXPEDITED			US-ABBVIE-19K-163-2657324-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378833	NON-EXPEDITED			US-ABBVIE-19K-163-2657214-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Injection Site Reaction; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378852	NON-EXPEDITED			US-ABBVIE-19K-163-2653583-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378864	NON-EXPEDITED			US-ABBVIE-19K-163-2653595-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Eruption; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378872	NON-EXPEDITED			US-ABBVIE-19K-163-2672101-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378876	NON-EXPEDITED			US-ABBVIE-19K-163-2672102-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378899	NON-EXPEDITED			US-ABBVIE-19K-163-2657386-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378900	NON-EXPEDITED			US-ABBVIE-19K-163-2656772-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378907	NON-EXPEDITED			US-ABBVIE-19K-163-2659092-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378927	NON-EXPEDITED			US-ABBVIE-19K-163-2656775-00		71 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; General Symptom; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous				Not Reported
	Humira			S					Not Reported
	Methotrexate			S	Unknown				Not Reported
	Methotrexate			S					Not Reported
	Enbrel			S	Unknown				Not Reported
	Enbrel			S					Not Reported
	Plaquenil			S	Unknown				Not Reported
	Plaquenil			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378938	NON-EXPEDITED			US-ABBVIE-19K-163-2657344-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Vectra (Valdecoxib)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378941	NON-EXPEDITED			US-ABBVIE-19K-163-2674610-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378947	NON-EXPEDITED			US-ABBVIE-19K-163-2659106-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Injection Site Rash; Nausea; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Simponi Aria		S	Unknown	Not Reported
	Otezla		S	Unknown	Not Reported
	Azathioprin		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378952	NON-EXPEDITED			US-ABBVIE-19K-163-2674641-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378953	NON-EXPEDITED			US-ABBVIE-19K-163-2655231-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378955	NON-EXPEDITED			US-ABBVIE-19K-163-2672763-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378956	NON-EXPEDITED			US-ABBVIE-19K-163-2657353-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378968	NON-EXPEDITED			US-ABBVIE-19K-163-2655234-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378969	NON-EXPEDITED			US-ABBVIE-19K-163-2680610-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378977	NON-EXPEDITED			US-ABBVIE-19K-163-2655240-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378978	NON-EXPEDITED			US-ABBVIE-19K-163-2672766-00		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chills; Diverticulitis; Ear Congestion; Neuritis; Pain; Rash; Sinus Congestion	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflumide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Calcium			C	Unknown					Not Reported
	Vitamin D			C	Unknown					Not Reported
	Fish Oil			C	Unknown					Not Reported
	Vitamin C			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378980	NON-EXPEDITED			US-ABBVIE-19K-163-2655230-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379003	NON-EXPEDITED			US-ABBVIE-19K-163-2658652-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379004	NON-EXPEDITED			US-ABBVIE-19K-163-2674609-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective	Methotrexate			S	Unknown	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379006	NON-EXPEDITED			US-ABBVIE-19K-163-2672139-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Bone Pain; Drug Ineffective; Drug Ineffective; Fatigue; Injection Site Reaction; Myalgia; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Other			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379009	NON-EXPEDITED			US-ABBVIE-19K-163-2680576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379013	NON-EXPEDITED			US-ABBVIE-19K-163-2656935-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Actemra				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379023	NON-EXPEDITED			US-ABBVIE-19K-163-2678299-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Reaction; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379024	NON-EXPEDITED			US-ABBVIE-19K-163-2655039-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379028	NON-EXPEDITED			US-ABBVIE-19K-163-2656934-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Headache	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379039	NON-EXPEDITED			US-ABBVIE-19K-163-2658600-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379050	NON-EXPEDITED			US-ABBVIE-19K-163-2672549-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379051	NON-EXPEDITED			US-ABBVIE-19K-163-2656936-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Vasculitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379054	NON-EXPEDITED			US-ABBVIE-19K-163-2680578-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379061	NON-EXPEDITED			US-ABBVIE-19K-163-2658650-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379066	NON-EXPEDITED		OT	US-ABBVIE-19K-163-2675710-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Treatment Failure; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379091	NON-EXPEDITED			US-ABBVIE-19K-163-2680465-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Epistaxis; Paraesthesia	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379114	NON-EXPEDITED			US-ABBVIE-19K-163-2675964-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Glucose Increased; Eye Disorder; Migraine; Nausea; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379119	NON-EXPEDITED			US-ABBVIE-19K-163-2680466-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Simponi			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379134	NON-EXPEDITED			US-ABBVIE-19K-163-2662836-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Avara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379154	NON-EXPEDITED			US-ABBVIE-19K-163-2680463-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Nausea; Pigmentation Disorder; Vomiting	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379158	NON-EXPEDITED			US-ABBVIE-19K-163-2680575-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379180	NON-EXPEDITED			US-ABBVIE-19K-163-2662835-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Exposure During Pregnancy; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379195	NON-EXPEDITED			US-ABBVIE-19K-163-2655279-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379198	NON-EXPEDITED			US-ABBVIE-19K-163-2675962-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dmards (Disease Modifying Antirheumatic Drugs)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379207	NON-EXPEDITED			US-ABBVIE-19K-163-2655292-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pruritus; Liver Function Test Increased	Humira			S	Subcutaneous	Treatment Length 2 Years		Not Reported
	Methotrexate			S	Unknown	Treatment Length 4 Years		Not Reported
	Actemra			S	Unknown	Treatment Length 3 Years		Not Reported
	Plaquenil			S	Unknown	Treatment Length 3 Years		Not Reported
	Prednisone			C		Continuing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379212	NON-EXPEDITED			US-ABBVIE-19K-163-2662839-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Risk Factor; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379229	NON-EXPEDITED			US-ABBVIE-19K-163-2678304-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Rash; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379230	NON-EXPEDITED			US-ABBVIE-19K-163-2662844-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379241	NON-EXPEDITED			US-ABBVIE-19K-163-2685718-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Therapeutic Product Effect Decreased; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379259	NON-EXPEDITED			US-ABBVIE-19K-163-2680577-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379260	NON-EXPEDITED			US-ABBVIE-19K-163-2662888-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379263	NON-EXPEDITED			US-ABBVIE-19K-163-2662915-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Muscular Weakness; Myalgia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379274	NON-EXPEDITED			US-ABBVIE-19K-163-2672164-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379275	NON-EXPEDITED			US-ABBVIE-19K-163-2675877-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379287	NON-EXPEDITED			US-ABBVIE-19K-163-2685876-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Hypersensitivity; Latent Tuberculosis; Nightmare; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379303	NON-EXPEDITED			US-ABBVIE-19K-163-2660549-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379325	NON-EXPEDITED			US-ABBVIE-19K-163-2660734-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379334	NON-EXPEDITED			US-ABBVIE-19K-163-2680399-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379340	NON-EXPEDITED			US-ABBVIE-19K-163-2685826-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Zofran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379348	NON-EXPEDITED			US-ABBVIE-19K-163-2676033-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379358	NON-EXPEDITED			US-ABBVIE-19K-163-2660552-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Liver Function Test Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379374	NON-EXPEDITED			US-ABBVIE-19K-163-2673857-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Hepatic Function Abnormal	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379444	NON-EXPEDITED			US-ABBVIE-19K-163-2685872-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379448	NON-EXPEDITED			US-ABBVIE-19K-163-2686454-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379475	NON-EXPEDITED			US-ABBVIE-19K-163-2686463-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindicated Product Administered; Rash; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379497	NON-EXPEDITED			US-ABBVIE-19K-163-2662758-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure; Vaginal Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379532	NON-EXPEDITED			US-ABBVIE-19K-163-2658790-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379547	NON-EXPEDITED			US-ABBVIE-19K-163-2690386-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Bupropion			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfa			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379562	NON-EXPEDITED			US-ABBVIE-19K-163-2687499-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported

	Diclofenac				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379563	NON-EXPEDITED			US-ABBVIE-19K-163-2682481-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Osteoporosis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379568	NON-EXPEDITED			US-ABBVIE-19K-163-2690387-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379598	NON-EXPEDITED			US-ABBVIE-19K-163-2683928-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379608	NON-EXPEDITED			US-ABBVIE-19K-163-2687505-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379610	NON-EXPEDITED			US-ABBVIE-19K-163-2690696-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Injection Site Reaction; Oedema Peripheral; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379613	NON-EXPEDITED			US-ABBVIE-19K-163-2687654-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Oral Pain; Urticaria; Urticaria	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379622	NON-EXPEDITED			US-ABBVIE-19K-163-2687656-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379626	NON-EXPEDITED			US-ABBVIE-19K-163-2690704-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379628	NON-EXPEDITED			US-ABBVIE-19K-163-2690481-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Drug	Humira			S	Subcutaneous			Not Reported

Hypersensitivity; Drug Ineffective	Xeljanz Xr		S	Unknown			Not Reported
	Hydroxychloroquine		S	Unknown			Not Reported
	Methotrexate		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379634	NON-EXPEDITED			US-ABBVIE-19K-163-2683932-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379742	NON-EXPEDITED			US-ABBVIE-19K-163-2699997-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Insulin			S	Unknown			Not Reported
	Lantus			S	Unknown			Not Reported
	Byetta			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379804	NON-EXPEDITED			US-ABBVIE-19K-163-2692420-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Immunodeficiency; Infection; Malaise; Skin Lesion; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379843	NON-EXPEDITED			US-ABBVIE-19K-163-2692238-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Matrix			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379884	NON-EXPEDITED			US-ABBVIE-19K-163-2694201-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379940	NON-EXPEDITED			US-ABBVIE-19K-163-2700215-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Humira			S	Subcutaneous			Not Reported

Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380132	NON-EXPEDITED			US-ABBVIE-19K-163-2720959-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Injection Site Reaction; Injection Site Reaction; Pain	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380314	NON-EXPEDITED			US-ABBVIE-19K-163-2684071-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380337	NON-EXPEDITED			US-ABBVIE-19K-163-2666928-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Metotrexate			S	Unknown			Not Reported

		Leflunomide			S	Unknown				Not Reported
		Enbrel			S	Unknown				Not Reported
		Orencia			S	Unknown				Not Reported
		Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380339	NON-EXPEDITED			US-ABBVIE-19K-163-2685846-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380341	NON-EXPEDITED			US-ABBVIE-19K-163-2692448-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380465	NON-EXPEDITED			US-ABBVIE-19K-163-2700189-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380607	NON-EXPEDITED			US-ABBVIE-19K-163-2665125-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17381346	NON-EXPEDITED			US-ABBVIE-19K-163-2787760-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Myalgia; Pain	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Otezla		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17382125	NON-EXPEDITED			US-ABBVIE-19K-163-2828069-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17383574	NON-EXPEDITED			US-ABBVIE-19K-163-2988548-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Naltrexone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384445	NON-EXPEDITED			US-ABBVIE-19K-163-2884124-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384724	NON-EXPEDITED			US-ABBVIE-19P-163-2655187-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Injection Site Reaction; Therapy Non-Responder; Tremor	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384744	NON-EXPEDITED		OT	US-ABBVIE-19K-163-2899418-00		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Myalgia; Swelling; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Livalo			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384758	NON-EXPEDITED			US-ABBVIE-19S-163-2678318-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Injection Site Reaction; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384792	NON-EXPEDITED			US-ABBVIE-19S-163-2690751-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384797	NON-EXPEDITED			US-ABBVIE-19S-163-2690760-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384888	NON-EXPEDITED			US-ABBVIE-19K-308-2957867-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Exercise Tolerance Decreased; Oropharyngeal Pain; Sinus Disorder; Throat Irritation	Humira	S	Subcutaneous			Not Reported
	Xeljanz Xr	S	Unknown			Not Reported
	Rosuvastatin	S	Unknown			Not Reported
	Ursodiol	S	Unknown	300 Mg		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Amlodipine	S	Unknown			Not Reported
	Lifitegrast	C		590 (Xiidra)		Not Reported
	Vitamin C	C				Not Reported
	Vitamin D Nos	C				Not Reported
	Flaxseed Oil	C				Not Reported
	Omega 3	C				Not Reported
	Turmeric	C				Not Reported
	Biotin	C				Not Reported
	Calcium + Magnesium + Zink	C				Not Reported
	Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17385384	NON-EXPEDITED			US-ABBVIE-19K-163-2905899-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Barrett'S Oesophagus; Cough; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Gastric Disorder; Nausea; Nightmare; Peripheral Swelling; Pruritus; Skin Papilloma; Trigger Finger; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Mobic			C	Oral			Not Reported

	Celebrex			C						Not Reported
	Celebrex			C						Not Reported
	Ibuprofen			C	Oral					Not Reported
	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386476	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Cosentyx			S	Unknown	150 Mg, Monthly		Not Reported
	Humira			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	200 Mg, 2x/Day		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cymbalta			C	Oral	60 Mg, 1x/Day		Not Reported
	Esomeprazole Magnesium/Naproxen Sodium			C	Oral			Not Reported
	Tylenol [Paracetamol]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386806	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200111049		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Tocilizumab			S	Unknown	360 Milligram		Not Reported
	Tocilizumab			S	Unknown	680 Milligram		Not Reported
	Sulfasalazine			S	Endocervical			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Rituxan		S	Intravenous drip	2000 Milligram	Not Reported
	Remicade		S	Intravenous drip		Not Reported
	Benadryl		C	Unknown		Not Reported
	Mogadon		C	Oral		Not Reported
	Colchicine		C	Unknown		Not Reported
	Nitrazepam		C	Oral	5 Milligram	Not Reported
	Dexilant		C	Oral		Not Reported
	Febuxostat		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Gravol		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Uloric		C	Oral		Not Reported
	Oxycodone		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386824	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-003377		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal	Topicort			S	Unknown	Not Specified		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral	Not Specified		Not Reported
	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown	Not Specified	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Atasol	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17388975	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17388990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	11666289	EXPEDITED (15-DAY)		OT	CA-ROCHE-1648220			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 577.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Duration:577.0		Not Reported
	Methotrexate			S	Unknown	Duration: 577.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577.0		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Duration: 577.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Duration: 577.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Duration: 577.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

			Hydroxychloroquine			S	Unknown			Not Reported
			Methotrexate			S	Unknown			Not Reported
			Cortisone			C	Oral			Not Reported
			Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12082828	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)	4-8mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Adequate Trial Of 3months In 2010		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 195 Days Form Of Admin Text: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 6 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 6 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Apo-Hydroxyquine	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Asa	C	Unknown		Not Reported
	Lantus	C	Subcutaneous	Solution	Not Reported
	Lozide [Indapamide]	C			Not Reported
	Prednisone	C			Not Reported
	Ramipril	C			Not Reported
	Ergocalciferol	C			Not Reported
	Vitamin D3	C			Not Reported
	Xeljanz	C	Oral		Not Reported
	Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12301325	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014360295		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Fibromyalgia; Hepatic Enzyme Increased; Joint Swelling; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Rheumatoid Arthritis; Spinal Stenosis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Between 17.5 Mg And 25mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	2 G, Daily		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S				Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Plaquenil			S		Unk		Not Reported

Plaquenil	S	Unknown	300 Mg, Weekly	Not Reported
Tramacet	S		Unk	Not Reported
Aclasta	S	Intravenous (not otherwise specified)	Unk, Single	Not Reported
Tramadol/Acetaminophen	S	Oral	Unk	Not Reported
Nortriptylin	C		20 Mg, 1x/Day At Bedtime (2 Tablets Per Day)	Not Reported
Nortriptylin	C			Not Reported
Metformin	C		5 Milligram, Qd	Not Reported
Metformin	C		500 Milligram, Bid	Not Reported
Lorazepam	C		1 Mg, 1x/Day Nightly	Not Reported
Vagifem	C		Unk	Not Reported
Lyrica	C	Oral	150 Mg, 2x/Day	Not Reported
Premarin	C		0.625 Mg, Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Depomedrol	C	Subcutaneous	40 Mg, Monthly	Not Reported
Depomedrol	C	Subcutaneous	Unk Unk, Qmo	Not Reported
Depomedrol	C			Not Reported
Tylenol Arthritis	C		Unk	Not Reported
Actonel Dr	C		35 Mg, Weekly	Not Reported
Ergocalciferol	C		Unk	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Mg, 1 Every 1 Month	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Monthly	Not Reported
Methylprednisolone Acetate	C			Not Reported
Nortriptyline Hydrochloride	C		20 Mg, Qd	Not Reported
Nortriptyline	C		Unk (Tablet And Capsule)	Not Reported
Nortriptyline	C			Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12678829	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016108462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Oral	20 Milligram		Not Reported
	Plaquenil			S	Oral	20 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13271760	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897736		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration 365 Days		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 3.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	C	Oral			Not Reported
	Prednisone	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13602521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-047783		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Synovitis; Throat Tightness	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14235038	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021663		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk (Cyclical)		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	1 Df, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, 1 Every 1 Hour		Apotex
	Leflunomide			S	Oral	20 Mg, Unk (Cyclical)		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actonel			S	Unknown	35 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	300 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Risedronic Acid			S	Oral	35 Mg, Q.Wk.		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unk (Cyclical)		Not Reported

	Simponi		S	Unknown	Unk			Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk			Not Reported
	Xeljanz		S	Oral	10 Mg, Qd			Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	Unk			Not Reported
	Risedronate		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14246628	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006309		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown			Apotex
	Apo-Prednisone			S	Unknown	7.5 Mg, Unk		Apotex
	Hydromorphone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14549382	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006552		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported

	Celebrex			S	Unknown	Unk	Not Reported
	Enbrel			S	Subcutaneous	Unk	Not Reported
	Lyrica			S	Unknown	Unk	Not Reported
	Methotrexate			S	Unknown	Unk	Not Reported
	Naprosyn /00256201/			S	Unknown	Unk	Not Reported
	Xeljanz			S	Oral	5 Mg, Bid	Not Reported
	Plaquenil /00072603/			S	Unknown	Unk	Not Reported
	Methotrexate			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14845152	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1364		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Qwk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Q2wk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported
Aleve	C	Unknown	Not Reported
Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15389282	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2667		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Loss Of	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete; Transplant Dysfunction; Transplant Rejection	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rapamune	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Prograf	S	Unknown	Not Reported
	Prograf	S	Oral	Not Reported
	Prograf	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15393834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184304		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Therapy Partial Responder	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Orencia			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Apo-Prednisone			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Actonel			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15436912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189344		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15439303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189946		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Asa	C	Unknown			Not Reported
	Clonazepam	C	Oral			Not Reported
	Desipramine	C	Unknown			Not Reported
	Gabapentin	C	Oral			Not Reported
	Nitroglycerin	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15454775	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2785		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Leflunomide		S	Unknown		Not Reported
					Leflunomide		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Bactrim		S	Unknown		Not Reported
					Hydroxychloroquine		S			Not Reported
					Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15679007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574090-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15696246	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015057052		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	10 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	5 Milliliter, Bid		Pfizer
	Xeljanz			S	Oral	10 Milliliter, Bid		Pfizer
	Xeljanz			S	Oral	Unk, Bid		Pfizer
	Xeljanz			S	Oral	10 Milliliter		Pfizer
	Xeljanz			S	Oral	5 Milliliter		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	200 Milligram, Qwk		Pfizer
	Vioxx			S	Oral	Unk		Not Reported
	Vioxx			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Wellbutrin	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15749108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3822		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown	200mg:1 And A Half Pill	Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Cyclical, On Day 0 And Day 15	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported

	Actonel	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral	Cyclic	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Risedronate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15851869	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634031-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
			Rituximab		S		Intravenous (not otherwise specified)			Not Reported
			Hydroxychloroquine Sulfate		S		Unknown			Not Reported
			Remicade		S		Intravenous (not otherwise specified)			Not Reported
			Prednisone		C		Unknown			Not Reported
			Prednisone		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16033390	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019168			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Unknown			Barr
	Rosuvastatin Calcium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Cephalexin			C	Unknown	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16214358	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16302392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076872		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy;	Orencia			S	Unknown			Bristol Myers Squibb

Drug Ineffective; Off Label Use; Pain In Extremity; Peripheral Swelling; Psoriasis	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16481798	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1203		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Medication Error; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Every 2 Week		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Gold	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Bifidobacterium Bifidum	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

		Sulfasalazine			C	Unknown				Not Reported
		Simponi			C	Unknown				Not Reported
		Wellbutrin			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16535717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346125			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Cetirizine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16820452	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Bactrim			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16901988	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2956672-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Humira	S	Subcutaneous	Not Reported
	Tenoxicam	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Bromocriptine	S	Unknown	Not Reported
	Colchicine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Pamidronate Disodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Mercaptopurine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16942141	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1098880		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Mylan
	Humira			S	Unknown	40 Milligram		Mylan
	Methotrexate			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17072593	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Oral			Ivax
	Ciclosporin			S	Oral			Ivax
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

							otherwise specified)			
					Infliximab	S	Intravenous (not otherwise specified)			Not Reported
					Plaquenil	S	Unknown			Not Reported
					Remicade	S	Intravenous (not otherwise specified)			Not Reported
					Sulfasalazine	S	Unknown			Not Reported
					Apo-Azathioprine	S	Unknown			Not Reported
					Lyrica	S	Unknown			Not Reported
					Orencia	S	Unknown			Not Reported
					Rituximab	S	Unknown			Not Reported
					Simponi	S	Unknown			Not Reported
					Piroxicam	C	Unknown			Not Reported
					Prednisone	C	Unknown			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
07-Feb-2020	17164952	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019538925		61 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer		
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer		
	Methotrexate Sodium			S	Oral	Unk		Pfizer		
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer		
	Xeljanz			S	Unknown	Unk		Pfizer		
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer		
	Humira			S	Subcutaneous	Unk		Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported		
	Orencia			S	Intravenous (not	Unk		Not Reported		

				otherwise specified)		
	Orencia		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	8 Milligram/Kilogram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388029	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Triamcinolone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540683			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537431		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389020	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020050435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 1 Every 12 Hours		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 1 Every 12 Hours		Not Reported
	Lyrica			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Xeljanz			C		5 Mg, Unk (Every 12 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389033	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389049	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020050421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Sulfasalazine		S	Unknown	1 G, 2x/Day	Pfizer
	Humira		S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, 2x/Day	Not Reported
	Leflunomide		S	Unknown	20 Mg, 1x/Day	Not Reported
	Prednisone		S	Oral	15 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389191	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536025		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported

		Methotrexate			C	Unknown				Not Reported
		Naproxen			C	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536665		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389826	EXPEDITED (15-DAY)		OT	NVSC2020CA030586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability;	Methotrexate			S	Unknown	Unk		Novartis
	Ibuprofen			S	Unknown	Unk		Not Reported

Pain; Rheumatoid Arthritis; Swelling; Vomiting	Codeine Phosphate		S	Unknown	Unk	Not Reported
	Crestor		S	Unknown	20 Mg, Qd	Not Reported
	Tylenol		S	Unknown	282 Ot	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Arava		S	Unknown	10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390361	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-003369		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Ophthalmic			Bausch And Lomb
	Topicort			S	Cutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseud Oephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Atasol	C		Not Reported
Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390484	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown	84.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	4.0 Years		Not Reported
	Leflunomide			S	Oral	4.0 Years		Not Reported

	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown	730.0		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390675	EXPEDITED (15-DAY)		HO, OT	ALC2020CA001016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Phenylephrine Hydrochloride Injection Usp			S	Unknown	Not Specified		Alcon
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Ot (1 Every 1 Month)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Mg		Not Reported
	Benzalkonium Chloride			S	Unknown	Unk		Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown	Unk		Not Reported
	Boric Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50.0 Mg, Ot (1 Every 1		Not Reported

			Weeks)	
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40.0 Mg Cyclical	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg (2 Every 1 Days)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	15.0 Mg 1 Every 1 Weeks	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Rho D Immune Globulin	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Sodium Borate	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tofacitinib Citrate	S	Unknown	5.0 Mg 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	10.0 Unk 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	5.0 G 2 Every 1 Week	Not Reported
Tofacitinib Citrate	S	Subcutaneous	5.0 Unk 2 Every 1 Days	Not Reported
Xeljanz	C	Oral	5.0 Mg 2 Every 1 Days	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Ibuprofen	C	Oral	400.0 Mg	Not Reported
Celebrex	C	Oral	400.0 Mg	Not Reported
Lipitor	C	Oral	10.0 Mg, Ot 1 Every 1 Days	Not Reported
Lipitor	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535761		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390821	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0675		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390834	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0681		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Glyburide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Pariet			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Trajenta			C	Unknown			Not Reported
	Vitamin B6			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390927	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540924			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

	Azathioprine		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390978	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535637		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
				Rosuvastatin Calcium	S	Oral				Not Reported
				Rosuvastatin Calcium	S	Unknown				Not Reported
				Sodium Aurothiomalate	S	Unknown				Not Reported
				Xeljanz	C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391199	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2537139			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Remicade		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536677		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 9.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 15.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Adalimumab			C	Unknown	Therapy Duration: 9.0		Not Reported

						Years			
	Prednisone			C	Unknown	Therapy Duration: 9.0 Years			Not Reported
	Sulfasalazine			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391712	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538305		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Methotrexate		S	Unknown		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Orencia		S	Unknown		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Arava		C	Unknown		Not Reported
					Humira		C	Unknown		Not Reported
					Leflunomide		C	Unknown		Not Reported
					Sulfasalazine		C	Unknown		Not Reported
					Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391716	EXPEDITED (15-DAY)		OT	NVSC2020DE026206			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Mother Dose:5 Mg, Qd (Initially 5 Mg/D Until Gw 6+2, Then Discontinued. From Gw 23+3 Until Delivery		Novartis
	Quensyl			S	Transplacental	Mother Dose: 200 Mg, Qd		Not Reported
	Folsaeure			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538050		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel		S	Subcutaneous	Not Reported
	Gold		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391992	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533842			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported

					Orencia		S	Intravenous (not otherwise specified)	Not Reported
					Prednisone		S	Oral	Not Reported
					Prednisone		S	Oral	Not Reported
					Sulfasalazine		S	Oral	Not Reported
					Triamcinolone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536228		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392107	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541650		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	577.0		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	577.0		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	577.0		Not Reported

Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	577.0		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	577.0		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown	577.0		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown	577.0		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	577.0		Not Reported
	Remicade	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Simponi	S	Subcutaneous	577.0		Not Reported
	Desoximetasone	C	Oral			Not Reported
	Desoximetasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539797		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Arava			C	Unknown				Not Reported
	Humira			C	Unknown				Not Reported
	Leflunomide			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392519	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540672		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536712		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered;	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Hydroxychloroquine			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Not Reported
	Potassium Chloride			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392847	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Leflunomide			C	Oral			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported

	Synthroid			C						Not Reported
	Tylenol			C						Not Reported
	Codeine			C						Not Reported
	Phosphoric Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17393269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540678		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17444146	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Palpitations	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	13277559	EXPEDITED (15-DAY)		HO, OT	CA-BAXTER-2017BAX008638		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter
	Arava			S	Oral	Dosage Form: Tablet		Not Reported

Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Cimzia		S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Dosage Form Not Specified	Not Reported
	Plaquenil		S	Oral	Dosage Form: Tablet	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Dosage Form Powder For Solution Intravenous	Not Reported
	Simponi		S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	15934147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656830-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Methyl Salicylate			S	Unknown				Not Reported
		Rituximab			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392885	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542449		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported

Neoral	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542453		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542450		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542472		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Endocervical	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Unknown	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392968	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Pneumonia; Rheumatoid Arthritis	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393039	EXPEDITED (15-DAY)		HO	CA-ROCHE-2535807		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542476		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535785		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Singulair			C						Not Reported
	Olopatadine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393176	EXPEDITED (15-DAY)		HO	CA-ROCHE-2535906		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Orencia			S	Unknown				Not Reported
		Prednisone			C					Not Reported
		Ciclosporin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393316	EXPEDITED (15-DAY)		HO	CA-ROCHE-2536017		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393407	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540921			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542447		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542467		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2020	17393740	EXPEDITED (15-DAY)		HO	NVSC2020FR028239		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Doxycycline			S	Oral	200 Mg, Qd		Novartis
	Metronidazole			S	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Tavanic			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	3 Df, Qd		Not Reported
	Lansoprazole			C	Oral	15 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg, Qd		Not Reported
	Fluconazole			C	Oral	200 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	11953789	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3.0 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Oral	50.0 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	15 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Oral	50 Mg, Qd		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Mg/Kg, Qmo		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Losec [Omeprazole]	C	Unknown			Not Reported
Naprosyn [Naproxen]	C	Unknown			Not Reported
Celexa [Citalopram Hydrobromide]	C	Unknown			Not Reported
Crestor	C	Unknown			Not Reported
Ketoprofen	C	Unknown	100 Mg, Bid		Not Reported
Citalopram Hydrobromide	C	Unknown			Not Reported
Rosuvastatin Calcium	C	Unknown			Not Reported
Naproxen	C	Unknown			Not Reported
Omeprazole	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12222790	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-020922		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported

Gastrointestinal Disorder; Hepatic Enzyme Increased; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Apo Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride;Perphenazine	S	Oral	10 Milligram, Qd	Not Reported
	Fentanyl Citrate	S	Epidural		Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Omega 3 [Fish Oil;Tocopherol]	C	Unknown	1200 Milligram, Bid	Not Reported
	Multivitamin [Ascorbic Acid;Calcium Pantothenate;Ergocalciferol;Nicoti	C	Unknown	Unk	Not Reported
	Tecta	C	Unknown	40 Mg, Qd	Not Reported
	Diphenoxylate	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate	C	Unknown	1 Dosage Form, Qd	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	400 Unit, Qd	Not Reported
	Actonel	C	Unknown	36 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	5 Milligram 1 Every 2 Hour	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported

Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Dosage Form Prn	Not Reported
Biotin W/Calcium Pantothenate/Colec/06004901/	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram 1 Every 1 Hour	Not Reported
Tylenol [Paracetamol]	C	Oral	1000 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Qd	Not Reported

Xeljanz	C	Unknown	5 Milligram	Not Reported
Vitamin B12 Aaa	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Vitamin A Nos	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
Vitamin C Acid	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram 1 Every One Hour	Not Reported
Nexium [Esomeprazole Sodium]	C	Unknown	40 Milligram, Bid	Not Reported
Genteal [Hypromellose]	C	Unknown		Not Reported
Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	C	Unknown	1 Dosage Form, As Required	Not Reported
Perphenazine	C	Unknown	40 Milligram, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	1 Dosage Form, Prn	Not Reported
Vitamin E [Tocopherol]	C	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported

D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown		Not Reported
Omega-3 [Salmo Salar Oil]	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Cholecalciferol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1000 Milligram, Qd	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	1200 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12689721	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016400948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Neoral			S	Oral	20 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not	3 Mg/Kg, Unk		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12709758	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0313		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Back Disorder; Blood Albumin Decreased; Condition Aggravated; Contraindicated Product Administered; Diverticulum; Drug Ineffective; Drug Intolerance; Headache; Intestinal Perforation; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Neck Mass; Off Label Use; Rheumatoid Arthritis; Spinal Operation; Thrombocytosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Abatacept			S	Subcutaneous			Not Reported
	Apo-Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown	4 Days A Week		Not Reported
	Gabapentin			C	Unknown			Not Reported

	Lovastatin	C	Unknown		Not Reported
	Metoprolol	C	Unknown	Strength: 50 Mg	Not Reported
	Vitamin D	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Naprelan	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen Sodium	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12967538	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Eye Disorder; Feeling Abnormal; Finger Deformity; Foot Deformity; Gait Disturbance; Gait Inability; Hyperhidrosis; Inflammation; Intervertebral Disc Protrusion; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness;	Abatacept			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Winpred			S	Unknown	5 Milligram		Not Reported
	Oxycodone Terephthalate			S	Oral			Not Reported
	Macrogol			S	Unknown			Not Reported

Off Label Use; Osteoarthritis; Osteoporosis; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Spinal Disorder; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Vomiting; Wrist Deformity	Apo Prednison	S	Unknown	5 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydromorphone	S	Oral	12 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Lax-A-Day	C	Unknown	Unk	Not Reported
	Monurol	C	Unknown		Not Reported
	Fosfomycin Trometamol	C	Unknown		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13424028	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017013202		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Cimzia			S	Subcutaneous	Usual Dose For More Than 3 Months		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Methotrexate			S		Usual Dose For More Than 3 Months		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Arava			S		Unk		Not Reported
	Leflunomide			S		Usual Dose For More Than 3 Months		Not Reported

	Plaquenil	S		Usual Dose For More Than 3 Months	Not Reported
	Humira	S	Subcutaneous	Usual Dose For More Than 3 Months	Not Reported
	Actemra	S		Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Aspirin	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Cymbalta	C		Unk	Not Reported
	Hydromorphone	C		Unk	Not Reported
	Penicillin	C		Unk	Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Remicade	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13610813	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

							otherwise specified)			
			Zostavax		S		Subcutaneous			Not Reported
			Hydroxychloroquine		S		Unknown			Not Reported
			Apo-Hydroxyquine		S		Unknown			Not Reported
			Varicella Zoster Vaccine Live		S		Subcutaneous			Not Reported
			Hydroxychloroquine Sulfate		S		Unknown			Not Reported
FDA Received Date	**Case #**	**Case Type**		**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**
10-Feb-2020	13840401	EXPEDITED (15-DAY)			OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091533			Female	CAN
Preferred Term	**Product**		**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**		**Mfr**
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting; X-Ray Abnormal	Orencia				S	Intravenous (not otherwise specified)	1 Dosage Form			Bristol Myers Squibb
	Enbrel				S	Subcutaneous	Unk			Not Reported
	Humira				S	Subcutaneous	40 Milligram			Not Reported
	Arava				S	Unknown				Not Reported
	Hydroxychloroquine Sulfate				S	Unknown	Unk			Not Reported
	Apo-Prednisone				S	Unknown				Not Reported
	Methotrexate				S	Oral	20 Milligram, Qwk			Not Reported
	Methotrexate				S	Unknown				Not Reported
	Prednisone				S	Unknown	10 Milligram			Not Reported
	Prednisone				S	Unknown				Not Reported
	Actemra				S	Unknown				Not Reported
	Hydroxychloroquine				S	Unknown	400 Milligram, Qd			Not Reported
	Leflunomide				S	Unknown				Not Reported
	Remicade				S	Intravenous (not otherwise specified)				Not Reported
	Apo-Leflunomide				S	Unknown	200 Milligram, Qd			Not Reported
	Desoximetasone				S	Oral				Not Reported
	Rituxan				S	Intravenous (not				Not Reported

							otherwise specified)			
		Pantoprazole			C		Unknown			Not Reported
		Xeljanz			C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14128708	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017042210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Ineffective; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14308679	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016008213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S		Unk		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not	Unk		Not Reported

Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment			otherwise specified)		
	Orencia	S		750 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tylenol	S		Unk	Not Reported
	Enbrel	S		50 Mg, Weekly (Qw)	Not Reported
	Enbrel	S		Unk	Not Reported
	Plaquenil	S		200 Mg, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk For 6 Months	Not Reported
	Acetaminophen	S		325 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day (Bid)	Not Reported
	Methotrexate	S		25 Mg/ Ml, Weekly (Qw)	Not Reported
	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Synthroid	C		Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Meloxicam	C		Unk, Weekly (Qw)	Not Reported
	Tylenol With Codein #3	C			Not Reported
	Acetaminophen W/Codeine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14704614	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012672		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort;	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Ev 4 Weeks		Not Reported
	Plaquenil			S		Unk		Not Reported

Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S				Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium	S	Oral	17.5 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Ev 2 Weeks(Qow)		Not Reported
	Coversyl	C				Not Reported
	Ergocalciferol	C		2000 International Unit		Not Reported
	Leucovorin	C				Not Reported
	Folinic Acid	C				Not Reported
	Perindopril Erbumine	C	Oral	4 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14909752	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018020609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S		Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Codeine			S		Unknown		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) For 5 Years		Not Reported
	Humira			S	Subcutaneous	40 Mg, For 9 Years		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw) For 15 Years		Not Reported
	Orencia			S		Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not	Unknown		Not Reported

				otherwise specified)		
	Simponi		S	Subcutaneous	Unknown	Not Reported
	Simponi		S	Subcutaneous	50 Mg, Monthly (Qm) For 127 Days	Not Reported
	Sulfasalazine		S		Unknown Dose	Not Reported
	Hydroxychloroquine		S		400 Mg, Unk	Not Reported
	Xeljanz		C		Unknown	Not Reported
	Prednisone		C		Unknown	Not Reported
	Adalimumab		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15285301	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA021912			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15922651	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653466-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Gabapentin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15935383	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656801-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration-5 Month		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration-6 Month		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Rabeprazole Sodium	C	Oral		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15975815	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013003		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

	Xeljanz	S	Oral	5.0 Milligram, Bid		Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16100906	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1025445		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Mylan
	Methotrexate			S	Oral	20 Milligram		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Oral	Unk		Mylan
	Apo-Hydroxyquine			S	Unknown	Unk		Mylan
	Apo-Hydroxyquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Oral	20 Milligram		Mylan
	Hydroxychloroquine			S	Oral	Unk		Mylan
	Hydroxychloroquine			S	Oral	Unk		Mylan
	Hydroxychloroquine			S	Subcutaneous	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Mylan
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Mylan
	Methotrexate Sodium			S	Subcutaneous	20 Milligram		Mylan
	Methotrexate Sodium			S	Subcutaneous	Unk		Mylan
	Methotrexate Sodium			S	Oral	20 Milligram		Mylan
	Methotrexate Sodium			S	Oral	20 Milligram		Mylan

Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Neoral	S	Subcutaneous	Unk	Mylan
Neoral	S	Subcutaneous	Unk	Mylan
Neoral	S	Subcutaneous	Unk	Mylan
Neoral	S	Oral	Unk	Mylan
Neoral	S	Oral	Unk	Mylan
Humira	S	Intravenous (not otherwise specified)	Solution Subcutaneous	Mylan
Humira	S	Unknown	Solution Subcutaneous	Mylan
Humira	S	Subcutaneous	Unk	Mylan
Humira	S	Subcutaneous	Unk	Mylan
Humira	S	Subcutaneous	Solution Subcutaneous	Mylan
Ciclosporin	S	Unknown	Unk	Mylan
Ciclosporin	S	Subcutaneous	Unk	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Mylan
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan

Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Mylan
Apo-Leflunomide	S	Oral	Unk	Mylan
Apo-Leflunomide	S	Unknown	Unk	Mylan
Orencia	S	Subcutaneous	125 Milligram	Mylan
Orencia	S	Subcutaneous	125 Milligram	Mylan
Orencia	S	Subcutaneous	125 Milligram	Mylan
Leflunomide	S	Unknown	Unk	Mylan
Leflunomide	S	Unknown	Unk	Mylan
Sulfasalazine	S	Oral	Unk	Mylan
Plaquenil /00072603/	S	Oral	Unk	Mylan
Plaquenil /00072603/	S	Unknown	Unk	Mylan
Rituximab	S	Intravenous (not otherwise specified)	Unk	Mylan
Rituximab	S	Oral	Unk	Mylan
Simponi	S	Subcutaneous	Unk	Mylan
Xeljanz	C	Unknown	2 Every 1 Day	Mylan
Xeljanz	C	Oral	10 Milligram, Qd (5 Mg, Bid)	Mylan
Xeljanz	C	Unknown	2 Ot, Qd	Mylan
Xeljanz	C	Oral	10 Milligram, Qd	Mylan
Xeljanz	C	Oral	10 Milligram, Qd (5 Mg, Bid)	Mylan
Xeljanz	C	Unknown	Unk	Mylan
Xeljanz	C	Oral	10 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16252372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039070		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	776 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	400 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	400 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16269769	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190409745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Otezla			S				Celgene
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

	Leflunomide			S	Oral	Not Reported
	Leflunomide			S		Not Reported
	Methotrexate			S	Unknown	Not Reported
	Methotrexate			S		Not Reported
	Orencia			S	Unknown	Not Reported
	Orencia			S		Not Reported
	Simponi			S	Subcutaneous	Not Reported
	Simponi			S		Not Reported
	Stelara			S	Subcutaneous	Not Reported
	Stelara			S		Not Reported
	Xeljanz			S	Unknown	Not Reported
	Xeljanz			S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16438452	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Desoximetasone			S	Oral	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Subcutaneous	Unknown		Not Reported

Actemra	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	S	Oral		Not Reported
Acetaminophen	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Dilaudid	S	Unknown		Not Reported
Apo-Acetaminophen	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Fosavance	C	Unknown		Not Reported
Hydrocortisone	C	Unknown		Not Reported
Hyzaar	C	Unknown		Not Reported
Methylprednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16839343	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-088706		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	10 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported

Change; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
	Prednisone	S	Unknown	1 Milligram, Every 1 Day	Not Reported
	Prednisone	S	Unknown	5 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Q12h	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	2 Dosage Form, Qcycle	Not Reported
	Asa	C	Unknown	325 Milligram	Not Reported
	Bisoprolol	C	Unknown	5 Milligram, Every 1 Day	Not Reported
	Endocet	C	Unknown	Unk	Not Reported
	Endocet	C	Unknown	1 Dosage Form , 2 Every 1 Days	Not Reported
	Folic Acid	C	Unknown	5 Milligram, Qcycle	Not Reported
	Indomethacin [Indometacin]	C	Unknown	Unk	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	75 Milligram, 2 Every 1 Day	Not Reported
	Naproxen Sodium	C	Unknown	1000 Milligram, Qcycle	Not Reported
	Pennsaid	C	Topical	Unk	Not Reported
	Vitamin B 12	C	Unknown	Unk	Not Reported

	D-Alpha Tocopherol			C	Unknown	12000 Milligram, Qd			Not Reported
	Fish Oil			C	Unknown	12000 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16933922	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2796105-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17225723	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2019M1131678		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Dyspnoea; Fatigue; Gastrointestinal Disorder; Interstitial Lung Disease; Product Use In Unapproved Indication; Pulmonary Embolism	Methotrexate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Rituximab			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	1 G, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17297595	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK)		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Losartan Potassium			S	Unknown	Unk		Lupin
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk (Tablet)		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin Hydrochloride			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram Every 1 Week		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
	Avelox	S	Unknown	Unk		Not Reported
	Penicillin Nos	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
	Iron Sucrose	C	Unknown	Unk		Not Reported
	Esomeprazole	C	Unknown	Unk		Not Reported
	Gold	C	Unknown	Unk		Not Reported
	Saccharated Iron Oxide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17356419	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1010578		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Omeprazole			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Azathioprine			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17393907	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17393996	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537096			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Humira			S	Subcutaneous				Not Reported
	Humira			S					Not Reported
	Ilaris			S	Subcutaneous				Not Reported
	Ilaris			S					Not Reported
	Leflunomide			S	Unknown				Not Reported
	Leflunomide			S					Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Orencia			S					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S					Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S					Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394059	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3265441-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537887		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394399	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536713		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Spleen Disorder; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			C	Unknown			Not Reported

	Sulfasalazine			C	Unknown					Not Reported
	Methotrexate			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394502	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Spiriva			S	Unknown			Boehringer Ingelheim
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lipitor			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Zenhale			S	Unknown			Not Reported
	Zenhale			S	Unknown	Aerosol, Metered Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394504	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1181893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Ciclosporin			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	20 Mg		Barr
	Methotrexate			S				Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine		S	Oral		Not Reported
	Hydroxychloroquine		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Neoral		S	Oral		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Endocervical		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394588	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537191			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Pseudoephedrine Hcl		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Apo-Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394661	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1179329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance; Intentional Product Use Issue	Ciclosporin			S	Unknown			Ivax
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394663	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2020-CA-1179313		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Alendronate Sodium			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Ivax
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis

Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ibuprofen	S	Oral	600 Milligram Daily;	Actavis
	Leflunomide	S	Oral		Barr
	Leflunomide	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Apo-Ibuprofen	S	Oral		Not Reported
	Apremilast	S	Unknown	120 Milligram Daily;	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported

	Tocilizumab		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported
	Oxycodone		C	Unknown	Not Reported
	Benadryl		C	Unknown	Not Reported
	Colchicine		C	Unknown	Not Reported
	Dexilant		C	Oral	Not Reported
	Febuxostat		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Gravol		C	Unknown	Not Reported
	Mogadon		C	Oral	Not Reported
	Nitrazepam		C	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported
	Uloric		C	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537374		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394679	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394727	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007436		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic	Orencia			S	Unknown			Bristol Myers Squibb

Enzyme Increased; Hypertension; Pneumonia	Actemra			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Rituximab			S	Intravenous drip		Not Reported
	Sulfasalazine			S	Unknown		Not Reported
	Azathioprine			S	Unknown		Not Reported
	Enbrel			S	Unknown		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Leflunomide			S	Unknown		Not Reported
	Methotrexate			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394921	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394929	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394930	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Esomeprazole Magnesium-Naproxen Sodium			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394934	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3265597-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastric Disorder; Therapeutic Product Effect Decreased; Visual Field Defect	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395045	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395100	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased; Bronchitis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Calcium Carbonate			C	Oral			Not Reported

					Desoximetasone		C	Unknown		Not Reported
					Hydromorphone		C	Oral		Not Reported
					Methotrexate		C	Oral		Not Reported
					Naproxen		C	Unknown		Not Reported
					Tylenol Arthritis Pain		C	Oral		Not Reported
					Folic Acid		C	Unknown		Not Reported
					Prednisolone		C	Unknown		Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
10-Feb-2020	17395178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540895			Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported		
	Enbrel			S	Unknown			Not Reported		
	Humira			S	Subcutaneous			Not Reported		
	Leflunomide			S	Unknown			Not Reported		
	Methotrexate			S	Unknown			Not Reported		
	Methotrexate			S	Unknown			Not Reported		
	Orencia			S	Unknown			Not Reported		
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported		
	Remicade			S	Intravenous (not otherwise specified)			Not Reported		
	Sulfasalazine			C	Unknown			Not Reported		
	Wellbutrin			C	Unknown			Not Reported		
	Xeljanz			C	Unknown			Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
10-Feb-2020	17395295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542486		63 YR	Female	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542479		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported

					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Apo-Leflunomide	S	Oral		Not Reported
					Ciclosporin	S	Unknown		Not Reported
					Enbrel	S	Subcutaneous		Not Reported
					Humira	S	Subcutaneous		Not Reported
					Hydroxychloroquine	S	Subcutaneous		Not Reported
					Hydroxychloroquine	S	Oral		Not Reported
					Methotrexate	S	Oral		Not Reported
					Orencia	S	Subcutaneous		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
					Remicade	S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Neoral	S	Subcutaneous		Not Reported
					Leflunomide	S	Unknown		Not Reported
					Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542481		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Hydroxychloroquine		S	Oral		Not Reported
					Hydroxychloroquine		S	Subcutaneous		Not Reported
					Methotrexate		S	Oral		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Leflunomide		S	Unknown		Not Reported
					Neoral		S	Oral		Not Reported
					Neoral		S	Subcutaneous		Not Reported
					Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539792			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Arava			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395477	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542443		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396501	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396506	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Limb Discomfort; Loss Of Consciousness; Mobility Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396588	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, 1 Every 12 Hours		Pfizer

	Leflunomide	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown	400 Mg, Unk		Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	300 Mg, 1 Every 8 Weeks		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396931	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2020-001252		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To Various Agents	Ibuprofen			S	Oral	Unk Unknown, Unknown		Par
	Hydroxychloroquine			S	Oral	6 G, Unknown		Not Reported
	Naproxen			S	Oral	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17397440	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050946		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S		100 Mg, Unk		Not Reported
	Celebrex			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate	S		1 Ml, Weekly (Qw)	Not Reported
	Plaquenil	S			Not Reported
	Apo-Prednisone	S		7 Mg, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once Daily (Qd); Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17398197	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020054650			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisone			C		25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17398288	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200200441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported

	Simponi		S	Subcutaneous	Not Reported
	Stelara		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Arava		C	Oral	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17399182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	12811220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015025966		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Viral Upper Respiratory Tract Infection	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Weekly (Qw)		Not Reported
	Tofacitinib			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Tofacitinib			S		Unk		Not Reported

Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk, Powder For Solution	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Arava	C		Unk	Not Reported
Prednisone	C	Oral		Not Reported
Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14299205	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050904		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	400 Mg, Weekly (Qw)		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S		15 Mg, Weekly (Qw)		Not Reported
	Orencia			S		125 Mg, Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Prednisone			S		Unk		Not Reported
	Prevacid			C		30 Mg, Once Daily (Qd)		Not Reported
	Folate			C		1 Milligram, Once Daily		Not Reported

							(Qd)			
		Actonel			C		35 Mg, Weekly (Qw)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14311631	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050957		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Unk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Naprosyn			S		500 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Lovastatin			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			S		20 Milligram		Not Reported
	Prednisone			S		2.5 Milligram, Weekly (Qw)		Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Tofacitinib			C				Not Reported
	Naproxen			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Vitamin D3			C		Unk		Not Reported
	Apo-Prednisone			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Weekly (Qw)		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14496258	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007159		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Off Label Use; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14921585	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate			C	Oral	15 Unk, Unk		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Simponi	C	Subcutaneous			Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15112426	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018028967			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw); Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib Citrate			S		Unk		Not Reported
	Tofacitinib			S				Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15365414	NON-EXPEDITED			US-PFIZER INC-2018362153		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer

	Methotrexate Sodium	S	Unk	Pfizer
	Arava	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Rituximab	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15394855	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016039015		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Df, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Oral	Solution		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	1 Dosgae Form, Ev 2 Weeks(Qow)		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			C	Oral	6 Mg, Once Daily (Qd)		Not Reported

	Prednisone	C	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Tylenol	C		Unk		Not Reported
	Advil	C		Unk		Not Reported
	Mefenamic Acid	C		Unk		Not Reported
	Dequalinium Chloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15411214	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186666		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral	1.0 Dosage Forms		Not Reported
	Varenicline Tartrate			S	Oral	1 Doses Form		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Oxycodone Hydrochloride			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported

	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Valtrex	C	Oral	Not Reported
	Valtrex	C	Unknown	Not Reported
	Naproxen	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15608532	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201843216			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 G, Unk		Shire
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, 1x/Week		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, 1x/Day:Qd		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, 1x/Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, 1x A Month		Not Reported
	Prednisone			S	Oral	5 Mg, 2x/Day:Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Unk		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Unk		Not Reported

Increased; Septic Shock; Synovitis; Vomiting	Sulfasalazine		S	Oral	250 Mg, 1x/Day:Qd	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Mg, 1x/Week	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Mg, 1x/2wks	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Kineret		S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Apo-Naproxen		S	Unknown	Unk	Not Reported
	Apo-Naproxen		S	Unknown	Unk	Not Reported
	Apo-Prednisone		S	Oral	3.0 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone		S	Oral	5.0 Milligram	Not Reported
	Triamcinolone Acetonide		S	Intra-articular	Unk	Not Reported
	Triamcinolone		C	Other	Unk	Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15775641	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0586		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Carpal Tunnel Syndrome; Drug Ineffective; Fibromyalgia; General Physical Health Deterioration; Joint Swelling; Liver Function Test Increased; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Radicular Pain; Rheumatoid Arthritis; Spinal Stenosis	Methotrexate (Trade Name Unknown)			S	Unknown	17.5 To 25 Mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Sulfasalazine	S	Oral		Not Reported
Humira	S	Unknown		Not Reported
Humira	S			Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S			Not Reported
Tramacet	S	Unknown		Not Reported
Aclasta	S	Intravenous (not otherwise specified)	Single	Not Reported
Tramadol/Acetaminophen	S	Oral		Not Reported
Nortriptylin	C	Unknown	Once At Bedtime	Not Reported
Nortriptylin	C	Unknown	Bedtime	Not Reported
Metformin	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Lorazepam	C	Unknown	Once Nightly	Not Reported
Vagifem	C	Unknown		Not Reported
Lyrica	C	Oral		Not Reported
Premarin	C	Unknown	Strength: 0.625mg	Not Reported
Vitamin D	C	Unknown		Not Reported
Calcium	C	Unknown		Not Reported
Depomedrol	C	Intramuscular		Not Reported
Depomedrol	C	Subcutaneous		Not Reported
Depomedrol	C	Subcutaneous		Not Reported
Tylenol Arthritis	C	Unknown		Not Reported
Actonel Dr	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Methylprednisolone Acetate	C	Unknown		Not Reported
Nortriptyline Hydrochloride	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Risedronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15809559	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616794-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Victim Of Crime	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15975888	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qd		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qwk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Gold			S	Unknown			Not Reported

Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Imuran [Azathioprine]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Certolizumab	S	Unknown	200 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Humira	S	Unknown	400 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Mg, Q4wk	Not Reported
	Actemra	S	Unknown	640 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	64 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Oral	Unk, Qcycle	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	300 Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Lyrica	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Oral	400 Milligram, Qd	Not Reported
	Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk, Cyclical	Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Milligram, Qwk, Cyclical	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown	640 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Piroxicam	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Folic Acid	C	Unknown	5 Milligram	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16447545	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported

Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16631284	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923301			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Human Normal Immunoglobulin			S	Unknown	Unk		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, 1x/Week		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, 1x/Week		Not Reported

	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	150 Milligram, 1x/Day:Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16631288	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923310			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, 1x/Week		Not Reported

Increased; Septic Shock; Synovitis; Underdose; Vomiting	Naproxen		S	Unknown	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone		S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
	Prednisone		S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Sulfasalazine		S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone Acetonide		S	Unknown	Unk	Not Reported
	Kineret		S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Anakinra		S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Adalimumab		S	Subcutaneous		Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	280 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16689275	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16842040	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27131		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction;	Infliximab			S	Unknown	Unknown		Not Reported

Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Actemra	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Cortisone Infiltration	C	Unknown	Unknown	Not Reported
	Dexamethasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown	Unknown	Not Reported
	Reactine	C	Unknown	Unknown	Not Reported

	Cetirizine Hydrochloride			C	Unknown	Unknown				Not Reported
	Desoximetasone			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16865618	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083770		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

					Methotrexate		S	Unknown		Not Reported
					Rabeprazole Sodium		C	Oral	20 Mg, Unk	Not Reported
					Methotrexate		C	Oral		Not Reported
					Prednisone		C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16946347	EXPEDITED (15-DAY)		OT	NVSC2019FR010234		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Urticarial Vasculitis	Omalizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Anakinra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16971655	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006447			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown	150 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			C	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17146210	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016038606		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Voltaren			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17181501	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6011		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17284429	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported

	Methotrexate	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
	Cyclophosphamide	S	Unknown	2000, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Ezetrol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399264	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		10 Milligram, Once Daily		Not Reported

				(Qd)	
	Sulfadiazine	S		Unk	Not Reported
	Baclofen	S		10 Milligram	Not Reported
	Baclofen	S		Unk	Not Reported
	Calcium Carbonate	C			Not Reported
	Folic Acid	C			Not Reported
	Hydromorphone	C			Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (Qw)	Not Reported
	Naproxen	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
	Tylenol [Paracetamol]	C			Not Reported
	Vitamin D [Ergocalciferol]	C			Not Reported
	Xeljanz	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399305	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000607			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399341	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000608			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Disease Progression; Therapy Non-Responder	Hydroxychloroquine	S	Unk		Concordia
	Doxycycline	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539634		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	8.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported
	Oxyneo			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399535	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538479		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration;L- 6.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration;- 4.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration:- 730.0		Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538069			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399645	EXPEDITED (15-DAY)		DS, HO, LT	CA-ROCHE-2538087		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous drip			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)	5.0 Months	Not Reported
	Infliximab	S	Unknown	9.0 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	3.0 Years, Kineret 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10.0 Years	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Orencia	S	Respiratory (inhalation)		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram (One Every Two Weeks		Not Reported

Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399847	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543705		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran [Azathioprine]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399861	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2020US00998			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide; Toxicity To Various Agents	Cyclobenzaprine			S	Oral	Unk		Invagen
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399923	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-006227		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Fluoxetine Dispersible Tablet			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Plaquenil			S	Unknown	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400029	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION			Unknown	CAN

					PHARMA-TREX2020-0757				

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400030	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540883		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	730.0		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400178	EXPEDITED (15-DAY)		OT	SE-ORION CORPORATION ORION PHARMA-20_00008421		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Product Use In Unapproved Indication; Tinnitus	Methotrexate (Trade Name Unknown)			S	Unknown	"Nov 2016 Mtx Was Raised To 8 Tab / Week"		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	7 Tablet		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	6 Tablet		Not Reported

	Methotrexate (Trade Name Unknown)	S	Unknown	6 Tabs. Methotrexate / Week +5 Mg Prednisolone For Many Years		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Prednisolone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400296	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542446		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Simponi			S	Subcutaneous				Not Reported
		Sulfasalazine			S	Oral				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540935		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1182316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr

Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546059		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	730.0 Days		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543630		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401148	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020004631		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Cimzia			S	Subcutaneous			Not Reported
	Arava			S		20 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxyquinoline Sulfate			S				Not Reported
	Leflunomide			S		20 Milligram		Not Reported
	Methotrexate			S		25 Milligram		Not Reported
	Neoral			S				Not Reported
	Plaquenil [Hydroxychloroquine			S				Not Reported

Stress; Transplant Dysfunction; Transplant Rejection	Sulfate]					
	Rapamune	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine	S		1 Gram		Not Reported
	Tacrolimus	S	Oral	2 Milligram, 2x/Day (Bid)		Not Reported
	Tacrolimus	S	Oral	3 Milligram, 2x/Day (Bid)		Not Reported
	Imuran [Azathioprine Sodium]	C		25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Cimzia		C	Subcutaneous	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401574	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2020US00792			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide; Toxicity To Various Agents	Meloxicam			S	Oral	Unk		Cipla
	Cetirizine			S	Oral	Unk		Cipla
	Hydroxyzine			S	Oral	Unk		Invagen
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Butalbital, Acetaminophen & Caffeine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401828	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016038081		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling	Cimzia	S	Subcutaneous	400 Mg, Weekly (Qw)	Not Reported
	Arava	S		20 Mg, Once Daily (Qd)	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly (Qw) 3.0 Month(S)	Not Reported
	Methotrexate Sodium	S		15 Mg, Weekly (Qw) 3.0 Month(S)	Not Reported
	Orencia	S		125 Mg, Unk	Not Reported
	Plaquenil	S		200 Mg, 2x/Day (Bid)	Not Reported
	Apo-Prednisone	S		5 Milligram	Not Reported
	Prednisone	S		Unk	Not Reported
	Prevacid	C		30 Mg, Once Daily (Qd)	Not Reported
	Actonel	C		35 Mg, Weekly (Qw)	Not Reported
	Folate	C		1 Mg, Once Daily (Qd)	Not Reported
	Folate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401907	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541324		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541350		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Durationl- 6.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Durationl- 4.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Durationl-730.0		Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17402084	EXPEDITED (15-DAY)		OT	NVSC2020CA033448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased;	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported

Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S	Oral	1 Df (10 Mg), Qw	Not Reported
	Methotrexate	S	Oral	1 Df (15 Mg), Qw	Not Reported
	Methotrexate	S	Oral	1 Df (20 Mg), Qw	Not Reported
	Methotrexate	S	Oral	1 Df (25 Mg), Q3w	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	600 Mg, Unknown (1 Every Six Weeks)	Not Reported
	Sulfasalazine	S	Unknown	2 Df (1 G), Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
	Acetaminophen And Codeine	C	Unknown	325 Mg, Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Baclofen	C	Unknown	Unk	Not Reported
	Betahistine Hydrochloride	C	Unknown	Unk	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Clonidine Hydrochloride	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
	Fluticasone Propionate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	1 Df (5 Mg), Qd	Not Reported
	Folinic Acid	C	Unknown	Unk	Not Reported
	Gabapentin	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Losartan	C	Unknown	Unk	Not Reported
	Metoprolol Tartrate	C	Unknown	Unk	Not Reported
	Mometasone Furoate	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	1 Df (300 Mg), Qd	Not Reported

	Tylenol With Codeine			C	Unknown	Unk				Not Reported
	Aspirine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17402539	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200200407		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Celgene
	Apo-Leflunomide			S	Unknown			Celgene
	Arava			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Celgene
	Cosentyx			S	Unknown			Celgene
	Enbrel			S	Unknown	50 Milligram		Celgene
	Hydroxychloroquine			S	Unknown			Celgene
	Hydroxychloroquine Sulfate			S	Unknown			Celgene
	Infliximab			S	Unknown			Celgene
	Leflunomide			S	Unknown			Celgene
	Methotrexate			S	Unknown	25 Milligram		Celgene
	Orencia			S	Unknown			Celgene
	Plaquenil			S	Unknown			Celgene
	Simponi			S	Subcutaneous			Celgene
	Sulfasalazine			S	Subcutaneous	50 Milligram		Celgene
	Acetaminophen			C	Unknown			Celgene
	Baclofen			C	Unknown	20 Milligram		Celgene
	Calcium			C	Unknown	500 Milligram		Celgene
	Dorzolamide Hydrochloride And Timolol Maleate			C	Ophthalmic			Celgene
	Ergocalciferol			C	Unknown			Celgene
	Ergocalciferol			C	Unknown			Celgene

Estradiol	C	Unknown	.6 Percent		Celgene
Estrogel	C	Unknown	.6 Percent		Celgene
Estrogel	C	Unknown			Celgene
Furosemide	C	Unknown	40 Milligram		Celgene
Gravol	C	Unknown			Celgene
Gravol Ginger	C	Unknown			Celgene
Levaquin	C	Unknown	50 Milligram		Celgene
Morphine	C	Unknown			Celgene
Potassium Chloride	C	Unknown	1500 Milligram		Celgene
Tofacitinib Citrate	C	Oral	10 Milligram		Celgene
Valsartan	C	Oral	320 Milligram		Celgene
Xalatan	C	Ophthalmic	50 Milligram		Celgene
Xeljanz	C	Oral	10 Milligram		Celgene
Zingiber Officinale	C	Oral	500 Milligram		Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403018	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020059792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Calcium Carbonate			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Asa			S		Unk		Not Reported
	Fosinopril			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported

	Synthroid	S		Unk		Not Reported
	Tylenol [Paracetamol]	S		Unk		Not Reported
	Tylenol [Paracetamol]	S	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403218	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020056477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S				Not Reported
	Arava			S				Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403272	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate Sodium			S	Unknown	25 G, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Cosentyx			S	Unknown	300 Mg, Unk		Not Reported
	Cosentyx			S	Unknown	450 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide			C	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17404196	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020054649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Etanercept	C	Unknown	Unk		Not Reported
	Humira	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17407178	DIRECT	Y	HO, LT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Seizure	Hydroxychloroquine			S		Other Frequency:First Dose;		Not Reported
	Metoprolol			C				Not Reported
	Carvedilol			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin D			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	11231180	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015214504		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand	Enbrel			S	Unknown	50 Milligram, Qwk		Unknown
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Cimzia	S	Subcutaneous	Unk	Not Reported
	Naprosyn	S	Unknown	500 Mg, 2x/Day	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		20 Mg, Daily	Not Reported
	Prednisone	S		2.5 Mg, Weekly	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Weekly	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naprelan	C		1000 Mg, 1x/Day	Not Reported
	Folic Acid	C		5 Mg, 3 Times/Wk	Not Reported
	Folic Acid	C	Unknown	5 Mg, 4 Times/Wk	Not Reported
	Folic Acid	C		5 Mg, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Metoprolol	C		50 Mg, Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Lovastatin	C		Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Tramadol Hydrochloride	C		Unk	Not Reported
	Naproxen	C	Unknown	500 Mg, 2x/Day	Not Reported
	Naproxen Sodium	C	Unknown	1000 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported

	Rosuvastatin			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	12913938	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	13571360	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017077269		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Unknown	50 Milligram, Qwk	Amgen
	Methotrexate Sodium	S	Oral	25 Milligram, 1x/Day	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1x/Day	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14213267	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3758		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Cyclic		Not Reported
	Cimzia			S	Subcutaneous	Cyclical		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Cyclic (Once Every 2 Weeks)		Not Reported
	Humira	S	Subcutaneous	Cyclical		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14446503	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0985		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2times/Wk		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Celebrex	S	Oral	Not Reported
Celebrex	S	Unknown	Not Reported
Vioxx	S	Oral	Not Reported
Vioxx	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14632688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020006		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Off Label Use; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15259069	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0134		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Vaginal	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Intolerance; Fibromyalgia; Herpes Zoster; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Times/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Cyclic	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Cyclic	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S			Not Reported
Rituximab	S	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Day 1 &15	Not Reported
Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported
Cortisone	C	Intra-articular		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Benadryl	C	Unknown	As Necessary	Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Pantoloc	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Vagifem	C	Vaginal		Not Reported
Leflunomide	C	Unknown		Not Reported
Abatacept	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lasix	C	Unknown		Not Reported
Enablex	C	Unknown		Not Reported
Enablex	C	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported

Acetaminophen	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Dyclone	C	Unknown	Not Reported
Kenalog	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Plantago Ovata	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Laxisoft	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15328824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15711487	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587408-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C				Not Reported

	Alprazolam	C		Not Reported
	Amlodipine	C	Oral	Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Celebrex	C		Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Metformin	C		Not Reported
	Pantoprazole	C		Not Reported
	Paroxetine	C		Not Reported
	Prednisone	C		Not Reported
	Risedronate	C		Not Reported
	Simvastatin	C		Not Reported
	Telmisartan	C		Not Reported
	Xeljanz	C		Not Reported
	Statex	C		Not Reported
	Mtx	C		Not Reported
	Morphine Sulphate	C		Not Reported
	Asa	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15838856	NON-EXPEDITED			US-PFIZER INC-2019013915		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16073865	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2703788-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased			otherwise specified)		
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16080945	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013872		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day		Not Reported
	Cephalexin	C	Unknown	500 Milligram, Four Times/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16689873	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21418		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not	Unknown		Not Reported

				otherwise specified)		
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Acetaminophen		C	Unknown		Not Reported
	Cetirizine Hydrochloride		C	Unknown		Not Reported
	Desoximetasone		C	Unknown	Unknown	Not Reported
	Dexamethasone		C	Unknown	Unknown	Not Reported
	Gabapentin		C	Unknown		Not Reported
	Reactine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16726516	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202738		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Arava			S	Unknown				Not Reported
		Leflunomide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16949982	EXPEDITED (15-DAY)		HO	NVSC2019DE011861			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Sepsis; Respiratory Failure; Septic Encephalopathy	Erelzi			S	Unknown	50 Mg, Qw		Novartis
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405028	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749484		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Folic Acid		S	Unknown	Not Reported
					Fosamax		S	Unknown	Not Reported
					Humira		S	Subcutaneous	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Methotrexate		S	Unknown	Not Reported
					Phthalylsulfathiazole		S	Unknown	Not Reported
					Prednisone		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2545008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Rivotril			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406023	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406024	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406028	EXPEDITED (15-DAY)		HO	CA-ROCHE-2542434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541689		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility	Actemra			S	Unknown	Therapy Duration:- 366.0		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration:- 7.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration:- -59.0, 4 Months		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406750	EXPEDITED (15-DAY)		DS	CA-ROCHE-2542981		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407002	EXPEDITED (15-DAY)		OT	SE-ACCORD-172239		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S		7 Tablets		Accord
	Plaquenil			S				Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			S		6 Tablets		Accord
	Methotrexate			S		6 Tab. Methotrexate / V +5 Mg Prednisolone For Many Years		Accord
	Methotrexate			S		In November 2016 Mtx Was Increased To 8 Tab / V		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546720		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407151	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698470		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Infection; Insomnia; Joint Swelling; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Months		Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.0 Months		Not Reported
	Gold			S	Unknown	7.0 Months		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407796	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020056860		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1 Every 12 Hours		Not Reported
	Prednisone			S	Oral	50 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Immunoglobulin G Human			C	Intravenous (not otherwise specified)	Unk Unk, Monthly		Not Reported
	Immunoglobulin G Human			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407906	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200201452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Otezla			S	Oral			Celgene
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17408807	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17409234	EXPEDITED (15-DAY)		OT	NVSC2020CA037016			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Calcium			S	Transplacental	Unk		Novartis
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	162 Mg, Qd		Not Reported
	Enoxaparin			S	Transplacental	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17409348	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020060642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate Sodium	S		25 Mg, Weekly		Pfizer
	Sulfasalazine	S		Unk		Pfizer
	Arava	S		20 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia	S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk, 1x/Day		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17410838	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2020062383		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Off Label Use; Product Use In Unapproved Indication; Tinnitus	Methotrexate Sodium			S		8 Df, Weekly (Mtx Was Raised To 8 Tab / Week)		Pfizer
	Methotrexate Sodium			S		6 Df, Unk		Pfizer
	Methotrexate Sodium			S		7 Df, Unk		Pfizer
	Methotrexate Sodium			S		6 Df, Weekly (Methotrexate / Week)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisolone			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411055	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03977			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Infliximab			S	Unknown	Unknown		Not Reported

Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Certolizumab Pegol	S	Unknown	Unknown	Not Reported
	Golimumab	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Plaquenil	C	Unknown	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Unknown	Not Reported
	Ventolin Hfa	C	Unknown	Unknown Metered-Dose (Aerosol))	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Advair	C	Unknown	Unknown	Not Reported
	Allopurinol	C	Unknown	Unknown	Not Reported
	Atrovent Hfa	C	Unknown	Unknown Metered-Dose (Aerosol)	Not Reported
	Codeine	C	Unknown	Unknown	Not Reported
	Cyclobenzaprine Hydrochloride	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Ibuprofen	C	Unknown	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Unknown	Not Reported
	Nexium Dr	C	Unknown	Unknown	Not Reported
	Dilaudid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411060	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Etanercept			S	Unknown	Unknown		Not Reported
	Amlodipine Besilate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411068	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Large Intestine Infection	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411069	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Etanercept	S	Unknown	Unknown		Not Reported
	Actemra	S	Unknown	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown		Not Reported
	Arava	S	Unknown	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide	S	Endocervical	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methylprednisolone	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown		Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411076	EXPEDITED (15-DAY)		HO	DE-SAMSUNG BIOEPIS-SB-2019-36506		83 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Diverticulitis	Benepali			S	Subcutaneous			Not Reported
	Hcq			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411086	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411089	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03835		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411442	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-006473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Ramipril			S	Unknown	12.5 Milligram, Once A Day		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	12.5 Milligram, Once A Day		Not Reported
	Buprenorphine			S	Unknown	10 Microgram, Once A Day		Not Reported
	Calcium			S	Unknown	Unk		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported
	Fish Oil			S	Unknown	Unk		Not Reported
	Lasix			S	Unknown	20 Milligram		Not Reported
	Magnesium Gluconate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported

		Vitamin D			S	Unknown	Unk			Not Reported
		Furosemide;Potassium Chloride			S	Unknown	20 Milligram			Not Reported
		Magnesium			S	Unknown	Unk			Not Reported
		Vitamin B6			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11176748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1589866		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)	Discontinued After 2 Cycles, Therapy Duration: 4 Months.		Not Reported
	Humira			S	Subcutaneous	For 4 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	Therapy Duration: 4 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11214316	EXPEDITED (15-DAY)		OT	AU-ROCHE-1596702		52 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Skin Lesion; Treatment Failure	Mycophenolate Mofetil	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Prednisone	S	Unknown	For One Month		Not Reported
	Prednisone	S	Unknown	For More Than 3 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11610346	EXPEDITED (15-DAY)		HO	CA-ROCHE-1643242		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Decreased Immune Responsiveness; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11688844	EXPEDITED (15-DAY)		OT	GB-ACCORD-034909		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Lethargy; Myelodysplastic Syndrome	Methotrexate			S	Unknown			Accord
	Metformin			S	Unknown			Accord
	Humira			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	12919683	EXPEDITED (15-DAY)		OT	CA-ROCHE-1850264		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Nausea; Off Label Use; Prescribed Overdose	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Naprosyn [Naproxen]			S	Unknown				Not Reported
	Celebrex			S	Unknown				Not Reported
	Celebrex			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Simponi			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	13190997	EXPEDITED (15-DAY)		HO	CA-ROCHE-1888707		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15275893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15298019	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803448		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder; Sleep Disorder	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Minocin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Methotrexate	C	Unknown	15 Milligram	Not Reported
	Abatacept	C	Unknown		Not Reported
	Orencia	C	Unknown	250 Milligrams	Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15311145	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP014163		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Naproxen			S	Oral	100 Mg, Qd		Apotex
	Naproxen			S	Oral	500 Mg, Bid		Apotex
	Naproxen			S	Oral	1000 Mg, Qd		Apotex
	Folic Acid			S	Unknown	5 Mg Twice In A Week		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Bid		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Q.O.Wk.		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	5 Mg, B.I.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg, Unknown		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	40 Mg, Qd		Apotex
	Pantoprazole			S	Unknown	40 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Atenolol			S	Unknown	25 Mg, Qd		Apotex
	Sulfasalazin			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazin			S	Oral	1000 Mg, Bid		Not Reported
	Co Atenolol			S	Unknown	25 Mg, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported

Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Oral	25 Mg, 1 Every 2 Weeks	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Q.O.Wk.	Not Reported
Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
Pantoloc /01263204/	S	Unknown	40 Mg, Qd	Not Reported
Pantoloc /01263204/	S			Not Reported
Arava	S	Unknown	20 Mg, Qd	Not Reported
Arava	S	Oral	20 Mg, Qd	Not Reported
Naprosyn /00256201/	S	Oral	500 Mg, Bid	Not Reported
Naprosyn /00256201/	S	Oral	1000 Mg, Qd	Not Reported
Naprosyn /00256201/	S	Oral	100 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	40 Mg, Qd	Not Reported
Enbrel	S	Subcutaneous	Unk, Unknown	Not Reported
Humira	S	Subcutaneous	Unk, Unknown	Not Reported
Orencia	S	Unknown	Unk,	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk, Unknown	Not Reported
Abatacept	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk, Unknown	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Mg, Qd	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported

Methotrexate	S	Oral	25 Mg, Unk		Not Reported
Methotrexate	S	Oral	Unk Unk, Q.O.Wk.		Not Reported
Methotrexate	S	Oral	20 Mg, Qd		Not Reported
Methotrexate	S	Oral	20 Mg, Q.Wk.		Not Reported
Methotrexate	S	Oral	20 Mg, Q.O.Wk.		Not Reported
Etanercept	S	Subcutaneous	Unk		Not Reported
Palafer	S	Unknown	Unk		Not Reported
Teva Pantoprazole	S	Unknown	40 Mg, Qd		Not Reported
Vitamin C /00008001/	S	Unknown	Unk, Qd		Not Reported
Celebrex	C	Oral	200 Mg, Qd		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Prednisone	C	Intracardiac	5 Mg, Qd		Not Reported
Prednisone	C	Unknown	Unk Unk, Q.O.Wk.		Not Reported
Celecoxib	C	Oral	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15394598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184764		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

						Remicade		S	Intravenous (not otherwise specified)	Not Reported
						Simponi		S	Subcutaneous	Not Reported
						Leflunomide		S	Unknown	Not Reported
						Apo-Leflunomide		S	Unknown	Not Reported
						Arthrotec		C	Unknown	Not Reported
						Ergocalciferol		C	Unknown	Not Reported
						Imuran [Azathioprine]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15730589	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15930195	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2654210-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16093680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709127-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Levothyroxine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16388002	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029948			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib Capsules			S	Unknown	200 Milligram, Once A Day		Aurobindo
	Citalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Sertraline			S	Unknown	25 Milligram		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Indomethacin			S	Unknown	50 Milligram, 3 Times A Day		Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Temazepam			S	Unknown	Unk		Not Reported
	Toradol			S	Intramuscular	10 Milligram		Not Reported
	Toradol			S				Not Reported
	Zopiclone			S	Unknown	7.5 Milligram		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Lidocaine			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Milligram		Not Reported
	Naproxen			C	Unknown	500 Milligram, Two Times A Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin D			C	Unknown	50000 International Unit,		Not Reported

Every Week

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16413232	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044080		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

		Tofacitinib Citrate			S	Unknown				Not Reported
		Kevzara			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16586116	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557146-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Infection; Pneumonia; Pneumonia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16714551	EXPEDITED (15-DAY)		OT	PHHY2019DE188505			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Omeprazole			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1))		Novartis
	Pregabalin			S	Unknown	3 Df, Qd		Not Reported
	Apixaban			S	Unknown	2 Df (1 Dosage Form, Bid (1-0-1))		Not Reported
	Apixaban			S	Unknown	5 Mg, Qd (2.5 Milligram, Bid)		Not Reported
	Sildenafil Citrate			S	Unknown	60 Mg, Qd		Not Reported
	Quensyl			S	Unknown	2 Df, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval)		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd (Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported
	Eliquis			S	Unknown	2 Df, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Unknown	162 Mg, Qw		Not Reported
	Volibris			S	Oral	30 Mg, Qd		Not Reported
	Volibris			S	Oral	1 Df, Qd		Not Reported
	Lyrica			S	Unknown	300 Mg, Qd (100		Not Reported

Milligram, Tid)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16716102	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Blood Cholesterol Increased; Bone Erosion; Bronchitis; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Hypertension; Infection; Joint Dislocation; Joint Stiffness; Malaise; Nasopharyngitis; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Psoriasis; Synovitis; Tachycardia; Upper Respiratory Tract Infection	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Telmisartan			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported

	Amitriptyline	C	Oral	Not Reported
	Betamethasone	C	Topical	Not Reported
	Betamethasone Dipropionate W/Calcipotriol	C	Unknown	Not Reported
	Melatonin	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16716446	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803878		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Otezla			S	Oral			Celgene
	Cosentyx			S	Subcutaneous	300 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous drip	600 Milligram		Not Reported
	Infliximab			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Oral	15 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Hydrochlorothiazide	S	Oral	25 Milligram	Not Reported
Clonidine Hydrochloride	C	Oral		Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral	40 Milligram	Not Reported
Fluticasone Propionate	C	Unknown		Not Reported
Gabapentin	C	Oral	2000 Milligram	Not Reported
Folinic Acid	C	Unknown		Not Reported
Folic Acid	C	Unknown	5 Milligram	Not Reported
Losartan	C	Unknown		Not Reported
Metoprolol Tartrate	C	Oral	100 Milligram	Not Reported
Mometasone Furoate	C	Nasal	50 Microgram	Not Reported
Naproxen	C	Unknown		Not Reported
Plaquenil	C	Unknown	300 Milligram	Not Reported
Acetaminophen And Codeine	C	Oral	325 Milligram	Not Reported
Amitriptyline Hydrochloride	C	Oral	50 Milligram	Not Reported
Aspirin	C	Unknown	81 Milligram	Not Reported
Baclofen	C	Unknown	20 Milligram	Not Reported
Betahistine Hydrochloride	C	Oral	16 Milligram	Not Reported
Caffeine	C	Oral		Not Reported
Calcium	C	Unknown	1000 Milligram	Not Reported
Clonidine	C	Unknown		Not Reported
Amoxicillin Trihydrate/Clarithromycin/Esomeprazole Magnesium Trihydrat	C	Unknown		Not Reported
Acetaminophen	C	Oral		Not Reported
Acetaminophen	C	Unknown	325 Milligram	Not Reported
Codeine	C	Oral		Not Reported
Codeine	C	Unknown	325 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17218862	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548324		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Erythema; Drug Ineffective; Hypoacusis; Off Label Use; Product Use Issue; Psoriatic Arthropathy	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily (Qd)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17395434	EXPEDITED (15-DAY)		HO	BR-STRIDES ARCOLAB LIMITED-2020SP001169		32 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Dental Necrosis; Off Label Use; Tooth Abscess; Tooth Fracture; Toothache	Tacrolimus			S	Unknown	2 Milligram Per Day		Strides
	Prednisolone			S	Unknown	5 Milligram Per Day		Not Reported
	Alendronate			S	Oral	70 Milligram, Once A Week		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Per Day		Not Reported
	Tamoxifen			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411606	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540641		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported

Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Adalimumab	S	Unknown			Not Reported
	Adalimumab	S	Subcutaneous	4.0 Years		Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	404.0 Days		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Etanercept	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Infliximab	S	Unknown			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous	5.0 Years		Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411609	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-235348		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia ; Tachycardia	Methotrexate			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Sun
	Mycophenolate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411672	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542957		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411767	EXPEDITED (15-DAY)		HO	CA-ROCHE-2539868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Onychomycosis	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Unknown				Not Reported
	Arava			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411790	EXPEDITED (15-DAY)		DS	CA-ABBVIE-20K-028-3270161-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Allopurinol			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546716		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
					Salazopyrin		S	Unknown	Not Reported
					Actemra		C	Unknown	Not Reported
					Bifidobacterium Bifidum		C		Not Reported
					Celebrex		C		Not Reported
					Loperamide		C		Not Reported
					Methotrexate		C		Not Reported
					Pantoprazole		C		Not Reported
					Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0796			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate (Trade Name Unknown)			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Cosentyx			S	Unknown				Not Reported
	Cosentyx			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Leflunomide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412024	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0799			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412049	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Leflunomide		S	Unknown		Not Reported
	Etanercept		C	Unknown		Not Reported
	Humira		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412097	EXPEDITED (15-DAY)		HO	US-ZYDUS-047509		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cardiac Event; Dizziness	Hydroxychloroquine			S	Oral			Zydus Pharm
	Albuterol			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Fluticasone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Isosorbide			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412105	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Actemra			S	Unknown			Not Reported

Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Oral				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Wellbutrin			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546734		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412232	EXPEDITED (15-DAY)		OT	SE-TEVA-2020-SE-1184606		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S	Unknown	"Nov 2016, Mtx Was Raised To 8 Tab/V".		Barr
	Methotrexate			S	Unknown	7 Tablets		Barr
	Methotrexate			S	Unknown	6 Tablets		Barr
	Methotrexate			S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon For Many Years".		Barr
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C		5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412298	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3270872-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412439	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Meloxicam			C				Not Reported

	Acetaminophen;Codeine Phosphate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412591	EXPEDITED (15-DAY)		HO	CA-ROCHE-1866268		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412841	EXPEDITED (15-DAY)		CA, HO, OT	GR-LUPIN PHARMACEUTICALS INC.-2020-00745			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Aorta Hypoplasia; Bradycardia Foetal; Congenital Aortic Stenosis; Echocardiogram Abnormal; Foetal Exposure During Pregnancy; Heart Block Congenital; Neonatal Respiratory Distress; Ventricular Septal Defect	Hydroxychloroquine			S	Transplacental	Unk			Lupin
	Acetylsalicylic Acid			S	Transplacental				Not Reported
	Prednisolone			S	Transplacental	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413195	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546743		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional	Actemra			S	Unknown			Not Reported

Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous drip		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Restasis	C	Oral		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413260	EXPEDITED (15-DAY)		OT	CA-SA-2020SA036521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Topicort			S				Sanofi
	Alendronate Sodium			S				Not Reported
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Topical			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543697		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413281	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413326	EXPEDITED (15-DAY)		HO	CA-ROCHE-2546133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546111			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413707	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2020M1016074		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Drug Ineffective; Hydrocephalus; Nocardiosis; Septic Shock; Shunt Infection	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S				Not Reported
	Prednisolone			S	Unknown	30 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Trimethoprim Sulfamethoxazole			S	Intravenous (not otherwise specified)	15 Mg/Kg Of Trimethoprim Divided In Three Doses		Mylan
	Trimethoprim Sulfamethoxazole			S				Mylan
	Amikacin			S	Intravenous (not	7.5 Milligram/Kilogram		Mylan

						otherwise specified)				
	Amikacin			S						Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413936	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form- Not Specified		Baxter
	Arava			S	Unknown	Dosage Form- Tablets		Not Reported
	Azithromycin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Azithromycin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Benadryl			S	Unknown	Dosage Form- Not Specified		Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Dosage Form- Solution Subcutaneous Single-Use Prefilled Syringe		Not Reported
	Demerol			S	Unknown	Dosage Form- Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form- Solution Subcutaneous		Not Reported
	Imuran			S	Unknown	Dosage Form- Not Specified		Not Reported
	Levofloxacin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Unknown	Dosage Form- Tablets		Not Reported

	Simponi				S	Subcutaneous	Dosage Form- Solution Subcutaneous			Not Reported
	Xeljanz				S	Oral				Not Reported
	Xeljanz				S	Oral				Not Reported
	Xeljanz				S	Oral				Not Reported
	Xeljanz				S	Oral				Not Reported
	Ezetrol				C	Unknown	Dosage Form- Tablets			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413946	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2020M1017169		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Retinal Toxicity	Hydroxychloroquine			S	Unknown	Later, Restarted At The Time Of Pregnancy Until 26weeks Of Gestational		Not Reported
	Azathioprine			S	Unknown	Initial Dosage Not Stated. Later, At The Time Of Pregnancy She Was Maintained On150 Mg Daily.		Not Reported
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	175 Milligram, Qd		Not Reported
	Nifedipine			S	Unknown	30 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Mylan
	Prednisone			S	Unknown	40 Milligram, Qd		Mylan
	Acetylsalicylic Acid			S	Unknown	162 Milligram, Qd		Mylan
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 Gram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Desoximetasone		C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17414259	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020058166		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Arava			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported
	Arnica Montana			C		Unk		Not Reported
	Asa			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415069	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546744		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Ineffective; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities	Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration 184.0		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Therapy Duration 0.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration 3.0 Years		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Therapy Duration 7.0 Months		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Etanercept	S	Unknown	Therapy Duration 31.0		Not Reported
	Arava	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415209	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020058429		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus;	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Quetiapine Fumarate			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Alendronate Sodium			C				Not Reported
	Amlodipine			C				Not Reported
	Ativan			C	Unknown	Unk Unk, As Needed		Not Reported
	Lipitor			C				Not Reported
	Methadone			C	Oral	10 Mg, 1x/Day		Not Reported

Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Pantoloc [Pantoprazole]	C				Not Reported
	Prednisone	C	Unknown			Not Reported
	Valtrex	C				Not Reported
	Zopiclone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415269	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184218		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Swelling;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

Toxicity To Various Agents; Visual Impairment	Orencia		S	Unknown		Not Reported
	Methotrexate		C	Subcutaneous		Not Reported
	Methotrexate		C	Subcutaneous		Not Reported
	Sulfasalazine		C	Oral	1 Gram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415271	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183917			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Hepatotoxicity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415275	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1184182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Fall; Gait Disturbance; Mobility Decreased; Peripheral Swelling; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Arava			S	Oral	200 Milligram Daily;		Not Reported
	Lovenox			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415297	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA032797		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Sleep Disorder; Spinal Stenosis	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminofen Tramadol			S	Oral	Unk		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Actonel			C	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	Unk		Not Reported
	Nortriptyline			C	Unknown	Unk		Not Reported
	Nortriptyline Hydrochloride			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown	Unk		Not Reported
	Vagifem			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Malaise; Nausea; Retinal Toxicity; Vomiting	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	100 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415556	EXPEDITED (15-DAY)		CA, OT	NVSC2020GR035293			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Foetal Exposure During Pregnancy; Heart Disease Congenital; Respiratory Distress	Acetylsalicylic Acid			S	Unknown	Unk, (Maternal Dose: Unk)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, (Maternal Dose: Unk)		Novartis
	Prednisolone			S	Unknown	Unk, (Maternal Dose: Unk)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	11278460	EXPEDITED (15-DAY)		OT	CA-ROCHE-1606928		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Rituxan			S	Intravenous (not otherwise specified)	1 Gm. 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported

	Naprosyn [Naproxen]	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	20-25 Mg, Therapy Duration: 6 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	11752885	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015121181		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Fatigue; Headache;	Enbrel			S	Subcutaneous	Unk		Amgen
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported

Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting; Weight Increased	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Indocid	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Gold (198 Au)	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25,Unk, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported

	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
	Folic Acid	C	Oral	Unk, Qwk	Not Reported
	Folic Acid	C	Oral	5 Milligram, Unk	Not Reported
	Cymbalta	C	Oral	30 Milligram, 30 Mg, Qd At Nights	Not Reported
	B Complex [Vitamin B Complex]	C		Unk	Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	12212678	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016036511		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Toxicity; Sensitivity To Weather	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Milligram, Cyclical		Not Reported
	Arava			S	Unknown	10 Milligram, Cyclical		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	1000 Milligram, Bid		Not Reported

Change; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vascular Graft	Plaquenil	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	1 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	5 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Lax-A-Day	C		Unk, Occ	Not Reported
	Vitamin B12	C	Sublingual	1200 Microgram, Qd	Not Reported
	Endocet	C		5+325 Mg, 1 Tablet 2 Times Per Day Prn	Not Reported
	Endocet	C		1 Dose 2 Every 1 Day	Not Reported
	Indomethacin	C		Unk	Not Reported
	Pennsaid	C		Unk	Not Reported
	Oxycocet	C		2 Tabs, 4-5x/Week	Not Reported
	Asa	C		325 Milligram, Occ	Not Reported
	Naprelan	C		1000 Milligram, Cyclical	Not Reported
	Metoprolol	C		75 Milligram, Bid	Not Reported
	Folic Acid	C		5 Milligram, Cyclical	Not Reported
	Bisoprolol	C		5 Milligram, Qd	Not Reported
	Omega 3	C		12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	12337536	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055447		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Apo-Hydroxyquine			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13161522	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-2016047597		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Adalimumab			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported

Carcinoma; Blood	Certolizumab Pegol	S	Unknown		Not Reported
Creatinine Increased; Blood Parathyroid	Ciclosporin	S	Oral	.6 Milligram	Not Reported
Hormone Decreased;	Ciclosporin	S	Unknown		Not Reported
Blood Pressure Systolic Increased; C-Reactive	Ciclosporin	S	Unknown		Not Reported
Protein Abnormal; C-	Ciclosporin	S	Unknown		Not Reported
Reactive Protein Abnormal; C-Reactive	Ciclosporin	S	Oral		Not Reported
Protein Increased;	Ciclosporin	S	Oral		Not Reported
Contraindicated Product Administered; Diarrhoea;	Ciclosporin	S	Unknown		Not Reported
Drug Eruption; Drug	Ciclosporin	S	Oral		Not Reported
Hypersensitivity; Drug Ineffective; Drug	Etanercept	S	Subcutaneous		Not Reported
Intolerance; Enthesopathy;	Etanercept	S	Unknown		Not Reported
Enthesopathy; Erythema;	Etanercept	S	Unknown		Not Reported
Erythema; Erythema; Fatigue; General Physical	Golimumab	S	Subcutaneous		Not Reported
Health Deterioration;	Infliximab	S	Intravenous drip	400 Milligram	Not Reported
Granuloma Skin; Headache;	Sulfasalazine	S	Endocervical		Not Reported
Hypercalcaemia;	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Hypersensitivity; Hypersensitivity;	Sulfasalazine	S	Unknown		Not Reported
Inflammation; Infusion Related Reaction;	Ustekinumab	S	Subcutaneous		Not Reported
Insomnia; Joint Injury;	Ustekinumab	S	Unknown		Not Reported
Joint Swelling; Loss Of Personal Independence In	Abatacept	S	Subcutaneous		Not Reported
Daily Activities; Loss Of	Enbrel	S	Subcutaneous		Not Reported
Personal Independence In Daily Activities; Loss Of	Enbrel	S	Unknown		Not Reported
Personal Independence In Daily Activities;	Enbrel	S	Unknown		Not Reported
Musculoskeletal Stiffness;	Enbrel	S	Unknown	25 Milligram	Not Reported
Nausea; Pain; Panniculitis;	Humira	S	Subcutaneous		Not Reported
Peripheral Swelling;	Stelara	S	Subcutaneous		Not Reported
Psoriatic Arthropathy;	Simponi	S	Subcutaneous		Not Reported
Rash; Rash Pruritic; Red	Orencia	S	Unknown		Not Reported
Blood Cell Sedimentation Rate; Red Blood Cell	Orencia	S	Subcutaneous		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Cimzia	S	Subcutaneous		Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	6 Dosage Forms	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Celebrex	S	Oral	200 Milligram	Not Reported
	Codeine	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Remicade	S	Intravenous drip		Not Reported
	Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
	Rituximab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Methotrexate	S	Oral		Not Reported
	Apo Ibuprofen	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Colchicine	C	Oral	.6 Milligram	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate Sodium	C	Oral	4.0 Dosage Forms	Not Reported
	Methotrexate Sodium	C	Unknown	10 Milligram	Not Reported
	Methotrexate Sodium	C	Oral		Not Reported
	Methotrexate Sodium	C	Unknown	2.5 Milligram	Not Reported

Mogadon	C	Unknown	5 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram Er	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram Er	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Uloric	C	Oral	160 Milligram	Not Reported
Uloric	C	Oral	80 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Febuxostat	C	Unknown	160 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Vitamin D3	C	Oral	2000 Iu (International Unit)	Not Reported

Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13348182	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017039391		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Triatec			C		Unk		Not Reported
	Atasol			C		Unk		Not Reported
	Tylenol			C	Unknown	650 Mg, Bid		Not Reported
	Atacand			C	Unknown	Unk		Not Reported
	Hydrodiuril			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Premarin			C		Unk		Not Reported
	Neurontin			C		600 Mg, Tid		Not Reported
	Acetaminophen			C		650 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13782530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017103905		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Enbrel			S	Unknown	Unk		Amgen

Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Cosentyx		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Methotrexate		C	Oral	Unk Unk, Qwk	Not Reported
	Morphine		C	Topical	Unk, Every Two Days	Not Reported
	Erythromycin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	14187184	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170219			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Rituxan	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Varenicline Tartrate	S	Oral	Unk Unk, Qd	Not Reported
Varenicline Tartrate	S	Oral	1 Dosage Form, Qd	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Valtrex	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium W/Naproxen	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
Acetaminophen	C		Unk	Not Reported
Naproxen	C		Unk	Not Reported
Oxycodone Hydrochloride	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	14246850	EXPEDITED (15-DAY)		HO	CA-ROCHE-2028708		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported

			Methotrexate		C	Unknown			Not Reported
			Methotrexate		C	Subcutaneous			Not Reported
			Methotrexate		C	Unknown			Not Reported
			Methotrexate		C	Unknown			Not Reported
			Prednisone		C	Unknown			Not Reported
			Prednisone		C	Unknown			Not Reported
			Prednisone		C	Unknown			Not Reported
			Xeljanz		C	Unknown			Not Reported
			Prednisolone		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15291603	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803571		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown	300 Milligram		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Infliximab			S	Intravenous drip	500 Milligram		Not Reported
	Infliximab			S	Unknown			Not Reported

	Infliximab			S	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	.6 Milliliter	Not Reported
	Methotrexate			S	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram	Not Reported
	Leflunomide			S	Unknown	20 Milligram	Not Reported
	Rituximab			S	Unknown		Not Reported
	Simponi			S	Unknown		Not Reported
	Remicade			S	Intravenous drip		Not Reported
	Pencillin (Benzyl Penicillin)			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15399793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083448			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15635328	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Minocycline			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Oral	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15842727	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021061		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; No Adverse Event; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Apo-Leflunomide	S	Oral	Unk	Not Reported
Ciclosporin	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Milligram	Not Reported
Orencia	S	Subcutaneous	125 Milligram, Unk	Not Reported
Orencia	S	Subcutaneous	12.5 Milligram, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz Xr	C		Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk, Qd	Not Reported
Xeljanz	S	Oral	10 Milligram, Qd	Not Reported
Xeljanz	S	Unknown	Unk Unk, Qd	Not Reported

	Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15866486	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1094		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisynthetase Syndrome; Rebound Effect	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417570	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-236079		32 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Dental Necrosis; Tooth Abscess	Alendronic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417741	EXPEDITED (15-DAY)		HO	CA-ROCHE-2547886		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417966	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184031		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram Daily;		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418219	EXPEDITED (15-DAY)		HO	US-ZYDUS-047474		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Zydus Pharm

; Leukopenia; Neutropenia	Mycophenolic Acid			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418399	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543618		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543745		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired	Actemra			S	Unknown			Not Reported

Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Arava			S	Unknown	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Orencia			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Rituxan			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Actonel			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543690		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	4.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543627		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration:- 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration:- 11.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

			Esomeprazole Magnesium Trihydrate		C					Not Reported
			Folic Acid		C	Unknown				Not Reported
			Naproxen		C	Unknown				Not Reported
			Xeljanz		C	Oral				Not Reported
			Xeljanz		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418616	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0811		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Asa			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184235		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1184190		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7857 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7143 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.5 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7143 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Alendronate Sodium			S	Unknown	10 Milligram Daily;		Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	12 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported

Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Oral	1.4286 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Ciclosporin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418684	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1184211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183936		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Impairment	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418705	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183932		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown	5 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418744	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0844		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name			S	Subcutaneous			Not Reported

Unapproved Indication	Unknown)								
	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Prednisone			S	Oral				Not Reported
	Prednisone			S	Oral				Not Reported
	Immunoglobulin G Human			C	Unknown				Not Reported
	Immunoglobulin G Human			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418787	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418909	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3275098-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Synovitis	Sulfasalazine		S	Oral	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543692		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419040	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1183361		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Leucovorin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr

	Prednisone	S	Unknown			Actavis
	Actemra	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown			Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419072	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007699		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Mycophenolate			S	Unknown	1 G, Bid		Novartis
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 G, (For 2 Days)		Not Reported
	Prednisone			C	Unknown			Not Reported
	Azathioprine			C	Unknown	100 Mg, Qd		Not Reported
	Cyclophosphamide			C	Intravenous (not otherwise specified)	500 Mg, Every Two Weeks For Six Doses		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419141	EXPEDITED (15-DAY)		DS	CA-ROCHE-2543637		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira			S	Subcutaneous					Not Reported
	Humira			S	Subcutaneous					Not Reported
	Hydroxychloroquine			S	Oral					Not Reported
	Hydroxychloroquine			S	Oral					Not Reported
	Hydroxychloroquine			S	Oral					Not Reported
	Methotrexate			S	Oral					Not Reported
	Methotrexate			S	Oral					Not Reported
	Orencia			S	Subcutaneous					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral					Not Reported
	Prednisone			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Xeljanz			S	Oral					Not Reported
	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

					Rituximab	S	Intravenous (not otherwise specified)			Not Reported
					Simponi	S	Subcutaneous			Not Reported
					Sulfasalazine	S	Unknown			Not Reported
					Acetaminophen	C	Unknown			Not Reported
					Mefenamic Acid	C	Unknown			Not Reported
					Prednisone	C	Oral	10 Milligram Daily;		Not Reported
					Prednisone	C	Oral	6 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419155	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1183858		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cefazolin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown	1000 Milligram Daily;		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543730		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419171	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1184234		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Leflunomide			S				Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis

Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Gold	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituximab	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Caffeine			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Dorzolamide Hydrochloride			C	Ophthalmic			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Meprobamate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Timolol Maleate			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419243	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183915		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rapamune	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Imuran	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419259	EXPEDITED (15-DAY)		DS	CA-ROCHE-2543752			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419385	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184192		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419404	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419406	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184201		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr

Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Indometacin	S	Unknown			Actavis
	Prednisone	S	Oral	25 Milligram Daily;		Actavis
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
	Cymbalta	C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid	C	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419417	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20200210530			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Meconium Aspiration Syndrome; Pneumonia Aspiration; Pulmonary Arterial Hypertension; Respiratory Distress	Cetirizine Hydrochloride			S	Transplacental	10 Milligram, 2x/Day (Bid)		Not Reported
	Prednisolone			S	Transplacental	5 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Milligram, Once Daily (Qd)		Not Reported
	Sulphasalazine			S	Transplacental	1 Gram, Once Daily (Qd)		Not Reported
	Naproxen			S	Transplacental	500 Mg Sos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419447	EXPEDITED (15-DAY)		HO	CA-ROCHE-2543639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419459	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

					Orencia		S	Unknown		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Prednisone		C	Unknown		Not Reported
					Piroxicam		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543693		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Investigation Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419543	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419562	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil [Hydroxychloroquine			C	Unknown			Not Reported

Sulfate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419637	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0861		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Methadone			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419638	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-844506		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel	S	Unknown			Teva
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown	20 Milligram Daily;		Barr
	Methotrexate	S	Subcutaneous			Barr
	Plaquenil	S	Unknown	300 Milligram Daily;		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419785	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419860	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1183922		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419889	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183510		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic	Alendronate Sodium			S	Unknown			Actavis
	Asa			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Fosinopril			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Morphine			S	Unknown			Not Reported

Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Synthroid		S	Unknown	Not Reported
	Tylenol		S	Unknown	Not Reported
	Tylenol		S	Unknown	Not Reported
	Vitamin D		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Unknown				Not Reported
	Prednisone			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543007		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Contraindicated Product Administered; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered;	Actemra			S	Unknown			Not Reported

Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420679	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective;	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter

Drug Intolerance; Interstitial Lung Disease; Therapeutic Product Effect Decreased	Cimzia	S	Unknown	Single-Use Prefilled Syringe; Dosage Form: Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Imuran	S	Unknown	Dosage Form Not Specified	Not Reported
	Plaquenil	S	Unknown	Tablets	Not Reported
	Simponi	S	Unknown	Dosage Form Solution Subcutaneous	Not Reported
	Arava	C	Unknown	Tablets	Not Reported
	Azithromycin	C	Unknown	Dosage Form Not Specified	Not Reported
	Celebrex	C	Unknown		Not Reported
	Ezetrol	C	Unknown	Tablets	Not Reported
	Methotrexate	C	Unknown	Dosage Form Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420765	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020062981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Retinopathy	Methotrexate Sodium			S	Oral	200 Mg, Weekly		Pfizer
	Sulfasalazine			S		1500 Mg, 2x/Day		Pfizer
	Plaquenil S			S		200 Mg, 2x/Day		Not Reported
	Xeljanz Xr			C		11 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543675		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420910	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020060246		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate Sodium			S	Oral	20 Mg Weekly		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Leflunomide			S		10 Mg, Daily		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421152	EXPEDITED (15-DAY)		OT	NVSC2020US039748		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Hypertrophic Cardiomyopathy; Thrombocytopenia; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis
	Metoprolol			C	Unknown			Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547897		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrina			S	Unknown			Not Reported
	Align			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543659			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	365.0		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	19.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	2.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2.0 Years		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422215	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04546		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549749		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422367	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17428134	DIRECT	Y	OT				Prefer not to disclose	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine Generic Manufactured By Zydus Pharmaceutical			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	12770694	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076721		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Oral	500 Milligram, Bid		Not Reported
	Celecoxib	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Prednisone	C	Unknown	2 Milligram, Qd		Not Reported
	Hydromorphone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	15346014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178067		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	17422660	EXPEDITED (15-DAY)		DE	CA-AUROBINDO-AUR-APL-2020-007472		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronic Acid			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo

	Flovent	S	Unknown	Unk	Not Reported
	Furosemide	S	Unknown	40 Milligram	Not Reported
	Ipratropium Bromide;Salbutamol	S	Unknown	Unk	Not Reported
	Lipitor	S	Unknown	10 Milligram	Not Reported
	Losec	S	Unknown	20 Milligram	Not Reported
	Nitrazadon	S	Unknown	10 Milligram	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	5 Milligram, Once A Day	Not Reported
	Salmeterol Xinafoate	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	12381245	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061262		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Mycophenolate Mofetil Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Unk, Qwk	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Teva Mycophenolate	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Lyrica	S	Oral	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Mycophenolate	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Prednisone	S	Unknown	25 Milligram, Qd Qd, Decrease Dose Weekly	Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	500 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	35 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15400433	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083739		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15978440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Stress	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk, Q2wk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Advil [Ibuprofen]	C	Unknown			Not Reported
	Prednisone	C	Oral	6 Milligram, Qwk		Not Reported
	Prednisone	C	Oral	10 Milligram, Qd		Not Reported
	Tylenol	C	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Mefenamic Acid	C	Unknown			Not Reported
	Dequalinium Chloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16387192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050922			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	1000 Milligram		Not Reported

				otherwise specified)		
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Acetaminophen		C	Oral	650 Milligram	Not Reported
	Diphenhydramine		C	Oral	50 Milligram	Not Reported
	Hydroxychloroquine		C	Unknown	Unk	Not Reported
	Methylprednisolone		C	Unknown	100 Milligram	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16440223	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056344		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16496259	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

						otherwise specified)			
			Rituxan		S	Unknown			Not Reported
			Sulfasalazine		S	Unknown	500 Milligram		Not Reported
			Sulfasalazine		S	Unknown			Not Reported
			Leflunomide		S	Unknown			Not Reported
			Leflunomide		S	Unknown			Not Reported
			Hydroxychloroquine Sulfate		S	Unknown			Not Reported
			Hydroxychloroquine Sulfate		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16671604	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077052			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422875	EXPEDITED (15-DAY)		OT	FR-ROCHE-2548690		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Urticarial Vasculitis	Omalizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422886	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422888	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422916	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009843		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Orencia			S	Unknown			Bristol Myers Squibb
	Procytox			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422931	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009742		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1000 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

					Enbrel		S	Unknown		Not Reported
					Humira		S	Subcutaneous	40 Milligram	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009905		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422987	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010408		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Cough; Off Label Use; Pain In Extremity; Pneumonia; Product Use Issue	Abatacept		S	Intravenous (not otherwise specified)	500 Milligram, Qmo	Bristol Myers Squibb
	Methotrexate		S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17423002	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17423205	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-007468		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	500 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	360 Milligram, 1 Every 1		Not Reported

Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer				Month	
	Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	360 Milligram 1 Every 1 Month	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Alendronate	C	Unknown	70 Milligram, Every Week	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11203581	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015010325		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Subcutaneous	20 - 25 Mg, Qwk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Rituxan			S	Unknown	1 Gram, 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Unknown	50 Milligram, Q4wk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, Qwk		Not Reported
	Orencia			S	Subcutaneous	150 Gram		Not Reported
	Orencia			S	Subcutaneous	150 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine	S	Unknown	10 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cortisone Acetate	S	Topical	Unk	Not Reported
	Naprosyn	C	Unknown	500 Milligram, Bid	Not Reported
	Naprosyn	C	Unknown	50 Milligram	Not Reported
	Celebrex	C	Unknown	200 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11271826	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015069415		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Enbrel			S	Subcutaneous	Unk		Amgen

Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Aspirin	S	Oral	Unk	Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Diclofenac Potassium	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Sodium Aurothiomalate	S	Oral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Motrin	S	Unknown	Unk	Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Voltaren	S	Unknown	Unk	Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Topical	Unk	Not Reported
Vitamin C	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Clopidogrel	S	Unknown		Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Apo Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Asa	S	Unknown	325 Mg, Unk	Not Reported
Apo-Sulfatrim	S	Unknown		Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid;Clopidogrel	S	Unknown	Unk	Not Reported
Sulfatrim [Sulfadiazine;Trimethoprim]	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Gold Sodium Thiomalate	S	Unknown		Not Reported
Tramadol	C	Unknown	Unk	Not Reported
Tramadol Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11308664	NON-EXPEDITED		OT	CA-AMGEN-CANSP2011017837		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Apo Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo		Not Reported
	Actemra			S	Intravenous (not	1 Dosage Form, Qd		Not Reported

		otherwise specified)		
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naprosyn	C	Unknown	Unk Unk, As Required	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Asa	C	Unknown	81 Milligram	Not Reported
Asa	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, As Required	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Lozide	C	Unknown	Unk	Not Reported
Lantus	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	81 Milligram	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11506729	EXPEDITED (15-DAY)		OT	CA-ROCHE-1632320		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12215314	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016171322		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	1000 Milligram, Bid		Not Reported

Plaquenil	S	Unknown	200 Milligram, 2 Every 1 Day	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Mg, On Monday-Wednesday-Friday	Not Reported
Arava	S	Unknown	10 Mg, 4x/Week	Not Reported
Arava	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	1 Milligram, Qd	Not Reported
Prednisone	S		5 Milligram	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Vitamin B12	C		1200 Ug, 1 Tablet 1 Time Per Day	Not Reported
Endocet	C		5 + 325mg 1 Tablet 2x/Day As Needed	Not Reported
Endocet	C		1 Dose 2 Every 1 Day	Not Reported
Indomethacin	C		Unk	Not Reported
Pennsaid	C		Unk	Not Reported
Oxycocet	C		2 Tablets, 4-5 Times Per Week	Not Reported
Asa	C		325 Mg, Occasionally	Not Reported
Naprelan	C		1000 Mg, 1-2 Times Per Month	Not Reported
Metoprolol	C		75 Milligram, Bid	Not Reported
Folic Acid	C		5 Mg, 3x/Week	Not Reported
Bisoprolol	C		5 Milligram, Qd	Not Reported
Lax-A-Day	C		Occasionally	Not Reported
Omega 3	C		12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12335793	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12377399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016252940		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown

Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate Sodium	S	Intra-arterial	Unk	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Lyrica	S	Oral	Unk	Pfizer
	Lyrica	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	1.5 Mg, Bid	Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Teva Mycophenolate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk Solution Subcutaneous	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Cellcept	S	Unknown	Unk	Not Reported
	Cellcept	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Powder For Solution For Intravenous	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

	Apo Mycophenolate		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil Hydrochloride		S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
	Cimzia		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	20 Mg, Unk	Not Reported
	Sodium Aurothiomalate		S	Parenteral	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Mycophenolate		S	Unknown	Unk	Not Reported
	Piroxicam		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	25 Mg, Qd, Decrease Dose Weekly	Not Reported
	Prednisone		S		1 Dosage Form, Qd	Not Reported
	Methotrexate		C		Unk	Not Reported
	Morphine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12570090	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016092146		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Methotrexate Sodium		S	Unknown	Unk	Not Reported
					Methotrexate		S	Unknown	Unk	Not Reported
					Methotrexate		S			Not Reported
					Azathioprine		S	Unknown	Unk	Not Reported
					Celecoxib		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12726405	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016247224		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12964814	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013262		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S	Topical	Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Elavil			S	Unknown	Unk		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13237730	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1892490		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Methotrexate			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13520473	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13594477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017081646		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Psoriatic Arthropathy; Treatment	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported

Failure	Humira	S	Subcutaneous	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Q6wk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram	Not Reported
	Inflectra	C	Intravenous (not otherwise specified)	400 Mg, (Q 0, 2, 6 Weeks, Then Every 8 Weeks)	Not Reported
	Infliximab	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13638421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017086096		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Every 10 Days	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Q4wk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	750 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

				Sulfasalazine	S	Unknown	Unk	Not Reported
				Methotrexate	C	Subcutaneous	Unk	Not Reported
				Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
				Methotrexate	C	Unknown	Unk	Not Reported
				Methotrexate	C	Oral	Unk	Not Reported
				Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported
				Rabeprazole Sodium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13915192	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127723		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Arthrotec	C	Oral	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Azathioprine	C		Unk	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14547724	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022052		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	776 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			C	Unknown	400 Milligram, Qwk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14556178	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022358			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14612490	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018030916			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Product Effect Decreased; Treatment Failure; Vomiting	Plaquenil		S	Unknown	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Pantoprazole		C	Unknown	Unk Unk, Tid	Not Reported
	Loperamide		C	Oral	Unk	Not Reported
	Bifidobacterium Bifidum		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14618306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031234		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14619670	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031034		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15235072	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0429		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral	200 Mg 2 Tablet	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Folic Acid	C	Oral	6 Days Per Week	Not Reported
	Prednisone	C	Oral		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15389696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082925			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd (1 Every 24 Hrs)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported

		Meloxicam			C	Unknown	Unk			Not Reported
		Synthroid			C	Unknown	Unk			Not Reported
		Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15707043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16058160	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16201961	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019057998		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Mesalazine			S	Oral	800 Milligram , 3 Every One Day		Not Reported

Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besylate	S	Oral	5 Milligram, Qd	Not Reported
	Amlodipine Besylate	S	Oral	Unk Unk, Qd	Not Reported
	Amlodipine Besylate	S	Unknown	Unk	Not Reported
	Asacol	S	Unknown	800 Milligram, Tid (Tablet (Enteric Coated))	Not Reported
	Diamicron	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Tylenol [Paracetamol]	C		500 Milligram	Not Reported

Vitamin D3	C	1000 International Unit, Qd	Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16342037	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028219		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram 1 Every 2 Weeks		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram Once In A Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form Once In A Week		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligramn Once In A Month		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Once A Day		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	488 Milligram, 1 Every Month		Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid			C	Unknown	Unk, 1 Every 2 Weeks		Not Reported
	Nasonex			C	Unknown	Unk, Two Times A Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Milligram, Once A Day		Not Reported

	Trazodone		C	Unknown	Unk	Not Reported
	Tylenol		C	Unknown	Unk	Not Reported
	Tylenol		C	Oral	1000 Gigabecquerel, Once A Day	Not Reported
	Tylenol		C	Oral	1000 Milligram, Once A Day	Not Reported
	Trazodone Hydrochloride		C	Oral	50 Milligram	Not Reported
	Zoledronic Acid		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16451229	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019260752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		11 Milligram, Qd		Not Reported
	Xeljanz			C		5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16797403	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16801343	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148283		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S				Amgen
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Ibuprofen			C		400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16805094	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147544			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Enbrel			S	Subcutaneous	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Teva Mycophenolate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16807517	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S	Unknown	Unk		Amgen
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16839489	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2019155407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16843338	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155462			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Mercaptopurine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Methylprednisolone			S	Unknown	Unk			Not Reported
	Pamidronate Disodium			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Tenoxicam			S	Unknown	Unk			Not Reported
	Ustekinumab			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17047641	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2019GR038794		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Emotional Disorder; Encephalitis Japanese B; Meningitis Bacterial; Product Use In Unapproved Indication; Speech Disorder; Treatment Failure	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S				Novartis
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17203052	NON-EXPEDITED			US-AMGEN-USASP2019212356		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17250153	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000432		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Pregabalin			S	Unknown	Unk		Not Reported
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Apo-Amitriptyline			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Diclo			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Topical	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

Celebrex	S			Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Celebrex	S			Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750 Milligram, Every Week	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not	2000 Milligram	Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Diarrhoea; Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia ; Leukopenia; Neutropenia; Parasitic Gastroenteritis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	5 Months Prior To Admission		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542982		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423346	EXPEDITED (15-DAY)		HO	CA-ROCHE-2543760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Actemra			S	Intravenous (not			Not Reported

Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Therapy Non-Responder; Treatment Failure			otherwise specified)		
	Benzalkonium Chloride	S	Unknown		Not Reported
	Boric Acid	S	Unknown		Not Reported
	Disodium Edetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Phenylephrine Hydrochloride	S	Unknown		Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Sodium Borate	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Celebrex	C			Not Reported
	Ibuprofen	C			Not Reported
	Lipitor	C			Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423991	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3270965-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Levofloxacin			C				Not Reported
	Gold			C				Not Reported
	Fentanyl			C				Not Reported
	Codeine			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423994	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183910		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram Daily;		Not Reported
	Aspirin[Acetylsalicylic Acid]	C	Unknown			Not Reported
	Cymbalta	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423995	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown	3.5714 Milligram Daily;		Barr

Response Decreased; Transaminases Increased	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;		Not Reported
	Levothyroxine Sodium	S	Oral	.075 Microgram Daily;		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
	Azathioprine	C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423999	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1183925			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported

Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Naproxen			S	Unknown	Teva
	Prednisone			S	Unknown	Actavis
	Actemra			S	Unknown	Not Reported
	Enbrel			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Xeljanz			S	Unknown	Not Reported
	Folic Acid			C	Unknown	Not Reported
	Methotrexate			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424032	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184252		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424034	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184199		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr

Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Subcutaneous		Barr
	Methotrexate		S	Unknown		Barr
	Codeine		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Myochrysine		S	Intramuscular		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Ciclosporin		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424035	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184224		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424036	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184223		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Barr
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424056	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Hyzaar			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424130	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0860		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Arnica Montana			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2548729		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Malaise; Mobility Decreased; Musculoskeletal Disorder;	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Cimzia		S	Subcutaneous	Single Use	Not Reported
	Codeine		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	5.0 Years	Not Reported
	Humira		S	Subcutaneous	9.0 Years	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown	15.0 Years	Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543685		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Methotrexate		S	Unknown				Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown				Not Reported
					Remicade		S	Intravenous (not otherwise specified)				Not Reported
					Simponi		S	Subcutaneous				Not Reported
					Arthrotec		C	Unknown				Not Reported
					Ergocalciferol		C					Not Reported
					Imuran [Azathioprine]		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424379	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184207		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424381	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Treatment Failure; Vomiting	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Morphine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543666		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cymbalta			C				Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex [Sumatriptan]			C				Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C				Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tenormin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424450	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184333		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Pain; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424451	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183903		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424479	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Overdose; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424513	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0882		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424557	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184311		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	1 Every 1 Week		Barr
	Naproxen			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424587	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184310		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	10 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424589	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184306			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported
	Bupropion			C	Unknown					Not Reported
	Sulfasalazine			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424592	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184274		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184285		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg		Barr
	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Subcutaneous	1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Methotrexate			S	Oral				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424594	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184312			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Varenicline Tartrate			S	Oral	1 Dosage Forms Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Oxycodone Hydrochloride			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424595	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424596	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184317		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424856	EXPEDITED (15-DAY)		HO	CA-ROCHE-2551552			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424985	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0830		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Anakinra			S	Unknown	100mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

	Simponi			S	Unknown					Not Reported
	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425593	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542835		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425921	EXPEDITED (15-DAY)		CA, HO	CA-ROCHE-2543640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Isoniazid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543671		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426308	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020066855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Enbrel		S	Unknown	Unk	Pfizer
	Sulfasalazine		S	Unknown	Unk	Pfizer
	Azathioprine		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Imuran [Azathioprine Sodium]		C		Unk	Not Reported
	Methotrexate		C		1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426433	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184330		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Prednisone			S	Oral			Actavis
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Oral		Not Reported
Sulfathalidine	S	Oral	2000 Milligram Daily;	Not Reported
Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
Topicort	S	Cutaneous		Not Reported
Salazopyrin	C	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426935	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427012	EXPEDITED (15-DAY)		HO	CA-ROCHE-2542851		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427045	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183889		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427052	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184155		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Tramacet			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Milligram Daily;		Not Reported
	Lyrica			C	Oral	300 Milligram Daily;		Not Reported
	Metformin			C	Unknown	1000 Milligram Daily;		Not Reported
	Metformin			C	Unknown	5 Milligram Daily;		Not Reported
	Methylprednisolone Acetate			C	Intramuscular			Not Reported

	Methylprednisolone Acetate	C	Subcutaneous			Not Reported
	Methylprednisolone Acetate	C	Intramuscular			Not Reported
	Methylprednisolone Acetate	C	Subcutaneous			Not Reported
	Nortriptyline Hydrochloride	C				Not Reported
	Nortriptyline Hydrochloride	C				Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram Daily;		Not Reported
	Premarin	C	Unknown			Not Reported
	Risedronate Sodium	C	Unknown			Not Reported
	Tylenol	C	Unknown			Not Reported
	Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427788	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184415		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea;	Rosuvastatin			S	Unknown			Teva
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Furosemide			S	Unknown			Ivax
	Ceftazidime			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Apo-Amiodarone Tablets			C				Not Reported
	Apo-Ketorolac			C				Not Reported
	Diphenhydramine			C				Not Reported
	Eprex Sterile Solution			C				Not Reported
	Escitalopram			C				Not Reported
	Humalog			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Januvia			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone Nos			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoloc /01263204/			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium Chloride			C				Not Reported
	Risedronate			C				Not Reported
	Slow-K Tab			C				Not Reported
	Tylenol			C				Not Reported
	Ventolin			C				Not Reported

Nerve Compression;
Neuropathy Peripheral;
Neutropenia;
Osteoarthritis;
Pancytopenia; Peripheral
Sensorimotor Neuropathy;
Peritonitis; Pneumonia;
Pseudomonal
Bacteraemia; Rheumatoid
Arthritis; Septic Shock;
Therapeutic Response
Decreased; Vomiting;
Weight Decreased; Weight
Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427953	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rosuvastatin			S	Unknown			Actavis
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Ceftazidime			S	Unknown			Not Reported
	Cellcept			S	Unknown	1000 Milligram Daily;		Not Reported
	Lasix			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Apo-Amiodarone Tablets			C				Not Reported
	Diphenhydramine			C				Not Reported
	Eprex Sterile Solution			C				Not Reported
	Escitalopram			C				Not Reported
	Hydrochloroquine			C				Not Reported

			Hydrochlorothiazide		C					Not Reported
			Insulin Lispro		C					Not Reported
			Januvia		C					Not Reported
			Metformin		C					Not Reported
			Methylprednisolone Nos		C					Not Reported
			Metoprolol		C					Not Reported
			Pantoloc		C					Not Reported
			Pantoprazole		C					Not Reported
			Potassium Chloride (Kcl Reatrd)		C					Not Reported
			Risedronate Sodium		C					Not Reported
			Slow-K Tab		C					Not Reported
			Tylenol		C					Not Reported
			Ventolin		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427971	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pneumococcal Vaccine Polysacch 23v			C	Unknown			Not Reported
	Prevnar 13			C	Unknown			Not Reported
	Varicella Zoster Vaccine Live			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428024	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184585		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Leflunomide	S	Unknown	2 Dosage Forms Daily;	Barr
	Naproxen	S	Unknown		Teva
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428042	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184562		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Oral	6 Milligram Daily;		Not Reported
	Tacrolimus			S	Oral	4 Milligram Daily;		Not Reported

	Azathioprine				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428069	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184867		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Mefenamic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428628	EXPEDITED (15-DAY)		DE, OT	IN-FRESENIUS KABI-FK202001491		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Nocardiosis; Shunt Infection	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428727	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020DEP000090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Potassium			S	Unknown	150 Mg, Qd		Assertio Therapeutics
	Methotrexate			S	Unknown	25 Mg, Every Week		Not Reported
	Naproxen			S	Unknown	1000 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Hydroxychloroquine			C		400 Mg, Qd		Not Reported
	Leflunomide			C		Unk		Not Reported
	Piroxicam			C		20 Mg, Bid		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	11800207	NON-EXPEDITED		OT	CA-AMGEN-KDL279454		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Plaquenil	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Advil	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Mefenamic Acid	C	Unknown	Unk		Not Reported
	Prednisone	C	Oral	10 Milligram, Qd		Not Reported
	Prednisone	C	Oral	6 Milligram, Qd		Not Reported
	Dequalinium Chloride	C		Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	12103915	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021127		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Amgen

Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Etanercept	S	Unknown	Unk	Amgen
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Arava	C		Unk	Not Reported
	Sodium Aurothiomalate	C		Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	12584285	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016355320		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb	Enbrel			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

Fracture	Celecoxib	S		Unk	Pfizer
	Azathioprine	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Imuran	S		Unk	Not Reported
	Neoral	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	13413043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017051637		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Drug Ineffective; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Milligram, Bid		Amgen
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Orencia			S	Unknown	1000 Milligram		Not Reported
	Leflunomide			C	Oral	20 Mg, Qd		Not Reported
	Celebrex			C		200 Mg, Bid		Not Reported
	Wellbutrin			C		300 Mg, Qd		Not Reported
	Vitamin D			C		4000 Iu, Qd		Not Reported
	Risedronate			C	Oral	35 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14627389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018099589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Celebrex			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported
	Loperamide			C	Oral	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14749800	EXPEDITED (15-DAY)		HO	CA-ROCHE-2103364			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Hydroxychloroquine		S	Unknown		Not Reported
					Hydroxychloroquine		S	Oral		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14750039	EXPEDITED (15-DAY)		HO	CA-ROCHE-2103271			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14823767	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018055160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14921647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Off Label Use; Peripheral Swelling; Pulmonary Hypertension	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Tylenol			C	Unknown	8 Hour		Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15313643	EXPEDITED (15-DAY)		HO, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-027152		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Adverse Event; Cough; Infection; Lower Respiratory Tract	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported

Infection; Malaise; Rash; Sinus Operation; Sinusitis; Swelling

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15635020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105499		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown	8.0 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15661545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018075758			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk (1 Every 1 Week(S))		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

			Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
			Orencia		S	Unknown	Unk			Not Reported
			Remicade		S	Intravenous (not otherwise specified)	Unk			Not Reported
			Leflunomide		C		Unk			Not Reported
			Sulfasalazine		C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15715431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018510528			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported

	Stelara			S	Subcutaneous	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15803741	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2618078-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15953498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012379		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	C	Unknown	0.8 Ml, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16075711	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Milligram		Aurobindo
	Actemra			S	Subcutaneous	Unk, Every Week		Not Reported
	Arava			S	Unknown	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Mobicox			S	Oral	7.5 Milligram, Once A Day		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16284954	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014093565		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported

Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Celebrex		S	Unknown	Unk		Not Reported
	Methotrexate		S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia		S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk		Not Reported
	Simponi		S	Subcutaneous	Unk		Not Reported
	Sulfasalazine		S	Oral	Unk		Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16721389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567 Milligram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16819168	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399007			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Enbrel			S	Subcutaneous	Unk		Pfizer

	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Teva Mycophenolate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16850473	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019412222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16865776	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000777			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Cardiotoxicity; Dyspnoea Exertional; Hypertrophic Cardiomyopathy; Palpitations; Pulmonary Hypertension; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	300 Mg, Qd (For More Than 20 Years)		Concordia
	Metoprolol			C		Unk		Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16938096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017005654		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Varenicline Tartrate			S	Oral	Unk Unk, 1x/Day (Qd)		Pfizer
	Varenicline Tartrate			S	Oral	1 Df, 1x/Day		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Rituxan			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Cyclic (Other Weeks)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C		Unk		Not Reported
	Valtrex			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Rosuvastatin Calcium			C		Unk		Not Reported
	Esomeprazole Magnesium/Naproxen			C		Unk		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C		Unk		Not Reported

	Acetaminophen	C	Unk	Not Reported
	Oxycodone Hydrochloride	C	Unk	Not Reported
	Naproxen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17333941	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17407715	EXPEDITED (15-DAY)		HO, OT	NVSC2020DK037178		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Product Use In Unapproved Indication; Weight Decreased	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425380	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425391	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202002000759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Hydroxychloroquine			S	Unknown	1 Dosage Form, Qd, Film Coated Tablet		Concordia
	Eliquis			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425627	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010683		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	200 Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543668		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Systemic Lupus Erythematosus	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S		Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA030850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Arava	S	Unknown	Unk		Sanofi
	Methotrexate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425952	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425975	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184657		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Swelling	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral	3000 Milligram Daily;		Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			C				Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426616	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184539			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Leflunomide			S	Unknown			Barr
	Atorvastatin			S	Oral	40 Milligram Daily;		Teva
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Asa Ec			C	Oral	81 Milligram Daily;		Not Reported

	Folic Acid		C	Oral	Not Reported
	Vitamin D3		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426843	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426861	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184581		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
		Rituximab			S		Intravenous drip			Not Reported
		Sulfasalazine			S		Unknown			Not Reported
		Xeljanz			C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17427313	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-0889		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17429397	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3272487-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported

Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Amitriptyline Hydrochloride W/Perphenazine	S	Unknown	Not Reported
	Apo-Amitriptyline	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Diclofenac Sodium W/Misoprostol	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S		Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Misoprostol	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported

					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Xeljanz		S	Oral		Not Reported
					Diclofenac Sodium		S	Unknown		Not Reported
					Winpred		S	Unknown		Not Reported
					Utofacitinib		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17430681	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17430922	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020064146		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Hepatic Cirrhosis	Sulfasalazine			S	Unknown			Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Escitalopram Oxalate			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazole			C				Not Reported

		Perindopril			C					Not Reported
		Prednisone			C					Not Reported
		Spironolactone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431103	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2020066727		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Sulfasalazine			S	Unknown			Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Accupril			C				Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Apo-Atorvastatin			C				Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Apo-Prednisone			C				Not Reported
	Apo-Zopiclone			C				Not Reported
	Diphenhydramine			C	Oral	50 Mg, Unk		Not Reported
	Gabapentin			C				Not Reported
	Lactaid			C				Not Reported
	Lactulose			C				Not Reported
	Levemir			C				Not Reported
	Methadone			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Nabilone			C				Not Reported
	Novorapid			C				Not Reported
	Pantoprazole			C				Not Reported
	Pms-Cetirizine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431408	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184850		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431443	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1187200		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Ipratropium Bromide And Salbutamol Sulphate Inhalation Solution			S	Unknown			Teva
	Metformin			S	Unknown	1000 Milligram Daily;		Actavis
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported

	Salmeterol Xinafoate			S	Unknown					Not Reported
	Tylenol			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431642	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011673		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Qmo		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431942	NON-EXPEDITED			NVSC2020US043346		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432560	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020026034		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Folic Acid	C		Unk		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432570	EXPEDITED (15-DAY)		HO, OT	CA-BAXTER-2020BAX002983		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Arava			S	Oral	Dosage Form:Tablet		Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous, Singe Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported
	Plaquenil			S	Oral	Dosage Form: Tablet		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432595	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2020GMK046108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood	Gabapentin			S	Oral	100 Mg, Unk		Glenmark

Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Od	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks; Formulation: Solution Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2.5 G, Od	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk; Formulation: Solution Intravenous	Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk; Formulation: Spray, Metered Dose	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432621	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011197		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Supeudol	C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432649	EXPEDITED (15-DAY)		HO, LT	CA-BAXTER-2020BAX002993		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Baxter
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Dosage Form: Not Specified		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17450144	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Hydroxychloroquine			S				Not Reported
	Leucinamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11213498	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015060003		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Salicylates Nos			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk		Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Every 24 Hour	Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11290381	EXPEDITED (15-DAY)		OT	CA-ROCHE-1610671		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 1 Year		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duration: 9 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year	Not Reported
Arava	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Xeljanz	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Unknown	11.0 Years	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Vaginal		Not Reported
Methotrexate	S	Unknown		Not Reported
Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported
Cortisone	C	Intra-articular		Not Reported
Cortisone	C	Oral		Not Reported
Darifenacin	C	Unknown	As Required	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	As Required	Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray, Metered Dose	Not Reported
Pantoprazole Sodium	C			Not Reported
Synthroid	C			Not Reported
Vagifem	C	Unknown	Vaginal Tablet	Not Reported
Anakinra	C			Not Reported
Abatacept	C			Not Reported
Leflunomide	C	Unknown		Not Reported
Lasix [Furosemide]	C	Unknown		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex [Darifenacin]	C	Unknown	Tablet (Extended Release)	Not Reported

		Pantoloc [Pantoprazole]			C	Unknown	Tablet (Enteric Coated)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11713409	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015115197		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Naproxen			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Unk		Not Reported
	Sulfasalazine			S	Oral	5000 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Qmo		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram (2 Every One Weeks)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported
	Risedronate			C	Oral	35 Milligram, Qwk		Not Reported

	Naroxin	C		Unk		Not Reported
	Arava	C	Oral	20 Milligram, Qd		Not Reported
	Folic Acid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11999139	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1704038		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12021392	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016014877		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated;	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	8 Milligram	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	750 Milligram	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported

	Meloxicam			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12336694	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2015094586		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Etanercept			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Etanercept			S				Amgen
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Subcutaneous	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Apremilast			S	Oral	30 Milligram, Bid		Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported
	Ibuprofen			S	Oral	600 Milligram, Every 3-4 Hours Regularly		Not Reported
	Ibuprofen			S	Oral	600 Milligram, Q4h		Not Reported

Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Unknown	6 Df, Qd	Not Reported
	Motrin	S	Oral	600 Milligram, Qd	Not Reported
	Motrin	S	Oral	Unk, Qd	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
	Methotrexate	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported

Methotrexate	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	2.5 Milligram, Qmo	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	7.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
Rituximab	S	Intravenous (not	1000 Milligram, Bid	Not Reported

		otherwise specified)		
Rituximab	S			Not Reported
Celebrex	S	Oral	200 Milligram, Bid	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Form, Qwk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Oxycodone	C		40 Milligram	Not Reported
Oxycodone	C		10 Milligram	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Naproxen	C		500 Milligram	Not Reported

	Cannabis Sativa	C		Unk		Not Reported
	Actonel	C	Oral	35 Milligram, Qwk		Not Reported
	Vitamin D 3	C	Oral	2000 International Unit		Not Reported
	Risedronate Sodium	C	Oral	35 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12598409	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015389516		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Lower Doses Initially & Increased Over The Yrs Around 1997		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25,Unk, Qd		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	1 G, 2x/Day: 6 Months		Pfizer
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	100 Milligram		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram, Unk		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported

Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; Weight Increased	Humira	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Indocid	S		Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day, For One Year	Not Reported
	Leflunomide	S	Unknown	20 Mg, Daily (For 1 Year)	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin [Indometacin]	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day	Not Reported

	Indometacin	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	C	Oral	Unk, 2x/Day	Not Reported
	Folic Acid Aventis	C	Oral	Unk, Weekly	Not Reported
	Folic Acid Aventis	C	Oral	5 Mg, Unk	Not Reported
	Cymbalta	C	Oral	30 Mg, 1x/Day (Nightly)	Not Reported
	B Complex [Vitamin B Complex]	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12913352	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-037942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	25 Unk	Not Reported
Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
Prednisone	C	Unknown	8.5 Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Alprazolam	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported

	Paroxetine	C	Unknown	Unk		Not Reported
	Risedronate	C	Unknown	Unk		Not Reported
	Simvastatin	C	Unknown	Unk		Not Reported
	Telmisartan	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Esomeprazole	C	Unknown			Not Reported
	Iron Sucrose	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13139174	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2011246063		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Unknown
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly		Not Reported
	Actemra			S	Intravenous (not	Unk, Qd		Not Reported

		otherwise specified)		
Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
Apo Hydroxyquine	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S		Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Ramipril	C		Unk	Not Reported
Asa Arthritis Strength Aspirin	C		81 Mg, Unk	Not Reported
Metformin	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Naproxen	C		Unk	Not Reported
Prednisone	C		Unk, As Required	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Lozide	C		Unk	Not Reported
Naprosyn	C		Unk Unk, As Required	Not Reported
Acetylsalicylic Acid	C		81 Mg, Unk	Not Reported
Acetylsalicylic Acid	C		Unk	Not Reported
Lantus	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported

		Ergocalciferol			C	Unknown	Unk			Not Reported
		Vitamin D3			C		Unk			Not Reported
		Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13775805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017297593		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13921718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017376122		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations;	Enbrel			S		Dose: 730.0		Pfizer
	Enbrel			S		Dose: 731.0		Pfizer
	Enbrel			S		Dose: 4.0 Year		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Dose: 5.0 Month		Not Reported

Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Arthrotec	C	Oral	Unk	Not Reported
	Gold	S		Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Azathioprine	C		Unk	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14187136	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017170029		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk, Bid		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14226198	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015231014		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S				Pfizer
	Ibuprofen			S	Unknown	Unk		Pfizer
	Sulfamethoxazole W/Trimethoprim			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Arava			S	Oral	Unk		Not Reported

Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Voltaren	S			Not Reported
Voltaren	S			Not Reported
Voltaren	S			Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Oral	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Apo Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Asa	S	Unknown	325 Mg, Unk	Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Tramadol Hydrochloride	S		Unk	Not Reported
Apo-Sulfatrim	S	Unknown	Unk	Not Reported
Clopidogrel	S		Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S		Unk	Not Reported
Diclofenac	S		Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Sulfatrim [Sulfadiazine;Trimethoprim]	S	Unknown	Unk	Not Reported
Gold Sodium Thiomalate	S	Unknown	Unk	Not Reported
Tramadol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14559058	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018072306		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	776 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	400 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14631653	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018102054		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Supeudol			C	Unknown	5.0 Mg, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14632234	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016103661		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qwk)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk, (Therapy Duration: 730.0)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Arava			C		Unk		Not Reported
	Sodium Aurothiomalate			C		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

			Xeljanz		C	Unknown	5 Mg, 2x/Day			Not Reported
			Leflunomide		C	Unknown	Unk			Not Reported
			Remicade		C	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15558530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018149419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Xeljanz			S	Oral	5 Milligram, Bid			Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk			Not Reported
	Morphine			S	Unknown	Unk			Not Reported
	Dilaudid			C		Unk			Not Reported
	Wellbutrin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15616222	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2550220-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Menorrhagia; Surgery; Uterine Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15632466	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105344		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported

			Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Bid			Not Reported
			Winpred		S	Oral	5 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15632602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110215			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Orencia			S	Unknown	40 Mg, Q2wk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Mg, Qd		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral	300 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Qd		Not Reported
	Folic Acid			C	Oral	2.5 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15733751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594183-00		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15756331	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015044981		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis;	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Unknown
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Celebrex			S		200 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Systemic Lupus Erythematosus; Vomiting	Xeljanz	S	Oral	5 Milligram	Pfizer
	Rituxan	S	Unknown	1 G, 1/2	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Unknown	50 Mg, Q4wk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Orencia	S	Subcutaneous	150 Mg, Qwk	Not Reported
	Orencia	S	Subcutaneous	150 G, Unk	Not Reported
	Orencia	S	Subcutaneous	150 Mg, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naprosyn	S	Unknown	500 Milligram, Bid	Not Reported
	Naprosyn	S	Unknown	50 Milligram, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine	S	Unknown	Unk	Not Reported

	Hydrochloride]					
	Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisone Acetate	S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15880461	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016097219		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Treatment Failure; Vomiting	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Qw		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk, 1x/Day		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer

Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
Xeljanz	S	Unknown	Unk, Qd	Pfizer
Xeljanz	S	Oral	10 Milligram, Qd	Pfizer
Xeljanz	S	Unknown	Unk Unk, Qd	Pfizer
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Ciclosporin	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Plaquenil S	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported

Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz Xr	C		Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15931620	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656087-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

						Enbrel		S	Unknown	Not Reported
						Hydroxychloroquine Sulfate		S	Unknown	Not Reported
						Orencia		S	Unknown	Not Reported
						Remicade		S	Intravenous (not otherwise specified)	Not Reported
						Rituxan		S	Intravenous (not otherwise specified)	Not Reported
						Sulfasalazine		S	Unknown	Not Reported
						Rituximab		S	Intravenous (not otherwise specified)	Not Reported
						Diclofenac		C		Not Reported
						Desoximetasone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15934011	EXPEDITED (15-DAY)		CA, DS, OT	CA-ABBVIE-19K-028-2656831-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Cymbalta			C						Not Reported
	Folic Acid			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16199946	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019059140		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled Syringe		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16209335	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167731		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, 1x/Day		Pfizer
	Amlodipine Besilate			S	Oral	Unk, Daily		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Asacol			S	Unknown	800 Mg, 3x/Day		Not Reported
	Diamicron			S		Unk		Not Reported
	Gliclazide			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Mesalazine			S	Oral	800 Milligram , 3 Every One Day		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Atacand Plus			C	Oral	Unk, Qd		Not Reported
	Bisoprolol Fumarate			C	Oral	2.5 Milligram		Not Reported

	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Mg, Unk	Not Reported
	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Tylenol [Paracetamol]	C		500 Milligram	Not Reported
	Vitamin D3	C		1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16216763	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020587		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril			S	Oral	Unk, Once A Day		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram,1 Every 4 Week		Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	7 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Levothyroxine			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Levothyroxine			S	Unknown	Unk, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Every Week		Not Reported
	Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported

Acetaminophen	S	Unknown	Unk	Not Reported
Cosopt	S	Unknown	Unk,1 Every 12 Hours	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Dorzolamide;Timolol	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
Dorzolamide;Timolol	S	Unknown	Unk, Two Times A Day	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported
Tylenol No.2	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16244983	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017146531		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Hepatotoxicity; Off Label Use	Enbrel			S	Subcutaneous	25 Milligram, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16444954	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	160 Milligram, Every Week		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Once A Day		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16570014	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039032		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam	S	Unknown	Unk	Aurobindo
	Acetaminophen	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Unknown	200 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	5 Milligram, Once A Day	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16570242	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038959		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Bronchitis; Drug Ineffective; Fatigue; Hypersensitivity; Immunosuppression; Influenza; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Pain In Extremity; Rash; Therapeutic Response Decreased; Treatment Failure	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	Unk, 1 Every Four Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, 1 Every 4 Week		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Humalog			C	Unknown	Unk		Not Reported
	Sertraline Hydrochloride			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16622993	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-041372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Meloxicam			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16804995	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16817877	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16824457	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019401916		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Enbrel			S		50 Mg, Weekly		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Ibuprofen			C		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16851776	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019414089			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance;	Enbrel			S	Unknown	Unk		Pfizer

Hepatotoxicity; Liver Function Test Increased	Doxycycline Hyclate	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methylprednisolone	S	Unknown	Unk	Pfizer
	Pamidronate Disodium	S	Unknown	Unk	Unknown
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Azathioprine	S	Unknown	150 Milligram, Qd	Not Reported
	Bromocriptine	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Colchicine	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Mercaptopurine	S	Unknown	Unk	Not Reported
	Tenoxicam	S	Unknown	Unk	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16865487	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3765		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Incomplete	Celecoxib	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Unknown	20 Mg On Monday-Wednesday-Friday	Not Reported
	Arava	S	Unknown	4 Times A Week	Not Reported
	Arava	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Vitamin B12	C	Unknown		Not Reported
	Endocet	C	Unknown	1 Tablet 2 Times Per Day As Needed,	Not Reported
	Indomethacin	C	Unknown		Not Reported
	Pennsaid	C	Unknown		Not Reported
	Oxycocet	C	Unknown	2 Tablets 4-5 Times Per Week	Not Reported
	Asa	C	Unknown	Occasionaly	Not Reported
	Naprelan	C	Unknown	1-2 Times	Not Reported
	Metoprolol	C	Unknown		Not Reported
	Bisoprolol	C	Unknown		Not Reported
	Lax-A-Day	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Folic Acid	C	Unknown	3 Times/Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16992212	EXPEDITED (15-DAY)		OT	PT-ACCORD-159728		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Gastrointestinal Disorder; Interstitial Lung Disease; Pulmonary Embolism	Methotrexate			S	Unknown	Unk		Accord
	Infliximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17334288	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dermatitis Exfoliative Generalised; Eczema; Rash Erythematous; Rash Maculo-Papular; Skin Exfoliation; Skin Lesion	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17359711	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1177821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Bisoprolol			S	Unknown	12.5 Milligram Daily;		Duramed
	Calcium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ramipril			S	Unknown	12.5 Milligram Daily;		Actavis
	Magnesium (Salt Not Specified)			S	Unknown			Not Reported

	Arava	S	Unknown			Not Reported
	Buprenorphine	S	Unknown	10 Microgram Daily;		Not Reported
	Cyanocobalamin	S	Unknown			Not Reported
	Fish Oil	S	Unknown			Not Reported
	Lasix	S	Unknown			Not Reported
	Magnesium Gluconate	S	Unknown			Not Reported
	Multivitamins	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rivaroxaban	S	Unknown	15 Milligram Daily;		Not Reported
	Vitamin B6	S	Unknown			Not Reported
	Vitamin D	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17369604	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020017394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, 1 Every 12 Hours		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17432990	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17432992	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000447			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Ipca
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Ipca
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433116	EXPEDITED (15-DAY)		HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			C	Unknown	5 Mg		Not Reported
	Prednisone			C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433216	EXPEDITED (15-DAY)		HO	CH-ROCHE-2551375		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Mabthera			S	Intravenous drip	2x 500 Mg		Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Zaldiar			S	Oral			Not Reported
	Cimifemin			S	Oral			Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			S	Oral			Not Reported
	Prednisolon [Prednisolone]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433353	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Amlodipine Besilate			C	Unknown				Not Reported
		Gabapentin			C	Unknown				Not Reported
		Prednisone			C	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547860		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433750	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011515		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow	Orencia			S	Unknown			Bristol Myers Squibb

Deformity; Headache; Liver Function Test Increased; Rheumatoid Arthritis	Arava		S	Oral	20 Milligram, Qd	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide		S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	2 Gram, Qd	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433782	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551846		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Intolerance; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433890	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000495			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; End Stage Renal Disease; Maculopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433987	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551545		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434002	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551543			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Zostavax	S	Subcutaneous	Powder For Suspension Subcutaneous		Not Reported
	Desoximetasone	C	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported
	Diclofenac	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434196	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Januvia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434197	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout;	Metformin			S	Unknown	Unk		Aurobindo
	Colchicine			S	Unknown	Unk		Not Reported

Hypertension; Palpitations	Januvia		S	Unknown	Unk			Not Reported
	Plaquenil		S	Unknown	Unk			Not Reported
	Sumatriptan Succinate		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434810	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071268		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435005	NON-EXPEDITED			NVSC2020US043433		8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435041	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1016772		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Milligram, Qd		Not Reported
	Tahor			S	Oral	1 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	400 Milligram		Mylan
	Coumadine			S	Oral	Unk		Mylan

	Kardegic	S	Oral	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435118	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020058496		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435391	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1018354		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Hypertrophic Cardiomyopathy; Overdose	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Metoprolol			C	Unknown	Unk		Mylan
	Losartan			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435435	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1018837		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Drug Ineffective;	Hydroxychloroquine			S	Oral	6 G Missing		Not Reported

Intentional Overdose; Pulmonary Oedema; Toxicity To Various Agents	Ibuprofen	S	Oral	Unk		Not Reported
	Naproxen	S	Oral			Not Reported
	Epinephrine	S	Unknown			Not Reported
	Potassium	S	Unknown	Unk		Not Reported
	Norepinephrine	S	Unknown	Unk		Not Reported
	Sodium Bicarbonate	S	Unknown	Drips		Mylan
	Calcium	S	Unknown	Unk		Mylan
	Dextrose	S	Unknown	Unk		Mylan
	Vasopressin	S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17436860	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1018093		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Palpitations	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17483874	DIRECT		DS, OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Depression; Pain	Plaquenil	Y		S	Oral	Quantity:90 Pills;Other Frequency:2x/Day For One Mon;	3 MTH	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	11418532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2013008516		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug	Enbrel			S	Subcutaneous	Unk		Amgen

Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Neoral	S	Unknown	Unk	Not Reported
	Prograf	S	Unknown	Unk	Not Reported
	Prograf	S	Oral	3.0 Mg, Q12h	Not Reported
	Prograf	S	Oral	2.0 Mg, Q12h	Not Reported
	Rapamune	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	3 Milligram 1 Every 12 Hours	Not Reported
	Azathioprine	C		25 Mg, Unk	Not Reported
	Imuran	C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	11519456	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015095516		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen

Peptide Antibody Positive; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk Unk, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	400 Milligram, Qmo	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported

Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Milligram	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Other	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Unk	Not Reported
Topicort (Hydrocortisone	S	Unknown	Unk	Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Acetate)				
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk (Tablet)	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	50 Milligram	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram (5mg/5ml)	Not Reported

Zyrtec [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1.0 Milligram	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol	C		Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12370997	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061225		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Condition Aggravated;	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Bid	Not Reported

		Prednisone			C		5 Milligram, Qd			Not Reported
		Prednisone			C	Unknown	10 Milligram			Not Reported
		Prednisone			C	Unknown	Unk			Not Reported
		Xeljanz			C	Oral	5 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12691303	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016051528		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram		Not Reported
	Gold	S	Unknown	50 Milligram		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	20 Milligram		Not Reported
	Leflunomide	S	Oral	20 Milligram		Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
	Meloxicam	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12890168	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013157		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Df, B.I.Wk.		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.I.W		Not Reported
	Nexium /01479302/			S	Unknown	40 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported

	Sulfasalazine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14262244	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-108976		38 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Intentional Product Use Issue; Maternal Exposure During Pregnancy	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Qmo		Bristol Myers Squibb
	Ibuprofen			S	Unknown	Unk		Bristol Myers Squibb
	Reuquinol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14496561	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Gabapentin			C	Unknown				Not Reported
		Tylenol 8 Hr Arthritis Pain			C	Unknown				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14634808	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14638057	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Apo-Prednisone			S	Oral	Unk Unk, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Oral	20 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	1 G, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported

	Arava			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14639973	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0745		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15305086	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-074825		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Sinusitis; Vulval Abscess	Abatacept			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Ibuprofen			S	Unknown	Unk		Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15400274	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Mg, Qmo		Not Reported
	Actemra			S	Unknown	680 Milligram, Qmo		Not Reported
	Alendronate			S	Unknown	70 Mg, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	1000 Gram, Bid		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Parenteral	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Ciclosporin			C	Unknown	150 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15574827	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018445878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported

	Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Dilaudid	C		Unk		Not Reported
	Wellbutrin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15639542	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106082		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Azathioprine	C	Oral	200 Mg, Qd	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
	Docusate Sodium	C	Oral	100 Milligram, Qd	Not Reported
	Doxycycline	C	Oral	Unk, 2 Every Day	Not Reported
	Elavil [Allopurinol]	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	8 Mg, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Oral	1.5 Gram, Bid	Not Reported
	Tobramycin	C	Unknown	0.3 Percent, Qid	Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15727088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Otezla		S	Unknown	Not Reported
					Otezla		S	Oral	Not Reported
					Plaquenil		S	Unknown	Not Reported
					Remicade		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Simponi		S	Unknown	Not Reported
					Simponi		S	Subcutaneous	Not Reported
					Stelara		S	Unknown	Not Reported
					Stelara		S	Subcutaneous	Not Reported
					Cosentyx		S	Unknown	Not Reported
					Arava		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15934107	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655644-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Leflunomide		S	Unknown		Not Reported
					Apo-Leflunomide		S	Unknown		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Arthrotec		C	Unknown		Not Reported
					Ergocalciferol		C	Unknown		Not Reported
					Imuran		C	Unknown		Not Reported
					Azathioprine		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15935702	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657574-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15984048	EXPEDITED (15-DAY)		OT	DE-ABBVIE-19K-062-2667153-00			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Humira			S	Subcutaneous	Unknownj		Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Unknown	Not Reported
	Plaquenil	S	Oral		Not Reported
	Neoral	S	Oral	Unknown	Not Reported
	Neoral	S	Subcutaneous	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Ciclosporin	S	Subcutaneous	Unknown	Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Oral	Unknown	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Oral	20 Mg. Unknown	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg. Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported

	Xeljanz			C	Oral	Unkown			Not Reported
	Xeljanz			C	Oral	10 Milligram, Qd			Not Reported
	Xeljanz			C	Unknown	2 Other, Qd			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid,			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16195868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741761-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16473690	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16831226	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3515			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16841691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019164824		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled Syringe		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16859652	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019419622			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17386166	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020053154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, 1 Every 12 Hours		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17424245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2548656		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17438913	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007930		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia;	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Depo-Medrol	C	Other	80 Milligram		Not Reported
	Diclofenac	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17438985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552195			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439437	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication;	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Warfarin Sodium			S	Unknown	Unk		Not Reported

Thrombosis; Uterine Disorder	Azathioprine	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Xarelto	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439574	EXPEDITED (15-DAY)		HO	CH-SA-2020SA038476		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Arava			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Qd		Sanofi
	Paracetamol/Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	2x 500 Mg Every 5 Month		Not Reported
	Cimifemin			S	Oral	13 Mg, Qd		Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			S	Oral	As Necessary		Not Reported
	Prednisolon [Prednisolone]			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439700	EXPEDITED (15-DAY)		LT, OT	GR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-237341		40 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Atrioventricular Block Second Degree; Foetal Exposure During Pregnancy; Heart Block Congenital; Intracardiac Mass; Respiratory Distress; Ventricular Septal Defect	Acetylsalicylic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown			Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011665		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020074282		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer

	Adalimumab		S	Subcutaneous	40 Mg, Unk		Not Reported
	Cimzia		S	Subcutaneous	Unk		Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
	Leflunomide		S	Unknown	Unk		Not Reported
	Orencia		S	Unknown	Unk		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sarilumab		S	Unknown	Unk		Not Reported
	Simponi		S	Subcutaneous	Unk		Not Reported
	Tocilizumab		S	Unknown	Unk		Not Reported
	Folic Acid		C		Unk		Not Reported
	Rabeprazole Sodium		C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440731	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Methotrexate Sodium			S	Subcutaneous	15 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	1 G, 1 Every 12 Hours		Pfizer
	Baricitinib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440835	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071257		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer

					Etanercept	S		Unk	Pfizer
					Hydroxychloroquine	S	Oral	300 Mg, Unk	Not Reported
					Tocilizumab	S		Unk	Not Reported
					Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17441491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	650 Milligram, Bid		Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, Tid		Not Reported
	Premarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17441763	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3283890-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17442543	EXPEDITED (15-DAY)		CA, OT	GR-ALLERGAN-2008282US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Heart Block Congenital; Pregnancy; Respiratory Distress	Prednisolone Unk			S	Transplacental	Unk		Allergan
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11200640	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015202903		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis;	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Methyl Salicylate	S	Unknown	Unk	Not Reported
	Salicylates Nos	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Every 24 Hour	Not Reported
	Prednisone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11227333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1524822			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Destruction; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Prior To 2010		Not Reported
	Myochrysine			S	Unknown	Before 2010		Not Reported

	Xeljanz				S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11525254	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015308388		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Wound	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Oral	25 Mg, 1x/Day		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Parenteral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer

Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Oral	Unk, Bid	Pfizer
Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Pfizer
Sulfasalazine	S	Unknown	1000 Mg, Unk	Pfizer
Paracetamol	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
Cimzia	S	Unknown	400 Mg, Monthly	Not Reported
Cimzia	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic Q2wk	Not Reported
Humira	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	S	Oral	Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk Tablet	Not Reported
Cortisone	S	Oral	25 Mg, Unk Tablet	Not Reported
Cortisone	S		25 Mg, Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, 1x/Day (1 Every 24 Hours)	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Other	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Oral	10 Mg, Unk	Not Reported

Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram (5mg/5ml) Unk Syrup	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Oral	25 Mg, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Mg, Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S		1 Mg, Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported

	Cosentyx	S	Unknown	Unk		Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Atasol	C	Unknown	Unk		Not Reported
	Ibuprofen	C	Unknown	Unk		Not Reported
	Leflunomide	C	Oral	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	20 Mg, Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Lisinopril	C	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported
	Prednisolone	C	Unknown	Unk		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported
	Tofacitinib Citrate	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	12701616	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1489		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Apo-Hydroxyquine		C	Unknown		Not Reported
					Ergocalciferol		C	Unknown		Not Reported
					Leucovorin		C	Unknown		Not Reported
					Prednisone		C	Unknown		Not Reported
					Calcium		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	14781801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107063			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	14826053	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-036485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Off Label	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Simponi			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
	Enbrel	S	Unknown	25 Milligram		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk		Not Reported
	Remicade	S	Unknown	200 Milligram, Cyclical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15345828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177475		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Contraindicated Product Administered; Fall; Off Label Use; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	00072603		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15620004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556866-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure			otherwise specified)			
	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Methotrexate	S	Unknown	Solution		Not Reported
	Leflunomide	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15634991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105511			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Unk	Not Reported
	Zostavax		S	Intravenous (not otherwise specified)		Not Reported
	Zostavax		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Desoximetasone		C	Oral		Not Reported
	Desoximetasone		C	Subcutaneous	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Xeljanz		C	Oral	10 Mg, Bid	Not Reported
	Diclofenac		C	Subcutaneous	100 Mg, Unk	Not Reported
	Cortisone Acetate		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15811039	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617171-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported

	Cyclosporine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C	Oral	Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Not Reported
	Tylenol Arthritis	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15855371	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015371800		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Week		Pfizer
	Sulfasalazine			S	Unknown	2 G, Unk		Pfizer
	Sulfasalazine			S	Oral	5000 Mg, 1x/Day		Pfizer
	Orencia			S	Unknown	Unk, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Apo-Naproxen			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day		Not Reported

	Rituxan	S		Unk	Not Reported
	Naproxen Sodium	S		Unk	Not Reported
	Hydroxychloroquine	S		400 Mg, Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Apo-Prednisone	S		Unk	Not Reported
	Methotrexate Sodium	C	Subcutaneous	25 Mg, Weekly	Not Reported
	Naroxin	C		Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Weekly	Not Reported
	Arava	C	Oral	20 Mg, 1x/Day	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15887790	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1610		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Pain; Product Use Issue; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name			S	Subcutaneous			Not Reported

Unknown)			
Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Ciclosporin	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil S	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported

	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz Xr	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15933878	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656787-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Incomplete	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Celebrex		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15936329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657755-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Bp		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16178013	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035747		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate Sodium	S	Oral		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16445871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056456			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituxan			S	Unknown	1 Gram		Not Reported
	Rituximab			S	Unknown	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16489797	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2052		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Arthroplasty; Nausea; Oedema; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Rituxan	S	Unknown	1/2	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine	S	Unknown		Not Reported

					Rituximab		S	Intravenous (not otherwise specified)	Not Reported
					Cortisone Acetate		S	Topical	Not Reported
					Naprosyn		C	Unknown	Not Reported
					Naprosyn		C	Unknown	Not Reported
					Celebrex		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16801774	EXPEDITED (15-DAY)		OT	PHHY2019CA210752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16830502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2929972-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hip Arthroplasty;	Humira			S	Subcutaneous	Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Tylenol		C	Unknown	Not Reported
	Prednisone		C	Oral	Not Reported
	Lyrica		C	Unknown	Not Reported
	Codeine		C	Unknown	Not Reported
	Acetaminophen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16839479	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019154934			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Tofacitinib			S	Unknown	5 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16877948	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2019-055587		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown			Santarus
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17272589	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020013698		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ibuprofen			S	Oral	Unk (200mg Tablets)		Pfizer
	Hydroxychloroquine			S	Oral	Unk (6 G Missing)		Not Reported
	Naproxen			S	Oral	Unk (750mg Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17278764	EXPEDITED (15-DAY)		OT	NVSC2019CA086426		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Live Birth; Musculoskeletal Stiffness;	Diclofenac			S	Unknown	50 Mg		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Diethylamine			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	0.5 Unk		Not Reported
	Folic Acid			S	Oral	25 Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	50 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported

Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Cimzia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Salazopyrine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Qd	Not Reported
	Paracetamol	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported

					Tocilizumab		S	Subcutaneous	Not Reported
					Winpred		S	Oral	Not Reported
					Stelera		S	Unknown	Not Reported
					Topicort		S	Subcutaneous	Not Reported
					Topicort		S	Oral Unk	Not Reported
					Sarilumab		S	Unknown	Not Reported
					Apo-Hydroxyquine		S	Unknown	Not Reported
					Hydrocortisone Acetate		S	Subcutaneous Unk	Not Reported
					Tofacitinib Citrate		C	Unknown	Not Reported
					Salazopyrin		C	Unknown Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17442941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547878		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17442962	EXPEDITED (15-DAY)		HO, OT	GR-IPCA LABORATORIES LIMITED-IPC-2020-GR-000567			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital; Respiratory Distress	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Prednisolone			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549601		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553485		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443340	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-237571		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Venlafaxine			S	Oral	1 Dosage Form, Daily		Sun
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Daily		Not Reported
	Reactine			C	Unknown	10 Milligram, Daily		Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553490		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Minocycline			C	Unknown			Not Reported
	Penicillamine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552179		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553491		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443476	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3283788-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443486	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552643		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Other			Not Reported
	Orencia			S	Subcutaneous			Not Reported

		Sulfasalazine			S	Unknown				Not Reported
		Xeljanz			S	Unknown				Not Reported
		Methotrexate			S	Oral				Not Reported
		Methotrexate			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443552	EXPEDITED (15-DAY)		HO	CA-ROCHE-2552666			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443585	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552671		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate			S	Subcutaneous					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown					Not Reported
	Zostavax			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443944	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554290		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

			Humira		S	Subcutaneous				Not Reported
			Orencia		S	Unknown				Not Reported
			Remicade		S	Unknown				Not Reported
			Simponi		C	Unknown				Not Reported
			Xeljanz		C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444871	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187147		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Cutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444898	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552836		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Sodium Aurothiomalate			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Enbrel			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445349	EXPEDITED (15-DAY)		OT	NVSC2020CA025358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength Decreased; Hepatitis; Pain	Methotrexate			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445421	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020073533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Pneumonia	Methotrexate Sodium	S	Unknown	20 Mg, Unk		Pfizer
	Sulfasalazine	S	Unknown	1 G, Every 12hours		Pfizer
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide	S	Unknown	20 Mg, Every Day		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445771	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446119	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-007		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; Incorrect Dose Administered; Maculopathy; Nephropathy Toxic; Renal Failure; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Hikma
	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			C	Unknown			Not Reported
	Mycophenolate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446901	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1187166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Prednisone	S	Oral	5 Milligram Daily;		Actavis
	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	2000 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446916	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Calcium Carbonate			S	Oral	3 Dosage Forms Daily;		Not Reported
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported
	Magnesium Aspartate			C	Oral	3 Dosage Forms Daily;		Not Reported
	Omega 3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446944	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446966	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187287		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal	Prednisone			S	Unknown			Actavis

Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Methotrexate		S	Unknown		Barr
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Immune Globulin (Human)		S	Unknown		Not Reported
	Immune Globulin (Human)		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446970	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187192			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447221	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187169			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Premature	Prednisone			S	Transplacental			Actavis
	Methotrexate			S	Transplacental			Barr
	Hydroxychloroquine			S	Transplacental			Not Reported

Baby	Immune Globulin (Human)	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447516	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acyclovir [Aciclovir]			C	Unknown			Not Reported
	Aerius [Ebastine]			C	Oral			Not Reported
	Amitriptyline			C	Oral	25 Milligram Daily;		Not Reported
	Constella			C	Oral	145 Milligram Daily;		Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Oral			Not Reported
	Sertraline Hydrochloride			C	Unknown			Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported
	Zomig			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447605	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073610			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate Sodium		S	Unknown	Unk			Pfizer
	Sulfasalazine		S	Unknown	Unk			Pfizer
	Humira		S	Subcutaneous	Unk			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk			Not Reported
	Tylenol 8 Hr Arthritis Pain		C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447732	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Red Blood Cell Sedimentation Rate Abnormal	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17333171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527581			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular	Solution Intramuscular		Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448001	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553779		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
					Remicade		S	Unknown	Not Reported
					Xeljanz		S	Oral	Not Reported
					Sulfasalazine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448020	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553790		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448022	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553470		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pulmonary Fibrosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553811			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2020	15630530	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105495		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Lyrica		C	Oral	Unk	Not Reported
	Lyrica		C	Unknown	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Enbrel		S	Subcutaneous	1 Df, Qwk	Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Arava		C	Unknown		Not Reported
	Prednisone		C	Oral		Not Reported
	Acetaminophen		C	Unknown		Not Reported
	Codeine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2020	17448256	EXPEDITED (15-DAY)		OT	PHHY2019CA055941		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single-Use Prefilled Syringe)		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

		Simponi			S	Subcutaneous				Not Reported
		Stelara			S	Subcutaneous	Unk			Not Reported
		Arava			S	Unknown	Unk			Not Reported
		Methotrexate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12310874	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014345227		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate			S		25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, Unk		Pfizer
	Rapamune			S		Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Neoral			S		Unk		Not Reported
	Prograf			S	Unknown	Unk		Not Reported
	Prograf			S	Oral	3.0 Mg, Q12h		Not Reported
	Prograf			S	Oral	2.0 Mg, Q12h		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	3 Milligram 1 Every 12 Hours		Not Reported

	Tacrolimus		S	Oral	3 Milligram, 2 Every 1 Day	Not Reported
	Tacrolimus		S	Oral	2 Milligram, 2 Every 1 Day	Not Reported
	Azathioprine		C		25 Mg, Unk	Not Reported
	Imuran		C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12355072	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2015306460		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction;	Etanercept			S	Subcutaneous	Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S		25 Milligram, 2 Times/Wk		Pfizer
	Enbrel			S		25 Milligram		Pfizer
	Enbrel			S		Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	20 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
	Infliximab Hospira			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Ibuprofen			S	Oral	600 Mg, Every 3-4 Hours Regularly		Pfizer
	Ibuprofen			S	Oral	600 Mg, Q4h		Pfizer
	Ibuprofen			S	Oral	600 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk (4.0 Dosage Forms), Qwk		Pfizer

Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Pfizer
	Celebrex	S	Oral	200 Milligram, Bid	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Unknown
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported

Abatacept	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S			Not Reported
Otezla	S			Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported

Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported

Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Xeljanz	C		Unk	Not Reported
Naproxen	C		500 Milligram	Not Reported
Cannabis Sativa	C		Unk	Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported
Risedronate Sodium	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12690990	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1432		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Lantus	C	Subcutaneous		Not Reported
	Lozide	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Naprosyn	C	Unknown	As Necessary	Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Asa Arthritis Strength Aspirin	C	Unknown	Strength: 81 Mg	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12696569	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1473		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal Loss Of Weight; Adverse Drug Reaction;	Methotrexate (Trade Name Unknown)			S				Not Reported
Arthropathy; Deafness;	Methotrexate (Trade Name			S				Not Reported

Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Unknown)			
	Methotrexate (Trade Name Unknown)	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Motrin	S	Unknown	Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Motrin	S		Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Aspirin	S	Unknown	Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Naprosyn	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Gold	S		Not Reported
	Gold	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Plaquenil	S		Not Reported

Voltaren	S	Unknown	Not Reported
Voltaren	S		Not Reported
Voltaren	S		Not Reported
Voltaren	S		Not Reported
Acetylsalicylic Acid	S	Unknown	Not Reported
Acetylsalicylic Acid	S		Not Reported
Acetylsalicylic Acid	S		Not Reported
Acetylsalicylic Acid	S		Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Vitamin C	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Clopidogrel	S	Unknown	Not Reported
Trimethoprim	S	Unknown	Not Reported
Apo Hydroxychloroquine	S	Unknown	Not Reported
Apo Asa	S	Unknown	Not Reported
Tramadol	S	Unknown	Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Apo-Sulfatrim	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported

	Naproxen	S	Unknown		Not Reported
	Sulfatrim	S	Unknown		Not Reported
	Asa	S	Unknown		Not Reported
	Gold Sodium Thiomalate	S	Unknown		Not Reported
	Acetylsalicylic Acid-Clopidogrel	S	Unknown		Not Reported
	Acetylsalicylic Acid-Clopidogrel	S			Not Reported
	Acetylsalicylic Acid-Clopidogrel	S			Not Reported
	Acetylsalicylic Acid-Clopidogrel	S			Not Reported
	Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12701557	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1498		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12957589	EXPEDITED (15-DAY)		CA, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	500 Milligram,Every One Day		Not Reported
	Naprosyn [Naproxen]	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	500 Mg, Bid		Not Reported
	Erythromycin	C	Unknown			Not Reported
	Morphine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	13107798	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0119		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Loss Of Personal Independence In Daily Activities; Pain; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo Hydroxychloroquin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

	Methyl Salicylate	S	Unknown	Not Reported
	Salicylates Nos	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	13929653	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	Dose: 730		Not Reported
	Enbrel			S	Unknown	Dose: 731		Not Reported
	Enbrel			S	Unknown	Dose: 4 Year		Not Reported
	Humira			S	Subcutaneous	Dose: 5 Month		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

		otherwise specified)	
Rituxan	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Arthrotec	C	Unknown	Not Reported
Imuran	C	Unknown	Not Reported
Vitamin D	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14223525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021445		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	1 Df, Unk		Not Reported

Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Valsartan	C	Unknown	320 Mg, Qd	Not Reported
	Xalatan	C	Unknown	50 Mg, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
	Xalatan	C	Unknown	Unk	Not Reported
	Xalatan	C	Unknown	50 Mg, Unk	Not Reported
	Xalatan	C	Unknown	5.0 Mg, Unk	Not Reported
	Dorzolamide + Timolol Genoptim	C	Unknown	Unk, Bid	Not Reported
	Estradiol	C	Unknown	6 %, Tid	Not Reported
	Furosemide	C	Unknown	40 Mg, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk, Q.Wk.	Not Reported
	Estrogel	C	Unknown	0.6 %, Tid	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Morphine	C			Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Atasol /00020001/	C	Unknown	Unk	Not Reported
	Baclofen	C	Unknown	10 Mg, Bid	Not Reported
	Calcium	C	Unknown	500 Mg, Unk	Not Reported

	Calcium Gluconate			C	Unknown	Unk				Not Reported
	Gravol			C	Unknown	Unk				Not Reported
	Levaquin			C	Unknown	500 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14634541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1464		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 730		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Actemra			S	Unknown					Not Reported
	Arava			C	Unknown					Not Reported
	Sodium Aurothiomalate			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported
	Leflunomide			C	Unknown					Not Reported
	Remicade			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14746351	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009116		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14782027	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14917342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-049997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	750 Milligram, Q4wk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every 10 Days		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown			Not Reported

	Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15399919	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Off Label Use; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

	Lyrica		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15400531	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Off Label Use; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15589215	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15688989	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1053		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Alopecia; Ankle	Methotrexate (Trade Name Unknown)			S	Oral	Lower Doses Initially And Increased Over The Years		Not Reported

Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Aspartate Aminotransferase Increased; Asthenia; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; C-Reactive Protein Increased; Chills; Contraindicated Product Administered; Cough; Deafness; Decreased Appetite; Disability; Drug Eruption; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Fatigue; Gastric Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypercholesterolaemia; Hypersensitivity; Infection; Inflammation; Insomnia; Limb Deformity; Loss Of Personal Independence In Daily Activities; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling; Product Use Issue; Product Use Issue;				Around 1997	
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported

Pyrexia; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Rosacea; Skin Necrosis; Skin Ulcer; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer; Vomiting; Weight Increased	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Lower Doses Initially And Incrased Over The Years Around 1997	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	25	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	2x/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported

Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Indocid	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	20	Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	5 Days Out Of 7	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported

Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Indomethacin	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Gold (198 Au) Colloidal	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular	Cyclic	Not Reported

Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Rituximab	S	Unknown		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Celebrex	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Fosamax	S	Unknown		Not Reported
Acetaminophen	S	Oral		Not Reported
Benadryl	S	Oral		Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)		Not Reported
Cymbalta	C	Oral	Nightly	Not Reported
Folic Acid	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

	Cyclosporine		C	Unknown	Not Reported
	Cyclosporine		C	Unknown	Not Reported
	B Complex		C	Unknown	Not Reported
	Fish Oil		C	Unknown	Not Reported
	Ciprodex		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15979301	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014058		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6wk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mole, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Wellbutrin			C	Unknown	Unk, Tablet Extended Release		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16095151	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2710698-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass			C				Not Reported
	Amoxil			C				Not Reported
	Amoxicillin And Clavulanate Potassium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16200433	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1110		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	2.5 Mg/Ml	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	4 Every 1 Week	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Four Every One Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Four Every One Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	4 Every 1 Week	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported

Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Subcutaneous	Not Reported

Tylenol	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Not Reported
Apo-Hydro	S	Unknown	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Amaryl	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Tylenol With Codeine No.3	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Hydromorphone Hcl	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported

	Methotrexate	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Glyburide	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lipitor	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Percocet	C		Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16507983	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2131		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Cyclic	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Risedronate	S	Unknown		Not Reported
	Risedronate	S	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16850467	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019413433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer

Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Tofacitinib	S	Unknown	5 Milligram, Bid		Pfizer
	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16854475	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3626		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17240411	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026873		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid (Therapy Duration: 730)		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17334290	EXPEDITED (15-DAY)		HO	JP-ADVANZ PHARMA-202001000333			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17394928	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17404343	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019507572		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Creatinine Increased; Bone Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Feeling Hot; Heart Rate Decreased; Loss Of Personal Independence In Daily Activities; Macular Degeneration	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Unk		Not Reported
	Shingrix			S		Unk		Not Reported
	Nitro [Glyceryl Trinitrate]			C	Topical	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17411576	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-202001000165			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	200 Mg, Qd (Film Coated Tablet)		Concordia
	Predonine			C		Unk		Not Reported
	Tracleer Dt			C		Unk		Not Reported
	Berasus			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Minocycline Hydrochloride			C		Unk		Not Reported
	Alprostadil			C		Unk		Not Reported
	Rebamipide			C		Unk		Not Reported
	Nexium 1-2-3			C		Unk		Not Reported
	Sucralfate			C		Unk		Not Reported
	Ritodrine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17416504	NON-EXPEDITED		HO	US-ACTELION-A-US2020-201797		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Blood Culture Positive; Brevibacterium Infection; Catheter Management; Catheter Site Infection; Device Related Infection; Ear Infection; Immunosuppression; Sepsis	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Veletri			S	Intravenous (not otherwise specified)	28 Ng/Kg, Per Min		Actelion
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Letairis			C				Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448570	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0942			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Neutropenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Sarilumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448571	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0941		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Psoriasis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448674	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201905-001299			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia

Retinal Depigmentation;
Visual Field Defect

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448792	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012554		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449079	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00768		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrophic Cardiomyopathy; Overdose; Thrombocytopenia	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Lupin
	Metoprolol			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Sinusitis; Urosepsis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 4 Weeks		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Certolizumab Pegol			C	Unknown	400 Mg, Q.O.Wk.		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	8.0 Mg/Kg, (One Evey Four Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449159	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188424		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematochezia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown	20 Mg		Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449167	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Arava			S	Unknown				Not Reported
	Cetirizine Hydrochloride			S	Unknown				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Folic Acid			S	Unknown				Not Reported
	Fosamax			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449227	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552826		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449309	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		50 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		1000 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Levothyroxine Sodium			S	Oral	0.075 Ug, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Azathioprine			C		50 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449466	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate	S	Unknown			Barr
	Prednisone	S	Unknown	5 Milligram Daily;		Actavis
	Acetaminophen	S	Unknown			Not Reported
	Meloxicam	S	Unknown			Teva
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449547	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000942			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine			S		Unk		Concordia
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449615	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188475		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine			S	Unknown			Not Reported

Hydrochloride				
Cimzia	S	Subcutaneous		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Diclofenac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450164	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0964		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555260		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450653	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2080818		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia ; Leukopenia; Neutropenia	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450830	EXPEDITED (15-DAY)		HO, LT, OT	PT-UNITED THERAPEUTICS-UNT-2020-002924			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Serositis	Remodulin Sq			S	Subcutaneous	0.046 Mg/H, Continuing		United Therapeutics
	Prednisolone			S	Unknown	5 Mg		Not Reported
	Mycophenolate Mofetil			S	Unknown	2.5 G		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Bosentan			S	Unknown	250 Mg		Not Reported
	Riociguat			C	Unknown	6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555709		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Tylenol With Codeine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451026	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451038	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075510			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk, 1x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg/Kg, 1 Every 12 Hours		Pfizer
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451060	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075442		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, Every Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Every Day		Not Reported
	Orencia			S	Unknown	125 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451063	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance;	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer

Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin Calcium	S	Oral	40 Mg, 1x/Day		Pfizer
	Leflunomide	S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil S	S	Unknown	Unk		Not Reported
	Plaquenil S	S	Oral	400 Mg, 1x/Day		Not Reported
	Acetaminophen	C	Oral	500 Mg, Unk		Not Reported
	Asa Ec	C	Oral	81 Mg, 1x/Day		Not Reported
	Folic Acid	C	Oral	5 Mg, Weekly		Not Reported
	Vitamin D3	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451087	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075507		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Adalimumab			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451102	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Atenolol			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Unknown	Unk		Not Reported
	Hctz			C	Unknown	Unk		Not Reported
	Leucovorin [Calcium Folinate]			C	Oral	5 Mg, Weekly		Not Reported
	Levothyroxine Sodium			C	Unknown	Unk		Not Reported
	Methotrexate			C	Intramuscular	12.5 Mg, Weekly		Not Reported
	Ranitidine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451130	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077701		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Intolerance; Haematochezia; Joint Swelling; Neuropathy Peripheral; Rash; Skin Burning Sensation	Sulfasalazine		S	Unknown	1000 Mg, 1 Every 12 Hours	Pfizer
	Sulfasalazine		S	Unknown	1000 Mg, 1 Every 12 Hours	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	400 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	400 Mg, 1x/Day	Not Reported
	Acetaminophen		C	Oral	500 Mg, Unk	Not Reported
	Asa Ec		C	Oral	81 Mg, 1x/Day	Not Reported
	Atorvastatin		C	Oral	40 Mg, 1x/Day	Not Reported
	Folic Acid		C	Oral	5 Mg, Weekly	Not Reported
	Leflunomide		C	Unknown	20 Mg, Unk	Not Reported
	Vitamin D3		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451149	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Januvia			S		Unk		Not Reported
	Metformin			S	Unknown			Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451169	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Methotrexate Sodium		S	Subcutaneous	25 Mg, Weekly	Unknown
	Sulfasalazine		S	Oral	1 G, 2x/Day, Every 12 Hours	Pfizer
	Hydroxychloroquine Sulfate		S	Oral	400 Mg, Daily	Not Reported
	Leflunomide		S	Unknown		Not Reported
	Depo-Medrol		C	Intra-articular	80 Mg, 1 Every 2 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451236	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012595			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Intravenous (not otherwise specified)	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552800		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mefenamic Acid	C		Not Reported
	Prednisone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451388	NON-EXPEDITED			US-PFIZER INC-2020076679		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Oedema Peripheral	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Mg One Tablet By Mouth Twice A Day)		Pfizer
	Lyrica			S		Unk, 3x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Prednisone			S		5 Mg, Alternate Day (Every Other Day)		Not Reported
	Prednisone			S		5 Mg, Alternate Day		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	5 Mg, Weekly (2.5 Mg Two		Not Reported

							Tablet By Mouth One Time A Week)			
	Orencia			S			Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452006	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020075115		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Lampren			S	Oral	100 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, 1x/Day		Not Reported
	Noxafil			S	Oral	300 Mg, 1x/Day		Not Reported
	Cholurso			C				Not Reported
	Propranolol			C				Not Reported
	Ethambutol Hydrochloride			C				Not Reported
	Pantoprazole			C				Not Reported
	Tramadol			C				Not Reported
	Aldactone [Spironolactone]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452106	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1018551		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452218	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020077853		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Enbrel			S	Unknown	Unk		Pfizer

Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	1 Df, Weekly	Pfizer
	Methotrexate Sodium	S			Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Unknown
	Methotrexate Sodium	S			Unknown
	Sulfasalazine	S	Oral	2 G, 1x/Day	Pfizer
	Aclasta	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown	20 Mg, 1 Every 1 Day	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Leflunomide	S	Unknown	20 Mg, 1 Every 1 Day	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Tramacet	S	Oral		Not Reported
	Tramacet	S	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Depo-Medrol	C	Subcutaneous	Unk Unk, Monthly	Not Reported
	Depo-Medrol	C	Intramuscular		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Mg, 1 Every 1 Day	Not Reported

	Lyrica	C	Oral	150 Mg, 2 Every 1 Day	Not Reported
	Metformin	C	Unknown	5 Mg, 1 Every 1 Day	Not Reported
	Metformin	C		500 Mg, 2 Every 1 Day	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Monthly	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	40 Mg, Monthly	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Monthly	Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported
	Nortriptyline	C	Unknown	2 Df, Unk	Not Reported
	Nortriptyline	C			Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Mg, 1x/Day	Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Oxycocet	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Weekly	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071737		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Blood Pressure Increased; Blood Pressure Systolic Increased; Cataract; Decreased Appetite; Dizziness; Dyspepsia; Heart Rate Decreased;	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported

Nausea; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Atorvastatin	C				Not Reported
	Benadryl	C	Oral	50 Mg, Unk		Not Reported
	Cymbalta	C				Not Reported
	Hydroxychloroquine	C				Not Reported
	Irbesartan	C				Not Reported
	Lipitor	C	Unknown			Not Reported
	Prednisone	C				Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Tramadol	C	Unknown	Unk Unk, As Needed		Not Reported
	Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452265	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188323			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452272	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187850		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Prednisone			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452273	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole			S	Unknown					Not Reported
	Remicade			S	Intravenous (not otherwise specified)					Not Reported
	Rituxan			S	Intravenous (not otherwise specified)					Not Reported
	Tocilizumab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Folate			S	Unknown			Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452569	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020074362		68 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma Stage I	Sulfasalazine			S		1 G, 3x/Day (En)		Pfizer
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported
	Diclofenac			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453023	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Prednisone		S	Unknown	25 Milligram Daily;		Actavis
	Methotrexate		S	Subcutaneous			Barr
	Methotrexate		S	Subcutaneous			Barr
	Folic Acid		S	Unknown			Not Reported
	Humira		S	Subcutaneous			Not Reported
	Humira		S	Subcutaneous			Not Reported
	Methotrexate		S	Oral			Not Reported
	Plaquenil		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188808		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Eliquis Film Coated			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188754			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Prednisone			S	Unknown	25 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	2.1429 Milligram Daily;		Not Reported

	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Varicella Zoster Vaccine Live	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17454177	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Qd		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Sulfasalazine	S	Unknown	1 Gram, Bid			Not Reported
Xeljanz	C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	9426564	EXPEDITED (15-DAY)		HO, OT	US-SANOFI-AVENTIS-2013SA075840		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Balance Disorder; Cervical Radiculopathy; Condition Aggravated; Contusion; Cutaneous Lupus Erythematosus; Dehydration; Depressed Mood; Depression; Diarrhoea; Fatigue; Gastritis; Gastroenteritis Viral; Grip Strength Decreased; Headache; Hot Flush; Limb Discomfort; Multiple Sclerosis Relapse; Nausea; Rash; Spinal Pain; Toothache; Vision Blurred; Visual Impairment	Teriflunomide			S	Oral	7 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Plaquenil			S				Sanofi
	Cymbalta			C	Unknown	90 Mg,1x		Not Reported
	Cymbalta			C				Not Reported
	Ritalin			C	Unknown	5 Mg,1x		Not Reported
	Orsythia			C		28 U, 1x		Not Reported
	Omeprazole			C	Unknown	20 Mg,1x		Not Reported
	Vitamin D3			C	Unknown	1000 Iu,1x		Not Reported
	Cyanocobalamin			C	Unknown	2000 Ug,1x		Not Reported
	Trazodone			C	Unknown	100 Mg,1x		Not Reported
	Trazodone			C				Not Reported
	Zanaflex			C	Unknown	4 Mg,1x		Not Reported
	Carbamazepine			C	Unknown	300 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	11115474	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1389528-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Gold			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	12253776	EXPEDITED (15-DAY)		DS	CA-ABBVIE-16K-028-1600446-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13118364	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION INC.-2015CA012467			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported

Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis;	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S		25 Milligram	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	20 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral	600 Mg, Q4h	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported

Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported

Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Mg, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S		Unk	Not Reported
Otezla	S		Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported

	Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
	Methotrexate Sodium	C	Oral	Unk, 1/Week	Not Reported
	Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Naproxen	C		500 Milligram	Not Reported
	Cannabis Sativa	C		Unk	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Risedronate Sodium	S	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13516208	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037950		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported

	Etanercept			S	Unknown				Not Reported
	Ibuprofen			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Ketorolac			C	Unknown				Not Reported
	Methotrexate			C	Unknown	20 Mg, Qwk			Not Reported
	Naproxen			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13525808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965986-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13537999	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-17K-028-1972796-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Humira 40mg/0.8ml	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14138176	EXPEDITED (15-DAY)		OT	CA-SA-2014SA144669		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia;	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi

Synovitis	Methotrexate	S	Intra-articular	Unk Unk,Unk		Not Reported
	Methotrexate	S	Intra-arterial	Unk Unk,Unk		Not Reported
	Naproxen Sodium	S	Unknown	Unk Unk,Unk		Not Reported
	Celecoxib	S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone	S	Unknown	5 Mg,Unk		Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Qw		Not Reported
	Gold	S	Unknown	Unk Unk,Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg,Qw		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14235931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3893		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Apo-Minocycline	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	C	Unknown	20 Unk	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Hydroxychloroquine	C	Subcutaneous		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Amoxil	C	Unknown		Not Reported
	Bcg Vaccine	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Clavulin	C	Unknown		Not Reported
	Clavulin	C	Unknown		Not Reported
	Amoxicillin Trihydrate And Clavulante Potass	C	Unknown		Not Reported
	Adalimumab	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Amoxicillin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14408887	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-18K-028-2225316-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine	S			Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S			Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Ilaris	S	Subcutaneous	Single-Use Vial Powder For Solution	Not Reported
Ilaris	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S			Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S			Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14532984	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2254850-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15146837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2150829		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; Gastric Disorder; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown	Therapy Duration: 5 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown	Therapy Duration: 4 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15395225	NON-EXPEDITED			US-PFIZER INC-2018371106		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil			S		Unk		Not Reported
	Minocycline			S		Unk		Not Reported
	Prilosec			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15543164	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016253265		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder And Solvent For Solution For Injection/Infusion)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

			Prednisone		C	Unknown	5 Mg, 1x/Day (Every 24 Hours)		Not Reported
			Prednisone		C	Unknown	10 Mg, 2x/Day		Not Reported
			Xeljanz		C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15712130	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588065-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15715888	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588290-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15716038	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587979-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Desoximetasone		C	Unknown		Not Reported
					Plaquenil		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15880483	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019002469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		162 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Imuran			C	Subcutaneous	50 Mg, Once Daily (Qd)		Not Reported
	Azathioprine			C	Subcutaneous	50 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15939703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658273-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15939769	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658337-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Sulfasalazine	C				Not Reported
	Wellbutrin	C	Unknown	Extended Release Tablet		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15941600	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658637-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Urticaria; Wrist Surgery	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Rocuronium			S	Unknown			Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15941848	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2659005-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15978220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15993853	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2672993-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Clonazepam	C	Oral	Not Reported
	Asa	C		Not Reported
	Nitroglycerin	C		Not Reported
	Gabapentin	C	Oral	Not Reported
	Desipramine	C		Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16174468	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736324-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

	Sulfasalazine			C						Not Reported
	Wellbutrin			C			Tablet (Extendedrelease)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16284690	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019017151		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Uveitis	Cimzia			S	Subcutaneous			Ucb
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S		Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S		Unk, Once Daily (Qd)		Not Reported
	Sulfasalazine			S		2 Gram		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16460073	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822502-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Apo-Leflunomide			S	Oral					Not Reported
	Apo-Hydro			S	Unknown					Not Reported
	Orencia			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16861198	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3753			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17069514	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-201911001949			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17370881	EXPEDITED (15-DAY)		DE, HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-004		77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiac Arrest; Drug Ineffective; Pancytopenia	Imunoglobulin (Immunoglobulin G Human)	S	Unknown	Not Reported
	Immunoglobulin (Iggiv)	S	Intravenous (not otherwise specified)	Not Reported
	Imunoglobulin (Immunoglobulin G Human)	S		Not Reported
	Dexamethasone	S	Oral	Westward
	Dexamethasone	S		Westward
	Dexamethasone	S		Westward
	Hydroxychloroquine	S	Unknown	Westward
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Subcutaneous	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Thalidomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Iron	C	Intravenous (not otherwise specified)	Not Reported

	Tadalafil	C	Unknown		Not Reported
	Ambrisentan	C	Unknown		Not Reported
	Ambrisentan	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17416957	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202002000701			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; End Stage Renal Disease; Maculopathy; Overdose; Retinopathy	Hydroxychloroquine			S	Unknown	300 Mg, Qd ((6.5 Mg/Kg Actual Body Weightper Day)		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (200 Mg Twice Daily,8.2 Mg/Kg Actual Body Weight Per Day)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd (8 Mg/Kg Actual Body Weightunk		Concordia
	Prednisone			C		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556590		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Methotrexate			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454391	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454474	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported

				Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
				Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
				Rituximab	S	Intravenous (not otherwise specified)		Not Reported
				Sulfasalazine	C	Unknown		Not Reported
				Wellbutrin	C	Unknown		Not Reported
				Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454489	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454580	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000601			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Condition Aggravated; Oedema Peripheral	Hydroxychloroquine			S	Unknown	200 Milligram		Ipca
	Paracetamol			C	Unknown	Take One Or Two Tablets Up To Four Times A Day ...		Not Reported
	Trimbow			C	Respiratory (inhalation)	4 Dosage Form, Qd		Not Reported
	Clenil Modulite			C	Respiratory (inhalation)	4 Dosage Form, Qd		Not Reported
	Terbutaline			C	Respiratory (inhalation)	1 Dosage Form, Prn		Not Reported
	Atorvastatin			C	Unknown	1 Dosage Form, Qd		Not Reported
	Levothyroxine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Prednisolone			C	Unknown	1 Dosage Form, Qd		Not Reported
	Lansoprazole			C	Unknown	1 Dosage Form, Qd		Not Reported
	Alendronic Acid			C	Unknown	1 Dosage Form, Q.W		Not Reported
	Cetirizine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Simvador			C	Unknown	1 Dosage Form, Hs		Not Reported
	Furosemide			C	Unknown	2 Dosage Form, Qd		Not Reported
	Braltus			C	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555257		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Rituxan			S	Intravenous (not			Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Advil [Ibuprofen]	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454626	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Oral	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552651		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	C			Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C			Not Reported
	Actemra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454967	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455012	NON-EXPEDITED		HO, OT	AU-AMGEN-AUSSP2020029522			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Ivabradine			S	Unknown	7.5 Milligram, Bid		Amgen
	5-Methyltetrahydrofolate			S	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			S	Unknown	100 Milligram		Not Reported
	Cannabis Sativa Oil			S	Unknown	Unk		Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Endone			S	Oral	5 Milligram, Qd		Not Reported
	Glucagen [Glucagon Hydrochloride]			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram 2x A Week		Not Reported
	Mirena			S	Unknown	52 Milligram		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Oxycontin			S	Oral	10 Milligram, Bid		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Prasugrel			S	Unknown	10 Milligram, Qd		Not Reported
	Sildenafil			S	Oral	12.5 Milligram		Not Reported
	Mycophenolate Mofetil			S	Oral	1500 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, 2x A Week		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Rosuvastatin			S	Unknown	10 Milligram		Not Reported

	Ezetimibe	S	Unknown	10 Milligram		Not Reported
	Ramipril	S	Unknown	Unk		Not Reported
	Topiramate	S	Unknown	200 Milligram		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Reboxetine	S	Unknown	8 Milligram, Qd		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Cyanocobalamin	S	Unknown	Unk		Not Reported
	Folic Acid	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455030	EXPEDITED (15-DAY)		OT	GB-EMCURE PHARMACEUTICALS LTD-2015-EPL-0087		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Heritage
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455416	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1188810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Prednisone			S	Unknown	6.25 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Indometacin			S	Unknown			Actavis

Arava	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455636	EXPEDITED (15-DAY)		OT	CA-SA-2020SA044419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C		Unk		Not Reported
	Tofacitinib			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556141		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Treatment Noncompliance	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455835	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-084092		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Tramadol Hydrochloride			S	Unknown	Unk		Aurobindo
	Sulfamethoxazole;Trimethoprim			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intracardiac	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Intracardiac	Unk		Not Reported
	Mortin			S	Intracardiac	Unk		Not Reported
	Voltaren			S	Intracardiac	Unk		Not Reported
	Acetylsalicylic Acid;Clopidogrel			S	Intracardiac	Unk		Not Reported
	Sodium Aurothiomalate			S	Intracardiac	Unk		Not Reported

	Diclofenac				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455855	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455961	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020006941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S				Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Sodium			S		Unk, 2x/Day (Bid)		Not Reported
	Plaquenil Sulfate			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456198	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-202002000973			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Infection; Infective Tenosynovitis; Vasculitic Ulcer	Prednisolone	S	Unk	Concordia
	Prednisolone	S	Reduse	Concordia
	Hydroxychloroquine	S	Unk	Not Reported
	Hydroxychloroquine	S	Increased Dose	Not Reported
	Hydroxychloroquine	S	Reduse	Not Reported
	Azathioprine	S	Unk	Not Reported
	Azathioprine	S	Reduse	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456353	EXPEDITED (15-DAY)		OT	NVSC2020IN045134		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Condition Aggravated; Depressed Level Of Consciousness; Nocardiosis	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Prednisolone			S	Unknown	30 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Unk, Qd		Not Reported
	Sulfamethoxazole And Trimethoprim			C	Intravenous (not otherwise specified)	15 Mg/Kg Divided In Three Doses		Not Reported
	Amikacin			C	Intravenous (not otherwise specified)	7.5 Mg/Kg, Bid		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	500 Mg Every 6 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456398	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546029		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Fatigue; Lower Respiratory Tract Infection; Off Label Use	Sulfasalazine			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456606	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1189404		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Arthralgia; Blister; Chills; Erythema; Lethargy; Neutrophil Count Increased; Oedema; Pain; Pain Of Skin; Palmar Erythema; Pyrexia; Rash Pruritic; Rash Pustular; Rebound Effect; Skin Exfoliation; Swelling; White Blood Cell Count Increased	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456924	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1019498		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17457814	EXPEDITED (15-DAY)		HO	CA-UCBSA-2020007174		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Interstitial Lung Disease	Cimzia	S	Subcutaneous	Unk	Not Reported
	Anakinra	S		Unk	Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Mycophenolate Mofetil	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Humira	C	Subcutaneous		Not Reported
	Celebrex	C			Not Reported
	Methotrexate	C		1 Milligram, Weekly (Qw)	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458210	EXPEDITED (15-DAY)		DS	CA-ABBVIE-20K-028-3290536-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leucovorin			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Calcium Citrate			C				Not Reported
	Magnesium Citrate Forte			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Clobetasol Propionate			C	Topical			Not Reported

Increased	Escitalopram Oxalate			C					Not Reported
	Naproxen			C					Not Reported
	Pantoprazole Magnesium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020006969		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Salazopyrin			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Ustekinumab			S				Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458254	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1190225		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Cardiotoxicity; Hypertrophic	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Teva
	Metoprolol			C	Unknown			Not Reported

Cardiomyopathy; Overdose	Losartan	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458528	EXPEDITED (15-DAY)		OT	CA-SA-2020SA045267			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Retinal Toxicity	Leflunomide			S		200 Mg, Qod		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Methotrexate			C	Oral	20 Mg		Not Reported
	Methotrexate			C	Intramuscular	20 Mg		Not Reported
	Sulfasalazine			C		1 G, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Asa Ec			C		650 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458535	EXPEDITED (15-DAY)		OT	CA-SA-2020SA045718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Mg, Qd (1 And 1/2 Tablets)		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Prednisone			S		(On And Off , Last Taken In Jun -2019)		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Actemra			S				Not Reported
	Remicade			S				Not Reported
	Methotrexate			C		20 Mg, Qw		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	9643129	EXPEDITED (15-DAY)		OT	CA-ROCHE-1287733		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Drug Hypersensitivity; Eye Disorder; Fatigue; Fibromyalgia; Infusion Related Reaction; Menopause; Oxygen Saturation Decreased; Pain; Rheumatoid Arthritis; Thermal Burn	Rituxan			S	Intravenous (not otherwise specified)	Most Recent Dose Prior To Sae: 06/May/2010, 17/Jun/2014, 26/Apr/2016		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Effexor			S	Unknown	Dosage Not Specified		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Arthrotec			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Nortriptyline			C	Unknown	As Required		Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Doxycyclin [Doxycycline]			C				Not Reported
	Restasis			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	12913694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053149		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Crestor	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Oral	0.5 Milligram, Bid	Not Reported
	Rosuvastatin Calcium	S	Oral	5.0 Milligram, Bid	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Rosuvastatin	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rosuvastatin	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Qid	Not Reported
	Coversyl [Perindopril Erbumine]	C	Unknown	Unk	Not Reported

	Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
	Allopurinol	C	Unknown	200 Milligram, Qd		Not Reported
	Cephalexin Monohydrate	C	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Hydroxychloroquine	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	13015479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865701		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	14921384	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043876		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Oral	20 Milligram, Qd		Not Reported
	Arava	S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel	S	Unknown	50 Milligram		Not Reported
	Humira	S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira	S	Unknown	40 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Bid		Not Reported
	Prednisone	S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid		Not Reported
	Leflunomide	S	Unknown	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	14921794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, 2 Every One Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Times/Wk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15002514	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1039822		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15059046	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015918		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported

	Loperamide	C	Oral	2 Mg, Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Pantoprazole	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15067535	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015876		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15665414	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2570644-00		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort;	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
Abdominal Discomfort;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Arava	S	Oral	Not Reported
Abnormal Loss Of Weight;	Arava	S		Not Reported
Abnormal Loss Of Weight;	Arava	S		Not Reported
Adverse Drug Reaction;	Arava	S		Not Reported
Adverse Reaction;	Diclofenac Potassium	S	Unknown	Not Reported
Arthropathy; Arthropathy;	Enbrel	S	Subcutaneous	Not Reported
Deafness; Deafness;	Enbrel	S		Not Reported
Deafness Transitory;	Enbrel	S		Not Reported
Deafness Transitory;	Enbrel	S		Not Reported
Decreased Appetite;	Methotrexate	S	Unknown	Not Reported
Decreased Appetite;	Methotrexate	S		Not Reported
Decreased Appetite;	Methotrexate	S		Not Reported
Dizziness; Dizziness; Drug	Motrin	S	Unknown	Not Reported
Hypersensitivity; Drug	Motrin	S		Not Reported
Hypersensitivity; Drug	Motrin	S		Not Reported
Hypersensitivity; Ear	Naprosyn	S	Unknown	Not Reported
Infection; Ear Infection;	Naprosyn	S		Not Reported
Ear Infection; Eating	Naprosyn	S		Not Reported
Disorder; Feeding	Plaquenil	S	Oral	Not Reported
Disorder; Feeding	Sodium Aurothiomalate	S	Intramuscular	Not Reported
Disorder; Feeding	Sodium Aurothiomalate	S	Oral	Not Reported
Disorder; Foot Operation;	Voltaren	S	Unknown	Not Reported
Foot Operation; Functional	Gold Sodium Thiomalate	S	Unknown	Not Reported
Gastrointestinal Disorder;	Gold Sodium Thiomalate	S		Not Reported
Functional Gastrointestinal	Gold Sodium Thiomalate	S		Not Reported
Disorder; Functional	Gold Sodium Thiomalate	S		Not Reported
Gastrointestinal Disorder;	Aspirin	S	Oral	Not Reported
Gastrointestinal Disorder;	Aspirin	S		Not Reported
Gastrointestinal Disorder;	Aspirin	S		Not Reported
Gastrointestinal Pain;				
Gastrointestinal Pain;				
Gastrointestinal Pain;				
Headache; Headache;				
Headache; Hypophagia;				
Hypophagia;				
Musculoskeletal Disorder;				
Musculoskeletal Disorder;				
Musculoskeletal Disorder;				

Nausea; Nausea; Nausea; Off Label Use; Pharyngitis; Pharyngitis; Pharyngitis; Shoulder Arthroplasty; Shoulder Arthroplasty; Vomiting; Vomiting; Vomiting; Weight Decreased; Weight Decreased	Aspirin	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Ascorbic Acid	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Trimethoprim	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Apo Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Clopidogrel	S	Unknown	Not Reported
	Apo Asa	S	Unknown	Not Reported
	Apo Diclofenac Ophthalmic	S	Topical	Not Reported
	Vitamin C	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15675837	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573839-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Macrobid			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15767354	EXPEDITED (15-DAY)		OT	PHHY2018FR192776		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Maternal Exposure During Pregnancy; Premature Baby; Premature Delivery; Premature Rupture Of Membranes	Ursodeoxycholic Acid			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram Daily		Not Reported
	Azathioprine			S	Unknown	2.2 Mg/Kg, Unk		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	5 Milligram Daily		Novartis
	Prednisone			S				Novartis
	Hydroxychloroquine			S	Unknown	150 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15855795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634312-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral		Not Reported
Arava	S	Oral	For 3 Months	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Intramuscular		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15935428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657038-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Humira			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15977831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-072428		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoporotic Fracture; Spinal Compression Fracture	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Simponi			S	Unknown	50 Mg, Q4wk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

					Azathioprine	S	Unknown	Unk	Not Reported
					Hydroxychloroquine Sulfate	S	Unknown		Not Reported
					Hydroxychloroquine	C	Unknown	Unk	Not Reported
					Tylenol Arthritis	C	Unknown	Unk	Not Reported
					Xeljanz	C	Oral	5 Mg, Bid	Not Reported
					Xeljanz	C	Unknown	10 Mg, Bid	Not Reported
					Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16120764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044085			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Qd		Not Reported
	Tiaprofenic Acid			C	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			C	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16226842	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110423		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Hydroxychloroquine Sulfate			S	Oral	2 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Ramipril			C				Not Reported
	Rosuvastatin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16232199	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110436		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Simponi			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16232647	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110439			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported
	Methotrexate			C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16388804	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050997		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Treatment Failure; Visual Impairment	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Unknown	25 Milligram		Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate	C	Subcutaneous	15.0 Milligram, Qwk		Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Sulfasalazine	C	Oral	1.0 Gram, Qd		Not Reported
	Xeljanz	C	Oral	5.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16842729	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3543		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Abnormal; Alanine Aminotransferase	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Increased; Arthralgia; Arthropathy; Aspartate	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Aminotransferase Increased; Basal Cell	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Carcinoma; Blood Creatinine Increased;	Methotrexate (Trade Name Unknown)			S				Not Reported
Blood Parathyroid Hormone Decreased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Blood Pressure Systolic Increased; C-Reactive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Protein Abnormal; Contraindicated Product	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Administered; Decreased Appetite; Diarrhoea; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Eruption; Drug Intolerance; Enthesopathy;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Erythema; Fatigue; Fear Of Injection; General Physical Health	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Overdose; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Ibuprofen	S	Oral	Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	2 Times/Wk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo Ibuprofen	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Abatacept	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported

Stelara	S	Unknown		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Ustekinumab	S	Subcutaneous		Not Reported
Ustekinumab	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Apremilast	S	Oral		Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cyclosporine	S	Oral		Not Reported
Cyclosporine	S	Unknown		Not Reported
Otezla	S	Oral		Not Reported
Otezla	S			Not Reported
Otezla	S			Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Unknown		Not Reported
Ciclosporin	S	Unknown		Not Reported
Sulfamethoxazole	S	Oral		Not Reported
Motrin	S	Oral	Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported

Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Unknown	4 Every 1 Week	Not Reported
Codeine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Arava	S	Unknown	Frequency: 1 Every 2 Day	Not Reported
Arava	S	Unknown	Frequency: 1 Every 2 Day	Not Reported
Celebrex	S	Oral		Not Reported
Cosentyx	S	Unknown		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Rituximab	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Diphenhydramine	S	Unknown		Not Reported
Anolamine Hydrochloride [Phenylpropanolamine Hydrochloride]	S	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Mogadon	C	Unknown		Not Reported
Uloric	C			Not Reported
Colchicine	C			Not Reported
Acide Folique	C	Unknown		Not Reported

	Folic Acid	C	Unknown	Not Reported
	Nitrazepam	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported
	Dexilant	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Febuxostat	C	Unknown	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Cannabis Sativa	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16904609	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-MAPI_00011608			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Metformin Hydrochloride			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17424304	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5764		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; Blood Creatinine Increased; Bone Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Feeling Hot; Heart Rate Decreased; Loss Of Personal Independence In Daily Activities; Macular Degeneration	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Shingrix	S	Unknown		Not Reported
	Nitro	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17425150	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202002000774			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Cell Death; Cholestasis; Dyspnoea; Eosinophil Count Increased; Epidermal Necrosis; Pustular Psoriasis; Pyrexia; Rash; Rash Pustular; Skin Exfoliation; Toxic Skin Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Levothyrox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17460784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554332			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Failure	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Citalopram Hydrobromide	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555255		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461703	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1002		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Aclasta	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Tramacet	S	Oral	Not Reported
	Tramacet	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Depo-Medrol	C	Subcutaneous	Not Reported
	Depo-Medrol	C	Intramuscular	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lorazepam	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Metformin	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported

	Nortriptyline	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Oxycocet	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461752	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1007		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461763	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

			Colchicine		S	Unknown				Not Reported
			Hydroxychloroquine Sulfate		S	Unknown				Not Reported
			Januvia		S	Unknown				Not Reported
			Metformin		S	Unknown				Not Reported
			Actemra		S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461770	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1019			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Musculoskeletal Stiffness	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461789	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461792	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1005			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462087	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551186		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Rituxan			S	Intravenous drip	3.0 Years		Not Reported
	Enbrel			S	Subcutaneous	3.0 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration- 3.0 Months, Frequency-Cyclical		Not Reported
	Methotrexate			S	Unknown	Therapy Duration-9.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3.0 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	2.0 Months		Not Reported
	Prednisone			S	Unknown	12.0 Months		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	Therapy Duration-2.0 Months		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	12.0 Months		Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Therapeutic Product Effect Decreased; Therapeutic	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported

Response Decreased	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Myochrysine		S	Intramuscular	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462583	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-015196		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Naproxen			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462604	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1026		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462721	EXPEDITED (15-DAY)		CA, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000636			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ebstein'S Anomaly; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	400 Milligram, Qd		Ipca
	Warfarin			S	Transplacental	Unk		Ipca
	Belimumab			S	Transplacental	10 Microgram/Kilogram		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	2.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462766	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462854	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293340-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cannabis Sativa			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463135	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1020524		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Prednisone			S		1 Df, Qd		Not Reported
	Aspegic /00002701/			S		Unk		Mylan
	Pentoxifylline			S		1 Df, Qd		Mylan
	Kardegic			S		Unk		Mylan
	Plaquenil /00072603/			S		1 Df, Qd		Mylan
	Lovenox			S		Unk		Mylan
	Gestarelle G			S		Unk		Mylan
	Doliprane			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463410	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189863		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease	Prednisone			S	Unknown			Actavis

Progression; Drug Ineffective; Immobile; Malaise	Methotrexate		S	Unknown		Barr
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Celebrex		S	Unknown		Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Naproxen Sodium		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463951	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553949		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553858			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate			S	Unknown	Not Reported
	Orencia			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Not Reported
	Cortisone Acetate			C	Subcutaneous	Not Reported
	Desoximetasone			C	Oral	Not Reported
	Diclofenac			C	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464189	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)			
			Rituxan		S	Intravenous (not otherwise specified)			Not Reported
			Simponi		S	Unknown			Not Reported
			Sulfasalazine		S	Unknown			Not Reported
			Topicort[Desoximetasone]		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2553935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464539	EXPEDITED (15-DAY)		OT	NVSC2020CA045634			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration;	Estradot			S	Transdermal	1 Df, Qw		Novartis
	Leflunomide			S	Unknown	20 Mg, Q24h		Not Reported

Nausea; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464549	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020085116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464712	NON-EXPEDITED		OT	NVSC2020US051130		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Liver Injury; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Novartis

	Prednisone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189663		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oedema Peripheral; Pain	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465230	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293377-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hepatic Enzyme Increased; Pyrexia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17483085	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine			S	Oral		1 MTH	Dr Reddys

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15630828	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105531		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hcl Timolol Maleate			C	Unknown	2 Df, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qd		Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1 Df= 0.6 Percent 3 Times, Qd		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Xalatan			C	Unknown	50 Mg, Qd		Not Reported
	Zingiber Officinale			C	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15856062	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633852-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15930670	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655655-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	16231133	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110410			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Prednisone			C	Oral	7 Mg, Qd		Not Reported
	Etanercept			C		50 Mg, Qw		Not Reported
	Cosentyx			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17041158	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201812-004125			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Spinal Compression Fracture; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported

	Prednisolone	S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone	S	Oral	15 Mg, Qd		Not Reported
	Prednisolone	S	Oral	5 Mg, Qd		Not Reported
	Prednisolone	S	Oral	6 Mg, Qd		Not Reported
	Prograf	S	Oral	2 Mg, Qd		Not Reported
	Ulcerlmin	C		Unk		Not Reported
	Bonoteo	C		50 Mg, Q4w		Not Reported
	Diovan	C		Unk		Not Reported
	Takepron	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465134	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility	Rituxan			S	Intravenous (not			Not Reported

Decreased; Osteomyelitis; Rheumatoid Arthritis			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Hydrocortisone Valerate	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Lyderm [Fluocinonide]	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465267	EXPEDITED (15-DAY)		OT	IT-ROCHE-2556901		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported

	Prednisone	S	Unknown	Unk (25 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)	Not Reported
	Tacrolimus	S	Unknown	Unk Unk, Qd	Not Reported
	Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020085748		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465380	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder;	Hydroxychloroquine			S	Unknown			Concordia

Menorrhagia; Surgery; Uterine Haemorrhage	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S				Not Reported
	Humira	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557866			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557916		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465564	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025776		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate	S	Unknown	22.5 Milligram		Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid		Not Reported
	Prednisone	C	Oral	5 Milligram		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465574	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557140		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465647	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293370-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554327			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465691	EXPEDITED (15-DAY)		HO	CA-ROCHE-2557122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465831	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1040		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased	Plaquenil		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1013			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Plaquenil S			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Asa Ec			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Reactine (Cetirizine)		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466010	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported

		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Rituximab			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466020	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1189746		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased;	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil Hydrochloride			S	Unknown			Teva
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gravol			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Neurontin			C				Not Reported

Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189912		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Drug Ineffective	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Tofacitinib			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466041	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189903			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Prednisone			S	Unknown	5 Mg		Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466207	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551554		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	9.0 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	9.0 Months		Not Reported
	Enbrel			S	Unknown	4.0 Years		Not Reported

	Humira	S	Subcutaneous	4.0 Years	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	2.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	2.0 Years	Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555862		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi			S	Subcutaneous					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466730	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06445			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Triamcinolone Hexacetonide			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466876	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189709		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia;	Prednisone			S	Unknown			Actavis

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Prednisone	S	Unknown		Actavis
	Alendronate Sodium	S	Oral		Actavis
	Diclofenac Sodium	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

					Rituxan		S	Intravenous (not otherwise specified)	Not Reported
					Sarilumab		S	Unknown	Not Reported
					Simponi		S	Subcutaneous	Not Reported
					Sulfasalazine		S	Subcutaneous	Not Reported
					Sulfasalazine		S	Oral	Not Reported
					Topicort		S	Unknown	Not Reported
					Xeljanz		S	Unknown	Not Reported
					Atasol [Paracetamol]		C	Unknown	Not Reported
					Leflunomide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466992	EXPEDITED (15-DAY)		DS	CA-ROCHE-2557149		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467082	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2016-05191		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Prednisone			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467235	NON-EXPEDITED		DE, OT	NVSC2020US047643		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	6 G		Novartis
	Ibuprofen			S	Unknown	200 Mg		Not Reported
	Naproxen			S	Unknown	750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467282	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020084507		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Musculoskeletal Disorder	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467333	NON-EXPEDITED			US-PFIZER INC-2020086812		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467359	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020083924			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Methotrexate Sodium			S	Oral	7.5 Mg, Once Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467817	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00009890		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Unknown		Unknown
	Cyclobenzaprine			S	Oral	Unknown		Unknown
	Esomeprazole			S	Oral	Unknown		Unknown
	Clindamycin			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17468132	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17469402	EXPEDITED (15-DAY)		OT	NVSC2020DE049601		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective For Unapproved Indication; Lupus Nephritis	Mycophenolate Mofetil			S	Unknown	Unk			Novartis
	Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17470523	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2008857US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	12769741	EXPEDITED (15-DAY)		OT	CA-ROCHE-1833370			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Sensation; C-Reactive Protein Increased; Colitis; Diarrhoea; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	50 Milligram		Not Reported
	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Oral	15 Milligram		Not Reported
	Methotrexate	S	Oral	20 Milligram		Not Reported
	Cosentyx	S	Unknown	150 Milligram		Not Reported
	Otezla	S	Oral	30 Milligram, Bid		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram		Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid		Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15218809	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1004		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Creatinine Decreased; Blood Pressure Diastolic Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

General Physical Health Deterioration; Glossodynia; Hand Deformity; Heart Rate Decreased; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Joint Swelling; Knee Arthroplasty; Live Birth; Malignant Melanoma; Maternal Exposure During Pregnancy; Monocyte Count Increased; Musculoskeletal Disorder; Musculoskeletal Stiffness; Neutrophil Count Increased; Off Label Use; Pain; Pemphigus; Pericarditis; Product Complaint; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seborrhoeic Keratosis; Sinusitis; Swelling; Synovial Disorder; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Subcutaneous		Not Reported
	Fosamax	S	Intracavernous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown		Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Subcutaneous	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported

Arava	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported

Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Oral		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown	5mg/5 Ml	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Unknown		Not Reported
Topicort (Desoximetasone)	S	Subcutaneous		Not Reported

Topicort (Desoximetasone)	S	Unknown		Not Reported
Topicort (Desoximetasone)	S	Oral		Not Reported
Topicort (Desoximetasone)	S	Other		Not Reported
Apo-Sulfasalazine	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Golimumab	S	Intravenous (not otherwise specified)		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Oral		Not Reported
Hydrocortisone Acetate	S	Other		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Zyrtec	S	Unknown	5 Mg/5ml	Not Reported
Zyrtec	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported

Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cosentyx	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Lisinopril	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Omega [Omeprazole]	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Vitamin C	C	Unknown	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Omeprazole Sodium	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Acetaminophen	C	Oral	Not Reported
Acetaminophen	C	Oral	Not Reported
Curamin	C	Unknown	Not Reported
Diphenhydramine Hcl	C	Oral	Not Reported
Leucovorine	C	Unknown	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Vitamin C	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15333538	NON-EXPEDITED		HO, OT	US-AMGEN-USASP2018118188		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Joint Warmth; Localised Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15935754	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656874-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16079910	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05962		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Prednisone		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Triamcinolone		S	Other	Unknown	Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide		S	Unknown	Unknown	Not Reported
	Triamcinolone Hexacetonide		S	Other	Unknown	Not Reported
	Apo-Naproxen		S	Unknown	Unknown	Not Reported
	Apo-Prednisone		S	Oral		Not Reported
	Apo-Prednisone		S	Oral		Not Reported
	Triamcinolone Acetonide		S	Intra-articular	Unknown	Not Reported
	Hydroxychloroquine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16539596	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every Day 1		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, 2 Every 1 Day		Not Reported
	Xeljanz			C	Oral	5 Milligram., 2 Every Day 1		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16891755	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-29184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown (Route Of Admin: Intracardiac)		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)		Not Reported
	Amlodipine			C	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17227197	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0002		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Prevnar 13			S	Intramuscular	Single Dose		Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine Sodium	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Ketoprofen	S	Topical	Not Reported
Leucovorin Calcium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate Sodium	C	Unknown	Not Reported
Lederle Leucovorin	C	Unknown	Not Reported
Shingrix	C	Unknown	Not Reported
Corticosteroids	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17431251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3275137-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17470756	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555241		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471374	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553868		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471381	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002001039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Balance Disorder; Cervical Radiculopathy; Condition Aggravated; Contusion; Cutaneous Lupus Erythematosus; Dehydration; Depressed Mood; Depression; Diarrhoea; Fatigue; Gastritis; Gastroenteritis Viral; Grip Strength Decreased; Headache; Hot Flush; Limb Discomfort; Multiple Sclerosis Relapse; Nausea; Rash; Spinal Pain; Toothache; Vision Blurred; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Aubagio			S	Oral	7 Mg, Qd		Not Reported
	Aubagio			S	Oral	14 Mg, Qd		Not Reported
	Cymbalta			C		Unk		Not Reported
	Cymbalta			C				Not Reported
	Ritalin			C		Unk		Not Reported
	Orsythia			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Cyanocobalamin			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Trazodone			C				Not Reported
	Zanaflex			C		Unk		Not Reported
	Carbamazepine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471519	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001042			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471549	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553830		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471598	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1192454		25 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Hidroxicloroquina			S	Unknown			Teva
	Deflazacort			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471689	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1190410			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 4 Every 1 Week		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	15 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	12 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	40 Milligram Daily; 10 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	17.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	10 Mg, 4 Every 1 Week		Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014443		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Baclofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472124	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472131	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1057		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Meloxicam			C	Unknown					Not Reported
	Sulfasalazine			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557127		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472233	EXPEDITED (15-DAY)		HO	CA-ROCHE-2556500		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tacrolimus	S	Unknown	6.0 Dosage Forms		Not Reported
	Tacrolimus	S	Unknown	5.0 Dosage Forms		Not Reported
	Prednisone	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472274	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1190487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness	Ibuprofen			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Aleve			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472279	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1069			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557159		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Rituxan			S	Intravenous drip			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17473105	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		30 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17473784	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2016M1049280		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17476461	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020086707		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17479336	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2020M1022918		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17480167	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-06411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

	Prednisone	S	Unknown	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Levothyroxine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	13667464	EXPEDITED (15-DAY)		OT	CA-ROCHE-1950692		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 10 Months		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 2 Years		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	15384083	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Off Label Use; Rheumatoid Arthritis; Stridor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16064781	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05865		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Acetazolamide			S	Unknown	Unknown		Not Reported
	Acetazolamide			S				Not Reported
	Alendronic Acid			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Calcium Carbonate			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Leflunomide	S				Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Calcium	S	Unknown	Unknown		Not Reported
	Alendronate Sodium	S	Unknown	Unknown		Not Reported
	Alendronate	C	Unknown	Unknown		Not Reported
	Alendronate	C	Unknown	Unknown		Not Reported
	Calcium	C	Unknown	Unknown		Not Reported
	Cyclosporin A	C	Unknown	Unknown		Not Reported
	Cyclosporine	C	Unknown	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown	Unknown		Not Reported
	Iron	C	Unknown	Unknown		Not Reported
	Mtx	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16079923	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported

Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular, Unknown		Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown		Not Reported
	Triamcinolone Acetonide	S				Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous, Unknown		Not Reported
	Naproxen	S	Unknown	Unknown		Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Triamcinolone	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16082145	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06072			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S			Not Reported

	Triamcinolone Acetonide			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16481525	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-16011		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer;	Infliximab			S	Oral	Unknown		Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Apo-Ibuprofen			S	Oral	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Ibuprofen			S	Oral			Not Reported

Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Oral	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
Stelara	S	Subcutaneous	Unknown, Solution	Not Reported
Sulfasalazine	S	Endocervical	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Delayed Release Capsule	Not Reported
Dexilant	C	Unknown	Unknown	Not Reported
Dexilant	C	Oral	Unknown	Not Reported
Febuxostat	C	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Mogadon	C	Oral		Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported

	Oxycodone	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Uloric	C	Unknown			Not Reported
	Uloric	C	Unknown			Not Reported
	Uloric	C	Oral	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown		Not Reported
	Alendronate Sodium	C	Unknown			Not Reported
	Alendronate Sodium	C	Unknown			Not Reported
	Ciclosporin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17345827	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-02545		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Allopurinol			S	Unknown	Unknown		Not Reported
	Amitriptyline			S	Unknown	Unknown		Not Reported
	Amitriptyline			S	Unknown	Unknown		Not Reported
	Amitriptyline Hydrochloride/Perphenazine			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Diclo			S	Unknown	Unknown, Tablet (Enteric Coated)		Not Reported
	Apo-Diclofenac			S	Topical	Unknown, Solution Topical		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Deformity	Arthrotec	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown, Capsule, Hard	Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Celecoxib	S			Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Misoprostol	S	Unknown	Unknown	Not Reported
	Naprosyn	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Nifedipine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Pregabalin	S	Unknown	Unknown	Not Reported

					Pregabalin		S	Unknown	Unknown	Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown	Unknown	Not Reported
					Winpred		S	Unknown	Unknown	Not Reported
					Xeljanz		S	Oral		Not Reported
					Xeljanz		S	Unknown		Not Reported
					Xeljanz		S	Oral		Not Reported
					Apo-Amitriptyline		S	Unknown	Unknown	Not Reported
					Diclofenac Potassium		S	Unknown	Unknown	Not Reported
					Tofacitinib		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559556		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477176	EXPEDITED (15-DAY)		DS	CA-ROCHE-2557988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Indometacin	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Simponi			S	Subcutaneous				Not Reported
		Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477277	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557130		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Infection	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557849		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	3.0 Months		Not Reported
	Enbrel			S	Subcutaneous	8.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	14.0 Years		Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported
		Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477823	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06466			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477873	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06742			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown (Solution Subcutaneous)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Unknown (Suspension Intra-Articular)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477939	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-06751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Arava			S	Oral	Unknown		Not Reported

Arava	S			Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Azathioprine	S			Not Reported
Ciclosporin	S	Unknown	Unknown	Not Reported
Ciclosporin	S			Not Reported
Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe, Solution Subcutaneous	Not Reported
Cimzia	S			Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S			Not Reported
Gold	S	Unknown	Unknown	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Humira	S			Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S			Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S			Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17479823	EXPEDITED (15-DAY)		OT	NVSC2020AU053402		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Xolair			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	13058844	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015725		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; Fracture; General Physical Health Deterioration; Hepatitis; Immobile; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Celecoxib			S	Unknown	Unk		Apotex
	Risedronate			S	Unknown	Unk		Apotex
	Risedronate			S	Oral	Unk		Apotex
	Sulfasalazine			S	Oral	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	50 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actonel			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	Unk, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prolia			S	Subcutaneous	Unk		Not Reported
	Prolia			S				Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk, Q.Wk.	Not Reported
	Methotrexate		S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Prednisolone Sodium Phosphate		S	Unknown	Unk	Not Reported
	Prednisolone Sodium Phosphate		S	Ophthalmic	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Cyclobenzaprine		C	Unknown	10 Mg, Unk	Not Reported
	Desoximetasone		C	Unknown	5 Mg, Qd	Not Reported
	Desoximetasone		C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide		C	Unknown	Unk	Not Reported
	Prednisone Acetate		C	Unknown	5 Mg, Qd	Not Reported
	Tylenol /00020001/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	15624942	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557652-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Cyclical		Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Sulfasalazine	C				Not Reported
	Wellbutrin	C	Oral	Modified-Release Tablet		Not Reported
	Xeljanz	C				Not Reported
	Bupropion	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	15674122	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573619-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	16156564	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2731999-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Xeljanz			S	Oral				Not Reported
		Plaquenil			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	17223599	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015738		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (Once In Every Two Moths)		Not Reported
	Humira			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	17480680	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06782			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug	Etanercept			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Unknown		Not Reported

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; Off Label Use; Respiratory Arrest; Visual Impairment	Enbrel			S	Subcutaneous		Not Reported
	Celebrex			S	Oral	Unknown	Not Reported
	Celecoxib			S	Oral	Unknown	Not Reported
	Methotrexate			S	Oral		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia			S	Subcutaneous	Unknown	Not Reported
	Plaquenil			S	Oral		Not Reported
	Prednisone			S	Unknown	Unknown	Not Reported
	Prednisone			S			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine			S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	15848950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633442-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17009894	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2019479538			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Sepsis; Respiratory Failure; Septic Encephalopathy	No Subject Drug			S		No Dose Given		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S		1000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Erelzi			S	Unknown	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		250 Mg, Unk		Not Reported
	Hydroxychloroquine			S		250 Mg, Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported

	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481109	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1193239		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Prednisolone			S	Unknown	Initial Dose Not Stated		Actavis
	Prednisolone			S	Unknown	20 Milligram Daily; The Dose Was Tapered Further		Actavis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cefradine			C	Unknown			Not Reported
	Amoxicillin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481183	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1070		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Arthralgia; Chills; Diarrhoea; Drug Ineffective; Fatigue; Heart Rate Increased; Liver Function Test Increased; Nausea; Ovarian Cyst; Ovulation Pain; Pain; Pyrexia; Quality Of Life Decreased; Rash; Uterine Cyst; Vomiting; Wheelchair User; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Benadryl			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481185	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1065		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Musculoskeletal Disorder; Therapeutic Response	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Decreased		Sulfasalazine			S	Unknown				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481186	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481193	EXPEDITED (15-DAY)		OT	US-HETERO-HET2020US00241		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Oseltamivir			S	Unknown			Hetero
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555253		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Wrist Deformity	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Naproxen			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482343	EXPEDITED (15-DAY)		DE, HO, OT	US-DRREDDYS-USA/USA/20/0120229		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Dyspnoea; Hypotension; Hypoxia; Pulmonary Oedema; Toxicity To Various Agents	Ibuprofen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482346	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482499	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020086129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Other	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483464	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1021060		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Warfarin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	High Dose		Not Reported
	Rivaroxaban			S	Unknown	Unk		Mylan
	Apixaban			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483713	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA054572			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported

	Enbrel	S	Unknown	Unk		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Plaquenil	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483715	EXPEDITED (15-DAY)		LT	NVSC2020CA054458		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis	Ilaris			S	Subcutaneous	Unk (Single Use Vial)		Novartis
	Ilaris			S	Subcutaneous	Unk (Single Use Vial)		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported

	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk (Tablet)	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Endocervical	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Powder For Solution)	Not Reported
	Rituxan	S	Unknown	Unk (Solution Intravenous)	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483909	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA054590			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Ilaris			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous	Unk, Solution		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone	S	Unknown	10.0 Mg	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk, Solution Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Unk, 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Unknown	500.0 Mg	Not Reported
	Xeljanz	S	Oral	Unk, 2 Every 1 Days	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17484426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559700		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

		Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17484491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559508		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485303	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06944		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

						otherwise specified)			
		Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
		Actemra			S	Intravenous (not otherwise specified)			Not Reported
		Apo-Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485752	EXPEDITED (15-DAY)		OT	US-EMCURE PHARMACEUTICALS LTD-2020-EPL-000218			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus-Like Syndrome; Maternal Exposure During Pregnancy	Hydralazine Hydrochloride			S		10 Milligram Per Day		Heritage
	Hydralazine Hydrochloride			S		60 Milligram Per Day		Heritage
	Hydrochlorothiazide			S		Unk		Heritage
	Meloxicam			S		15 Milligram Daily		Heritage
	Meloxicam			S				Heritage
	Sulfasalazine			S		2 Gram, Bid		Heritage
	Sulfasalazine			S				Heritage
	Dicloxacillin			S		500 Milligram, Three Doses Over A 12-Hour Period		Not Reported
	Hydroxychloroquine			S		400 Milligram Per Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S		7.5 Milligram Daily		Not Reported
	Prednisone			S		20 Milligram Daily		Not Reported
	Naproxen			C		Daily		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485880	EXPEDITED (15-DAY)		OT	CA-CANTON LABORATORIES, LLC-2081207		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Naprosyn	S	Unknown	Canton Laboratories
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	11999787	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1618751		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cough; Drug Hypersensitivity; Fatigue; Fatigue; Immune System Disorder; Infusion Related Reaction; Nasopharyngitis; Oxygen Saturation Decreased; Oxygen Saturation Decreased; Pneumonia; Pneumonia Fungal; Pyrexia; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Rosuvastatin			C				Not Reported
	Aas			C				Not Reported
	Perindopril			C				Not Reported
	Dexilant			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported

	Actonel	C	Not Reported
	Methotrexate	C	Not Reported
	Hydroxychloroquine	C	Not Reported
	Docusate	C	Not Reported
	Hydromorphone	C	Not Reported
	Calcium	C	Not Reported
	Clonazepam	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	12770684	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076867		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	1 Dosage Form, Qwk		Bristol Myers Squibb
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Actemra			S	Oral			Not Reported
	Nortriptyline Hydrochloride			S	Oral	10 Milligram, Qh		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q3wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported

In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Celecoxib	S	Oral		Not Reported
	Apo Celecoxib	S	Oral		Not Reported
	Xeljanz	S	Oral	5 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Fentanyl Matrix	S	Unknown		Not Reported
	Nortriptyline Hydrochloride;Perphenazine	S	Oral	10 Milligram, Qd, Cyclical	Not Reported
	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Aclasta	C	Unknown	488 Milligram, Qmo	Not Reported
	Actonel	C	Unknown	36 Mg, Qwk	Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Biotin	C	Unknown		Not Reported
	Calcium	C	Unknown	Unk Unk, Qd	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
	Diphenoxylate Hydrochloride And Atropine Sulfate	C	Unknown		Not Reported
	Diphenoxylate Hcl	C	Unknown	2.5 Milligram, Qd	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk, Qd	Not Reported
	Epa Dha 720	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, 2 Every 1 Day	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ferrous Fumarate	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Fish Oil	C	Unknown	1200 Milligram, Bid	Not Reported
Folic Acid	C	Unknown		Not Reported
Genteal [Hypromellose]	C	Ophthalmic	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
Loperamide	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	40 Mg, Bid	Not Reported
Vitamin B3	C	Unknown		Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Oxycodone And Acetaminophen	C	Unknown		Not Reported
Oxycodone Terephthalate	C	Unknown		Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram, Qd	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Q2h	Not Reported
Pyridoxine	C	Unknown		Not Reported
Retinol Palmitate	C	Unknown		Not Reported
Riboflavin	C	Unknown		Not Reported
Thiamine Hcl	C	Unknown		Not Reported
Thiamine Mononitrate	C	Unknown		Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Cyclical	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qh	Not Reported
Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C	Unknown		Not Reported

	Tylenol	C	Oral	1000 Mg, Qd	Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Vitamin A [Retinol]	C	Unknown		Not Reported
	Vitamin B12 [Cyanocobalamin]	C	Unknown		Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	400 Dosage Form, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Fergon	C	Unknown	300 Milligram, Qd	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
	Multivitamin [Ascorbic Acid;Biotin;Calcium Pantothenate;Cyanocobalamin	C	Unknown		Not Reported
	Omega 3 2100	C	Unknown	1200 Milligram, Bid	Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]	C	Unknown	1 Dosage Form, As Required	Not Reported
	Pyridoxine Hydrochloride	C	Unknown		Not Reported
	Tecta	C	Unknown	40 Milligram, Qd	Not Reported
	Vitamin B1 [Thiamine]	C	Unknown		Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown		Not Reported
	Acetaminophen	C	Oral	1000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	13903125	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP016854		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain;	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Ramipril			S	Unknown	1 Df, Qd		Apotex
	Ramipril			S	Unknown	Unk Every One Day		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	7 Mg, Qd		Not Reported

Rheumatoid Arthritis; Sciatica; Treatment Failure	Prednisone	S	Unknown	7 Mg, Unk Every One Day	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Apotex
	Dorzolamide ,Timolol	S	Ophthalmic	Unk	Apotex
	Dorzolamide ,Timolol	S	Unknown	Unk, Bid	Apotex
	Dorzolamide ,Timolol	S	Ophthalmic	Unk, Bid	Apotex
	Dorzolamide ,Timolol	S	Ophthalmic	Unk	Apotex
	Dorzolamide ,Timolol	S	Ophthalmic	2 Df, Qd	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	600 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Levothyroxine	S	Unknown	Unk Unk, Qd	Not Reported
	Levothyroxine	S	Unknown	Unk Every One Day	Not Reported
	Levothyroxine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Cosopt	S	Unknown	Unk, Bid	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Acetaminophen With Codeine	C	Unknown	Unk As Required	Not Reported
	Acetaminophen, Caffeine And Dihydrocodeine Bi	C	Unknown		Not Reported

	Dorzolamide Hydrochloride W/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported
	Plaquenil /00072602/	C	Unknown	400 Mg, Qd	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
	Tylenol With Codein /00116401/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	15855790	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633737-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	16719246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892951-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17222231	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2019M1131972		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Mylan
	Exemestane			S	Unknown	Unk		Mylan
	Exemestane			S		Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Ramipril			S	Unknown	Unk		Mylan
	Ramipril			S	Unknown	Unk		Mylan

Levothyroxine Sodium	S	Unknown	Unk	Mylan
Lansoprazole	S	Unknown	Unk	Mylan
Lansoprazole	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Belimumab	S	Unknown	Unk	Mylan
Azathioprine	S	Unknown	Unk	Mylan
Azathioprine	S	Unknown	Unk	Mylan
Prednisolone	S	Unknown	Unk	Mylan
Prednisolone	S	Unknown	Unk	Mylan
Thyroxine	S	Unknown	Unk	Mylan
Thyroxine	S	Oral	Unk	Mylan
Hydroxychloroquine Sulfate	S	Unknown	Unk	Mylan
Dicumarol	C	Unknown	Unk	Mylan
Dicumarol	C	Unknown	Unk	Mylan
Dicumarol	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17226111	EXPEDITED (15-DAY)		OT	CA-INTERCEPT-PMOCA2018001237		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Alkaline Phosphatase Abnormal; Decreased Appetite; Fatigue; Gamma-Glutamyltransferase Increased; Malaise; Nausea; Therapy	Ocaliva			S	Oral	5 Mg, Qd		Intercept Pharmaceuticals
	Ursodiol			S		750 Mg, Qd		Not Reported
	Ursodiol			S		750 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported

Interrupted; Weight Decreased; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17466040	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555235			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17485751	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001128			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17485790	EXPEDITED (15-DAY)		OT	AU-ROCHE-2560432		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Xolair			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486058	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Form: Solution.		Not Reported
	Depo-Medrol			C	Other	Form: Suspension Intraarticular		Not Reported
	Depo-Medrol			C	Other			Not Reported

Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Diclofenac	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown	Tablet (Entericcoated)		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486321	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-006133			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk, Tablet		Concordia
	Arava			S	Oral	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Intra-articular	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486336	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201801-000172			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk Unk, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	25 Mg, Monthly (Q4w)		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S		25 Mg, Weekly		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Etanercept			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486441	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2558002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486453	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191742			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

		Humira			S	Subcutaneous				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported
		Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486497	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560384		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486594	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1128		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Humira			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Losartan			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486971	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238900		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Hydroxychloroquine			S	Unknown			Sun
	Prednisolone			S	Unknown	60 Milligram		Taro
	Prednisolone			S				Taro
	Mycophenolate			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487663	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020089097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported
	Mycophenolate			S		1 G, 2x/Day		Not Reported
	Myfortic			S		Unk		Not Reported
	Prednisone			S		Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487715	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020092939			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487719	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020091248		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487720	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020093003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate Sodium			S		Unk, 1x/Day		Pfizer
	Anakinra			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Orencia			S				Not Reported

	Prednisone			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487793	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020091022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17495298	EXPEDITED (15-DAY)		DE, OT	US-FRESENIUS KABI-FK202002123		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolic Stroke; Endocarditis; Thrombocytopenia; Whipple'S Disease	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	14746343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009150		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Risedronate			S	Unknown	Unk		Apotex

Disease; Malaise; Mass; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Risedronate	S	Oral	35 Mg, Q.Wk.		Apotex
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Novo-Rythro	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	200 Mg, Bid		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	4000 Iu, Qd		Not Reported
	Marijuana	C	Unknown	Unk		Not Reported
	Risedronate	C	Oral	35 Mg, Q.Wk.		Not Reported
	Wellbutrin	C	Unknown	Unk		Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd		Not Reported
	Bupropion	C	Unknown	300 Mg, Qd		Not Reported
	Cannabis Sativa	C	Unknown	Unk, Unknown		Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15207176	EXPEDITED (15-DAY)		OT	PHHY2018GB052187		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Levothyroxine			S	Unknown	75 Mg, Qd		Not Reported
	Domperidone Maleate			S	Unknown	10 Mg, Tid		Not Reported
	Prednisolone Acetate			S	Unknown	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

	Immunoglobulin I.V	S	Unknown	Unk		Not Reported
	Creon	S	Unknown	10 Mg, Tid		Not Reported
	Lansoprazole	S	Unknown	30 Mg, Qd		Not Reported
	Uniphyllin	S	Unknown	200 Mg, Bid		Not Reported
	Carbocisteine	S	Unknown	2 Df, Qd		Not Reported
	Carbocisteine	S	Unknown	750 Mg, Bid		Not Reported
	Risedronate	S	Unknown	35 Mg		Not Reported
	Amylase	S	Unknown	10 Mg, Tid		Not Reported
	Propanolol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15320874	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018341914		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Joint Warmth; Localised Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15619748	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555750-00		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported

Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15735711	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2595527-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15849613	EXPEDITED (15-DAY)		OT	CA-SA-2019SA012286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Humira			S		40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S		Unk		Not Reported
	Prednisone			C				Not Reported
	Arava			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	16752576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2456918-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Joint Swelling;	Humira 40mg/0.8ml			S	Subcutaneous	Frequency- Cyclical		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Knee Operation; Musculoskeletal Stiffness; Off Label Use; Product Use Issue; Psoriasis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Salmeterol/Fluticason	C	Respiratory (inhalation)	250-50 Mcg		Not Reported
	Levothyroxine Sodium	C	Oral			Not Reported
	Alprazolam	C	Oral	Prn		Not Reported
	Prednisone	C				Not Reported
	Celebrex	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17395555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007224		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Q.H.		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk, Cyclical		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qid		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Q.H.		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Q.Wk.		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk, Cyclical		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex

Hydroxychloroquine	S	Unknown	Unk	Apotex
Actemra	S	Intravenous (not otherwise specified)	8 Df, Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	300 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk, Cyclical	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Oral	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17484448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559662		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Cyclosporine			C	Unknown			Not Reported
	Depo-Provera			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17490734	EXPEDITED (15-DAY)		OT	IT-LAURUS LABS LIMITED-202000070		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome; Off Label Use	Hydroxychloroquine			S	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560163		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491499	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560158		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491788	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491790	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005553			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Visual Impairment	Hydroxychloroquine			S	Oral	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Simponi			C		Unk		Not Reported
	Inflectra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559690		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Cimzia	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492138	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559679		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492232	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001950			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	Unk Unk, Weekly	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	640 Mg,	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Certolizumab	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis;	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Weight Increased	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492506	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Naproxen Sodium			S	Oral	500 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492547	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202002000969			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492862	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493033	EXPEDITED (15-DAY)		HO	CA-ROCHE-2555409		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493052	EXPEDITED (15-DAY)		DS	CA-ROCHE-2560161		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Bupropion			C	Unknown	Not Reported
	Esomeprazole			C	Unknown	Not Reported
	Folic Acid			C	Unknown	Not Reported
	Levothyroxine			C	Unknown	Not Reported
	Naproxen			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493140	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Methotrexate			S	Oral				Not Reported
		Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493887	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1192504		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17494074	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2020-US-1193378		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Drug Ineffective; Overdose; Pulmonary Oedema; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	6 G Missing		Not Reported
	Ibuprofen			S	Oral			Actavis
	Epinephrine			S	Unknown			Teva
	Naproxen			S	Oral			Teva
	Potassium			S	Unknown			Actavis
	Norepinephrine			S	Unknown			Teva
	Sodium Bicarbonate			S	Unknown	Drips		Not Reported

		Calcium			S	Unknown				Not Reported
		Dextrose-50			S	Unknown				Not Reported
		Vasopressin			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17494702	EXPEDITED (15-DAY)		DE, OT	IN-APPCO PHARMA LLC-2081256		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Death; Nocardiosis; Septic Shock; Shunt Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17497976	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-016630		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17498115	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17498463	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form- Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form- Suspension Intra-Articular		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	13950566	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-080121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	14310480	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Unevaluable Event; Vomiting	Cimzia			S	Subcutaneous	Solution		Not Reported
	Actemra			S		162 Milligram		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Once Daily (Qd)		Not Reported
	Gold			C				Not Reported
	Plaquenil			C		Unk		Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			S		400 Milligram		Not Reported
	Prednisone			C		15 Milligram, Once Daily (Qd)		Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	14956006	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2017-		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Adalimumab	S			Not Reported
	Abatacept	S	Intravenous drip		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
	Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported

Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Triamcinolone Aq	S	Unknown	Unknown	Not Reported
Apo-Triamcinolone Aq	S	Unknown	Spray Metered Dose	Not Reported
Apo-Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Unknown	Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported

Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown. Solution	Not Reported
Humira	S	Unknown	Unknown	Not Reported

	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Kineret	S	Subcutaneous	Per Syringe Single-Use, Preservative-Free Pre-Filled Syringes, Solution Subcutaneous		Not Reported
	Kineret	S				Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
	Triamcinolone Hexacetonide	S				Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	15635243	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105931			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Off Label Use; Product Label Confusion; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Phosphate]					
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Enbrel	C	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Etanercept	S	Unknown			Not Reported
	Tocilizumab	S	Unknown	160 Milligram		Not Reported
	Cimzia	C	Subcutaneous			Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	15814007	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018375765			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Chronic Obstructive Pulmonary Disease; Haemorrhoids; Mucosal Inflammation; Rheumatoid Arthritis; Transaminases Increased; Weight Decreased	No Subject Drug			S		No Dose Given		Not Reported
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Unk, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Unk, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Leflunomide			S		10 Mg, Unk		Not Reported
	Leflunomide			S		10 Unk, Unk		Not Reported

	Leflunomide	S	10 Mg, Unk	Not Reported
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Roactemra	S	162 Mg, Unk	Not Reported
	Erelzi [Etanercept]	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	16471647	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15759		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease; Off Label Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

Esomeprazole	C	Unknown			Not Reported
Lumigan Rc	C	Ophthalmic	Unknown		Not Reported
Nexium	C	Unknown	Unknown		Not Reported
Suphedrine	C	Unknown			Not Reported
Trazodone	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Wellbutrin Xl	C	Unknown	Extended Release		Not Reported
Wellbutrin Xl	C	Unknown			Not Reported
Esomeprazole Sodium	C	Unknown	Unknown		Not Reported
Acetaminophen	C	Unknown			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	16480475	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201804782			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Arthritis; Back Pain; Blood Cholesterol Abnormal; Blood Sodium Increased; Blood Uric Acid Increased; Chest Pain; Depression; Dizziness; Eye Haemorrhage; Fatigue; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Hypertension; Hypoaesthesia; Immune System Disorder; Infection; Influenza; Insomnia; Malaise;	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Unknown	40 Units/1 Ml		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units / 0.5 Ml, 1 Time Weekly, Sunday		Mallinckrodt

Memory Impairment; Menorrhagia; Mental Fatigue; Mobility Decreased; Mood Altered; Muscle Spasms; Muscular Weakness; Nausea; Nervousness; Pain; Pain In Extremity; Pallor; Papilloedema; Poisoning; Polymenorrhoea; Product Dose Omission; Proteinuria; Renal Impairment; Sciatica; Sensitivity To Weather Change; Somnolence; Stress; Systemic Lupus Erythematosus; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 1 Time Weekly, Sunday		Mallinckrodt
	Plaquenil	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	5 Mg, Unk		Not Reported
	Prednisone	C	Unknown	Unk, Every Other Day		Not Reported
	Prednisone	C	Unknown	Unk, Once A Day		Not Reported
	Cellcept	C	Unknown	Unk		Not Reported
	Benlysta	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17388691	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP006368		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Back Pain; Constipation; Dactylitis; Diarrhoea; Disability; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Inappropriate Schedule Of Product Administration; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Loss Of	Amitriptyline			S	Unknown	Unk, Unknown		Apotex
	Allopurinol			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Clonazepam			C	Unknown	1 Mg, Unk		Not Reported

Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Psoriasis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Ergocalciferol	C	Unknown	4000 Iu, Qd		Not Reported
	Flaxseed Oil	C	Unknown	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	D-Alpha Tocopherol	C	Unknown	Unk, Unknown		Not Reported
	Linum Usitatissimum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	7412801	EXPEDITED (15-DAY)		OT	TR-SANOFI-AVENTIS-2010SA030554		57 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Visual Acuity Reduced; Visual Impairment	Hydroxychloroquine			S	Unknown	200 Mg,Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17498943	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238987		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499155	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3300813-00		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Multimorbidity; Off Label Use; Product Use Issue;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Synovitis	Hydroxychloroquine			S	Unknown					Not Reported
	Azathioprine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499291	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-005903			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	50 Die		Not Reported
	Azathioprine			C		Unk		Not Reported
	Imuran			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499294	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1188			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499295	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499478	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000125			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown		Concordia
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Concordia
	Hydroxychloroquine	S	Unknown		Concordia
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly, (Qow)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Weekly (Q4w)	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Powder And Solution For Solution For Injection	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Myocrisin	S	Unknown	Unk	Not Reported
	Arava	C		20 Mg, Qd	Not Reported
	Arava	C		Unk	Not Reported
	Ativan	C			Not Reported
	Dilaudid	C			Not Reported
	Enablex	C			Not Reported
	Lasix	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C			Not Reported
	Omnaris	C			Not Reported
	Pantoloc	C			Not Reported
	Synthroid	C			Not Reported
	Vagifem	C			Not Reported
	Abatacept	C			Not Reported
	Rituxan	C			Not Reported
	Kineret	C			Not Reported
	Benadryl Allergy	C			Not Reported
	Cortisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Diphenhydramine	C			Not Reported
	Plantago Ovata	C			Not Reported
	Actemra	C			Not Reported

	Sodium Aurothiomalate			C						Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499831	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Haemorrhage	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Erelzi			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500067	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559521		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500766	EXPEDITED (15-DAY)		OT	US-ZYDUS-048013		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema; Macule; Pain Of Skin; Skin Plaque; Varicella Zoster	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown			Zydus Pharm

Virus Infection	Prednisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501274	EXPEDITED (15-DAY)		DE, LT, OT	US-STRIDES ARCOLAB LIMITED-2020SP002142		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Crying; Dyspnoea; Hypotension; Oxygen Saturation Decreased; Pulmonary Oedema; Pupil Fixed; Salivary Hypersecretion	Ibuprofen			S	Oral	Unk, (Tablets)		Strides
	Naproxen			S	Oral	Unk, (Tablets)		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501565	NON-EXPEDITED			US-PFIZER INC-2020097824		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Phenobarbital			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501605	NON-EXPEDITED			US-PFIZER INC-2020097853		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer

	Azulfidine	S	Unk	Pfizer
	Phenobarbital	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17504725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1193099		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17504736	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1193102		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Amoxicillin Sodium;Clavulanate Potassium		C	Unknown		Not Reported
	Amoxil [Amoxicillin]		C	Unknown		Not Reported
	Bacillus Calmetteguerin Bcg		C	Intravenous (not otherwise specified)		Not Reported
	Leflunomide		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	13103523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876554		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Lyrica	S	Oral			Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown			Not Reported
	Apo Mycophenolate	S	Unknown			Not Reported
	Mycophenolate	S	Unknown			Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Cimzia	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Piroxicam	C				Not Reported
	Leflunomide	C				Not Reported
	Morphine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	14767196	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018049244		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	15067533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product	Leflunomide			S	Unknown	Unk		Apotex
	Rituximab			S	Unknown	Unk		Not Reported

Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown	Unk	Not Reported
	Celebrex			S	Unknown	Unk	Not Reported
	Enbrel			S	Unknown	Unk	Not Reported
	Methotrexate			S	Unknown	Unk	Not Reported
	Orencia			S	Unknown	Unk	Not Reported
	Rituxan			S	Unknown	Unk	Not Reported
	Plaquenil /00072602/			S	Unknown	Unk	Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk	Not Reported
	Loperamide			C	Oral	Unk	Not Reported
	Pantoprazole			C	Unknown	Unk, Tid	Not Reported
	Xeljanz			C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	15076376	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015960		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Etanercept			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Citalopram			C	Unknown	20 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd		Not Reported
	Losec /00661201/			C	Unknown	20 Mg, Qd		Not Reported
	Naprosyn /00256201/			C	Unknown	500 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16284325	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019016961		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Unk		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Methotrexate			S		10 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Prednisone			C		10 Milligram		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16519993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017276980		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16600153	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068088		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil S			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

Viral Upper Respiratory
Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16838640	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-27173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Subcutaneous	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Arava			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17142317	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2019051903		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Cimzia			S	Subcutaneous	Solution		Not Reported
	Alendronate Sodium			S		70 Milligram, 4x/Week		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S		60 Milligram, 2x/Day (Bid)		Not Reported
	Apremilast			S		Unk		Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Infliximab			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S		70 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		12 Milligram, 4x/Week		Not Reported
	Methotrexate			S		17.5 Milligram, 4x/Week		Not Reported
	Methotrexate			S		10 Milligram, 4x/Week		Not Reported
	Methotrexate			S		15 Milligram, Weekly (Qw)		Not Reported

Methotrexate	S		12.5 Milligram, 4x/Week	Not Reported
Motrin [Ibuprofen]	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Once Daily (Qd)	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Orencia	S		Unk	Not Reported
Orencia	S			Not Reported
Otezla	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)	Not Reported
Simponi	S	Subcutaneous	Solution	Not Reported
Stelara	S	Subcutaneous	Solution	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S		360 Milligram	Not Reported
Tocilizumab	S		680 Milligram	Not Reported
Enbrel	S		25 Milligram, 2x/Week	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S			Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C			Not Reported
Colchicine	C		Unk	Not Reported
Dexilant	C			Not Reported
Febuxostat	C			Not Reported
Folic Acid	C			Not Reported
Gravol	C		Unk	Not Reported
Mogadon	C			Not Reported
Nitrazepam	C			Not Reported
Oxycodone	C			Not Reported
Prednisone	C		Unk	Not Reported
Uloric	C			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17370536	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2020047226		51 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection	Sulfasalazine			S		Unk		Pfizer
	Trexan			S		Unk		Pfizer
	Oxiklorin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17405600	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspepsia; Eczema; Nodule; Psoriatic Arthropathy; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Otezla			S	Oral	60 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17456605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007874		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Meloxicam			S	Unknown	15 Mg, Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	20 Mg, Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	100 Mg, Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

	Plaquenil /00072602/			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17505326	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000222			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Dysgeusia; Fluid Retention; Lower Respiratory Tract Infection; Musculoskeletal Pain; Pain In Extremity	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Folic Acid			S	Unknown	1 Mg, Qd		Not Reported
	Meloxicam			S	Unknown	15 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17505473	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193773			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Increased; Coeliac Disease; Discomfort; Malaise; Nausea; Pain	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17506038	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1207			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Psoriasis	Humira			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17506284	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin;Clavulanate Potassium			C				Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17507539	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-175043		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction; Off Label Use	Methotrexate			S	Subcutaneous			Accord
	Dolquine			S	Oral	Strength: 200 Mg, 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17508707	EXPEDITED (15-DAY)		HO, OT	IT-IPCA LABORATORIES LIMITED-IPC-2020-IT-000811			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563624		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509657	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1023932		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Hydroxychloroquine			S	Unknown			Not Reported

Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methylprednisolone		S	Unknown	Mylan
	Celecoxib		C	Unknown	Mylan
	Cyclobenzaprine		C	Unknown	Mylan
	Immunoglobulin /07494701/		C	Intravenous (not otherwise specified)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509914	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06905		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic;	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported

	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17510338	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197076		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Sulfasalazine		S	Unknown	2000 Milligram Daily;	Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17511324	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198114		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563594		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Methotrexate			S	Subcutaneous				Not Reported
		Minocycline			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563684		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563709		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514081	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514088	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Arthritis	Rituxan			S	Intravenous (not otherwise specified)	Not Reported
	Enbrel			S	Unknown	Not Reported
	Humira			S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Methotrexate			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine			S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Not Reported
	Desoximetasone			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514090	EXPEDITED (15-DAY)		DS	CA-ROCHE-2563708		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564021		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563829		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2020	17511813	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-010743			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombotic Stroke; Transient Ischaemic Attack	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2020	16749699	EXPEDITED (15-DAY)		OT	PHHY2019DE192163			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Not Reported
	Ramipril			S				Not Reported
	Omeprazole			S	Oral	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Novartis
	Omeprazole			S				Novartis
	Sildenafil			S	Unknown	60 Mg, Qd		Not Reported
	Eliquis			S	Unknown	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Not Reported
	Eliquis			S	Unknown	2.5 Mg, Bid		Not Reported
	Lyrica			S	Unknown	3 Df, Qd 1 Dosage Form, Tid (1-1-1)		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd (15 (Unit Unspecified)		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Quensyl			S	Unknown	2 Df, Qd 1 Dosage Form,		Not Reported

						Bid (1-0-1)			
	Roactemra			S	Unknown	162 Mg, Qwk			Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qwk			Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qwk			Not Reported
	Volibris			S	Unknown	Unk			Not Reported
	Volibris			S	Oral	1 Df, Qd			Not Reported
	Volibris			S	Oral	30 Mg, Qd			Not Reported
	Ambrisentan			S	Unknown	30 Mg, Qd			Not Reported
	Ambrisentan			S	Unknown	1 Df, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	13053105	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870952		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15332459	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176746		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15438204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported

	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Sulfasalazine		C	Unknown	Dosage Form: Not Specified	Not Reported
	Wellbutrin		C	Unknown		Not Reported
	Xeljanz		C	Unknown	Tablet Extended Release	Not Reported
	Bupropion		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15841668	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018134129		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported

Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Clindamycin Hcl	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Atenolol	C		Unk	Not Reported
	Colchicine	C		Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported

	Leucovorin [Folinic Acid]	C		Unk	Not Reported
	Levothyroxine Sodium	C		Unk	Not Reported
	Ranitidine	C		Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	16242893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1269		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Enzyme Increased; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Losartan Potassium			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported

Cephalexin Monohydrate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Lopressor	S	Unknown	Not Reported
Penicillin G	S	Unknown	Not Reported
Penicillin G (2-Amino-4-Methoxy-6-Methylpyrim)	S	Unknown	Not Reported
Plaquenil S	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Biaxin	S	Unknown	Not Reported
Cephalexin	S	Unknown	Not Reported
Clindamycin Hydrochloride	S	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Colchicine	C	Unknown	Not Reported
Coversyl	C	Unknown	Not Reported
Leucovorin	C	Unknown	Not Reported
Levothyroxine Sodium	C	Unknown	Not Reported
Ranitidine	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Iron Sucrose	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	16858320	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-SHIRE-SK201931249			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Maternal	Human Normal Immunoglobulin			S	Transplacental	Unk		Shire
	Human Normal Immunoglobulin			S				Shire

Exposure During Pregnancy; Oligohydramnios; Premature Baby	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S			Not Reported
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Vitamin K Nos	S			Not Reported
	Bisulepin	S	Transplacental	Unk	Not Reported
	Bisulepin	S			Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Nadroparine	S			Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental		Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S			Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S			Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S			Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S			Not Reported
	Albumin	S	Transplacental	Unk	Not Reported
	Albumin	S			Not Reported
	Paracetamol	S	Transplacental	Unk	Not Reported
	Paracetamol	S			Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Folic Acid	S			Not Reported
	Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported

Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S			Not Reported
Dicynon	S	Transplacental	Unk	Not Reported
Dicynon	S			Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Cefixime	S			Not Reported
Vitamin D [Colecalciferol]	S	Transplacental	Unk	Not Reported
Vitamin D [Colecalciferol]	S			Not Reported
Ornidazole	S	Transplacental	Unk	Not Reported
Ornidazole	S			Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Omeprazole	S			Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S			Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Fluconazole	S			Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S			Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S			Not Reported
Vulmizolin	S	Transplacental	Unk	Not Reported
Vulmizolin	S			Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
Aminomethylbenzoic Acid	S			Not Reported
Hydroxychloroquine	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17240953	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056593		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Kevzara			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Folic Acid			C				Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17462267	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002000962			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug-Induced Liver Injury; Hepatic Steatosis; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17514982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197337		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17514985	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515012	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197749		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515017	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

					Enbrel		S	Unknown		Not Reported
					Folic Acid		S	Unknown		Not Reported
					Fosamax		S	Unknown		Not Reported
					Humira		S	Subcutaneous		Not Reported
					Orencia		S	Unknown		Not Reported
					Phthalylsulfathiazole		S	Unknown		Not Reported
					Pseudoephedrine Hcl		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Rituximab		S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197995		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram Daily;		Not Reported

Zingiber Officinale	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515026	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197604		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515117	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197685		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Meningitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563785		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan	S	Intravenous drip		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515200	EXPEDITED (15-DAY)		OT	GB-MICRO LABS LIMITED-ML2020-00579		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S				Micro Labs
	Apixaban			S				Micro Labs
	Rivaroxaban			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Clopidogrel			S				Not Reported
	Warfarin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515331	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197063		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

Peripheral Swelling; Rheumatoid Arthritis	Actemra		S	Unknown		Not Reported
	Apo-Prednisone		S	Oral	5 Milligram Daily;	Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Humira		S	Subcutaneous	2 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515947	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2020SP003312		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram, Unknown		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17516183	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020100139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S				Pfizer
	Arava			S				Not Reported
	Humira			S		Once Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17516870	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517057	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243755		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Interstitial Lung Disease; Treatment Failure	Stelara			S	Subcutaneous	4.0 Years		Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mercaptopurine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Xeljanz			S	Unknown	2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517125	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517277	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001247			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17518881	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198199		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Losartan			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17518920	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001368			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519592	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1024194		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Fluoxetine	S	1 Df, Qd	Not Reported
	Plaquenil /00072602/	S	200 Mg, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519909	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cetirizine			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral	Unknown,		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown	Unknown		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Subcutaneous	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not	Unknown, Powder For		Not Reported

						otherwise specified)	Solution Intravenous		
		Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
		Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
		Sulfasalazine			S	Unknown			Not Reported
		Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519910	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07738		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

	Hydroxychloroquine Sulfate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519917	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07767		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Winpred			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519921	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown				Not Reported
Leflunomide	S	Unknown				Not Reported
Leflunomide	S	Unknown				Not Reported
Orencia	S	Unknown	Unknown			Not Reported
Rituximab	S	Unknown	Unknown			Not Reported
Simponi	S	Subcutaneous				Not Reported
Methotrexate	C	Unknown				Not Reported
Prednisone	C	Unknown				Not Reported
Xeljanz	C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519967	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001365			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519980	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001364			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519984	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001363			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During	Hydroxychloroquine			S		Unk		Concordia

Pregnancy; Premature Baby

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519985	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001362			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519989	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001367			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519991	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001366			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519999	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001369			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17520010	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001371			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17520013	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001370			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	15632273	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105425		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Methotrexate	S	Oral	25 Mg, Unk		Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Qd		Not Reported
Apo-Prednisone	S	Unknown	5 Milligram		Not Reported
Cetirizine Hydrochloride	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Unknown			Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16085204	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05925		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknwon Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16191539	EXPEDITED (15-DAY)		HO, LT, OT	JP-GLAXOSMITHKLINE-JP2019JPN049251		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aplasia Pure Red Cell; Haemolysis	Belimumab			S	Intravenous drip	400mg, Once In Every Two Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	400mg, Once In Every Four Weeks		Glaxosmithkline

	Plaquenil	S	Oral	200mg, 400mg Alternate Day	Not Reported
	Prograf	S	Oral	3 Mg, 1d	Not Reported
	Predonine Tablets	C		14 Mg, 1d	Not Reported
	Predonine Tablets	C		14 Mg, 1d	Not Reported
	Predonine Tablets	C		13 Mg, 1d	Not Reported
	Predonine Tablets	C		12 Mg, 1d	Not Reported
	Predonine Tablets	C		22 Mg, 1d	Not Reported
	Predonine Tablets	C		32 Mg, 1d	Not Reported
	Predonine Tablets	C		45 Mg, 1d	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16237399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018386187		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram, 1/Week		Pfizer
	Pantoprazole			S		Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, Bid		Pfizer
	Clindamycin Hcl			S	Unknown	Unk		Pfizer
	Lopressor			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Biaxin	S	Unknown	Unk	Not Reported
Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
Cephalexin [Cefalexin]	S		Unk	Not Reported
Enalapril	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Hctz	S	Unknown	Unk	Not Reported
Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Losartan	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S		Unk	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Enalapril Maleate	S		Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Losartan Potassium	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Atenolol	C		Unk	Not Reported
Colchicine	C		Unk	Not Reported
Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
Leucovorin [Folinic Acid]	C		Unk	Not Reported
Levothyroxine Sodium	C		Unk	Not Reported
Ranitidine	C		Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported

		Hydroxychloroquine		C	Unknown	Unk			Not Reported
		Iron Sucrose		C	Unknown	Unk			Not Reported
		Prednisone		C	Unknown	8.5 Milligram, Qd			Not Reported
		Prednisone		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16438993	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2017-04887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia; Off Label Use	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S				Not Reported
	Acetaminophen			C	Unknown	Unknown		Not Reported
	Pregabalin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16838864	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27398		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Infliximab	S	Unknown	Unknown		Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown		Not Reported
	Actemra	S	Unknown	Unknown		Not Reported
	Arava	S	Unknown	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Remicade	S	Unknown	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported
	Cephalexin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518377	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518870	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001248			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518875	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2 Every 2 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Celebrex			C	Oral	200 Milligram, Bid		Not Reported

	Hydromorphone Hydrochloride	C	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
	Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518925	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564559		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518935	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564545		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519028	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001249			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519034	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197395		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate	S	Unknown			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519069	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001250			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519160	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001398			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519161	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001397			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519188	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519189	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001392			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519200	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001394			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519203	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519483	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001381			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519484	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001380			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519489	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001379			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519490	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001389			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519495	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001383			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519498	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519533	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-07587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Actemra	S	Unknown	Unknown		Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Anakinra	S	Unknown	Unknown		Not Reported
	Apo-Naproxen	S	Unknown	Unknown		Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Solution, Unknown		Not Reported
	Humira	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Intra-articular	Unknown		Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Actemra			S	Unknown			Not Reported

Actemra	S		Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Not Reported
Hydroxychloroquine /00072603/	S		Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Plantago Ovata	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported
Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519544	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001252			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Concordia
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519545	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001253			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Pleural Effusion; Pneumonia	Hydroxychloroquine	S	Transplacental	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519551	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001254			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Rectal Haemorrhage	Hydroxychloroquine			S	Transplacental	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519651	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1196061		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Micofenolato De Mofetilo (7330lm)			S	Oral	500 Mg 12 Hours		Teva
	Colchimax (Colchicine/Dicycloverine Hydrochloride)			S	Oral	0.5 Mg 24 Hours		Not Reported
	Dolquine 200 Mg Comprimidos, 30 Comprimidos			S	Oral	200 Mg 12 Hours		Not Reported
	Rituximab (2814a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519653	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197404			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported

	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198000			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519660	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198122			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Dermatitis Allergic; Hepatic Cirrhosis; Hypersensitivity; Psoriasis; Rash Papular; Therapeutic	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S		400 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Product Effect Decreased	Sulfanilamide			S	Unknown			Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519699	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram Daily;		Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519737	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unknown,		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unknown		Not Reported
	Naproxen			C	Unknown	Unknown		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519854	EXPEDITED (15-DAY)		OT	NVSC2020CA064906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Plaquenil			S	Oral	20 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521749	EXPEDITED (15-DAY)		OT	CA-SA-2020SA060110		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Topicort			S	Cutaneous	Unk		Sanofi
	Actemra			S				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported
	Arava			S	Oral			Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S	Oral			Not Reported
	Orencia			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Prednisone			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521788	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130309		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine	S				Sanofi
	Methotrexate	S	Oral	20 Mg, Qd		Not Reported
	Methotrexate	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Leflunomide	S	Oral	20 Mg, Qd		Sanofi
	Cimzia	S	Subcutaneous			Not Reported
	Cosentyx	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S		Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Desvenlafaxine Succinate	C				Not Reported
	Prednisone	C				Not Reported
	Quetiapine Fumarate	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521819	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020103635		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Off Label Use; Product Use Issue; Skin Reaction; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	Unk, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17522043	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020101975		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
	Apo-Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	25 Mg, 1x/Day	Not Reported
	Apo-Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
	Arava	S	Unknown	20 Mg, 1x/Day	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold Radioactive Colloidal	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Indomethacin	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	50 Mg, Weekly	Not Reported
	Prednisone	S	Oral	25 Mg, 1x/Day	Not Reported
	Prednisone	S		50 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cymbalta			C	Unknown	30 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	Unk Unk, Weekly		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524186	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1198464			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524188	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198197		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198573			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524518	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198591		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gadolinium-Zeolite Xanthan Gum Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram Daily;		Not Reported
	Humira			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Oral	40 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;		Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526155	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07599		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown,		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526171	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07695		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Myochrysine		S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S			Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Prednisone		C	Unknown	Unknown	Not Reported
	Xeljanz		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Morphine			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526220	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07630		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Infliximab			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Gabapentin			C	Unknown			Not Reported

	Acetaminophen		C	Unknown	Not Reported
	Cetirizine Hydrochloride		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526909	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526918	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	13855498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070302		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Methotrexate			C	Subcutaneous	25 Milligram, Qwk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	14735736	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Align Digestive Aid		Not Reported
	Loperamide			C	Oral	2mg/1-2-Tabs 4x Per Day; Ongoing		Not Reported
	Pantoprazole			C	Unknown	Unk Unk,Tid		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	14747168	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098040		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity;	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk, Unk		Sanofi

Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Erythromycin	S	Unknown	Unk		Sanofi
	Risedronate Sodium	S	Oral	35 Mg, Qw		Not Reported
	Methotrexate	S	Oral	22.5 Mg,Qw		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Oral	400.0 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Orencia	S		Unk, Unk		Not Reported
	Marijuana	C	Unknown	Unk		Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd		Not Reported
	Celebrex	C	Unknown	200 Mg, Bid		Not Reported
	Ergocalciferol	C	Unknown	4000.0 Iu, Qd		Not Reported
	Bupropion	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	15350172	EXPEDITED (15-DAY)		OT	CA-ROCHE-2179240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17259828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514035		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17434256	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002000843			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatitis Cholestatic; Pneumonia; Rash; Stevens-Johnson	Hydroxychloroquine			S		Unk		Concordia
	Azathioprine			S		Unk		Not Reported
	Oseltamivir			S		Unk		Not Reported

Syndrome; Toxic Epidermal Necrolysis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17448695	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP007808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Localised Infection; Skin Discolouration; Skin Exfoliation; Soft Tissue Necrosis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	80 Mg, Unk		Not Reported
	Sulfasalazine			C	Oral	1500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17485746	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001107			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Mg, Qd (1 And 1/2 Tablets), Tablet		Concordia
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk, On And Off		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17498908	EXPEDITED (15-DAY)		DE, HO	NVSC2020US060102		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Trametinib			S	Oral	2 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17523978	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198588		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17523994	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020101881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Methotrexate Sodium			S	Subcutaneous	20 Mg, Once Weekly		Pfizer
	Actemra			S		300 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous	1 Every 2 Months		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17524962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198780		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198768		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529557	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1199245		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atrovent			C				Not Reported
	Benztropine Mesylate			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Folic Acid			C				Not Reported
	Levomepromazine Maleate			C				Not Reported
	Methotrexate			C				Not Reported
	Pantoprazole			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Salbutamol			C				Not Reported
	Trifluoperazine [Trifluoperazine Hydrochloride]]			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529613	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1199352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid	Indometacin			S	Unknown			Actavis

Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra	S	Unknown			Not Reported
	Celebrex	S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate	S	Oral			Not Reported
	Naprosyn [Naproxen Sodium]	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199350		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Oral	40 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529653	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198795		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Nasopharyngitis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529761	EXPEDITED (15-DAY)		OT	NVSC2020CA065255		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Cyclosporine	S	Unknown	Unk	Novartis
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg (Solution)	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk (Solution)	Not Reported
	Rituxan	S	Unknown	Unk (Solution)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	30 Mg/Kg	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw (1 Every 1 Weeks)	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529893	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2020-0010681		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529928	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2020-0010695		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Morphine Sulfate			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17530605	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC-2020105703		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Rash; Rash Vesicular;	Methotrexate Sodium			S	Unknown	2.5 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

Skin Lesion;
Thrombocytopenia;
Varicella Zoster Virus
Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17532248	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			C	Oral	15 Milligram, Qwk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram, Qd		Not Reported
	Tenofovir Disoproxil			C	Unknown	Unk		Not Reported
	Tenofovir Disoproxil			C	Unknown	300 Milligram		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	9421143	EXPEDITED (15-DAY)		OT	PHHY2013FR077105		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Erythema; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lupus Vasculitis; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Exfoliation; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Omeprazole			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	10592296	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014089242		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qd		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	14 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not	Unk, Qmo		Not Reported

Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting			otherwise specified)			
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk Unk, Bid		Not Reported
	Prednisone	S	Unknown	14 Milligram, Qd		Not Reported
	Dilaudid	C	Unknown	4 Milligram, Tid		Not Reported
	Lyrica	C	Oral	Unk		Not Reported
	Furosemide	C	Unknown	Unk, Qd		Not Reported
	Hydromorph Contin	C	Unknown	18 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11457175	NON-EXPEDITED		CA, DS, HO, OT	CA-AMGEN-CANSP2015088317		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

	Orencia		S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram	Not Reported
	Apo-Leflunomide		S	Unknown	10 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11962064	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2012074066		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported
	Aleve			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported

Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Hcq	C		Unk	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	20 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12133375	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported

Event	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	50 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Humira	S	Subcutaneous	400 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram	Not Reported
	Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Nanogram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Minocycline	S	Unknown	50 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk Unk, Qmo	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

Minocycline	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	100 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qwk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg Vaccine	C	Unknown	Unk	Not Reported
Adalimumab	C		Unk	Not Reported
Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk	Not Reported
Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk	Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
Amoxicillin	C		Unk	Not Reported
Amoxil [Amoxicillin Trihydrate]	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported

		Hydroxychloroquine		C	Unknown	400 Milligram				Not Reported
		Hydroxychloroquine		C	Unknown	100 Milligram				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12146308	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016130747		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Q2weeks		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Pantoprazole Sodium Anhydrous			S		40 Mg, 1x/Day		Not Reported
	Pantoprazole Sodium Sesquihydrate			S		40 Mg, 1x/Day		Not Reported
	Apo-Folic Acid			S		5 Mg, 2x/Week		Not Reported
	Apo-Folic Acid			S		5 Mg, 2x/Week		Not Reported
	Co Atenolol			S		25 Milligram, Qd		Not Reported
	Co Atenolol			S		20 Milligram, Qd		Not Reported
	Atenolol			S		25 Mg, 1x/Day		Not Reported

Naprosyn	S	Oral	100 Milligram, Qd	Not Reported
Naprosyn	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn	S	Oral	500 Mg, 2x/Day	Not Reported
Naprosyn	S	Oral	1000 Mg, 1x/Day	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Qd	Not Reported
Palafer Cf	S	Unknown	Unk, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S		Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S		Unk	Not Reported
Ascorbic Acid	S		Unk, 1x/Day	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported

Folic Acid	S	Unknown	5 Milligram, 2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Ferrous Fumarate/Folic Acid	S		Unk, 1x/Day	Not Reported
Remicade	S		Unk	Not Reported
Naproxen Sodium	S		500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S		1000 Mg, 1x/Day	Not Reported
Naproxen Sodium	S	Oral	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	100 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	1000 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S		400 Mg, Weekly	Not Reported
Hydroxychloroquine	S		40 Mg, Weekly	Not Reported
Palafer	S		Unk	Not Reported
Pantoprazole Sodium	S		40 Mg, 1x/Day	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C		Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Celecoxib	C	Oral	Unk	Not Reported
Celecoxib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12172769	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016029473		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q4wk		Not Reported
	Actemra			S	Oral	Unk		Not Reported

Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Qmo	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Orencia	S	Subcutaneous	Unk, Qwk	Not Reported
	Orencia	S	Vaginal	750 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Qd	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	7.5-12.5 Milligram, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Omega-3	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram 1-3 Tabs, Qhs	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported

Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Vitamin D	C		400 Unit, Qd	Not Reported
Actonel	C		36 Mg, Qwk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, (Every Four Weeks)	Not Reported
Aclasta	C		750 Milligram, Qmo	Not Reported
Calcium	C		Unk	Not Reported
Genteal	C		3m Use As Directed	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, Od	Not Reported
Nexium	C		40 Milligram One Tab, Bid	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qhs	Not Reported
Nasonex	C		2 Sprays Per Nostrils, Bid	Not Reported
Percocet	C		1 Tab, 4-6h Prn For Pain	Not Reported
Lomotil	C		2.5 Milligram, 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Milligram, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk, Q2wk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C		Unk, Qd	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Loperamide Hydrochloride	C		2.5 Milligram	Not Reported

	Ergocalciferol	C		400 International Unit, Qd	Not Reported
	Perphenazine	C	Oral	10 Milligram	Not Reported
	Tecta	C		40 Milligram, Qd	Not Reported
	Vitamin E [Tocopherol]	C		Unk	Not Reported
	Fergon	C		300 Milligram, Qd	Not Reported
	Ascorbic Acid	C		Unk	Not Reported
	Biotin	C		Unk	Not Reported
	Cholecalciferol	C		Unk	Not Reported
	Ferrous Fumarate	C		Unk	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
	Folic Acid	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Retinol Palmitate	C		Unk	Not Reported
	Thiamine Hydrochloride	C		Unk	Not Reported
	Riboflavin	C		Unk	Not Reported
	Vitamin A [Retinol]	C		Unk	Not Reported
	Vitamin B3	C		Unk	Not Reported
	Vitamin B1 [Thiamine]	C		Unk	Not Reported
	Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C			Not Reported
	Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12316477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054049			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported

Device Implantation	Actemra		S	Intravenous (not otherwise specified)	2000 Milligram, Qmo	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine		S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Qd	Not Reported
	Hydroxychloroquine		S	Unknown	200 Milligram, Qd	Not Reported
	Plaquenil		S	Unknown	200 Milligram, Qd	Not Reported
	Folic Acid		S	Unknown	1 Milligram, Qd	Not Reported
	Arava		S	Unknown	20 Milligram, Qd	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12321534	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054557		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qmo		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid		Not Reported
Apo-Hydroxyquine	S	Oral	400 Mg, Qd		Not Reported
Methotrexate Sodium	S	Oral	25 Mg, Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Orencia	S	Subcutaneous	125 Milligram, Qwk		Not Reported
Plaquenil	S	Oral	400 Milligram, Qd		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd		Not Reported
Prednisone Acetate	S	Unknown	Unk		Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12430947	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014016405		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis;	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methadone	S	Unknown	Unk	Not Reported
	Rampril	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, Bid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Qwk	Not Reported
	Gravol Ginger	C		500 Milligram, As Needed	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported
	Estradiol	C		Unk, Tid	Not Reported

	Estrogel	C		0.6 Percent, Tid		Not Reported
	Estrogel	C	Unknown	1 Dosage Form, Qd		Not Reported
	Calcium	C		500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12685066	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016109223		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	100 Milligram		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Methotrexate Sodium		S	Unknown	25 Mg, Unk		Not Reported
	Rituximab		S	Intravenous drip	Unk		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide		C	Unknown	Unk		Not Reported
	Leflunomide		C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	13251335	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006763		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	1.0 Df, Qd		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported
	Piroxicam			S	Unknown	Unk		Not Reported
	Apo-Mycophenolate			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Intra-arterial	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

					Remicade		S	Unknown	Unk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Simponi		S	Subcutaneous	Unk	Not Reported
					Sulfasalazine		S	Unknown	Unk	Not Reported
					Plaquenil /00072602/		S	Oral	Unk	Not Reported
					Gold		S	Unknown	Unk	Not Reported
					Sodium Aurothiomalate		S	Parenteral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	13890626	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP016769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Apo-Meloxicam			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Mobicox			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown	500 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	14872540	EXPEDITED (15-DAY)		OT	PHHY2018CA005549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	14921584	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044591			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	160 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown	400 Milligram		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Mobicox	S	Unknown	Unk		Not Reported
	Humira	C	Subcutaneous	Unk		Not Reported
	Diclofenac	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15207382	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Arava			S	Oral	10 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 3 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, 1 Every 2 Days		Not Reported
	Arava			S	Oral	10 Mg, Qd 3 Months		Not Reported
	Arava			S	Oral	200 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Arava			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Arava			S	Oral	10 Mg, Q3wk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Oral	10 Mg, Bid		Not Reported

Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Mg, Qd	Not Reported
Methotrexate Sodium	S	Unknown	Unk 2 Year	Not Reported
Methotrexate Sodium	S	Intramuscular	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Intramuscular	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate	S	Intramuscular	12.5 Mg, Qd	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	Unk Unk, 1 Every 2 Years	Not Reported

				Methotrexate		S	Unknown	Unk	Not Reported
				Hydroxychloroquine		S	Unknown	Unk	Not Reported
				Hydroxychloroquine		S	Unknown	Unk	Not Reported
				Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
				Hydroxychloroquine Sulfate		S	Oral	Unk	Not Reported
				Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15415981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187426		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15486757	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016023969		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Amgen
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Zostavax	S	Subcutaneous	Unk	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Zostavax	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Voltaren	C	Unknown	100 Milligram, Qd	Not Reported
	Cortisone	C		10 Milligram, Qd	Not Reported
	Cortisone	C	Oral	Unk	Not Reported
	Cortisone	C	Subcutaneous	Unk	Not Reported

	Desoximetasone		C	Oral	10 Milligram, Qd	Not Reported
	Desoximetasone		C	Unknown	10 Milligram, Qd	Not Reported
	Desoximetasone		C	Subcutaneous	Unk	Not Reported
	Diclofenac		C	Unknown	100 Milligram, Qd	Not Reported
	Diclofenac		C	Unknown	100 Milligram	Not Reported
	Diclofenac		C	Subcutaneous	100 Milligram	Not Reported
	Cortisone Acetate		C	Subcutaneous	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz		C	Oral	10 Milligram, Bid	Not Reported
	Xeljanz		C	Oral	Unk (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16174170	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019151161		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Pantoprazole			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Pfizer
	Clindamycin Hcl			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, 1/Week		Pfizer
	Avelox			S	Unknown	Unk		Not Reported
	Keflex [Cefalexin]			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Hctz	S	Unknown	Unk	Not Reported
Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Losartan Potassium	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
Lopressor	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
Penicillin [Benzylpenicillin]	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Hydroxychloroquine	C		Unk	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Cipro [Ciprofloxacin]	C	Unknown	Unk	Not Reported
Cipro [Ciprofloxacin]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16697992	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2884328-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Drug Intolerance; Drug-Induced Liver Injury	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17395700	EXPEDITED (15-DAY)		OT	NVSC2020CN032994		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Placenta Praevia; Premature Delivery; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk (3 Day Shock Therapy)		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Vita-D			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17449223	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007791		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	40 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Unk		Not Reported

Methotrexate	S	Subcutaneous	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Kevzara	S	Unknown	Unk		Not Reported
Prednisone	C	Unknown	10 Mg, Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17449475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188488		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn E			S	Unknown	1000 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous	17.8571 Milligram Daily;		Not Reported
	Orencia			S	Sunconjunctival			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Apo-Methotrexate		S	Subcutaneous		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Lovastatin		C	Unknown		Not Reported
	Metoprolol		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported
	Naproxen Sodium		C	Unknown		Not Reported
	Pantoprazole		C	Unknown		Not Reported
	Rosuvastatin		C	Unknown		Not Reported
	Rosuvastatin Calcium		C	Unknown		Not Reported
	Tramadol Hydrochloride		C	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17488215	EXPEDITED (15-DAY)		OT	NVSC2020CA054557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17491286	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008190		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown	Unk, Unknown		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk, Unknown		Not Reported
	Rituximab			S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17507283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17528339	EXPEDITED (15-DAY)		OT	GB-ABBVIE-20K-167-3311302-00			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral	10mg To 15mg		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Intramuscular			Not Reported
	Cosentyx			S	Oral			Not Reported
	Abatacept			C	Subcutaneous			Not Reported
	Tocilizumab			C	Subcutaneous			Not Reported
	Leflunomide			C				Not Reported
	Leflunomide			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17528689	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565797		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529273	EXPEDITED (15-DAY)		DE	US-TEVA-2020-US-1196969		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Teva
	Celecoxib			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529304	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198615			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported
	Tylenol Arthritis Pain 8h			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529403	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1199756		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported

Incomplete; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;			Not Reported
	Sulfasalazine			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529425	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199839		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199813		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199821			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529855	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530810	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067074		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566092		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530896	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201901-000152			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Plaquenil		Concordia
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

	Actemra	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	40 Mg, Qd		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Prednisone	C		Unk		Not Reported
	Arava	C		Unk		Not Reported
	Simponi	C		Unk		Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17531084	EXPEDITED (15-DAY)		DS	CA-ROCHE-2563674		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17532826	NON-EXPEDITED			US-PFIZER INC-2020106873		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity	Cytotec	S	Unk	Pfizer
	Prevacid	S	Unk	Not Reported
	Cyclosporine	S	Unk	Not Reported
	Zelnorm	S	Unk	Not Reported
	Amitiza	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Reglan	S	Unk	Not Reported
	Maxzide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533105	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA126625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Prednisone			S	Oral	5 Mg,Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Domperidone			C	Oral	10 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533202	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020105885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate Sodium	S		20 Mg, Weekly	Pfizer
	Arava	S			Not Reported
	Diclofenac	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Arthrotec	C			Not Reported
	Desoximetasone	C			Not Reported
	Ibuprofen	C			Not Reported
	Naproxen	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral		Not Reported
	Prednisone	C	Oral	Unk, 1x/Day	Not Reported
	Sulfasalazine	C			Not Reported
	Synthroid	C		Unk, 1x/Day	Not Reported
	Tramadol	C	Oral	Unk, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533357	EXPEDITED (15-DAY)		OT	NVSC2020CN068678		57 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Product Use In Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533406	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020101939		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 3x/Day		Pfizer

Pulmonary Mass	Hydroxychloroquine	S		700 Mg, 1x/Day	Not Reported
	Kevzara	S		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Vitamin D [Ergocalciferol]	C		Unk	Not Reported
	Candesartan	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534005	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1198666		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Intravenous (not otherwise specified)			Not Reported

Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Ilaris Single-Use Vial	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534213	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1200643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534440	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1200638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown	18.9 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534762	EXPEDITED (15-DAY)		OT	CA-PURDUE-CAN-2020-0010680		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17535515	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17535606	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1200575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	11368759	NON-EXPEDITED		DE, HO, LT, OT	CA-AMGEN-CANSP2014104837		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported

Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported

Oxycodone	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Unknown	Unk	Not Reported
Ilaris	S	Unknown	Unk	Not Reported
Ilaris	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk, Solution For Infusion	Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q2wk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Kineret	C		Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Prednisone	C		Unk Unk, Qd	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	11493051	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015093019		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Enbrel			S	Subcutaneous	Unk		Amgen

Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12072431	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016015699		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported

			Hydroxychloroquine		S	Unknown	Unk			Not Reported
			Methotrexate		S	Unknown	Unk			Not Reported
			Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
			Rituximab		S	Intravenous drip	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12164789	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016118471		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, 2x/Day (Bid)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported

Zostavax	S	Subcutaneous	Unk	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
Zostavax	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Voltaren [Diclofenac]	C	Unknown	100 Mg, 1x/Day	Not Reported
Cortisone	C		10 Mg, Daily	Not Reported
Desoximetasone	C	Oral	10 Mg, 1x/Day	Not Reported
Desoximetasone	C		10 Milligram, Qd	Not Reported
Desoximetasone	C	Oral	5 Mg, 2x/Day	Not Reported
Desoximetasone	C	Subcutaneous	Unk	Not Reported
Diclofenac	C	Unknown	100 Mg, 1x/Day	Not Reported
Diclofenac	C	Oral	100 Mg, Unk	Not Reported
Diclofenac	C	Oral	5 Mg, 2x/Day	Not Reported
Diclofenac	C	Unknown	100 Mg, Unk	Not Reported
Diclofenac	C	Subcutaneous	100 Mg, Unk	Not Reported
Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
Cortisone	C	Subcutaneous	Unk	Not Reported
Cortisone	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12224346	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015029495		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	25 Milligram, 2 Times/Wk	Amgen
	Enbrel	S	Unknown	25 Milligram, Bid	Amgen
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Amgen
	Enbrel	S	Unknown	25 Milligram	Amgen
	Enbrel	S	Unknown	25 Milligram, Q2wk	Amgen
	Enbrel	S	Subcutaneous	25 Milligram	Amgen
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Methotrexate	S	Vaginal	25 Milligram, 4 Times/Wk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, 4 Times/Wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported

Orencia	S	Unknown	Unk Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	4.0 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Milligram	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Benadryl	C	Unknown	Unk Unk, As Necessary	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lasix	C		40 Milligram, Tid	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex	C	Unknown	Unk, As Necessary	Not Reported
Enablex	C	Unknown	Unk	Not Reported

Ativan	C	Unknown	1 Gram, Qd At Bedtime	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk Unk, Bid	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Cortisone	C	Intra-arterial	Unk	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
Dilaudid	C		4 Milligram	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C		100 Milligram	Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Furosemide	C		40 Milligram, 3 Times/Wk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk Unk, As Required	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk Unk, As Necessary	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Norflex	C	Unknown	Unk Unk, Bid	Not Reported
Norflex	C		Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported

Anakinra	C	Unknown	100 Milligram	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Milligram	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dyclonine Hydrochloride	C		Unk	Not Reported
Orphenadrine	C	Unknown	1 Dosage Form, Bid	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12298212	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016050673		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Etanercept			S	Unknown	50 Milligram, Qwk		Amgen
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram, Qwk		Not Reported

Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	780 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	760 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	680 Milligram, Qmo	Not Reported

Actemra	S	Unknown	680 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	17.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported

Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h	Not Reported
Prednisone	C	Unknown	10 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisolone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12650430	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089419		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported

Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qwk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Prednisone	C	Unknown	15 Milligram, Qd	Not Reported
	Prednisone	C			Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12682616	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018624		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, 4 Every 1 Week		Amgen
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	200 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Apo-Hydro			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Unk		Not Reported

Cell Count Increased	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Acetaminophen	S	Unknown	325 Milligram	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Amaryl	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported

	Stelara	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Unknown	25 Dosage Form, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk, Qwk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Tylenol With Codeine No.3	C		Unk	Not Reported
	Celebrex	C	Oral	200 Milligram, Bid	Not Reported
	Hydromorphone Hcl	C		Unk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown		Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Glyburide	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Lipitor	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk Unk, Qd	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12691420	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016405201		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Pfizer

Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	25 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Milligram	Pfizer
	Methotrexate Sodium	S	Unknown	25 Milligram	Pfizer
	Sulfasalazine	S	Unknown	500 Milligram	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Xeljanz	S	Unknown	5 Milligram, Bid	Pfizer
	Minocycline	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	100 Milligram	Not Reported
	Azathioprine	S	Unknown	100 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Azathioprine	S	Unknown	100 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12973995	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016163638		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12982514	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016166769		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Leflunomide	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	Unk (4 Years)	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Coversyl	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Cephalexine	C	Unknown	500 Milligram, Qid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13814083	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017109326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituxan			S	Unknown	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

				Rituximab		S	Unknown	Unk	Not Reported
				Cortisone		C		10 Milligram, Qd	Not Reported
				Gold		C	Unknown	Unk	Not Reported
				Prednisone		C	Unknown	Unk	Not Reported
				Desoximetasone		C	Unknown	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13857420	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017119578		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Foot Operation; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	300 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Cyclical		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1.0 Dosage Form, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported

	Gold		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	300 Milligram, Qd	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported
	Rituximab		S	Intravenous drip	1 Gram	Not Reported
	Actonel		S	Unknown	35 Milligram, Qwk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide		S	Unknown	1.0 Dosage Form	Not Reported
	Risedronate		S	Unknown	Unk	Not Reported
	Risedronate		S	Unknown	35 Milligram, Qwk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13859207	NON-EXPEDITED		HO	CA-AMGEN-CANSP2017119169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14551816	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022286		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14680239	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018039685		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported

Kevzara	S	Unknown	20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	20 Milligram	Not Reported
Sarilumab	S	Subcutaneous	20 Milligram, Q2wk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Nicotinamide	S	Unknown	Unk	Not Reported
Thiamine Hydrochloride	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Act Esomeprazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Adalimumab	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	400 Mg, Qd	Not Reported
Nexium	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Magnesium	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Dexpanthenol	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Esomeprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14767128	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018049251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15227464	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016244288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk 2 Year		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	40 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer

Methotrexate Sodium	S	Intramuscular	12.5 Mg, Qd	Pfizer
Methotrexate Sodium	S	Unknown	12.5 Mg, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	Unk Unk, 1 Every 2 Years	Pfizer
Methotrexate Sodium	S	Unknown	Unk	Pfizer
Arava	S	Oral	10 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 3 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 1 Every 2 Days	Not Reported
Arava	S	Oral	10 Mg, Qd 3 Months	Not Reported
Arava	S	Oral	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Unk	Not Reported
Arava	S	Unknown	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Q3wk	Not Reported
Arava	S	Unknown	10 Mg, 1x/Day	Not Reported
Arava	S	Oral	10 Mg, Bid	Not Reported
Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported

					Apo-Hydroxyquine		S	Unknown	Unk	Not Reported
					Hydroxychloroquine		S	Unknown	Unk	Not Reported
					Hydroxychloroquine		S	Unknown	Unk	Not Reported
					Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
					Hydroxychloroquine Sulfate		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15552704	EXPEDITED (15-DAY)		OT	PHHY2018CA041941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15620611	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2018-CA-975882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency;	Methotrexate	S	Subcutaneous		Barr
Antibody Test Positive;	Methotrexate	S	Subcutaneous		Barr
Arthralgia; Arthritis;	Methotrexate	S	Unknown		Barr
Arthropathy; Body Height Below Normal; Bone	Methotrexate	S	Subcutaneous		Barr
Density Decreased; C-Reactive Protein	Methotrexate	S	Subcutaneous		Barr
Increased; Condition Aggravated;	Methotrexate	S	Intravenous (not otherwise specified)		Barr
Contraindicated Product Administered; Diarrhoea;	Methotrexate	S	Subcutaneous		Barr
Dizziness; Drug Ineffective; Drug	Naproxen	S	Unknown		Teva
Intolerance; Drug Specific Antibody; Drug Specific	Prednisone	S	Oral	10 Milligram Daily;	Actavis
Antibody Present; Gastroenteritis Viral;	Prednisone	S	Oral	2 Dosage Forms Daily;	Actavis
Gastroenteritis Viral; Human Anti-Human	Prednisone	S	Oral	6 Milligram Daily;	Actavis
Antibody Test; Human Antichimeric Antibody	Prednisone	S	Unknown	100 Milligram Daily;	Actavis
Positive; Hypocalcaemia; Hypokalaemia;	Prednisone	S	Unknown		Actavis
Hypotension; Immunodeficiency;	Prednisone	S	Unknown		Actavis
Immunodeficiency; Impaired Quality Of Life;	Prednisone	S	Oral	2.6 Milligram Daily;	Actavis
Joint Destruction; Joint Effusion; Joint Injury;	Prednisone	S	Oral	2.6 Milligram Daily;	Actavis
Juvenile Idiopathic Arthritis; Liver Function	Prednisone	S	Oral	6 Milligram Daily;	Actavis
Test Abnormal; Liver Function Test Abnormal;	Prednisone	S	Oral	6 Milligram Daily;	Actavis
Loss Of Consciousness; Loss Of Personal	Prednisone	S	Oral	10 Milligram Daily;	Actavis
Independence In Daily Activities; Mobility	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Decreased; Nausea; Obesity; Off Label Use;	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Pleural Effusion; Polyarthritis; Prescribed	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Underdose; Product Use	Orencia	S	Intravenous (not		Not Reported

In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Underdose; Vomiting; Wheelchair User			otherwise specified)		
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported

Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Subcutaneous		Not Reported
Infliximab	S	Unknown		Not Reported
Gamastan S/D Medicinal Ingredient Also Know As Immuneglobulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate Tablets, Usp	S	Oral	5 Mg/Kg Daily;	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Unknown		Not Reported
Prednisone	S	Oral	6 Milligram Daily;	Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported

	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram Daily;	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg Daily;	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S	Oral	6 Milligram Daily;	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Anakinra	S			Not Reported
	Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15702406	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089441		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Qwk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Sulfasalazine	C	Oral	1 Gram, Qd	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	16439059	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018011428		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Aleve	C		Unk Unk, As Needed	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Bupropion	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	16882113	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05704		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

Apo-Azathioprine	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Unknown	Not Reported
Arava	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Other	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Actemra	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Solution Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
Xeljanz	S	Unknown	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Tofacitinib	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17205119	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353124		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Leflunomide			S		25 Mg, Qw		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Arava			S		25 Mg, Qw		Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17448568	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007862		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17450389	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007813		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Apotex
	Apremilast	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Infliximab	C	Unknown	Unk	Not Reported
	Penicillin /00000901/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567108		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566151		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535341	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566061		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Methotrexate			S	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported
		Gabapentin			C	Unknown				Not Reported
		Amlodipine Besilate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535690	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Vision Blurred	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535822	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1201117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535930	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1304		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold Radioactive Colloidal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Indomethacin	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536008	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201159		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Off Label Use; Product Use Issue; Somnolence	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Oral			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536095	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201014		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536102	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cartilage Injury; Depression; Dizziness; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Palpitations; Panic Attack; Renal Function Test Abnormal; Tremor	Methotrexate	S	Unknown			Barr
	Arava	S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
	Diclofenac	C				Not Reported
	Diclofenac	C	Oral			Not Reported
	Diclofenac	C	Oral			Not Reported
	Diclofenac	C				Not Reported
	Sulfasalazine	C		2 Gram Daily;		Not Reported
	Tamsulosin Hydrochloride	C	Oral			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536155	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201165		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Rash; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536157	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

		Neoral			S	Oral				Not Reported
		Plaquenil			S	Oral				Not Reported
		Enbrel			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536347	EXPEDITED (15-DAY)		DS	CA-ROCHE-2567157		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536389	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-012470		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S	Unknown	High Dose		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536668	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine		S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536746	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020039826		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536862	EXPEDITED (15-DAY)		OT	NVSC2020CA065750		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Oral	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported

Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Mg	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Cyclosporine	S	Unknown		Novartis
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Humira	S	Subcutaneous		Not Reported
Chloroquine	S	Subcutaneous		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Unk	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566115		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536988	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001464			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537638	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566129		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Off Label Use; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537665	EXPEDITED (15-DAY)		OT	NVSC2020CA071564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cosentyx			S	Unknown	Unk		Novartis

	Methotrexate			S	Oral	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk, Bid (2 Every 1 Days)			Not Reported
	Xeljanz			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537726	EXPEDITED (15-DAY)		OT	NVSC2020CN068677		49 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Product Use In Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S				Novartis
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S				Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

		Plaquenil			S	Unknown	Unk			Not Reported
		Remicade			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17540780	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201306		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17541043	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)	
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Xeljanz	S	Unknown	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported

	Pantoloc /01263204/			C	Unknown	Not Reported
	Pantoprazole Sodium			C	Unknown	Not Reported
	Restasis			C	Unknown	Not Reported
	Synthroid			C	Unknown	Not Reported
	Trimethoprim			C	Unknown	Not Reported
	Urispas			C	Unknown	Not Reported
	Vagifem			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	12507876	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016083007		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

					Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported
					Methotrexate		C	Oral	25 Milligram, Qwk		Not Reported
					Methotrexate		C	Unknown	25 Milligram, Qwk		Not Reported
					Prednisone		C	Unknown	30 Milligram, Qd		Not Reported
					Cortisone		C		Unk		Not Reported
					Desoximetasone		C	Unknown	Unk		Not Reported
					Methotrexate Sodium		C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	13436464	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016078528		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	125 Milligram, Qwk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported

	Gabapentin	C	Oral	400 Milligram, Tid 2 Tablets In The Mornings. 1 Tablet In The Aftenoon And 2 Tablets In The Evenings		Not Reported
	Gabapentin	C				Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd		Not Reported
	Tylenol Arthritis	C	Unknown	650 Milligram, Qid		Not Reported
	Acetaminophen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	13913466	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017129066		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	16968290	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2979286-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Humira			S	Subcutaneous			Not Reported

Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Arava	C			Not Reported
	Prednisone	C			Not Reported
	Aleve	C		Frequency-As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17433139	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016091942		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue;	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported

Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S			Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Methotrexate	S	Unknown	25 Milligram (1 Every 24 Hours)	Not Reported
Methotrexate	S			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Vitamin C	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Glucosamine	C		Unk	Not Reported
Lansoprazole	C		30 Mg, Bid	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17541781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565716			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17541831	EXPEDITED (15-DAY)		HO	CA-ROCHE-2566096			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)					
		Hydroxychloroquine		S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	14400613	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017193304		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Cyclical (Q2weeks)		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Cyclical (1/Week)		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Q2wk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Pantoprazole Sodium Anhydrous			S	Unknown	40 Milligram, Qd		Not Reported
	Pantoprazole Sodium Sesquihydrate			S	Unknown	40 Milligram, Qd		Not Reported
	Apo-Folic Acid			S	Unknown	5 Milligram, Bid		Not Reported
	Apo-Folic Acid			S	Unknown	5 Milligram, Bid		Not Reported
	Co Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Milligram, Qd		Not Reported
	Atenolol			S	Unknown	25 Milligram, Qd		Not Reported

Naprosyn [Naproxen]	S	Oral	100 Milligram, Qd	Not Reported
Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn [Naproxen]	S	Oral	1000 Milligram, Qd	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Qd	Not Reported
Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported

Ferrous Fumarate	S	Unknown	Unk, Qd	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	40 Milligram, Qwk	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Prednisone	C		5 Milligram, Qd	Not Reported
Celecoxib	C	Oral		Not Reported
Celecoxib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	15620376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556697-00		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported

Daily Activities; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Enbrel	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Actemra	S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Leflunomide	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Rituximab	S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Plaquenil	S	Unknown			Not Reported
	Hydroxychloroquine	C				Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	16867027	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2944310-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	17542644	NON-EXPEDITED		HO	CA-AMGEN-CANSP2020042344		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	9459293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1162770		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Diastolic Increased; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Cataract; Cystitis; Drug Intolerance; Dry Mouth; Dyslipidaemia; Fall; Hepatic Enzyme Increased; Inflammation; Joint Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Musculoskeletal Stiffness; Nasopharyngitis; Osteoporosis; Painful Respiration; Pharyngeal Mass; Pneumonia; Poor Venous Access; Synovitis; Upper Limb Fracture; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Synthroid			C				Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Tylenol			C				Not Reported
	Folic Acid			C				Not Reported
	Garlic [Allium Sativum]			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Naprosyn [Naproxen]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	11350033	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-PFIZER INC-2015262877		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Kineret	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk, Single Use Vial	Not Reported
	Ilaris	S	Unknown	Unk, Single Use Vial	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S	Unknown	Unk (Powder For Injection)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported

	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Apo-Sulfasalazine	S		Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine	S			Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Q2wk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk Unk, Qd	Not Reported
	Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	11382867	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-PFIZER INC-2015267393		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	5 Mg, Unk		Pfizer

Onychomycosis	Actemra	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Plaquenil	S	Oral	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Oral	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Arava	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12091497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016085227		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly (50		Pfizer

Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Product Use Issue; Rheumatoid Arthritis				Milligram, Qwk)	
	Enbrel	S	Unknown	Unk	Pfizer
	Enbrel	S	Subcutaneous	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day (5 Milligram, Bid)	Pfizer
	Xeljanz	S		5 Ng, 2x/Day (5 Nanogram, Bid)	Pfizer
	Xeljanz	S		5 Mg, 2x/Day (5 Milligram, Bid)	Pfizer
	Sulfasalazine	S		Taken For 2 Years	Pfizer
	Sulfasalazine	S	Oral	500 Mg, 1x/Day (500 Milligram, Qd)	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk (25 Milligram)	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly (25 Milligram, Qwk)	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk (25 Milligram)	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Plaquenil	S	Unknown	400 Mg, Taken For 2 Years	Not Reported
	Plaquenil	S	Oral	200 Mg, 2x/Day (200 Milligram, Bid)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S		40 Mg, 2x/Week (40 Milligram, Q2wk)	Not Reported
	Humira	S		40 Mg, Unk (40 Milligram)	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk (400 Milligram)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Azathioprine	S		100 Mg, Unk (100 Milligram)	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	50 Mg, Unk (50 Milligram)	Not Reported
Minocycline Hydrochloride	S		Unk	Not Reported
Minocycline	S		Unk	Not Reported
Azathioprine	S	Unknown	100 Mg, Unk (100 Milligram)	Not Reported
Arava	S	Oral	20 Mg, Weekly (20 Milligram, Qwk)	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, 1x/Day (20 Milligram, Qd)	Not Reported
Apo-Minocycline	S		50 Mg, Unk	Not Reported
Orencia	S		Unk, Monthly (Qmo)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk (400 Milligram)	Not Reported
Hydroxychloroquine Sulfate	S		400 Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported

	Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
	Bcg Vaccine	C	Unknown	Unk (Powder For Solution For Intravesical Use)	Not Reported
	Adalimumab	C		Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Qwk	Not Reported
	Amoxicillin	C		Unk	Not Reported
	Amoxil [Amoxicillin Trihydrate]	C		Unk	Not Reported
	Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12185482	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016145185		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Pfizer
	Sulfasalazine			S	Oral	2.5 G, Daily		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day		Pfizer
	Gabapentin			S	Oral	100 Mg, 2x/Day		Pfizer
	Gabapentin			S	Unknown	100 Mg, 1 Every 2 Days		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Celebrex			S		Unk, Occlusive Dressing Technique		Pfizer

Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Fentanyl	S	Unknown	Unk	Pfizer
	Fentanyl	S	Unknown	Unk	Pfizer
	Celecoxib	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 1x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, Unk	Pfizer
	Plaquenil	S	Unknown	400 Mg, Daily (Qd)	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Subcutaneous	Unk, Weekly	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
	Nortriptyline Hydrochloride/Perphenazine	S	Oral	10mg Tablets 1-3 Tablets Every Evening	Not Reported
	Nortriptyline Hydrochloride/Perphenazine	S	Oral	10 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Monthly	Not Reported
	Actemra	S	Oral	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Cyclic Q4wk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo Fentanyl Matrix	S		Unk	Not Reported

Apo Celecoxib	S	Oral	Unk	Not Reported
Apo Gabapentin	S		Unk	Not Reported
Apo Gabapentin	S	Oral	100 Mg, 2x/Day	Not Reported
Arava	S	Oral	20 Mg, Qd	Not Reported
Fentanyl Matrix	S	Unknown	Unk Patch	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Omega-3 [Salmo Salar Oil]	S		Unk	Not Reported
Omega-3 Fatty Acids	C		1200 Mg, 2x/Day	Not Reported
Multivitamin	C		Unk	Not Reported
Tecta	C		40 Mg, Daily	Not Reported
Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
Vitamin D	C		400 Iu, Daily	Not Reported
Vitamin D	C		400 Df, 1x/Day	Not Reported
Actonel	C		36 Mg, Weekly	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported
Prednisone	C		Unk5.0 Gbq, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, (Every Four Weeks)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Fergon	C		300 Mg, Daily	Not Reported
Fergon	C		300 Mg, 1x/Day	Not Reported
Fergon	C		Unk	Not Reported

Tylenol	C	Oral	500 Mg 2 Tabs, 1x/Day	Not Reported
Tylenol	C	Oral	1000 Mg, 1x/Day	Not Reported
Nexium	C		40 Mg, 2x/Day	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day At Bedtime	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day	Not Reported
Nasonex	C	Nasal	2 Sprays, 2x/Day	Not Reported
Nasonex	C		Unk Unk, Bid (Spray Metered Dose)	Not Reported
Nasonex	C		2 Df, 2x/Day	Not Reported
Percocet	C		1 Tab 4-6h As Needed	Not Reported
Lomotil	C		2.5mg 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Mg, Qd	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, 2x/Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Iu, 1x/Day	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Df, Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole	C		400 Mg, 2x/Day	Not Reported
Esomeprazole	C		Unk	Not Reported
Loperamide Hydrochloride	C		2.5 Mg, Unk	Not Reported
Ergocalciferol	C		400 Iu, 1x/Day	Not Reported

Ergocalciferol	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1x/Day	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclic Qh	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega 3 2100	C		1200 Mg, 2x/Day	Not Reported
Omega 3 2100	C		Unk, Q2wk	Not Reported
Genteal [Hypromellose]	C		Unk	Not Reported
Fish Oil	C		1200 Mg, 2x/Day	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Nicotinamide	C		Unk	Not Reported
Pantoprazole	C		400 Mg, 1x/Day	Not Reported
Pantoprazole	C		40 Mg, 1x/Day	Not Reported
Pantoprazole	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Pyridoxine Hydrochloride	C		Unk	Not Reported
Sodium	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vit D3	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		1200 Mg, 2x/Day	Not Reported
Docosahexaenoic	C	Unknown	Unk Unk, Qd	Not Reported

Acid/Eicosapentaenoic Acid Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk, Q2wk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Sodium Ascorbate	C		Unk	Not Reported
Thiamine Mononitrate	C		Unk	Not Reported
Vitamine C	C		Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	C		Unk	Not Reported
Nortriptyline	C		Unk	Not Reported
Oxycodone And Acetaminophen	C		Unk	Not Reported
Epa Dha 720	C		Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Unk	Not Reported
Thiamine	C		Unk	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12301979	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014315082		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Celebrex			S		200 Mg, 2x/Day (Bid)		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Unk, Daily (Qd)		Pfizer
	Methotrexate Sodium			S				Pfizer
	Arava			S		Unk		Not Reported
	Arava			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Monthly		Not Reported
	Actemra			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Apo-Prednisone			S		14 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 2x/Day		Not Reported
	Prednisone			S	Unknown	14 Mg, 1x/Day		Not Reported
	Dilaudid			C		4 Mg, 3x/Day		Not Reported
	Dilaudid			C				Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Furosemide			C		Unk, 1x/Day		Not Reported
	Hydromorph Contin			C		18 Mg, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12302274	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016221150		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate	Enbrel			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Pfizer
	Enbrel	S	Unknown	25 Mg, 2x/Week	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Enbrel	S	Unknown	25 Mg, Unk (1 Every 2 Week)	Pfizer
	Enbrel	S	Unknown	50 Mg, Unk	Pfizer
	Etanercept	S	Unknown	25 Mg, 2x/Week	Pfizer
	Etanercept	S	Unknown	50 Mg, Weekly	Pfizer
	Celebrex	S		Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Pfizer

Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	Unk	Pfizer
Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Pfizer
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Pfizer
Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Infliximab Hospira	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported

Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Unknown	1000 Mg, 2x/Day	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported

	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	70 Mg, Weekly	Not Reported
	Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
	Prednisone	C		10 Mg, Unk	Not Reported
	Prednisone	C	Unknown	10 Mg	Not Reported
	Prednisone	C	Unknown	20 Mg, Unk	Not Reported
	Cyclosporin	C	Unknown	150 Mg, 1x/Day	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, 2x/Day	Not Reported
	Prednisolone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12338904	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016241427		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Rash; Skin Mass; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Mg, Once A Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid (2 Every 1 Day)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, Bid		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd (1 Every 24 Hours)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Once Every Two		Not Reported

				Weeks	
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	50 Mg, Weekly (1 Every 1 Week(S))	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, Qd (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd (1 Every 24 Hour)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12416801	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016278196		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma;	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported

Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	1 Dose	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methadone	S		Unk	Not Reported
	Rampril	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, 2x/Day	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Weekly	Not Reported

	Jampk20	C		1500 Mg, 1x/Day	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
	Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
	Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
	Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12659993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016335872		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram, Qd		Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day(Bid)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd		Not Reported
	Lyrica	C	Oral	Unk		Not Reported
	Prednisone	C	Unknown	15 Mg, Daily (Qd)		Not Reported
	Prednisone	C				Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12842578	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1958		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Inappropriate Schedule Of Product Administration; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported

Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Apo Folic Acid	S	Unknown	Twice In A Week	Not Reported
	Apo Folic Acid	S	Unknown	Twice A Week	Not Reported
	Naprosyn	S	Oral		Not Reported
	Naprosyn	S	Oral		Not Reported
	Naprosyn	S	Oral		Not Reported
	Naprosyn	S	Oral		Not Reported
	Palafer Cf	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Abatacept	S	Unknown		Not Reported
	Ascorbic Acid	S	Unknown		Not Reported
	Ascorbic Acid	S	Unknown		Not Reported
	Ferrous Fumarate	S	Unknown		Not Reported

Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown	2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Ferrous Fumarate-Folic Acid	S	Unknown		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Atenolol	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Etanercept	S	Unknown		Not Reported
Palafer	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown		Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown		Not Reported

	Celebrex			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Celecoxib			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13033547	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-095488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13128781	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017005116		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy;	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen

Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	25 Mg, Unk	Amgen
	Enbrel	S	Subcutaneous	Unk	Amgen
	Enbrel	S	Unknown	25 Mg, Bid	Amgen
	Arava	S	Unknown		Not Reported
	Rituximab	S	Unknown	1 Gram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Cyclical	Not Reported
	Humira	S	Unknown	40 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6wk	Not Reported
	Remicade	S	Unknown	300 Mg, Unk	Not Reported
	Remicade	S	Unknown	300 Mg, Cyclical	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
	Apo-Hydroxyquine	S	Unknown	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported

	Actemra	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Bid		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate	S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate	S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	200 Mg, Qwk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	1 G, Bid		Not Reported
	Wellbutrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13549390	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017071781		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, As Necessary		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13761472	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017105360		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Celebrex			C		Unk, As Necessary		Not Reported
	Xeljanz			C		Unk		Not Reported
	Prednisone			C		Unk Unk, As Necessary		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13805299	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112357		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Glaucoma Surgery; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13862390	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017119633		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported
	Erythromycin			C		Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13908900	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128230		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Minocycline	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Stelera	S	Subcutaneous	Unk	Not Reported
Stelera	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Myochrysine	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Sirukumab	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Minocin	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported

					Simponi		S	Unknown	Unk		Not Reported
					Orencia		S	Unknown	250 Milligram, Unk		Not Reported
					Orencia		S	Unknown	Unk		Not Reported
					Orencia		S	Intravenous (not otherwise specified)	Unk		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk		Not Reported
					Sulfasalazine		S	Unknown	Unk		Not Reported
					Methotrexate		S	Unknown	Unk		Not Reported
					Methotrexate		S	Unknown	15 Milligram, Qwk		Not Reported
					Methotrexate		S	Oral	Unk		Not Reported
					Rheumatrex		C		Unk		Not Reported
					Prednisone		C	Unknown	5 Milligram		Not Reported
					Abatacept		C	Unknown	Unk		Not Reported
					Hydroxychloroquine Sulfate		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13909412	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128000		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		2.5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish	C	Unknown	Unk	Not Reported

	Pantoprazole			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13909421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127635		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled Syringe)		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

	Rituximab			S	Intravenous drip	Unk			Not Reported
	Imuran			C	Unknown	Unk			Not Reported
	Arthrotec			C	Unknown	Unk			Not Reported
	Ergocalciferol			C	Unknown	Unk			Not Reported
	Ergocalciferol			C		Unk			Not Reported
	Azathioprine			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13926256	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375036		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Pfizer
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14156261	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017164983			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported

	Methotrexate	S	Oral	1.0 Dosage Form, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	10 Milligram, Qd	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk Unk, Qwk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Milligram, Qd	Not Reported
	Citalopram Hydrobromide W/Mirtazapine	C	Unknown	40 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14185061	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170005		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14186410	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Cyclical		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk (Solution Subcutaneous)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk (Solution Subcutaneous)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Q6wk, (Powder For Solution Intravenous)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qwk		Not Reported
	Rituxan			S	Intravenous (not	Unk (Solution Intravenous)		Not Reported

						otherwise specified)				
		Sulfasalazine			C	Unknown	Unk			Not Reported
		Wellbutrin			C	Unknown	Unk			Not Reported
		Wellbutrin			C	Oral	Unk			Not Reported
		Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14190825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490362		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk (Emulsion)		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14216870	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017174939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mobicox			S	Oral	7.5 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14217819	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175088		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported

	Sulfasalazine			S	Unknown	10000 Milligram, Bid			Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14224287	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175535		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14562748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018073659		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Sulfasalazine	S	Unknown	2 Gram, Qd		Pfizer
	Apo-Prednisone	S	Unknown	5 Milligram, Unk		Not Reported
	Arava	S	Oral	20 Milligram, Qd		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd		Not Reported
	Prednisone	S	Unknown			Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14623298	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Tocilizumab	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Sarilumab	S	Unknown	Unk		Not Reported
	Tofacitinib	S	Unknown	Unk		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported
	Prednisone	C		10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14775658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018157923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15209356	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018101357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported

Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Adalimumab	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Q2wk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Unk, Unk (Three In One Week)		Not Reported
	Hydroxychloroquine	S	Unknown	200 Unk		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15286198	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016077975		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

	Plaquenil			S	Unknown	Unk			Not Reported
	Gold			S	Unknown	Unk			Not Reported
	Apo Hydroxyquine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Rituximab			S	Intravenous drip	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15416427	EXPEDITED (15-DAY)		OT	PHHY2018CA102776		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Injection		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not	3 Mg		Not Reported

				otherwise specified)		
	Actemra		S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Orencia		S	Subcutaneous	125 Mg	Not Reported
	Sulfasalazine		S	Oral	Unk	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Oral	Unk	Not Reported
	Xeljanz		C	Unknown	2 Ot, Qd	Not Reported
	Xeljanz		C	Oral	10 Mg, Qd	Not Reported
	Xeljanz		C	Unknown	2 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15577112	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2541011-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	579		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate Sodium	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Xeljanz	C	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15583667	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372752		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	2.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Mg, Daily	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15585218	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2540122-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

Reactive Protein Increased; Contraindicated Product Administered; Disability; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira 40mg/0.8ml	S				Not Reported
	Etanercept	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Gp2013		Not Reported
	Rituximab	S	Unknown			Not Reported
	Leflunomide	S	Oral			Not Reported
	Leflunomide	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Infliximab	S				Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S				Not Reported
	Abatacept	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15629800	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558453-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis;	Humira			S	Subcutaneous			Not Reported

Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acidophilus	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Deflazacort	C		Not Reported
	Dilaudid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride	C	Intramuscular	Not Reported
	Januvia	C		Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Lidocaine	C	Topical	Not Reported
	Metronidazole	C		Not Reported
	Nitroglycerin	C		Not Reported
	Pantoloc	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Risedronate	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Salbutamol	C		Not Reported
	Triamcinolone	C		Not Reported
	Tylenol	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Triamcinolone Acetonide	C		Not Reported
	Salicylic Acid	C		Not Reported
	Rosuvastatin	C	Unknown	Not Reported

	Risedronate Sodium			C	Unknown					Not Reported
	Acetaminophen			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15687047	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018170659		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Orencia			S	Oral	200 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15700850	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018119653		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition	Enbrel			S		Unk		Pfizer

Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Sulfasalazine	S		Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, Bid	Pfizer
	Adalimumab	S	Unknown	Unk	Not Reported
	Act Esomeprazole	S	Unknown	Unk	Not Reported
	Ciclosporin	S	Unknown	Unk	Not Reported
	Esomeprazole Sodium	S	Unknown	Unk	Not Reported
	Folic Acid	S		Unk	Not Reported
	Nicotinamide	S		Unk	Not Reported
	Azathioprine	S		Unk	Not Reported
	Thiamine Hydrochloride	S		Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Qwk, Six Months	Not Reported
	Kevzara	S		20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
	Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
	Sarilumab	S	Subcutaneous	20 Mg, 2x/Week	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Riboflavin	C		Unk	Not Reported
	Vitamin A [Retinol]	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Dexpanthenol	C		Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
	Esomeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15704441	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Acetaminophen			C		650 Milligram, Bid		Not Reported
	Aluminium Acetate W/Benzethonium Chloride			C		Unk		Not Reported
	Atacand			C		Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Hydrodiuril			C	Unknown	Unk		Not Reported
	Neurontin			C	Unknown	600 Milligram, Tid		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	650 Mg, Bid		Not Reported
	Aluminium Acetate			C	Unknown	Unk		Not Reported
	Benzethonium Chloride			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15924554	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653465-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine[Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16120373	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045643		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk (Tablets)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Orencia			S	Unknown	75 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil S			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Risedronate			C	Oral	35 Milligram, Qwk		Not Reported
	Cimzia			C	Subcutaneous	200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16140862	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083231		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg		Not Reported
	Orencia			S				Not Reported
	Rituxan			S		Solution Intra Venous		Not Reported
	Salazopyrin			S				Not Reported
	Actemra			C				Not Reported
	Bifidumbacterin			C				Not Reported
	Celebrex			C				Not Reported
	Loperamide			C				Not Reported
	Methotrexate			C				Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16181416	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738191-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16291815	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087638			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density	Aleve			S	Unknown	Unk		Bayer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Kineret			S	Subcutaneous	50.0 Mg, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported

Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Apo-Prednisone	S	Oral	5.0 Mg, Bid	Not Reported
	Enbrel	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 4iw	Not Reported
	Enbrel	S	Subcutaneous	25 Unk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Hydroxychloroquine	S	Oral	5.0 Mg, Qd	Not Reported
	Infliximab	S	Unknown	5.0 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg, Ow	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg, Ow	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250.0 Mg, Q1mon	Not Reported
	Prednisone	S	Oral	3.0 Mg, Bid	Not Reported
	Prednisone	S	Oral	5.0 Unk	Not Reported
	Sulfasalazine	S	Oral	250.0 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280.0 Mg, Q2wk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Ow	Not Reported
	Triamcinolone	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Gamastan	S		70.0 G	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5.0 Mg/Kg, Qd	Not Reported
	Naproxen	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Immunoglobulin I.V	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16330442	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019077665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16470848	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018036164		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	10 Milligram, 1x/Day	Not Reported
Leflunomide	S	Unknown	10 Milligram, 1x/Day	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

	Bupropion	C	Unk	Not Reported
	Sulfasalazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16471566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017312936		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16483146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017349309		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1.0 Dosage Form, Qd	Not Reported
	Hydroxychloroquine	S	Oral	300 Mg, 1x/Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, 1 Every 1 Hour(S)	Not Reported
	Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
	Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Mg, 1x/Day	Not Reported
	Actonel	S	Unknown	35.0 Mg, Weekly	Not Reported
	Rituximab	S	Intravenous (not	Unk	Not Reported

				otherwise specified)		
	Rituximab		S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Risedronate		S	Unknown	Unk	Not Reported
	Risedronate		S		35 Mg, Weekly	Not Reported
	Methotrexate		C		Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16628388	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2863507-00		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Cimzia			S	Subcutaneous	Not Reported
	Tofacitinib Citrate			S	Unknown	Not Reported
	Xeljanz			S	Unknown	Not Reported
	Rituximab			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16793789	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018056893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported

	Leflunomide	S	Unknown	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Unknown	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16797341	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019146895		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity;	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Ergocalciferol	C		Unk Unk, Qwk		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate	C	Unknown	Unk Unk, Bid		Not Reported
	Estrogel	C		0.6 Percent, Tid		Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd		Not Reported
	Morphine	C	Unknown	Unk		Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan	C		320 Milligram, Qd		Not Reported
	Xalatan	C		50 Microgram, Qd		Not Reported
	Zingiber Officinale	C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16807532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported

			Hydroxychloroquine Sulfate		S	Oral	400 Milligram		Not Reported
			Gold		S	Unknown	50 Milligram		Not Reported
			Meloxicam		C	Unknown	Unk		Not Reported
			Sulfasalazine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16848358	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155529			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16948402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972424-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

						otherwise specified)				
		Enbrel			S	Subcutaneous				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17036954	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019493883		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased;	Pantoloc			S	Unknown	40 Milligram		Pfizer
	Omnaris			S	Unknown	50 Microgram		Not Reported
	Alvesco			S	Unknown	200 Microgram, Qd		Not Reported
	Ivermectin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Prednisone			S	Oral	50 Milligram		Not Reported
	Salbutamol Sulfate			S	Unknown	100 Microgram		Not Reported
	Umeclidinium Bromide			S	Unknown	62.5 Microgram		Not Reported
	Zenhale			S	Unknown	2 Df, Bid		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

Wheezing

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17038283	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1116759		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder;	Furosemide			S	Unknown			Ivax
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Piperacillin Sodium /Tazobactam Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Rosuvastatin Calcium			S	Unknown			Teva
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Actonel			C				Not Reported
	Apo Amlo			C				Not Reported
	Apo-K			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Epoetin Alfa			C				Not Reported
	Escitalopram			C	Unknown			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ventolin [Salbutamol Sulfate]			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported
	Slow-K			C				Not Reported
	Risedronate			C				Not Reported
	Pantoprazole			C				Not Reported

Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Pantoloc [Pantoprazole]	C		40 Milligram Daily;	Not Reported
	Metoprolol	C			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Metformin	C			Not Reported
	Kcl	C			Not Reported
	Januvia	C			Not Reported
	Insulin Lispro	C			Not Reported
	Hydroxychloroquine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17205986	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA353135		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Arava			S	Oral	10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S		12.5 Df		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S		Unk		Not Reported

Actemra	S			Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Subcutaneous	25 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous	250 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
Rituximab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Bifidobacterium Bifidum	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Pantoprazole	C			Not Reported
Prednisone	C		40 Mg	Not Reported
Prednisone	C		250 Unk	Not Reported
Simponi	C			Not Reported
Sulfasalazine	C			Not Reported
Wellbutrin	C			Not Reported
Xeljanz	C	Oral	5 Mg	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C		200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17211808	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA354607			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported

Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Methotrexate	S		20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Plaquenil	S		200 Mg	Sanofi
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Mg Bid	Not Reported
	Prednisone	S		20 Mg, Qd	Not Reported
	Prednisone	S		20 Mg, Qd	Not Reported
	Arava	S		10 Mg, Qd	Sanofi
	Sodium Aurothiomalate	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Bim	Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17215414	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353952		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect	Sodium Aurothiomalate			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk/Gold		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported

Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Methotrexate	C	Subcutaneous	15 Mg, Qw	Not Reported
	Methotrexate	C	Unknown	15 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Mg	Not Reported
	Methotrexate	C	Unknown	17.5 Mg	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Oral	1 G, Qd	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17427584	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1186381		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Hypogammaglobulinaemia	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

; Leukopenia; Neutropenia; Weight Decreased	Mycophenolate Mofetil			S	Unknown					Teva
	Rituximab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17434479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019415671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449016	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007838		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Deformity; Gastrointestinal Disorder; Loss Of Personal Independence In Daily	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Parenteral	15 Mg, Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Unk		Not Reported

Activities; Nausea	Sulfasalazine			S	Unknown	Unk, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Aleve			C	Unknown	Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Sulfasalazine			C	Oral	2000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17482799	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008186		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; C-Reactive Protein; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sarilumab			C	Unknown	Unk, Unknown		Not Reported
	Xeljanz			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17485926	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542948	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dequalinium Chloride			C				Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022567		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543200	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

Arthritis; Systemic Lupus Erythematosus	Arava		S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride		S	Unknown	10 Milligram	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate		S	Unknown	Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk	Not Reported
	Folic Acid		S	Unknown	5 Milligram	Not Reported
	Fosamax		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Acetaminophen		C	Unknown	Not Reported
	Prednisone		C	Oral	Not Reported
	Prednisone		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543233	EXPEDITED (15-DAY)		DE, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1339		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Product Use Issue; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543235	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1364		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Actemra			S	Unknown				Not Reported
	Celebrex			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543244	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543246	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		66 YR	Male	CAN

PHARMA-TREX2020-1323

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin			C	Unknown			Not Reported

	Trihydrate;Clavulanate Potassium									
	Amoxil [Amoxicillin]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201880			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Cefazolin			C	Unknown			Not Reported
	Clindamycin			C	Unknown			Not Reported

	Prednisone			C	Unknown	10 Milligram		Not Reported
	Tylenol W/Codeine No. 3			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543729	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202304		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543733	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202183		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

		Neoral			S	Unknown					Not Reported
		Plaquenil			S	Unknown					Not Reported
		Remicade			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543737	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202308		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543813	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder;	Methotrexate			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva

Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Sulfamethoxazole W/Trimethoprim		S	Unknown		Teva
	Apo-Diclofenac		S	Topical		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Gold Sodium Thiomalate		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Naprosyn		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Voltaren		S	Unknown		Not Reported
	Tramadol Hydrochloride		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543832	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201901			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544307	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020899		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not	8 Milligram/Kilogram,		Not Reported

				otherwise specified)	Q4wk	
	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C	Unknown		Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544337	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567702		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567710		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544665	NON-EXPEDITED			US-PFIZER INC-2020112039		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544958	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1026331		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Unknown
	Cefotaxime			S	Unknown	Unk		Mylan
	Cefotaxime			S		Unk		Mylan
	Privigen			S	Unknown	Unk		Mylan
	Privigen			S		Unk		Mylan
	Prednisone			S	Unknown	Unk		Mylan
	Methylprednisolone			S	Unknown	Unk		Mylan
	Dexamethasone			S		Unk		Mylan
	Dexamethasone			S	Unknown	Unk		Mylan
	Vitamin B Complex /04259401/			S	Unknown	Unk		Mylan
	Cefixime			S	Unknown	Unk		Mylan
	Metoprolol Tartrate			S	Unknown	Unk		Mylan

	Bisoprolol Fumarate	S	Unknown	Unk	Mylan
	Penicillin G /00000903/	S	Unknown	Unk	Mylan
	Vulmizolin	S	Unknown	Unk	Mylan
	Bisulepin	S	Unknown	Unk	Mylan
	Ornidazole	S	Unknown	Unk	Mylan
	Albumin	S	Unknown	Unk	Mylan
	Aminomethylbenzoic Acid	S	Unknown	Unk	Mylan
	Magnesium Lactate	S	Unknown	Unk	Mylan
	Folic Acid	S	Unknown	Unk	Mylan
	Nadroparin Calcium	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Unknown	Unk	Mylan
	Vitamin D /00318501/	S	Unknown	Unk	Mylan
	Hydrocortisone	S	Unknown	Unk	Mylan
	Etamsylate	S	Unknown	Unk	Mylan
	Flebogamma Dif /00025201/	S	Unknown	Unk	Mylan
	Fluconazole	S	Unknown	Unk	Mylan
	Potassium Chloride	S	Unknown	Unk	Mylan
	Paracetamol	S	Unknown	Unk	Mylan
	Vitamin K Nos	S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544990	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166761		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased;	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Plaquenil	S	Oral	400 Mg,Qd	Sanofi
	Plaquenil	S	Unknown	400 Mg, Qd	Sanofi
	Orencia	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Adalimumab	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Mg,Unk	Not Reported
	Methotrexate	C	Subcutaneous	15 Mg,Qw	Not Reported
	Methotrexate	C	Unknown	17 Mg	Not Reported
	Methotrexate	C	Unknown	15 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
	Sulfasalazine	C	Oral	1 G,Qd	Not Reported
	Xeljanz	C	Oral	5 Mg,Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544993	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA210576		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Arava			S	Oral	10 Mg,Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk,Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk Unk,Unk		Sanofi
	Methotrexate			S		20 Mg, Qw, Solution		Not Reported
	Methotrexate			S	Unknown	12.5 Df,Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Orencia			S	Subcutaneous	25 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg,Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Gold			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Enbrel			S		50 Mg		Not Reported
	Actemra			S				Not Reported
	Actemra			S		Unk		Not Reported
	Remicade			S	Intravenous (not	300 Mg, Q6w		Not Reported

				otherwise specified)		
	Prednisone		C	Unknown	40 Mg, For 3 Years	Not Reported
	Prednisone		C	Unknown	250 Mg, For 7 Months	Not Reported
	Bifidobacterium Bifidum		C			Not Reported
	Celebrex		C			Not Reported
	Loperamide		C			Not Reported
	Sulfasalazine		C			Not Reported
	Pantoprazole		C			Not Reported
	Xeljanz		C	Oral	5 Mg	Not Reported
	Simponi		C			Not Reported
	Wellbutrin		C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Oral	200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545125	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1026414			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Rituximab			S	Unknown	500 Mg, Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545370	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020112214			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545594	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Headache; Joint Swelling; Pain In Jaw; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Meloxicam			S		15 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C		20 Mg		Not Reported
	Symbicort			C		Unk		Not Reported
	Gabapentin			C		100 Mg		Not Reported
	Lansoprazole			C		30 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546119	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1198500			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Haemorrhage	Hydroxychloroquine Sulfate Teva			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546196	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020111601		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis Superficial	Torvast			S				Pfizer
	Paracetamol Alter			S	Oral	1 G, 1x/Day		Not Reported
	Xarelto			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546249	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA069998		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Oxycodone			S	Unknown	10 Mg		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S				Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported

Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S			Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S			Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S			Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Rituximab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546340	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3318751-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose;	Humira			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo Azathioprine	S	Unknown	Not Reported
	Apo Leflunomide	S	Oral	Not Reported
	Apo Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S		Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Codeine Phosphate	C		Not Reported
	Altace	C		Not Reported
	Apo Gabapentin	C	Oral	Not Reported
	Atorvastatin Calcium	C		Not Reported
	Escitalopram	C		Not Reported
	Citalopram Hydrobromide	C		Not Reported

	Conjugated Estrogens	C		Not Reported
	Cymbalta	C		Not Reported
	Escitalopram	C		Not Reported
	Estrace	C		Not Reported
	Gabapentin	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Hydromorphone Hcl	C		Not Reported
	Mupirocin	C	Topical	Not Reported
	Pantoprazole	C		Not Reported
	Shark Liver Oil	C		Not Reported
	Tapentadol Hydrochloride	C		Not Reported
	Taro Mupirocin	C	Topical	Not Reported
	Tramacet	C	Oral	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021288		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546844	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202539		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Methotrexate			S	Unknown			Barr
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546910	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202524		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C				Not Reported
	Lozide			C				Not Reported

	Metformin			C	Unknown	Not Reported
	Naproxen			C	Unknown	Not Reported
	Naproxen			C	Unknown	Not Reported
	Prednisone			C		Not Reported
	Ramipril			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	11624328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1476711-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Benadryl			C				Not Reported
	Cortisone			C	Intramuscular			Not Reported
	Cortisone			C	Intra-arterial			Not Reported
	Dilaudid			C				Not Reported
	Enablex			C				Not Reported
	Lasix			C				Not Reported
	Leflunomide			C				Not Reported
	Loperamide			C				Not Reported

	Norflex	C			Not Reported
	Omnaris	C	Spray, Metered Dose		Not Reported
	Pantoprazole Sodium	C			Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Vagifem	C	Vaginal		Not Reported
	Synthroid	C			Not Reported
	Abatacept	C			Not Reported
	Desoximetasone	C	Intra-arterial		Not Reported
	Darifenacin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12696887	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1453		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported

Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Infliximab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12702886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016087030		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S		Unk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	40milligram, 4 Every 1 Week		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer

Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Enbrel	S	Unknown	40 Milligram, Four Every One Week	Pfizer
	Enbrel	S	Unknown	50 Milligram, Qwk	Pfizer
	Enbrel	S	Unknown	50 Milligram, Qd	Pfizer
	Enbrel	S	Unknown	50 Milligram, Qwk	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Enbrel	S	Unknown	50 Milligram, 4 Every 1 Week	Pfizer
	Sulfasalazine	S	Oral	2000 Mg, Unk	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Pfizer
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	2.5 Mg/Ml, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (4 Every 1 Week)	Pfizer
	Methotrexate Sodium	S	Unknown	Unk, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Df, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S		10 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported

Plaquenil	S		200 Mg, Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S		200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	800 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	200 Milligram, Unk	Not Reported
Orencia	S	Unknown	200 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Mg, Unk	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Apo-Hydro	S		Unk	Not Reported
Apo-Hydro	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Amaryl	S	Unknown	Unk	Not Reported

Otezla	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Tylenol With Codeine No.3	C		Unk, As Needed	Not Reported
Tylenol With Codeine No.3	C		Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, 2x/Day	Not Reported
Celebrex	C		200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Methotrexate	C	Unknown	Unk Unk, Weekly	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Methotrexate	C	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide (Micronized)	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Lipitor	C	Unknown		Not Reported
Metformin	C	Unknown	Unk Unk, Qd	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported

Xeljanz	C	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12716207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1611		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasis; Synovitis; Tooth Loss	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Unknown			Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Diclofenac	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Cortisone Acetate	C	Unknown	Not Reported
Zostavax	C	Unknown	Not Reported
Voltaren	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12912801	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091708		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Joint Laxity; Limb	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Q12h		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported

Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Endocervical	400 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
	Insulin	C	Oral	Drops Oral	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown		Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Metformin	C	Unknown	1 Dosage Form	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12933730	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA201530		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava			S	Oral	10 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	500 Mg,Bid		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	20 Mg,Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			S		Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 G,Qcy		Not Reported
	Rituxan			S		2 Unk, Qcy		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 G, Q6m		Not Reported
	Etanercept			S		50 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13519996	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13520451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-039843		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex [Sumatriptan]			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sumatriptan			C	Unknown			Not Reported

	Amitriptyline	C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13657154	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA105779		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg,Qw		Not Reported
	Alendronate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg		Not Reported
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S		12 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q4w		Not Reported
	Methotrexate			S		12.5 Unk		Not Reported
	Methotrexate			S		12 Mg		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Q4w		Not Reported

Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S		17.5 Mg, Qw	Not Reported
	Methotrexate	S		15 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Q4w	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q4w	Not Reported
	Alendronic Acid	S		70 Mg, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qm	Not Reported
	Myochrysine	S	Parenteral	50 Mg, Qm	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported
	Actemra	S	Unknown	680 Mg,Qm	Not Reported
	Actemra	S	Unknown	360 Mg,Qm	Not Reported
	Actemra	S		380 Mg	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported

Enbrel	S	Unknown	50 Mg,Biw	Not Reported
Enbrel	S	Unknown	25 Mg,Biw	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S		50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Humira	S		40 Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	780 Mg,Qw	Not Reported
Orencia	S		780 Mg	Not Reported
Orencia	S		780 Mg, Qw	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Remicade	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S		Unk	Not Reported
Rituximab	S		1000 Mg, Bid	Not Reported
Tocilizumab	S		680 Mg, Q4w	Not Reported
Ciclosporin	C	Unknown	150 Mg,Qd	Not Reported
Prednisolone	C	Unknown	10 Mg,Unk	Not Reported
Prednisone	C	Unknown	10 Mg,Qd	Not Reported
Prednisone	C		10 Mg, Qd	Not Reported
Xeljanz	C			Not Reported
Alendronate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported

	Leflunomide			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869342	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017351180		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported
	Erythromycin			C		Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13870276	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017350057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk	Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk	Pfizer
	Actemra			S	Subcutaneous	162 Mg, Qwk	Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk	Not Reported
	Folic Acid			S	Unknown	Unk	Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd	Not Reported
	Simponi			S	Subcutaneous	Unk	Not Reported
	Apo-Folic Acid			S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd	Not Reported
	Cymbalta			C	Unknown	Unk	Not Reported
	Xeljanz			C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13921480	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372781		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Prefilled Syringe)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid (1 Every 12 Hours)		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14227055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Mg, Unk		Not Reported

			Plaquenil		S	Unknown	Unk			Not Reported
			Mobicox		S	Oral	7.5 Mg, Qd			Not Reported
			Sulfasalazine		C	Oral	Unk			Not Reported
			Hydroxychloroquine Sulfate		S	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14227318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506298		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14230778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017510773		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Pfizer

Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Sulfasalazine	S	Oral	1 G, Qd	Pfizer
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14570743	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0535		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cystitis; Deformity; Depressed Mood; Encephalitis; Encephalitis Brain Stem; Fibromyalgia; Immunosuppression; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Peripheral Swelling; Product Use Issue; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Seizure; Sepsis; Spinal Deformity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorph Contin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14632418	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020711		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown	70 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown	680 Mg, Qmo	Not Reported
Tocilizumab	S	Unknown	360 Mg, Qmo	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Leflunomide	S	Unknown		Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ciclosporin	S	Unknown	150 Milligram, Qd	Not Reported
Xeljanz	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15215485	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018305256		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Q2wk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, 2x/Week		Not Reported
	Hydroxychloroquine	S	Unknown	400 Unk, Unk (Three In One Week)		Not Reported
	Leflunomide	S		Unk		Not Reported
	Prednisone	C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15246107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015106204		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Enbrel			S		25 Mg, 2x/Day		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Cyclic Q2wk		Pfizer
	Enbrel			S		25 Mg, (3 Years, Freq: 2 Week; Interval: 1)		Pfizer
	Enbrel			S		25 Mg, Cyclic Q2wk		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer

Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Vaginal	25 Mg, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S		25 Mg, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, 11 Years, Freq: 1 Week; Interval: 1	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic Every Two Weeks (Duration Reported As 365 Units Not Reported	Not Reported
	Humira	S	Unknown	200 Mg, 2x/Day	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	200 Mg, 2x/Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly, Therapy Duration Reported As 61 (Unit Not Reported), (Freq: 1 Month; Interval: 1)	Not Reported
	Orencia	S		Unk, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Therapy Duration Reported As 184 (Unit Not Reported),	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not	300 Mg, Unk	Not Reported

		otherwise specified)		
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	4 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Mg, Daily	Not Reported
Arava	S		1 Mg, Every 1 Day	Not Reported
Arava	S		20 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Mg, Day 1 &15	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported
Cortisone	C	Intra-articular	Unk	Not Reported
Benadryl	C		Unk, As Needed	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Lasix	C		40 Mg, 3x/Day	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk, As Needed	Not Reported

Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 G, Daily At Bedtime	Not Reported
Ativan	C		1 Mg,Every 1 Day	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Loperamide	C		2 Mg, 2x/Day	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk, 2x/Day	Not Reported
Norflex	C	Unknown	Unk, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Norflex	C		Unk	Not Reported
Omnaris	C	Unknown	Unk (Spray, Metered Dose)	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Dilaudid	C		4 Mg, Qd	Not Reported
Dilaudid	C	Unknown	4 Mg, Every 6 Hours	Not Reported
Dilaudid	C		4 Mg, Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C		100 Mg, Unk	Not Reported
Furosemide	C	Unknown	40 Mg, Three Every One Day	Not Reported
Furosemide	C	Unknown	40 Mg, 3x/Week	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk (Freq: As Needed)	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported

Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Mg, Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Mg, Unk	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C		Unk Unk, As Necessary (Freq: As Needed)	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dyclonine Hydrochloride	C		Unk	Not Reported
Orphenadrine [Orphenadrine Hydrochloride]	C	Unknown	1 Dosage Form, Bid	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

Triamcinolone Acetonide	C	Intra-articular	40 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15357865	EXPEDITED (15-DAY)		HO	PHHY2018DK086994		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Mycoplasmal	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Insulin			C	Unknown	Unk (On Pump)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15383851	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported

Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Hydroxychloroquine Phosphate			S	Unknown	Unk	Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Milligram	Not Reported
	Rituximab			S	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab			S	Unknown		Not Reported
	Actemra			S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk	Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Adalimumab			S	Unknown		Not Reported
	Etanercept			S	Subcutaneous	15 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15617576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555631-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619140	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555653-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619319	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554744-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lipitor			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619584	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2555197-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy;	Humira			S	Subcutaneous			Not Reported

Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Actemra	S	Unknown			Not Reported
	Leflunomide Apotex	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Aspirin	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15620413	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555889-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Plaquenil		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15621393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557319-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15627588	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2559128-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Pain; Synovitis	Methotrexate		S	Subcutaneous			Not Reported
	Orencia		S	Unknown			Not Reported
	Sulfasalazine		S	Oral			Not Reported
	Sulfasalazine		S	Unknown			Not Reported
	Leflunomide		S	Unknown			Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution		Not Reported
	Plaquenil		S	Oral			Not Reported
	Naproxen Sodium		S	Unknown			Not Reported
	Xeljanz		C	Oral			Not Reported
	Risedronate		C	Oral			Not Reported
	Arava		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15629381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558926-00		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15660935	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016545757		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S		4 Years		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Prednisone			C		10 Mg, 1x/Day		Not Reported
	Coversyl [Perindopril Erbumine]			C		Unk		Not Reported
	Hydroxychloroquine			C				Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15710031	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015280551		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

			Leflunomide		S	Unknown	Unk			Not Reported
			Actemra		S	Unknown	Unk			Not Reported
			Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
			Apo-Leflunomide		S	Unknown	Unk			Not Reported
			Methotrexate Sodium		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15720388	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017364037		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Pfizer
	Minocin			S	Unknown	Unk		Pfizer
	Minocycline Hcl			S	Unknown	Unk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Ustekinumab	S	Unknown	Unk	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Abatacept	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15781901	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017013508		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S		25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S		200 Mg, Bid		Not Reported

	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1 Gram	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Sulfasalazine	C		1 G, 2x/Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15851696	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633984-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15926889	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651972-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Tablet		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

						otherwise specified)				
			Rituximab		S	Intravenous (not otherwise specified)				Not Reported
			Hydroxychloroquine Sulfate		S	Oral				Not Reported
			Xeljanz		C	Oral				Not Reported
			Xeljanz Xr		C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15934368	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2655903-00		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15953507	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012131		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Prednisone			C	Unknown	5 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15995703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674768-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Vaginal	Dosage Form Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown	Spray, Metered Dose		Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported
	Pantoloc			C		(Enteric Coated)		Not Reported
	Darifenacin Hydrobromide			C				Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Benadryl	C	Unknown		Not Reported
	Plantago Ovata	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16075583	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012946		14 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Intentional Product Use Issue; Lymphoproliferative Disorder; Off Label Use; Off Label Use Of Device; Product Use In Unapproved Indication; Renal Cell Carcinoma	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Ferrous Fumarate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	100.0 Milligram, 1 Every 1 Month		Not Reported
	Infliximab			S	Unknown	1000.0 Milligram, 1 Every 1 Month		Not Reported
	Infliximab			S				Not Reported
	Insulin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Nutropin			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Not Reported
	Sulfamethoxazole			S	Unknown	Unk		Not Reported
	Androderm			S	Unknown	Unk		Not Reported
	Protropin			S	Intramuscular	Unk		Not Reported

				Acetazolamide		S	Unknown	Unk	Not Reported
				Calcium Carbonate		S	Unknown	Unk	Not Reported
				Cyclosporine		S	Unknown	Unk	Not Reported
				Cyclosporine		S			Not Reported
				Ferric Hydroxide Polymaltose Complex		S	Unknown	Unk	Not Reported
				Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
				Leflunomide		S	Unknown	Unk	Not Reported
				Leflunomide		S			Not Reported
				Insulin Human		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16332181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019210438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Estradot			S	Transdermal	Unk, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16334554	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018103158		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer

Methotrexate Sodium	S	Subcutaneous	Unk	Pfizer
Methotrexate Sodium	S	Unknown	10 Milligram	Pfizer
Methotrexate Sodium	S	Unknown	20 Milligram	Pfizer
Tofacitinib Citrate	S	Unknown	Unk	Pfizer
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, (1 Every 2 Week(S))	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported
Prednisone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16343860	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019217974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity;	Enbrel			S	Unknown	Unk		Pfizer

Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate Sodium		S	Unknown	20 Milligram, Qwk	Pfizer
	Sulfasalazine		S	Unknown	2 Gram, Qd	Pfizer
	Actemra		S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16387751	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050993		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	200 Milligram, Bid		Not Reported
	Humira			S	Unknown	1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	4 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Vagifem			C	Vaginal			Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Ativan	C	Unknown	1 Gram	Not Reported
Darifenacin	C	Unknown		Not Reported
Desoximetasone	C	Oral		Not Reported
Dilaudid	C	Unknown	4 Milligram	Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Furosemide	C	Unknown	40 Milligram, 3 Times/Wk	Not Reported
Loperamide	C	Unknown	Unk, Bid	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk, Bid	Not Reported
Omnaris	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Milligram	Not Reported
Lasix [Furosemide]	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported

	Trimethoprim			C	Unknown	Unk			Not Reported
	Urispas			C	Unknown	200 Milligram			Not Reported
	Leflunomide			C	Unknown				Not Reported
	Desoximetasone			C	Intramuscular				Not Reported
	Desoximetasone			C	Intra-arterial				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16537770	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063625		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100.0 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16600726	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Orencia	S	Subcutaneous		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk Unk, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported

	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16691316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885135-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16802106	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396164		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased;	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Cimzia	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Ergocalciferol	C		Unk, Weekly		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate	C		Unk, 2x/Day		Not Reported
	Estrogel	C		0.6 %, 3x/Day		Not Reported
	Furosemide	C		40 Mg, 1x/Day		Not Reported
	Morphine	C	Unknown	Unk		Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, 1x/Day		Not Reported
	Valsartan	C		320 Mg, 1x/Day		Not Reported
	Xalatan	C		50 Ug, 1x/Day		Not Reported
	Zingiber Officinale	C	Oral	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16817883	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399548			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold	S	Unknown	50 Milligram		Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16830577	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17033629	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019493322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Pantoprazole			S	Unknown	Unk		Pfizer
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported

Sulfasalazine	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Calcium	C	Unknown		Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Ergocalciferol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Gravol Ginger	C	Unknown		Not Reported
Morphine	C	Unknown	Unknown	Not Reported
Potassium Chloride	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Xalatan	C	Unknown		Not Reported
Xalatan	C	Ophthalmic	Solution Ophthalmic	Not Reported
Xeljanz	C	Oral		Not Reported
Zingiber Officinale	C	Oral		Not Reported
Estrogel	C	Unknown		Not Reported
Estrogel	C	Unknown		Not Reported
Baclofen	C	Unknown		Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Gravol Ginger Nighttime	C	Unknown	Unknown	Not Reported
Levaquin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Oral		Not Reported
Acetaminophen	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17283605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005143		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk (Once In 4 Weeks)		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk Unk, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid			C	Unknown	5 Mg, Unk		Not Reported
	Naproxen			C	Unknown	500 Mg, Bid		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17390882	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018169790		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Off Label Use	Enbrel	S		50 Mg, Weekly	Pfizer
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Pfizer
	Enbrel	S		50 Mg, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ciclosporin	S		Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Methotrexate Sodium	C		25 Mg, Weekly	Not Reported
	Hydroxychloroquine	C		200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17422939	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010154		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every One Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every One Day	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Remicade	S	Unknown	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17440627	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016346047		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram (1 Every 24 Hours)		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Milligram		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer

Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Wound	Sulfasalazine	S		1 Gram, Bid	Pfizer
	Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Pfizer
	Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Arava	S		Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported

Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S		Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Vitamin C	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Alaskan Salmon Oil	C		Unk	Not Reported
Glucosamine	C		Unk	Not Reported
Lansoprazole	C		30 Mg, 2x/Day	Not Reported
Ativan	C		2 Mg, 3x/Day, As Needed	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547396	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-059951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Cefixime			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk		Not Reported
	Imuran			S	Oral	100 Milligram		Not Reported

					Infliximab	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
					Methotrexate	S	Unknown	Unk	Not Reported
					Morphine	S	Unknown	Unk	Not Reported
					Nifedipine	S	Unknown	Unk	Not Reported
					Plaquenil	S	Unknown	Unk	Not Reported
					Prednisone	S	Unknown	Unk	Not Reported
					Rivotril	S	Unknown	Unk	Not Reported
					Zantac	S	Unknown	Unk	Not Reported
					Zopiclone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568992			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547563	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001263			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Align			C		Unk		Not Reported
	Actemra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547565	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001261			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

	Enbrel	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum	C		Unk		Not Reported
	Loperamide	C		Unk		Not Reported
	Pantoprazole	C				Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547716	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001646			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Tablet		Concordia
	Silver			S	Oral	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Penicillin G Sodium			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Tofacitinib Citrate			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547762	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001274			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Oral	Unk	Concordia
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Concordia
	Erythromycin	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk, Subcutaneous Solution	Not Reported
	Methotrexate	S	Oral	22.5 Mg, Weekly	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Novo-Rythro	S	Unknown	Unk	Not Reported
	Risedronate Sodium	S	Oral	35 Mg, Weekly	Not Reported
	Marijuana	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Celebrex	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023061		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported

	Rituximab			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Sulfasalazine			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1391			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548364	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548444	EXPEDITED (15-DAY)		OT	NVSC2020CA073084		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qw		Not Reported
	Humira			S	Unknown			Not Reported

					Hydroxychloroquine		S	Subcutaneous	Unk	Not Reported
					Hydroxychloroquine		S	Oral	Unk	Not Reported
					Orencia		S	Subcutaneous	125 Mg	Not Reported
					Plaquenil		S	Oral		Not Reported
					Remicade		S	Intravenous (not otherwise specified)	3 Mg	Not Reported
					Rituxan		S	Unknown		Not Reported
					Sulfasalazine		S	Oral	Unk	Not Reported
					Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548451	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567814		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Therapeutic Product Effect	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported

Decreased; Treatment Failure	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral			Not Reported
	Acetaminophen	C	Unknown	1300 Milligram Daily;		Not Reported
	Atacand	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydrodiuril	C	Unknown			Not Reported
	Kevzara	C	Unknown			Not Reported
	Neurontin	C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548476	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Calcium			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Magnesium			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium			C				Not Reported
	Tramadol			C				Not Reported
	Vitamin D[Colecalciferol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548477	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203601		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xalatan			S		50 Microgram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Dorzolamidehydrochloride/Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C		1.8 Percent Daily;		Not Reported
	Furosemide			C		40 Milligram Daily;		Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C		1500 Milligram Daily;		Not Reported
	Valsartan			C		320 Milligram Daily;		Not Reported
	Zingiber Officinale			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

					Enbrel		S	Unknown	Not Reported
					Folic Acid		S	Unknown	Not Reported
					Fosamax		S	Unknown	Not Reported
					Humira		S	Subcutaneous	Not Reported
					Hydroxychloroquine Sulfate		S	Oral	Not Reported
					Orencia		S	Subcutaneous	Not Reported
					Reactine [Cetirizine]		S	Unknown	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Not Reported
					Rituximab		S	Intravenous drip	Not Reported
					Simponi		S	Subcutaneous	Not Reported
					Sulfasalazine		S	Unknown	Not Reported
					Topicort		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548712	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported
	Desoximetasone			C		20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203616		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Methotrexate	S	Subcutaneous		Barr
	Anakinra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Arava	S	Unknown	10 Milligram Daily;	Not Reported
	Arava	S	Unknown	10 Milligram Daily;	Not Reported
	Meloxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548868	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204060		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate		S	Unknown	Barr
	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549539	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR042663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Product Use Issue; Toxicity To Various Agents	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549774	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-012083		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Neutrophilia; Whipple'S Disease	Methylprednisolone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclobenzaprine			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550494	NON-EXPEDITED			NVSC2020US075268		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550624	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			C	Unknown	500 Milligram, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550986	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08585		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe		Not Reported

	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution, Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown, Solution, Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Piroxicam	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551371	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased;	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

Neutropenia; White Blood Cell Count Decreased	Leflunomide			S	Unknown	Not Reported
	Rituximab			S	Unknown	Not Reported
	Enbrel			C	Unknown	Not Reported
	Methotrexate			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551480	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023095		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551711	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021350		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

				Hydroxychloroquine		S	Oral		Not Reported
				Rituximab		S	Intravenous (not otherwise specified)		Not Reported
				Methotrexate		C	Unknown	0.8 Milliliter	Not Reported
				Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552311	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021309		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204244		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate		S	Unknown	Barr
	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Anakinra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Warfarin		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552337	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1204372		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552354	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203747			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552356	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552357	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204242		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

Xeljanz	S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552382	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1204376		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3324326-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Haemophilus Influenzae			C		Vaccine		Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Tetanus Vaccine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552428	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021329		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Orencia			S	Unknown			Bristol Myers Squibb

Enzyme Increased; Pneumonia	Actemra		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552505	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552708	EXPEDITED (15-DAY)		OT	NVSC2020CA073106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Neoral	S	Subcutaneous	Unk	Novartis
	Cyclosporine	S	Unknown	Unk	Novartis
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported

	Orencia			S	Subcutaneous	125 Mg	Not Reported
	Orencia			S	Subcutaneous	125 Mg	Not Reported
	Plaquenil			S	Unknown	Unk	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Rituxan			S	Unknown	Unk	Not Reported
	Sulfasalazine			S	Oral	Unk	Not Reported
	Xeljanz			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552911	EXPEDITED (15-DAY)		OT	NVSC2020CA071955		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Unknown	3 Mg		Not Reported
	Sulphasalazine			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17553141	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027175			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Milligram, Qd For 3 Months		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13816053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017329621		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

					Prednisone	C	Oral	Unk	Not Reported
					Prednisone	C	Unknown	Unk	Not Reported
					Arava	C		Unk	Not Reported
					Codeine	C	Unknown	Unk	Not Reported
					Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
					Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
					Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
					Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
					Lyrica	C	Oral	Unk	Not Reported
					Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13856372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13929661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2691		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14447073	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043369		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis;	Arava			S	Oral	Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk Unk,Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi

Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Hydroxychloroquine Sulfate		S	Unknown	Unk	Sanofi
	Benzylpenicillin Sodium		S	Unknown	Unk Unk, Unk	Not Reported
	Phenoxymethylpenicillin Potassium		S	Unknown	Unk	Not Reported
	Sulfamethoxazole/Trimethoprim		S	Unknown	Unk Unk, Unk	Not Reported
	Actemra		S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira		S	Subcutaneous	Unk Unk,Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Gold		S	Unknown	Unk Unk, Unk	Not Reported
	Rituximab		S		Unk	Not Reported
	Prednisone		C	Unknown	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14570820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0542		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14630900	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP007493		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Apo-Prednisone			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk (Therapy Duration 365 Unit Unspecified)		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Apo-Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg, Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unit Unspecified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Therapy Duration: 365 Unspecified Unit)	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid (Therapy Duration 365 Unit Unspecified)	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14634899	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0737		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

	Zopiclone	C	Unknown		Not Reported
	Pantoprazol Sodium	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Tenofovir	C	Unknown		Not Reported
	Pantoprazol	C	Unknown		Not Reported
	Tenofovir Disoproxil	C	Unknown		Not Reported
	Pantoprazole Sodium	C	Unknown		Not Reported
	Pantoprazole Bluefish	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14788664	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14836032	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1328		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	2x/Week		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Plaquenil	S	Oral			Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Plaquenil	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Gold	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15242994	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1069		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Musculoskeletal Stiffness; Pain; Peripheral Swelling; Product Use Issue; Rash; Skin Mass; Therapy Non-Responder	Xeljanz	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15243408	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0441		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name			S	Unknown			Not Reported

Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Unknown)			
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methadone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Cosopt	C	Unknown	Not Reported

	Furosemide		C	Unknown	Not Reported
	Valsartan		C	Unknown	Not Reported
	Vitamin D		C	Unknown	Not Reported
	Jampk20		C	Unknown	Not Reported
	Dorzolamide Hcl/Timolol Maleate		C	Unknown	Not Reported
	Baclofen		C	Unknown	Not Reported
	Levaquin		C	Unknown	Not Reported
	Potassium Chloride		C	Unknown	Not Reported
	Zingiber Officinale		C	Unknown	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Cortisone		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported
	Estradiol		C	Unknown	Not Reported
	Morphine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15293692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1469		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

			Arava			S	Unknown			Not Reported
			Plaquenil			S	Unknown			Not Reported
			Gold			S	Unknown			Not Reported
			Apo Hydroxyquine			S	Unknown			Not Reported
			Hydroxychloroquine			S	Unknown			Not Reported
			Hydroxychloroquine Sulfate			S	Unknown			Not Reported
			Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15621032	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557288-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Oxycodone			S	Unknown	Cr Tablet		Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Enbrel			C				Not Reported
	Leflunomide			C				Not Reported
	Lyrica			C	Oral			Not Reported
	Oxycodone			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622638	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557282-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported

	Prednisone Acetate			S	Unknown					Not Reported
	Ergocalciferol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557461-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557508-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15624172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556726-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported

		Etanercept			S	Subcutaneous				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported
		Desoximetasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15721414	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1025		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Loss Of Personal Independence In Daily Activities; Nodule; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15855189	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017546580		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Sulfasalazine	S	Unknown	Unk	Pfizer
	Xeljanz	S	Oral	50 Mg, 2x/Day	Pfizer
	Xeljanz	S	Unknown	Unk	Pfizer
	Tofacitinib Citrate	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Pfizer
	Kevzara	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Every 10 Days	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q (Every)14 Day	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Q4wk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported

	Adalimumab		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Adalimumab		S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	750 Milligram, Q4wk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sarilumab		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rabeprazole Sodium		C	Oral	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15956472	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190209141		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; C-Reactive Protein Increased; Crohn'S Disease; Decreased Appetite; Drug Ineffective; Drug Intolerance; Exostosis; Fatigue; Foot Deformity; Hepatic Cirrhosis; Hypoaesthesia; Joint Dislocation; Joint Stiffness; Malaise; Mobility Decreased; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Rash; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Visual Impairment	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Azathioprine	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Minocycline	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Sirukumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported
Bupropion Hydrochloride	C		Not Reported
Hydromorphone Hydrochloride	C		Not Reported
Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16075445	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported

Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	2.68 Milligram, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	680.0 Milligram, 1 Every 1 Month	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1	Not Reported

			Week	
Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 2 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Parenteral	50.0 Milligram, 1 Every 1 Month	Not Reported
Remicade	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680.0 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	15.5milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5milligram, 1 Every 1 Week	Not Reported

	Ciclosporin		C	Unknown	150 Milligram, Once A Day	Not Reported
	Prednisone		C	Unknown	10 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz		C	Unknown	5 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported
	Prednisolone		C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16075451	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012895		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week(S)		Aurobindo
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 2 Week(S)		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 1 Week(S)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram, 1 Every 1 Week(S)		Not Reported
	Orencia			S	Unknown	78 Milligram, 1 Every 1		Not Reported

Skin Ulcer				Week(S)	
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram, 2 Every 1day(S)	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	680 Milligram, 1 Every 1month(S)	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every 1month(S)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every Week (S)	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1 Every Week (S)	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every Week (S)	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	780 Milligram, Once A Day	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every Week (S)	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16080822	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-012964			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib Capsules	S	Unknown	Unk		Aurobindo
	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2 Everey 1 Week		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	2 Milligram, Once A Day		Not Reported
	Hydromorphone	C	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16081413	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013665		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst;	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Every 1 Month		Not Reported

Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Incorrect Route Of Product Administration; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Celebrex	S	Oral	Unk	Not Reported
	Celebrex	S	Unknown	Occlusive Dressing Technique	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Once A Day	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram	Not Reported
	Apo-Gabapentin	S	Oral	100 Milligram, Two Times A Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every One Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 3 Weeks	Not Reported
	Orencia	S	Vaginal	750 Milligram, Every 1 Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Vitamin B1	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
Omega-3	S	Unknown	Unk	Not Reported
Omega-3	S	Unknown	1200 Milligram, Two Times A Day	Not Reported
Fentanyl Matrix	S	Unknown	Unk	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	1 Dosage Form	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	70 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750.0 Milligram, 1 Every 4 Weeks	Not Reported
Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	400 International Unit, Once A Day	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Two Times A Day	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Two Times	Not Reported

			A Day	
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Unknown	Unk	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Oxycocet	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Vitamin E	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times	Not Reported

				A Day	
	Nicotinamide	C	Unknown	Unk	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Sodium	C	Unknown	Unk	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200.0 Milligram, Two Times A Day	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Once A Day	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Every Week	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16205757	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020198		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency;	Amlodipine Tablets			S	Oral	Unk, 1 Every 1 Day		Aurobindo
	Amlodipine Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
	Asacol			S	Unknown	800 Milligram, 3 Every 1 Day		Not Reported
	Asacol			S	Unknown	800 Milligram, 3 Every 2 Day		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported

Weight Increased	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk, 1 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16206143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Plaquenil			S	Oral	Unk				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16347402	EXPEDITED (15-DAY)		OT	CA-SA-2019SA139156		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Sarilumab			S		20 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Esomeprazole Magnesium Trihydrate			S				Not Reported
	Nicotinamide			S				Not Reported
	Thiamine Hydrochloride			S				Not Reported
	Esomeprazole Sodium			S				Not Reported
	Folic Acid			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S				Not Reported
	Enbrel			S				Not Reported
	Adalimumab			C				Not Reported
	Ergocalciferol			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Metformin			C				Not Reported
	Nexium [Esomeprazole Sodium]			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Magnesium			C		Unk		Not Reported
	Gold			C				Not Reported
	Vitamin A [Retinol]			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported

	Dexpanthenol	C	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Not Reported
	Riboflavin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16387694	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029951		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month(S)		Not Reported
	Actemra			S	Unknown	680 Milligram, Once A Day, 1 Every 1 Month(S)		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week(S)		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Week(S)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	10.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	12.0 Milligram, Every Week		Not Reported

Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
Myochrysine	S	Intramuscular	50.0 Milligram, 1 Every 1 Month(S)	Not Reported
Myochrysine	S			Not Reported
Orencia	S	Unknown	780.0 Milligram, Every Week	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram, Two Times A Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Daily	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16387698	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-029940		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug	Alendronic Acid Tablets			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, 4 Every Week		Aurobindo
	Actemra			S	Unknown	2.68 Milligram,Once Every 4 Weeks		Not Reported
	Actemra			S	Unknown	360 Milligram,Once In A Month		Not Reported
	Actemra			S	Unknown	360 Milligram, Every Week		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4		Not Reported

Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response Decreased; Tongue Disorder; Ulcer				Weeks	
	Apo-Ibuprofen	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Enbrel	S	Unknown	25 Milligram, 1 Every 2 Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram,Once In Aweek	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
	Methotrexate	S	Unknown	70.0 Milligram,Once In	Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

			Aweek	
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	12.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,4 Every 1 Year	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported

Myochrysine	S	Parenteral	50 Milligram,Once In A Month	Not Reported
Nitrazepam	S	Oral	5 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram,Once In A Week	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram, Once A Day	Not Reported
Tocilizumab	S	Unknown	360.0 Milligram,	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16388032	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-030631		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram Once In A Week		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Golimumab			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Hydrocortisone Acetate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported

Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Prednisone	S	Oral	25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Topicort	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

	Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16440716	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822523-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16729866	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896155-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16739745	EXPEDITED (15-DAY)		OT	DE-ACCORD-152811			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1 - 1 - 1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1 - 0 - 1) 2.5 Mg Twice Daily		Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported

					Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
					Apixaban	S		2.5 Milligram, Bid	Not Reported
					Trospium Chloride	S		30 Mg, Qd Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
					Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
					Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
					Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16758967	EXPEDITED (15-DAY)		OT	PHHY2019CA200445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Lopresor			S	Unknown	Unk		Novartis
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Losartan Potassium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qd		Not Reported
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported
	Keflex			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Penicillin			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

				Fosamax	S	Unknown	Unk		Not Reported
				Hydrochlorothiazide	S	Unknown	Unk		Not Reported
				Arava	S	Unknown	Unk		Not Reported
				Plaquenil	S	Unknown	Unk		Not Reported
				Biaxin	S	Unknown	Unk		Not Reported
				Celebrex	S	Unknown	Unk		Not Reported
				Hydroxychloroquine	S	Unknown	Unk		Not Reported
				Cipro	C	Unknown	Unk		Not Reported
				Esomeprazole	C	Unknown	Unk		Not Reported
				Gold	C	Unknown	Unk		Not Reported
				Hydroxyquinoline Sulfate	C	Unknown	Unk		Not Reported
				Iron Sucrose	C	Unknown	Unk		Not Reported
				Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16820448	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3439		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Ergocalciferol			C	Unknown	Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown	Not Reported
	Estrogel			C	Unknown	Not Reported
	Furosemide			C	Unknown	Not Reported
	Morphine			C	Unknown	Not Reported
	Potassium Chloride			C	Unknown	Not Reported
	Valsartan			C	Unknown	Not Reported
	Xalatan			C	Unknown	Not Reported
	Zingiber Officinale			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16866723	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17001941	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989075-00		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Levothyroxin			C				Not Reported
	Raloxifene			C				Not Reported
	Lidoderm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17099946	EXPEDITED (15-DAY)		HO, OT	CA-COVIS PHARMA B.V.-2019COV00285		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder	Alvesco			S	Respiratory (inhalation)	200 Mg, 1x/Day		Covis
	Omnaris			S	Nasal	50 Mg, Unk		Covis
	Pantoloc			S		40 Mg, Unk		Not Reported
	Ivermectin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Prednisone			S		50 Mg, Unk		Not Reported
	Salbutamol Sulfate			S		100 Mg, Unk		Not Reported
	Umeclidinium Bromide			S		62.5 Mg, Unk		Not Reported
	Zenhale			S		Unk, 2x/Day		Not Reported
	Sulfasalazine			C				Not Reported
	Arava			C				Not Reported

Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17440774	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2018AP013701		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S				Apotex
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported

Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	Unk, Bid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17523584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Pantoprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17526969	EXPEDITED (15-DAY)		HO	DE-CELLTRION INC.-2020DE020115			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Rituximab (Unknown)			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported

	Hydroxychloroquine			S	Unknown	400 Mg, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17543429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2497274-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553452	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001630			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Domperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553454	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001673			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567770			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Myochrysine		S	Intramuscular	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205022		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554157	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1205088			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554179	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity;	Methotrexate			S	Unknown			Barr

Rheumatoid Arthritis	Moxifloxacin Hydrochloride		S	Oral			Teva
	Amoxicillin Trihydrate/Clavulanate Potassium		S	Unknown			Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554197	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554209	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020112925		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported

	Tramadol			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554234	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205191		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554424	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1205198		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S		Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported

	Prednisone	S	Unknown			Not Reported
	Xeljanz	S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554632	EXPEDITED (15-DAY)		OT	NVSC2020CA072976		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Plaquenil			S	Oral	20 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg 1 Every 1 Weeks		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565792		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Arava		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555043	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565721		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567695		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568898		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1412		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Pain; Rash; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported

Sleep Disorder	Minocin	S	Unknown	Not Reported
	Minocycline Hcl	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Myochrysine	S	Subcutaneous	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Stelara	S	Unknown	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Apremilast	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Abatacept	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555803	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027221		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		(7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S		15 Mg, Qd		Not Reported
	Prednisone			S		Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		(15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		Unk Unk, Qd		Not Reported
	Mycophenolate Mofetil			S		Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Mylan

	Methylprednisolone	C	Unk (Pulses)		Mylan
	Rituximab	C	Unk		Mylan
	Immunoglobulin I.V	C	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020114584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17556462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1027359			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Abatacept			S	Unknown	Unk		Mylan
	Roactemra			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557419	NON-EXPEDITED			NVSC2020US076875		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Tacrolimus			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557715	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown	250 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Hydrocortisone Valerate			C	Unknown			Not Reported
	Hydromorphone			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Lyderm			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sodium Aurothiomalate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557720	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205274		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	C	Subcutaneous	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Leucovorin [Folinic Acid]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557745	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205311		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557806	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache; Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Rheumatoid Arthritis; Weight Fluctuation	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Actemra			C				Not Reported
	Enbrel			C	Subcutaneous	50 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558048	NON-EXPEDITED		OT	NVSC2020US076308		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Gait Inability; Herpes Zoster; Rash; Skin Necrosis	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558470	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020114627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Pfizer

Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Xeljanz	S	Oral	5 Mg, 1 Every 1 Day	Pfizer
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	12956625	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP014656		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Norflox			S	Unknown	400 Mg, Unk		Apotex
	Apo-Bisoprolol			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Levofloxacin			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported

	Celecoxib			S	Oral	200 Mg, Qd		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Every Two Months		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Meperidine Hcl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk		Not Reported
	Metronidazole			S	Unknown	5 Mg/Ml, Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Flagyl /00012501/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13254292	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006753		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lyrica	C	Oral			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Prednisone	C	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13516429	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Gold			S	Unknown	Unk			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Anakinra			S	Unknown	Unk			Not Reported
	Methotrexate			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13823542	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2252		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

	Codeine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13929206	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2675		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Imuran	C	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13988289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083265		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Orencia			S	Unknown	40 Milligram, Q2wk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Methotrexate	C	Oral	10.0 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	15.0 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	1 Dosage Form, Qwk	Not Reported
Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
Pantoprazole	C	Oral	40 Milligram, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram	Not Reported
Pantoprazole Sodium Sesquihydrate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil	C	Unknown	Unk	Not Reported
Tenofovir	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14223269	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021499			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Rheumatoid Arthritis	Hydroxychloroquine		S	Unknown	Unk	Apotex
	Cyclosporine		S	Unknown	Unk	Apotex
	Actemra		S	Unknown	640 Mg, Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	200 Mg, Unk	Not Reported
	Enbrel		S	Unknown	50 Mg, Unk	Not Reported
	Humira		S	Subcutaneous	40 Mg, Unk	Not Reported
	Imuran /00001501/		S	Unknown	Unk	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14236211	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14545702	EXPEDITED (15-DAY)		OT	CA-ROCHE-1715783		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Blood Pressure Diastolic Increased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Increased; Cough; Decreased Appetite; Epistaxis; Headache; Heart Rate Increased; Influenza Like Illness; Infusion Related Reaction; Infusion Site Pain; Medication Error; Nausea; Pain; Platelet Count Decreased; Pruritus; Pyrexia; Sensation Of Foreign Body; Vomiting; Weight Increased; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015, Most Recent Dose On 06/Jun/2017 (683 Mg)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Atovaquone			C				Not Reported
	Alendronate			C				Not Reported
	Vit D3			C				Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone			C	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14727278	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2018JPN056741		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Cytomegalovirus Infection; Neutrophil Count Decreased; Pancreatitis Acute; Pneumocystis Jirovecii Pneumonia; White Blood Cell Count Decreased; White Blood Cell Count Decreased	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Two Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, 1d		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline
	Furosemide			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	70 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	60 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	50 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	40 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Intravenous drip	40 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Intravenous drip	60 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	40 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	30 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	25 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	22.5 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	20 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	25 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	40 Mg, 1d		Glaxosmithkline

Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	35 Mg, 1d	Glaxosmithkline
Prograf	S	Oral	Unk	Not Reported
Cellcept	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Meropenem	S	Intravenous drip	1 G, Tid	Not Reported
Meropenem	S	Intravenous drip	Unk	Not Reported
Miraclid	S	Intravenous drip	300000 Iu, 1d	Not Reported
Omeprazole	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Solu Medrol	C	Intravenous (not otherwise specified)	1000 Mg, 1d	Not Reported
Solu Medrol	C	Intravenous (not otherwise specified)	125 Mg, 1d	Not Reported
Valixa	C		Unk	Not Reported
Bonalon	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Baktar	C		1 Df, We	Not Reported
Baktar	C			Not Reported
Daikenchuto	C		Unk	Not Reported
Sodium Picosulfate Hydrate	C		Unk	Not Reported
Tenelia	C		Unk	Not Reported
Pitavastatin Calcium	C		Unk	Not Reported
Cardenalin	C		Unk	Not Reported
Rabeprazole Sodium	C		Unk	Not Reported
Azilva	C		Unk	Not Reported
Amlodipine Besilate	C		Unk	Not Reported
Azelnidipine	C		Unk	Not Reported
Carvedilol	C		Unk	Not Reported
Bayaspirin	C		Unk	Not Reported

	Sennoside	C	Unk		Not Reported
	Insulin Glargine (Genetical Recombination)	C	Unk		Not Reported
	Spironolactone	C	Unk		Not Reported
	Humalog	C	Unk		Not Reported
	Persantin-L	C	Unk		Not Reported
	Feburic	C	Unk		Not Reported
	Bonviva	C	Unk		Not Reported
	Novolin R	C	Unk		Not Reported
	Trazenta	C	Unk		Not Reported
	Polaprezinc	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15207582	NON-EXPEDITED			US-PFIZER INC-2018300600		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15605753	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3227		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Sarilumab	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Prednisone	C	Unknown	Not Reported
Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15675159	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2495		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Cephalexine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15962909	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013651		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoarthritis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Synovitis	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200.0 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	200 Milligram, 2 Every 1 Day	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16075449	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012871		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	680 Milligram, Every Month		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1		Not Reported

Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer				Week	
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Everey 2 Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram,11 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Myochrysine	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	780 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported

	Tocilizumab		S	Unknown	360 Milligram, Every Month	Not Reported
	Alendronate Sodium		C	Unknown	70 Milligram, Every Week	Not Reported
	Ciclosporin		C	Unknown	150 Milligram, Once A Day	Not Reported
	Prednisone		C	Unknown	10 Milligram, Once A Day	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16082171	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06027		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Acidophilus			C	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Calcium			C	Unknown	Unknown		Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	Unknown		Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported

Hydromorphone Hydrochloride	C	Unknown		Not Reported
Januvia	C	Unknown	Unknown	Not Reported
Lidocaine	C	Topical		Not Reported
Metronidazole	C	Unknown	Unknown	Not Reported
Nitroglycerin	C	Unknown	Unknkown	Not Reported
Pantoloc	C	Unknown	Unknown	Not Reported
Pregabalin	C	Unknown		Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported
Risedronate	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
Salbutamol	C	Unknown	Unknown	Not Reported
Salicylic Acid/Triamcinolone Acetonide	C	Intra-articular		Not Reported
Triamcinolone	C	Unknown		Not Reported
Tylenol	C	Unknown	Unknown	Not Reported
Xeljanz	C	Oral		Not Reported
Calcium Gluconate	C	Unknown	Unknown	Not Reported
Lactobacillus Acidophilus	C	Unknown	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Unknown	Not Reported
Salicylic Acid	C	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Suspension, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16095354	EXPEDITED (15-DAY)		OT	CA-BECTON DICKINSON-2019BDN00113		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister;	Chlorhexidine			S				Becton Dickinson
Confusional State;	Chlorhexidine Gluconate			S				Becton Dickinson
Contraindicated Product	Abatacept			S	Intravenous (not			Not Reported

Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased			otherwise specified)		
	Acetaminophen	S			Not Reported
	Acetaminophen/Oxycodone Hydrochloride	S			Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate	S			Not Reported
	Act Oxycodone Cr	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
	Actemra	S		Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg; 4 Every 1 Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
	Apo-Acetaminophen	S			Not Reported
	Chlorhexidine Gluconate Oral Rinse	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported

Enbrel	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Oxycodone	S			Not Reported
Oxycodone-Acetaminophen	S			Not Reported
Oxycodone Cr	S			Not Reported
Oxycodone Hydrochloride	S			Not Reported
Oxycodone Terephthalate	S			Not Reported
Periogard	S			Not Reported
Periogard Alcohol Free	S	Buccal		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Sulfamethoxazole	S			Not Reported
Sulfamethoxazole/Trimethoprim	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Arava	C		Unk	Not Reported
Cetirizine	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Desogestrel/Ethinyl Estradiol	C			Not Reported
Hydroxychloroquine Phospate	C			Not Reported
Hydroxychloroquine Sulfate	C		400 Mg, 1x/Day	Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Paracetamol	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Reactine	C		10 Mg, 2x/Day	Not Reported

	Reactine			C		Unk			Not Reported
	Tylenol			C					Not Reported
	Tylenol With Codeine			C					Not Reported
	Tylenol #1			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16444894	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033815		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Coumadin			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Imuran			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16770849	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1100415			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension;	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The		Actavis

Therapeutic Product Effect Incomplete; Visual Impairment				Interval: 12 Definition Of The Interval: Hour	
	Sildenafil Citrate	S	Unknown	60 Milligram Daily; 60 Milligram, Daily Dose	Actavis
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qwk	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram Daily; 30 Milligram, Qd	Not Reported
	Lyrica	S	Unknown	300 Milligram Daily; 100 Milligram, Tid	Not Reported
	Apixaban	S		10 Milligram Daily; 2.5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16866958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-092201		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug	Abatacept			S	Unknown			Bristol Myers Squibb

Ineffective; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Adalimumab	S	Subcutaneous	40 Milligram		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	50 Milligram		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
	Kevzara	S	Unknown	Unk		Not Reported
	Mefenamic Acid	S	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17124253	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not	280 Milligram, Qwk		Not Reported

Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk (12.5 Milligram, 4 Every 1 Week)	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Unknown	Unk	Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Oral	10 Milligram, Qd (5 Milligram, 2 Every 1 Day)	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17390832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0682		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17397400	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA032774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported

	Xeljanz			S	Unknown	Unk				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17450142	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1058		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Wound	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Atasol [Paracetamol]			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine;Hydrochloride;Pseudo ephedrine			S	Unknown			Not Reported

Cortisone Acetate	S	Topical	Not Reported
Desoximetasone	S	Oral	Not Reported
Diclofenac	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Topicort	S	Subcutaneous	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Vitamin C	C	Unknown	Not Reported
Vitamin D	C	Unknown	Not Reported
Alaskan Salmon Oil	C	Unknown	Not Reported
Glucosamine	C	Unknown	Not Reported

	Lansoprazole	C	Unknown			Not Reported
	Ativan	C	Unknown	As Needed		Not Reported
	Salazopyrin	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557868	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013437		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	1 Milliliter, Every Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, 1 Every 1 Month		Not Reported
	Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported

Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 1 Month	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Altace	C	Unknown	5 Milligram	Not Reported
Altace	C	Unknown	10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C	Unknown	300 Milligram	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once A Day	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Once A Day	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	0.625 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	20 Milligram	Not Reported
Cymbalta	C	Unknown	30 Milligram, Four Times/Day	Not Reported
Cymbalta	C	Unknown	60 Milligram	Not Reported
Cymbalta	C	Unknown	120 Milligram, Once A Day	Not Reported
Cipralex	C	Unknown	20 Milligram	Not Reported
Escitalopram	C	Unknown	10 Milligram	Not Reported
Estrace	C	Unknown	0.5 Milligram	Not Reported
Gabapentin	C	Oral	100 Milligram	Not Reported
Gabapentin	C	Unknown	3000 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Milligram, Two Times A Day	Not Reported

	Hydromorphone Hydrochloride		C	Oral	30 Milligram, Two Times A Day	Not Reported
	Mupirocin		C	Topical	Unk	Not Reported
	Pantoloc		C	Intravenous (not otherwise specified)	20 Milligram, Once A Day	Not Reported
	Shark Liver Oil		C	Unknown	Unk	Not Reported
	Tapentadol Hydrochloride		C	Unknown	50 Milligram	Not Reported
	Taro-Mupirocin		C	Topical	Unk	Not Reported
	Tramacet		C	Oral	Unk	Not Reported
	Tramadol Hydrochloride		C	Oral	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557974	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558021	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201711-006521			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia
	Apo-Folic			S	Unknown	1 Dosage Form, Biw(Twice A Week)		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Not Reported

	Apo-Prednisone			S	Unknown	5 Mg, Qd	Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd	Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Times In A Week	Not Reported
	Xeljanz			S	Oral	5 Mg, Bid	Not Reported
	Xeljanz			S	Oral	5 Mg, Bid	Not Reported
	Xeljanz			S	Oral	5 Mg, Qd	Not Reported
	Xeljanz			S	Oral	5 Mg, Unk	Not Reported
	Sulfasalazine			C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558061	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013432		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10.0 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400.0 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5.0 Milligram		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20.0 Milligram, Once A Day		Not Reported
	Methotrexate			S	Oral	25.0 Milligram		Not Reported

	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400.0 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000.0 Milligram, Two Times A Day	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558697	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Cetrizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

			Folic Acid	S	Unknown	Unk		Not Reported
			Humira	S	Subcutaneous	Unk		Not Reported
			Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
			Methotrexate	S	Unknown	Unk		Not Reported
			Phthalylsulfathiazole	S	Unknown			Not Reported
			Prednisone	S	Unknown	Unk		Not Reported
			Remicade	S	Intravenous (not otherwise specified)			Not Reported
			Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Usp		Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	C		Not Reported
	Ciclosporin	C		Not Reported
	Minocycline	C		Not Reported
	Penicillamine	C		Not Reported
	Prednisone	C		Not Reported
	Actemra	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558984	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201806-002196			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Vitreous Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	100 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod (Film-Coated Tablet)		Concordia
	Onetram			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Prorenal			C		Unk		Not Reported
	Seroquel			C		Unk		Not Reported
	Magnesium Oxide			C		Unk		Not Reported
	Cefalexin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08978		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559017	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08970		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Parenteral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

						otherwise specified)				
		Sulfasalazine			S	Unknown	Unknown			Not Reported
		Arava			C	Unknown	Unknown			Not Reported
		Prednisone			C	Unknown	Unknown			Not Reported
		Tofacitinib			C	Unknown	Unknown			Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569481		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559216	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021540		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Unk			Not Reported
	Anakinra			S	Unknown	Unk			Not Reported
	Arava			S	Unknown	Unk			Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Desoximetasone			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559409	EXPEDITED (15-DAY)		DS	CA-ROCHE-2568722		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Rituxan			S	Intravenous (not			Not Reported

Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C		Not Reported
	Folic Acid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565794		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559517	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568861		89 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559606	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2081773		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021632		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559938	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1439		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Morphine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559980	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021788		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Cimzia		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560048	EXPEDITED (15-DAY)		OT	GB-ACCORD-176336		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin/Atorvastatin Calcium			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown			Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

		Rivaroxaban			S	Unknown				Not Reported
		Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560261	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202003001629			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia; Hangnail; Nail Avulsion; Onychoclasis; Sjogren'S Syndrome; Stomatitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Resumption		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560263	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003001668			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Concordia

Hypersensitivity	(Authorized Generic),Plaquenil				
	Nivaquine	C	100 Mg		Not Reported
	Nivaquine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560475	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	5 Milligram, Q12h		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021576		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb

Off Label Use	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560673	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021952		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Carotid Arteriosclerosis; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	2.5 Milligram, Qd		Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561009	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020118255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate Sodium			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561066	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Atorvastatin Calcium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Alprazolam			C		1 Mg, Unk		Not Reported
	Folic Acid			C		5 Mg, Unk		Not Reported
	Naprosyn [Naproxen]			C		500 Mg, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561096	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA202009727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Therapeutic Product Effect Incomplete	Human Normal Immunoglobulin		S	Intravenous (not otherwise specified)			Shire
	Azathioprine		S	Unknown			Not Reported
	Cyclophosphamide		S	Unknown			Not Reported
	Tofacitinib Citrate		S	Unknown			Not Reported
	Hydroxychloroquine		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561109	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Etanercept			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561204	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021856		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown	325 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, 4 Every One Week		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Q12h	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous	2000 Milligram	Not Reported
	Leflunomide	S	Unknown	200 Milligram, Qd	Not Reported
	Tylenol	S	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk, Qwk	Not Reported
	Synthroid	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561711	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561810	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1206362		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydromorph Contin			C				Not Reported
	Prednisone			C				Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561811	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1206466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561822	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206400		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Amlodipine			C	Unknown	5 Milligram Daily;		Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

	Paroxetine			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Risedronate Sodium			C	Unknown				Not Reported
	Simvastatin			C	Unknown				Not Reported
	Telmisartan			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561842	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Lyrica			S	Oral				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206324		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561870	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206272		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo-Naproxen			C		1000 Milligram Daily;		Not Reported
	Apo-Prednisone			C				Not Reported
	Desoximetasone			C				Not Reported
	Ergocalciferol			C	Oral			Not Reported

	Folic Acid	C		1 Milligram Daily;	Not Reported
	Leucovorin Calcium	C			Not Reported
	Pantoprazole Magnesium	C		40 Milligram Daily;	Not Reported
	Pantoprazole Magnesium	C		1 Dosage Forms Daily;	Not Reported
	Vitamin C [Ascorbic Acid]	C	Oral		Not Reported
	Wellbutrin	C		300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561877	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206389			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562040	NON-EXPEDITED			US-PFIZER INC-2020117515		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Ciprofloxacin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562437	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562446	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020116277		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Dobupal			S		Unk Unk, 1x/Day (1/24)		Pfizer
	Hydrochlorothiazide/Losartan Potassium			S		50 Mg/12.5 Mg		Not Reported
	Eutirox			S		Unk Unk, 1x/Day (1/24)		Not Reported
	Dolquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567649			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300-400 ; Ongoing		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Ongoing		Not Reported
	Simponi			S	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206591		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022558		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021523		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal;	Orencia			S	Unknown			Bristol Myers Squibb

Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Acetaminophen	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk		Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2000 Milligram		Not Reported
	Meloxicam	C	Unknown			Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown			Not Reported
	Synthyroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	12928888	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Millilitre Per Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Oral	Unk		Not Reported

Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide	S	Oral	20 Milligram, Qh	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qcycle	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qh	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Qcycle	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actonel	S	Oral	35 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qcycle	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, One Every One Week		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Xeljanz	S	Oral	10 Milligram, Qd		Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Risedronic Acid	S	Unknown	35 Milligram, Qwk		Not Reported
Hydroxychloroquine	C	Unknown	300 Milligram, Qd		Not Reported
Risedronate	C	Unknown			Not Reported
Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13519848	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-000478		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Off Label Use; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis;	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Minocycline Hcl			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cannabis Sativa			S	Unknown			Not Reported

Urticaria	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Gram	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Q2wk	Not Reported
	Actemra	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Oxycodone	C	Unknown	10 Milligram	Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13594604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941652		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13901217	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170125543		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hepatotoxicity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pain; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Gold	S	Unknown	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Actonel	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate Sodium	S	Other	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Adalimumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	14326215	NON-EXPEDITED			US-AMGEN-USASP2017190208		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Asa			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Macrobid [Nitrofurantoin]			S	Unknown	Unk		Not Reported

			Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk			Not Reported
			Simponi		S	Unknown	Unk			Not Reported
			Xeljanz Xr		C		Unk			Not Reported
			Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15385213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184735		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15565611	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-CELLTRION INC.-2018CA023567			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

			Hydroxychloroquine		S	Unknown	Unk			Not Reported
			Hydroxychloroquine		S	Oral	Unk			Not Reported
			Arava		C	Unknown	Unk			Not Reported
			Arava		C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15620814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556952-00		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15622519	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557164-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C		Enteric Coated	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C			Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Bluefish	C			Not Reported

	Tenofovir Disoproxil			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15625325	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557482-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15629661	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557290-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased			otherwise specified)		
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Asa	C			Not Reported
	Clonazepam	C	Oral		Not Reported
	Desipramine	C	Unknown		Not Reported
	Nitroglycerin	C			Not Reported
	Rosuvastatin Calcium	C	Oral		Not Reported
	Gabapentin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15635193	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Oral		Not Reported
	Desoximetasone		C	Unknown	Unk	Not Reported
	Methotrexate		C	Oral	25 Mg, Qwk	Not Reported
	Prednisone		C	Unknown	30 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15741776	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181218371		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Procytox			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16075459	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012877		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every		Aurobindo

Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer				Week	
	Actemra	S	Unknown	680 Milligram, 1 Every 4 Week	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every Week	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every Month	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Every Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, 1 Every Month	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Two Times A Day	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

	Xeljanz	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16122724	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	20 Nanogram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Qwk		Not Reported

	Methotrexate	C	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate	C	Unknown	Unk, Q4wk		Not Reported
	Synthroid	C	Unknown	Unk		Not Reported
	Acetaminophen & Cod. Phosp.	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16145460	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA019978			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly, Unknown		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	25 Mg, 2x/Week (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Etanercept			S	Unknown	50 Mg, Weekly		Not Reported
	Celebrex			S		Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15.5, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Q4wk		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Q4wk		Not Reported

Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Not Reported

Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg,Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported

Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk,	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported

Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisolone	C		Unk	Not Reported
Alendronate	C	Unknown	Unk	Not Reported
Alendronate	C	Unknown	70 Mg, Weekly	Not Reported
Alendronate	C	Unknown	70 Mg, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16211394	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020276		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Meloxicam	S	Unknown	Unk	Aurobindo
	Actemra	S	Unknown	160 Milligram, Every Week	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Depo Medrol	C	Intra-articular	80 Milligram	Not Reported
	Depo Medrol	C	Intramuscular	80 Milligram, Once A Day	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16216662	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020655		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder;	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate			S	Unknown	16.35 Milligram, 1 Every 2 Weeks		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, 1 Every 1 Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actonel			S	Unknown	35 Milligram, 1 Every 1		Not Reported

Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis				Week	
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Cyclical	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, One Every One Hour	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every Two Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, One Every One Hour	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, 1 Every 1 Week	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported

	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
	Risedronate	C	Unknown	35 Milligram, Every Week	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16227903	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA020634			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Dose		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Plaquenil	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Humira	S		Unk	Not Reported
Methadone	S		Unk	Not Reported
Rampril	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
Estrogel	C	Unknown	1.0 Df Qd	Not Reported
Estradiol	C		Unk, Tid	Not Reported
Calcium	C		500 Milligram, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
Cosopt	C		Unk, 2x/Day	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Vitamin D	C		10000 Unit, Weekly	Not Reported
Jamp K20	C		1500 Mg, 1x/Day	Not Reported
Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported

	Gravol Ginger			C	Oral	500 Milligram, As Needed			Not Reported
	Baclofen			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16446297	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2822466-00		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16510049	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570129-00		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16682901	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-22253		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Off Label Use; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Acetaminophen And Codeine			C	Unknown			Not Reported
	Acetaminophen And Codeine			C	Unknown	Unknown		Not Reported
	Acetaminophen And Codeine			C	Unknown	Unknown		Not Reported
	Amitriptyline Hydrochloride			C	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Baclofen			C	Unknown	Unknown		Not Reported
	Betahistine Hydrochloride			C	Unknown	Unknown		Not Reported

	Caffeine	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Clonidine	C	Unknown	Unknown	Not Reported
	Clonidine Hydrochloride	C	Unknown	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unknown	Not Reported
	Fluticasone Propionate	C	Unknown	Unknown	Not Reported
	Folinic Acid	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Unknown	Not Reported
	Losartan	C	Unknown	Unknown	Not Reported
	Metoprolol Tartrate	C	Unknown	Unknown	Not Reported
	Mometasone Furoate	C	Unknown	Unknown	Not Reported
	Naproxen	C	Unknown	Unknown	Not Reported
	Naproxen	C	Unknown	Unknown	Not Reported
	Tylenol With Codeine	C	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Plaquenil	C	Unknown		Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Codeine	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16700535	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2885154-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated;	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Route: Suspension Intra-		Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Wheelchair User	Triamcinolone Acetonide	S	Articular	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Naproxen	S		Not Reported
	Apo-Naproxen	S	Subcutaneous	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naproxen	S		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Triamcinolone	S		Not Reported
	Triamcinolone	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Anakinra	S		Not Reported
	Anakinra	S	Oral	Not Reported
	Prednisone	S		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S		Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Triamcinolone Hexacetonide	S		Not Reported

	Folic Acid			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16820459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3442			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Product Use Issue; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16833020	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2933128-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Arava	C				Not Reported
	Plaquenil	C	Oral			Not Reported
	Prednisone	C				Not Reported
	Simponi	C				Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16878971	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2569757-00		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Plaquenil			S	Unknown				Not Reported
		Desoximetasone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17144108	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2800982-00		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Chest Discomfort; Chest X-Ray Abnormal; Fall; Glaucoma; Joint Swelling; Macular Degeneration; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Folic			C	Unknown			Not Reported
	Eliquis			C				Not Reported
	Prilosec			C				Not Reported
	Zantac			C				Not Reported
	Losartan			C				Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17153987	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027344			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

	Morphine Sulfate	S	Unknown	Unk	Not Reported
	Morphine Hydrochloride	S	Unknown	Unk	Not Reported
	Cefixime	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Oral	100 Milligram	Not Reported
	Nifedipine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rivotril	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported
	Zopiclone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17324085	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005924		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Ilaris	S	Subcutaneous			Not Reported
	Ilaris	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17412202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000692			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pleural Effusion	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17439290	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011929		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Skin Eruption	Coumadine		S	Oral	Unk	Bristol Myers Squibb
	Innohep		S	Oral	Unk	Not Reported
	Omnipaque		S	Intravenous (not otherwise specified)	55 Milliliter	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Unk	Not Reported
	Kardegic		S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17530620	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17549765	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-013114		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk,6 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563119	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022177		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	2 Dosage Form, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1 Dosage Form, Qd		Not Reported

	Furosemide	C	Unknown	40 Milligram, Qd		Not Reported
	Morphine	C	Unknown			Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd		Not Reported
	Zingiber Officinale	C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, 3 Every 1 Day		Not Reported
	Premarin			C	Unknown			Not Reported
	Tylenol			C	Unknown	650 Milligram, 2 Every 1		Not Reported

Day

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566876		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral	Solution		Not Reported
	Orencia	S	Unknown			Not Reported
	Vioxx	S	Unknown			Not Reported
	Naproxen	S	Unknown			Not Reported
	Leflunomide	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563528	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-176291		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Drainage; Pericardial Effusion; Pericardiotomy; Pleural	Mycophenolic Acid			S	Unknown	2.5 G, Qd		Accord
	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Not Reported
	Remodulin Sq			S	Subcutaneous	0.046 Mg, Q1hour		Not Reported
	Riociguat			C	Unknown	6 Mg, Qd		Not Reported

Effusion; Prohormone
Brain Natriuretic Peptide
Increased; Rales; Serositis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563805	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022560			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563950	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Simponi	C	Subcutaneous		Not Reported
Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564021	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Tenderness; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Herpes Simplex Hepatitis; Lethargy; Lymphopenia; Musculoskeletal Chest Pain; Nausea; Somnolence; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564032	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP008890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564060	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573629-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564141	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Consciousness; Mobility Decreased	Anakinra		S	Unknown	Not Reported
	Arava		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566946			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564456	EXPEDITED (15-DAY)		OT	CA-SA-2020SA067248			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Leflunomide		S		20 Mg, Qd		Sanofi
	Plaquenil		S		400 Mg, Qd		Sanofi
	Methotrexate		S	Unknown	20 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17565635	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022535		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Unk		Not Reported
	Prednisone			S	Unknown	20 Nanogram		Not Reported
	Rituximab			S	Intravenous drip	2 Gram		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Unk		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566118	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-095261		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Alendronic Acid			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Apo-Alendronate			S	Unknown	Unk		Not Reported

Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	17.5 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	10 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram,Four In One Week	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram,Two Every One Week	Not Reported

Enbrel	S	Unknown	25 Milligram	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram	Not Reported
Ibuprofen	S	Unknown	600 Milligram, Once A Day	Not Reported
Ibuprofen	S	Unknown	Unk, Once A Day	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Motrin	S	Oral	600 Mg, Qd	Not Reported
Motrin	S	Oral	Unk Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram,One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Milligram,One Every Four Week	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported

Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Humira	C	Unknown	40 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	70 Milligram, Every Week	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	C	Unknown	680 Milligram	Not Reported
Tocilizumab	C	Unknown	360 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Two Times A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566974	EXPEDITED (15-DAY)		OT	NVSC2020CA079201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Disorder; Off Label Use; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Desvenlafaxine Succinate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Oral	20 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Quetiapine Fumarate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567557	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022569		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Use; Rheumatoid Arthritis; Suicidal Ideation	Alendronate Sodium		C	Unknown		Not Reported
	Fosamax		C	Unknown		Not Reported
	Ibuprofen		C	Unknown		Not Reported
	Lisinopril		C	Unknown		Not Reported
	Vitamin D 3		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567657	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022553		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Xeljanz			S	Unknown	5.0 Milligram 2 Every 1 Days		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

	Synthroid			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567671	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA078923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Stelara			S	Subcutaneous	Unk (Solution)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567912	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022607		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567934	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022780		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568087	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022579		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported

Use Issue	Methotrexate	S	Subcutaneous	25.0 Milligram		Not Reported
	Plaquenil S	S	Unknown	200.0 Milligram, Qwk		Not Reported
	Amitriptyline	C	Unknown			Not Reported
	Hydromorph Contin	C	Unknown			Not Reported
	Lyrica	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022615		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 1 Every 1 Days		Not Reported
	Morphine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568283	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA068487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contusion; Drug Ineffective	Hydroxychloroquine Sulfate		S				Sanofi
	Leflunomide		S	Oral	20 Mg		Sanofi
	Methotrexate		S	Subcutaneous			Not Reported
	Methotrexate		S	Oral	17.5 Mg		Not Reported
	Xeljanz		S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568289	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15622307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557499-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15624381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556781-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15663999	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570464-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Itravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Ntravenous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S		Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15683294	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573840-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Diclofenac			C				Not Reported

Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure	Depo-Medrol			C	Intra-arterial				Not Reported
	Xeljanz			C	Oral				Not Reported
	Prednisone			C	Unknown				Not Reported
	Pantoprazole Magnesium			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	16718423	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892907-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17563703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3328160-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Pneumothorax	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17567968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2020025732			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Clopidogrel	S	Unknown	Unk		Macleods
	Atorvastatin	S	Unknown	Unk		Not Reported
	Apixaban	S	Unknown	Unk		Not Reported
	Warfarin	S	Unknown	Unk		Not Reported
	Rivaroxaban	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17572435	DIRECT					39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral	Hydroxychloroquine	Y		S			6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	13186699	EXPEDITED (15-DAY)		OT	CA-ROCHE-1888735		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	14906435	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1678150-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tylenol			S	Unknown	Dosage Maintained		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Tylenol No. 3			C				Not Reported
	Celebrex			C				Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported
	Hydromorphone Hcl			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	14921809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Gold			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Remicade			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	100 Mg, Unk		Not Reported
	Ativan			C	Unknown	1 Gram, Qd		Not Reported
	Ativan			C	Unknown	1 Milligram		Not Reported

Codeine	C	Unknown		Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Intra-articular	Unk	Not Reported
Dexamethasone	C	Unknown		Not Reported
Dilaudid	C	Unknown	4 Milligram, Qid	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Diphenhydramine	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Mg, Unk	Not Reported
Lasix [Furosemide]	C	Unknown	40 Milligram, Tid	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Vagifem	C	Vaginal		Not Reported
Dyclonine Hydrochloride	C	Unknown	Unk	Not Reported
Benadryl Cold	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk, Prn	Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported

	Rituximab			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15328456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15683363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574500-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin			C				Not Reported

		Cymbalta			C					Not Reported
		Hydromorphone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17530404	EXPEDITED (15-DAY)		OT	NVSC2020CA070217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17533813	EXPEDITED (15-DAY)		OT	NVSC2020CA069732		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Df		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	50 Mg		Not Reported
	Zingiber Officinale			C	Oral	500 Mg		Not Reported
	Zingiber Officinale			C	Unknown	500 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xalatan			C	Ophthalmic	50 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Jamp K20			C	Unknown	1500 Mg, Qd		Not Reported
	Gravol			C	Unknown	500 Mg		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported

	Estrogel	C	Unknown	1 Df, Qd		Not Reported
	Estrogel	C	Unknown	0.6 % Tid		Not Reported
	Estradiol	C	Unknown	0.6 % Tid		Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qw		Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qw		Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qd		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk Unk, Bid		Not Reported
	Calcium	C	Unknown	500 Mg, Qd		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Tofacitinib Citrate	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17542710	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA071289		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Naprosyn	C	Unknown			Not Reported
	Erythromycine	C	Unknown	Unk		Not Reported
	Morphine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17545270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17569409	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022556		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram 1 Every 1 Months		Not Reported
	Alendronate			S	Unknown	70 Milligram 1 Every 1 Weeks		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	12.0 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Unknown	10.0 Milligram 1 Every 1 Weeks		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	1000 Milligram 2 Every 1 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram 1 Every 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Milligram 1 Every 1 Weeks		Not Reported

	Methotrexate	S	Oral	10 Milligram 1 Every 1 Weeks		Not Reported
	Ciclosporin	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	11865597	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2012292491		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (Q12h)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, Daily (2 In 1 Day)		Pfizer
	Xeljanz			S		12.5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day Qd (1 Every 1 Day)		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aleve			S	Unknown	Unk		Not Reported

Adalimumab	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Oral	5 Mg, 2x/Day (Q12h)	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Naproxen	S		Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hcq	C		Unk	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported

					Insulin	C	Unknown	Unk	Not Reported
					Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
					Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
					Methotrexate	C	Unknown	20 Milligram	Not Reported
					Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	12769492	EXPEDITED (15-DAY)		CA, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Orencia			S	Endocervical	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	Unk, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Vioxx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Oral	500 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Milligram, 2 Times/Wk		Not Reported
	Naproxen Sodium			S	Oral	500.0 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide			S	Unknown	20 Milligram			Not Reported
	Actemra			S	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid			Not Reported
	Leflunomide			C	Unknown	10 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13147266	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005239		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13251292	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006546		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	0.8 Ml, Q.Wk.		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14235040	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2017AP021690		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	50 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14238496	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021706			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Varenicline Tartrate			S				Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported
	Valtrex			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14239514	EXPEDITED (15-DAY)		HO, OT	CA-PURDUE PHARMA-CAN-2016-0006553		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Skin Lesion; Sleep Disorder; Treatment Failure	Oxycontin	S	Unknown	Unk	Purdue
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Monthly	Not Reported
	Arava	S	Oral	20 Mg, Daily	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk Unk, Weekly	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 3 Weeks	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Daily	Not Reported
	Sulfasalasin	S	Oral	2.5 G, Daily	Not Reported
	Acetaminophen W/Oxycodone	C		1 Df, Prn	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Actonel	C	Unknown	36 Mg, Weekly	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
	Tocopherol	C	Unknown	Unk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Daily	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Daily	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Daily	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported

Ferrous Gluconate	C	Unknown	300 Mg, Daily	Not Reported
Loperamide Hcl	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Pantoprazole	C	Unknown	40 Mg, Daily	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Daily	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Daily	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14757583	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009592			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Penicillin			S	Unknown	Unk		Apotex

Nodule; Synovitis; White Blood Cell Count Decreased	Acetylsalicylic Acid	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Aspirin /00002701/	S	Unknown	Unk		Not Reported
	Penicillin G /00000901/	S	Unknown	Unk		Not Reported
	Penicillin G Potassium	S	Unknown	Unk		Not Reported
	Penicillin G Procaine	S	Unknown	Unk		Not Reported
	Pregabalin	C	Unknown	Unk		Not Reported
	Tylenol /00020001/	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15619609	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555410-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	11 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

					Sodium Aurothiomalate		S	Unknown		Not Reported
					Gold		S	Unknown		Not Reported
					Leflunomide		S	Unknown		Not Reported
					Xeljanz		C	Oral		Not Reported
					Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15623842	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557025-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Toe Amputation; Victim Of Crime	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Ophthalmic			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Vitamins Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15629783	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557408-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16357705	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-TREX2019-1532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)		S	Subcutaneous	Not Reported
	Xeljanz		S	Oral	Not Reported
	Estradot		S	Transdermal	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16473931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1994		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Inflammation; Joint Stiffness; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16857402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574079-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Urticaria	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17529190	EXPEDITED (15-DAY)		OT	NVSC2020AU065740			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma	Tacrolimus			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	10 Mg, Unknown		Not Reported
	Prednisone			S	Unknown	Up To 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	0.25 Mg/Kg, Unknown		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Remicade			S	Unknown				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023149			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Endocervical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569480	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001670			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1000 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Gliclazide			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported

	Rabeprazole	C	Unk	Not Reported
	Mr	C	Unk	Not Reported
	Metformin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569650	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022575		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Alendronate			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, Bid		Not Reported

	Sulfasalazine			S	Unknown	Unk				Not Reported
	Xeljanz			C	Unknown	Unk				Not Reported
	Prednisone			C	Unknown	Unk				Not Reported
	Ciclosporin			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569669	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023123			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569671	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022648		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

	Arava			S	Unknown	Unk			Not Reported
	Enbrel			S	Subcutaneous	Unk			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565726		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569843	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022714		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Qmo	Not Reported
	Arava	S	Intravenous (not otherwise specified)	20 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Gabapentin	S	Unknown	100 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	2.5 Gram, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported

	Prednisone	C	Unknown	5 Gbq 1 Every 1 Day	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qd	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	1000 Milligram, Qd	Not Reported
	Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569878	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1451			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Atorvastatin Calcium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Alprazolam	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570139	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201611-005804			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Unk		Concordia
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg (Tablet)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not	2 G,Qcy; Iv Nos		Not Reported

			otherwise specified)		
	Rituxan	S	Unknown	2 Unk, Qcy; Unknown	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m; Iv Nos	Not Reported
	Etanercept	S		50 Mg, Weekly	Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570142	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000092			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Levothyroxin			C		Unk		Not Reported
	Raloxifene			C		Unk		Not Reported
	Lidoderm			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570259	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb

Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra	S	Unknown			Not Reported
	Anakinra	S	Subcutaneous	Unk Unk, Qd		Not Reported
	Anakinra	S	Unknown			Not Reported
	Apo-Naproxen	S	Unknown			Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid		Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Humira	S	Unknown			Not Reported
	Hydroxychloroquine	S	Oral	Unk Unk, Qd		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone	S	Intra-articular			Not Reported
	Triamcinolone	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rash	Leflunomide			S		10 Mg		Sanofi
	Plaquenil			S	Oral	200 Mg, Q12h		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570308	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068804			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Interstitial Lung Disease	Leflunomide	S	Unknown	Unk		Sanofi
	Plaquenil	S	Unknown	400 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570311	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068793			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hepatotoxicity; Rash; Treatment Failure	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S		1 Df		Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S		1 Df		Not Reported
	Orencia			S	Subcutaneous	125 Df, Qw		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570367	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023442		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Humira		S	Unknown	Not Reported
	Hydroxychloroquine Sulphate		S	Unknown	Not Reported
	Hydroxychloroquine Sulphate		S	Unknown	Not Reported
	Ilaris		S	Subcutaneous	Not Reported
	Ilaris		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituximab		S	Intravenous drip	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Other	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570370	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-01473		52 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Lupin
	Prednisone			S	Unknown	60 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd In 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570449	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2500975-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Platelet Count Decreased; Rhinorrhoea; Skin Mass	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Synthetic Morphine			C	Unknown	Unknown Dose 1 Or 2		Not Reported
	Tylenol			C		Unknown Hs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570439		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not			Not Reported

Lymphoma; Rheumatoid Arthritis			otherwise specified)	
	Apo-Azathioprine	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571132		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Arava		C	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Xeljanz		C	Oral		Not Reported
	Xeljanz Xr		C	Oral		Not Reported
	Xeljanz Xr		C	Unknown		Not Reported
	Xeljanz Xr		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570607	EXPEDITED (15-DAY)		OT	NVSC2020CA077910		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	6.78 Mg/Kg (Cumulative Dose 1.24 Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570792	EXPEDITED (15-DAY)		OT	NVSC2020CA079412		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicaide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Stelara		S	Subcutaneous	Unk			Not Reported
	Sulfasalazine		S	Unknown	Unk			Not Reported
	Leflunomide		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570987	NON-EXPEDITED			US-PFIZER INC-2020121578		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk (0, 2, 6 Wks, Then Every 8 Wks.)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk (Every 8 Weeks)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk (Every 7 Weeks)		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Otrexup			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Other	Unk		Pfizer
	Enbrel			S	Unknown			Pfizer
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		20 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571456	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA079635		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Oral	75 Mg, Bid		Novartis
	Apo Diclo			S	Oral	75 Mg, Bid		Not Reported
	Apo Lisinopril			S	Oral			Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac Potassium			S	Oral	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Lisinopril			S	Unknown			Not Reported
	Lisinopril Dihydrate			S	Unknown			Not Reported

	Methotrexate			S	Subcutaneous	20 Mg, Qw	Not Reported
	Pantoprazol			S	Unknown		Not Reported
	Pantoprazol			S	Oral	Unk	Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk	Not Reported
	Sulfasalazine			S	Oral	2 G, Qd	Not Reported
	Synthroid			S	Oral		Not Reported
	Tecta			S	Oral		Not Reported
	Xeljanz			S	Oral	10 Mg, Qd	Not Reported
	Gold			C	Unknown		Not Reported
	Depo-Medrol			C	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572198	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024000			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

	Sulfasalazine				S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572243	EXPEDITED (15-DAY)		OT	US-SA-2020SA071865			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Drug Interaction; Retinopathy; Visual Field Defect	Hydroxychloroquine			S				Sanofi
	Docetaxel			S				Sanofi
	Anastrozole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572378	EXPEDITED (15-DAY)		OT	NVSC2020CA079465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573060	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1029307			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock;	Mycophenolate Mofetil			S	Unknown	2.5 Gram		Not Reported

Serositis	Bosentan		S	Unknown	250 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Mylan
	Prednisolone		S	Unknown	5 Milligram	Mylan
	Remodulin		S	Subcutaneous	0.046 Mg/H, Continuing	Mylan
	Riociguat		C	Unknown	6 Milligram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573076	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA079709		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573103	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1031278		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	For 6 Weeks		Not Reported
	Prednisone			S	Oral	1 Milligram/Kilogram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573142	EXPEDITED (15-DAY)		OT	NVSC2020CA079502		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573170	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023021		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Q6wk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Wellbutrin			C	Unknown				Not Reported
	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573206	EXPEDITED (15-DAY)		OT	NVSC2020CA079493		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Unknown	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Depo-Medrol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573227	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Topicort Lp	S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023109		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported

	Prednisone			C	Unknown	30 Milligram, Qd				Not Reported
	Desoximetasone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573405	NON-EXPEDITED			NVSC2020US082232			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Hydroxychloroquine			S	Oral	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17581632	DIRECT					66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Plaquenil			S	Oral			Not Reported
	Tirosint			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	13058057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015766		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

						Enbrel	S	Subcutaneous		Not Reported
						Actemra	S	Unknown		Not Reported
						Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
						Prednisone	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	13251448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Hydroxyquine			S				Apotex
	Apo-Cyclosporine			S	Unknown			Apotex
	Apo-Cyclosporine			S				Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S				Apotex
	Azathioprine			S	Unknown	Unk		Apotex
	Azathioprine			S				Apotex
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Gold			S	Unknown			Not Reported

	Gold	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Imuran /00001501/	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown	640 Mg, Q.Wk.	Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	14498265	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Off Label Use; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15629234	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558776-00		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pneumonia; Rash; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Dose Decreased		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Intravenous Drip		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Apo-Acetaminophen	S	Unknown	Not Reported
Doxycycline	S	Unknown	Not Reported
Doxycycline Hyclate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
Meloxicam	C		Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Synthroid	C	Unknown	Not Reported
Codeine Phosphate	C		Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Celebrex	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15632850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105426		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

	Hydroxychloroquine			S	Unknown	200 Milligram	Not Reported
	Methotrexate			S	Oral	Unk	Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram	Not Reported
	Xeljanz			C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15681461	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575030-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

					Synthroid	C	Unknown			Not Reported
					Remicade	C	Intravenous (not otherwise specified)			Not Reported
					Orencia	C				Not Reported
					Acetylsalicylic Acid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15689905	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324553AA		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Anakinra			S		50 Mg, Qd		Not Reported
	Humira Ac			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15707284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584423-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Rituxan			S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Sulfasalazine			C		Not Reported
	Wellbutrin			C		Not Reported
	Xeljanz			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15712957	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588343-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Gold			S	Unknown				Not Reported
		Certolizumab Pegol			S	Unknown				Not Reported
		Azathioprine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16079901	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05867			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown.	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown, Suspension Intra-Articular	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16211049	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA020214		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis	Hydroxychloroquine			S	Oral	5 Mg/Kg,Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Human Immunoglobulins			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Human Immunoglobulins			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Human Immunoglobulins			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2,Qow		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Qw		Not Reported

Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Naproxen	S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone	S	Oral	5 Mg,Bid	Not Reported
	Prednisone	S	Oral	3 Mg,Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Isoniazid/Rifampicin	S	Intravenous (not otherwise specified)	Unk	Sanofi
	Sulfasalazine	S	Oral	250 Mg,Qd	Not Reported
	Adalimumab	S	Unknown	Unk Unk,Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	250 Mg,Qm	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg,Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg,Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg,Qw	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg,Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg,Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg,Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg,Qw	Not Reported
	Tocilizumab	S		250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qcy (Every 2 Weel)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Folic Acid	C			Not Reported

	Triamcinolone Hexacetonide			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16778722	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201706-003601			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid	Hydroxychloroquine			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	680 Mg, Monthly		Not Reported
	Actemra			S	Unknown	360 Mg, Monthly		Not Reported
	Actemra			S	Unknown	380 Mg, Unknown		Not Reported
	Actemra			S	Unknown	360 Mg, Monthly		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Weekly		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Freq: 2 X 1 Week		Not Reported
	Enbrel			S	Unknown	50 Mg, Freq: 2 X 1 Week, Biw		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Freq: 1 X 2 Weeks, Qow		Not Reported
	Humira			S		40 Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg Qow		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Oral	10 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Unk		Not Reported

Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	10 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	12.5 Unk	Not Reported
	Methotrexate	S	Unknown	12 Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported

Methotrexate	S	Unknown	17.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	15 Mg Q4w	Not Reported
Methotrexate	S	Unknown	12 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg Q4w	Not Reported
Methotrexate	S	Unknown	17 Unk	Not Reported
Methotrexate	S	Unknown	12.5 Unk, Q4w	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Unknown	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Powder And Solvent For Intravesical Suspension	Not Reported
Remicade	S	Unknown	, Powder And Solvent For Intravesical Suspensionunk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk Mg	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Monthly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Freq: 1 X 2 Weeks, Qow	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Tocilizumab	S	Unknown	680 Mg Q4w	Not Reported

	Ciclosporin	C	Unk		Not Reported
	Prednisolone	C			Not Reported
	Prednisone	C	Unk		Not Reported
	Prednisone	C	Unk		Not Reported
	Xeljanz	C			Not Reported
	Alendronate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16836959	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27185		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported

Ciclosporin	S	Unknown	Unknown	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
Cimzia	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not	Powder For Solution	Not Reported

				otherwise specified)	Intravenous	
	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Rituximab		S	Unknown	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unknown	Not Reported
	Varicella Zoster Vaccine Live		S	Subcutaneous	Unknown	Not Reported
	Piroxicam		C	Unknown	Unknown	Not Reported
	Prednisone		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16977712	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001380			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Neutropenia; Pain In Extremity; Rash; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	Unk, Weekly		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prevacid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17404137	EXPEDITED (15-DAY)		CA, HO, OT	NVSC2020CA032705		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unknown		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574330	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201711-006281			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	300 Mg		Concordia
	Arava			S	Oral	10 Mg		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Weekly; Solution	Not Reported
Methotrexate	S	Unknown	12.5 Mg	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
Salazopyrin	S	Unknown		Not Reported
Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Every Six Weeks	Not Reported
Orencia	S	Subcutaneous	25 Mg	Not Reported
Bifidobacterium Bifidum	C			Not Reported
Prednisone	C			Not Reported
Sulfasalazine	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Pantoprazole	C			Not Reported
Xeljanz	C			Not Reported
Simponi	C			Not Reported
Wellbutrin	C			Not Reported
Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574349	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005363			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Weekly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk, Solution Subcutaneous		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported

	Depo-Medrol	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Tylenol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574376	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001688			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Kevzara			S	Subcutaneous	20 Mg, Qow		Not Reported
	Leflunomide			S	Oral	20 Mg		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Cyclosporin			S	Intracardiac	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Xeljanz			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574713	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023101		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Orencia			S	Unknown			Bristol Myers Squibb

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Actemra	S	Unknown	160 Milligram, Qwk	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574715	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate			S	Oral	35 Milligram, Every Week		Aurobindo
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Milligram, Two Times A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	1 Gram, Two Times A Day		Not Reported
	Azathioprine			C	Oral	50 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	150 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	100 Milligram, Two Times		Not Reported

						A Day		
	Humira		C	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported
	Ketoprofen		C	Unknown	Unk		Not Reported
	Methotrexate		C	Oral	Unk		Not Reported
	Methotrexate		C	Subcutaneous	25 Milligram, Every Week		Not Reported
	Prolia		C	Subcutaneous	60 Milligram (1 Every 6 Months)		Not Reported
	Rituximab		C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574931	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	300-400 Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575142	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000867			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperhidrosis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Ipca
	Prednisolone			C	Unknown	Unk, Take As Directed		Not Reported
	Dermol			C	Unknown	Unk, Use As Directed		Not Reported
	Dermovate			C	Unknown	Unk, Apply 1-2 Times/Day Thinly To All Affected Areas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575254	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023112		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, 4 Every 1 Week		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575456	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Intentional Product Use Issue; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling;	Orencia			S	Intracavernous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, 2 Every 1 Day		Not Reported

Pneumonia Viral; Soft Tissue Swelling; Synovitis	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575525	NON-EXPEDITED			US-PFIZER INC-2020123929		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575752	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023400		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575760	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020120639			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575864	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567757		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate			S	Oral	Not Reported
	Cimzia			S	Subcutaneous	Not Reported
	Enbrel			S	Subcutaneous	Not Reported
	Humira			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported
	Prednisone			C	Oral	Not Reported
	Lyrica			C	Unknown	Not Reported
	Arava			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576314	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023435		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			C	Unknown	100 Milligram		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576658	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisone			C	Unknown	50 Milligram, 1 Every 1 Day		Not Reported
	Prevacid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	50 Milligram, 2 Every Q Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome;	Orencia			S	Unknown			Bristol Myers Squibb

Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Nystatin	S	Unknown		Not Reported
	Nystatin	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tramadol	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Indometacin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577584	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

Azathioprine				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577628	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023475		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023552		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported

	Septra			C	Unknown					Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023607		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown	100 Milligram		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Kadian			C	Unknown	Unk		Not Reported

	Kenalog [Triamcinolone Acetonide]			C	Intra-articular	Unk			Not Reported
	Loperamide			C	Unknown	Unk			Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown				Not Reported
	Omnaris			C	Unknown	Unk			Not Reported
	Oxyneo			C	Unknown				Not Reported
	Pantoprazole			C	Unknown				Not Reported
	Restasis			C	Unknown				Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	Unk			Not Reported
	Synthroid			C	Unknown	Unk			Not Reported
	Trimethoprim			C	Unknown				Not Reported
	Urispas			C	Unknown	200 Milligram			Not Reported
	Vagifem			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578076	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown			Not Reported
	Infliximab	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Prednisone	C	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate	C	Oral	15 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578458	EXPEDITED (15-DAY)		OT	US-JNJFOC-20200329683			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Gastric Disorder; Gastritis; Nail Discolouration; Nail Disorder; Nausea; Pancreatitis; Skin Lesion; Tuberculosis; Vomiting; Weight Decreased	Simponi Aria		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Spironolactone		C			Not Reported
	Verapamil		C			Not Reported
	Omeprazole		C			Not Reported
	Vitamin D /00107901/		C			Not Reported
	Calcium /00060701/		C			Not Reported
	Albuterol /00139501/		C			Not Reported
	Carafate		C			Not Reported
	Dulera		C			Not Reported
	Prednisone		C		5 Mg For The First 3 Days/ / -/ / Tablets Taper Dose Down	Not Reported
	Ipratropium Bromide		C			Not Reported
	Albuterol Sulfate		C			Not Reported
	Singulair		C			Not Reported
	Claritin /00917501/		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020123955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578942	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024664		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578947	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024594		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578991	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024991			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported

Synovitis; White Blood Cell Count Decreased	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023964		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17579024	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug	Orencia			S	Unknown			Bristol Myers Squibb

Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Acetaminophen	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown	20 Milligram, Qwk		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2000 Milligram		Not Reported
	Synthroid	C	Unknown			Not Reported
	Methotrexate	C	Unknown	Unk, Qwk		Not Reported
	Meloxicam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	12701613	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1490		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Xeljanz	S	Oral	2 In 1 Day	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Aleve	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Cyclical	Not Reported
	Leflunomide	S	Unknown		Not Reported

	Leflunomide			S	Unknown	Not Reported
	Leflunomide			S	Oral	Not Reported
	Plaquenil			S	Unknown	Not Reported
	Prednisone			S	Unknown	Not Reported
	Folic Acid			C	Unknown	Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Not Reported
	Hcq			C	Unknown	Not Reported
	Acetaminophen And Codeine			C	Unknown	Not Reported
	Celebrex			C	Unknown	Not Reported
	Insulin			C	Unknown	Not Reported
	Metformin			C	Unknown	Not Reported
	Tylenol			C	Unknown	Not Reported
	Methotrexate			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	12911486	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	13152994	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004666		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14145032	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-095890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Drug Ineffective; Hospitalisation; Meningitis; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Unk				Not Reported
	Methotrexate			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14539306	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0138		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo Hydroxychloroquine			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S				Not Reported
	Methotrexate			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14917725	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-071465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	577 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Product Effect Decreased; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	577 Absent	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	577 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	577 Absent	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	577 Milligram	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	577 Milligram	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	577 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	577 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported

	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	577.0 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown	577 Absent		Not Reported
	Desoximetasone	C	Oral	Unk		Not Reported
	Cortisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14921371	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043739		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	40 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15674968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573976-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15949326	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16073575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05670		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

	Enbrel	S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown		Not Reported
	Methotrexate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16125465	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk Unk, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	40 Mg (Titer), Q2wk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16248273	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2761854-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16439513	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-14998		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Enbrel		S	Subcutaneous			Not Reported
	Leflunomide		S	Oral	Unknown		Not Reported
	Methotrexate		S	Subcutaneous			Not Reported
	Methotrexate		S	Subcutaneous	Unknown		Not Reported
	Orencia		S	Unknown	Unknown		Not Reported
	Orencia		S				Not Reported
	Plaquenil		S	Unknown	Unknown		Not Reported
	Rituximab		S	Unknown			Not Reported
	Rituximab		S	Intravenous (not otherwise specified)			Not Reported
	Rituximab		S	Unknown	Unknown		Not Reported
	Sulfasalazine		S	Unknown	Unknown		Not Reported
	Tocilizumab		S	Unknown	Unknown		Not Reported
	Tocilizumab		S				Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown		Not Reported
	Actemra		S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16485230	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2835174-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740243	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA196426		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	1 Df, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Tramacet			S	Unknown			Not Reported
	Actonel			C	Unknown	35 Mg, Qw		Not Reported
	Calcium			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	Lyrica			C	Oral	150 Mg, Bid		Not Reported
	Metformin			C	Unknown	5 Mg, Qd		Not Reported
	Metformin			C	Unknown	500 Mg, Bid		Not Reported

	Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C			Not Reported
	Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Mg, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Every Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740961	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2386588			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthralgia; Arthropathy; Atrial Fibrillation; Bronchitis; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Ambrisentan			S	Unknown	30 Mg, Qd		Not Reported
	Ambrisentan			S	Unknown	30 Milligram, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid (1 - 1 - 1)		Not Reported
	Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Spasmolyt			S	Unknown	30 Mg (0 -0 -1)		Not Reported
	Spasmolyt			S	Unknown	15 (Unit Not Specified), Qd		Not Reported

						((1 - 0 - 0)			
		Omeprazole			S	Oral	1 Df, Bid (1 - 0 - 1)		Not Reported
		Ramipril			S	Oral	1 Df, Bid (1 - 0 - 1)		Not Reported
		Eliquis			S	Unknown	2.5 Mg Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17390605	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006953		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram(2 Every One Week)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17399035	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010345		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Orencia	S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Ilaris	C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Rituximab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578578	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb

Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia	S	Unknown	500 Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
	Leflunomide	S	Oral	20 Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578721	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001831			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Diarrhoea; Nausea; Nightmare; Renal Pain; Sleep Terror; Therapeutic Response Decreased; Treatment Failure; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Weekly		Not Reported
	Azathioprine			C				Not Reported
	Humira			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prevnar 13			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578725	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001913			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unknown, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unknown		Not Reported
	Benzylpenicillin Sodium			S	Unknown	Unknown		Not Reported
	Phenoxymethylpenicillin Potassium			S	Unknown	Unk		Not Reported

	Rituximab			S	Unknown	Unk				Not Reported
	Prednisone			C		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023426		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568831		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

		Tacrolimus			S	Unknown					Not Reported
		Prednisone			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578910	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579095	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Leflunom|De			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579314	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES			Unknown	USA

LIMITED-IPC-2020-US-000918

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Cardiotoxicity; Renal Impairment	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Furosemide			S	Intravenous (not otherwise specified)	Unk		Ipca
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579324	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567801		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579865	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1208924		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Levofloxacine			S	Oral	1000 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	2 Dosage Forms		Not Reported

	Ideos	S	Oral	2 Dosage Forms		Not Reported
	Acarizax	S	Oral			Not Reported
	Lutenyl	C				Not Reported
	Cortancyl	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025463		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580009	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020124022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S		20 Mg, Weekly (Therapy Duration: 7 Years)		Pfizer
	Enbrel			S		Unk (Therapy Duration: 9 Months)		Pfizer
	Rituximab			S		Unk (Therapy Duration: 3 Years)		Not Reported

	Humira	S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks, Therapy Duration: 346 Days)		Not Reported
	Hydroxychloroquine	S		200 Mg, 2x/Day (Therapy Duration: 9 Years)		Not Reported
	Remicade	S		Unk (Therapy Duration: 2 Years)		Not Reported
	Xeljanz	C		5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580222	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580309	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023667		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Naproxen Sodium		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Prednisone Acetate		S	Unknown		Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Folic Acid		C	Unknown		Not Reported
	Hydroxychloroquine Sulfate		C	Unknown		Not Reported
	Naproxen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580690	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023759		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported
	Folic Acid			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581498	NON-EXPEDITED			US-PFIZER INC-2020122192		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581796	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	12.5 Milligram, Bid		Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581877	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Weight Gain; Alopecia; Chest Pain; Dizziness; Dyspnoea; Fatigue; Joint Swelling; Nausea; Photosensitivity Reaction; Syncope; Tremor	Hydroxychloroquine 200 Mg			S	Oral	Quantity:2 Tablet(S);	5 YR	Not Reported
	Prem-Pro 0.3mg/1.5mg			C				Not Reported
	Ventolin Inhaler			C				Not Reported
	Vit B (Complex)			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Grape Seed Extract			C				Not Reported
	St Johns Wort			C				Not Reported
	Stainging Nettle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581909	EXPEDITED (15-DAY)		DE, HO, LT, OT	NVSC2020CA083709			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Apo-Leflunomide	S				Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581930	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030615		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction	Methotrexate			S	Subcutaneous	10 Milligram, Qw		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid (12 Hours)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581934	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis

Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris	S	Subcutaneous	Unk	Novartis
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Methotrexate Sodium	S	Intra-arterial	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581956	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083719		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported

	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581969	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030618		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Mycophenolate Mofetil			S	Oral	500 Milligram, Bid		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid		Mylan
	Rituximab			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583060	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025465		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous drip	Not Reported
	Humira		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583075	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583096	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025534			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

	Enbrel			S	Subcutaneous					Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12889782	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013285		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	5 Mg, Q.12h		Apotex
	Apo-Leflunomide			S	Unknown	Unk Unk, Bid		Apotex
	Apo-Naproxen			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Q.12h		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

Abnormal; Synovitis	Adalimumab	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Actemra	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Humira	C	Subcutaneous	Unk		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12914312	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091576		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Gold			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Parenteral	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
Infliximab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk, Qd	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	6 Milligram, Bid	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	6 Milligram, Qd	Not Reported
D-Penicillamine	C	Unknown	Unk	Not Reported
Phenylbutazone	C	Unknown		Not Reported
Methotrexate	C	Parenteral	25 Milligram, Q4wk	Not Reported

	Humira			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057420	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1869749		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057569	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015705		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling;	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex

Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Qd		Not Reported
	Etanercept	S	Unknown	Unk		Not Reported
	Advil /00109201/	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Ketorolac	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown	20 Mg, Q.Wk.		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13059083	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015740		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Shoulder Operation; Therapeutic Response Decreased	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13180365	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA012856		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate		S	Unknown	Unk	Not Reported
	Neoral		S	Unknown	Unk Unk, Unknown	Novartis
	Celebrex		S	Unknown	Unk Unk, Unknown	Not Reported
	Cimzia		S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Enbrel		S	Unknown	Unk Unk, Unknown	Not Reported
	Humira		S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Imuran		S	Unknown	Unk Unk, Unknown	Not Reported
	Plaquenil		S	Unknown	Unk Unk, Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk, Unknown	Not Reported
	Azathioprine		S	Unknown	Unk	Not Reported
	Celecoxib		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13968018	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017267		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not	500 Mg, Unk		Not Reported

Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed			otherwise specified)			
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Unk		Not Reported
	Cortisone	C	Unknown			Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported
	Tylenol Arthritis	C	Unknown			Not Reported
	Naprosyn /00256201/	C	Unknown			Not Reported
	Rabeprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	14692979	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018CA055436		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported

Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazin	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Xeljanz	C	Oral	2 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15386769	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-20713376		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15411090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186044		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15635401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25.0 Mg, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15680306	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575130-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15867265	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190123564		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15946323	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010990		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Codein			C	Unknown			Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Tylenol			C	Unknown			Not Reported

	Xeljanz		C	Oral	5 Mg, Bid		Not Reported
	Prednisone		C	Oral			Not Reported
	Acetaminophen		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16125329	EXPEDITED (15-DAY)		OT	PHHY2019CA064258		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Subcutaneous			Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg,Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Every 1 Week		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine		S	Oral	Unk	Not Reported
	Orencia		S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituxan		S	Intravenous drip	Unk	Not Reported
	Rituxan		S	Intravenous drip	Unk	Not Reported
	Sulfasalazine		S	Oral	Unk	Not Reported
	Xeljanz		C	Unknown	Unk, Qd	Not Reported
	Xeljanz		C	Oral	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16128012	EXPEDITED (15-DAY)		OT	PHHY2019CA064350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

	Hydroxychloroquine			S	Subcutaneous	Unk	Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil			S	Oral	Unk	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan			S	Oral	Unk	Not Reported
	Sulfasalazine			S	Oral	Unk	Not Reported
	Simponi			S	Subcutaneous		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid	Not Reported
	Xeljanz			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16480411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-16027		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

	Desoximetasone			C	Unknown	Unknown			Not Reported
	Methotrexate			C	Oral				Not Reported
	Prednisone			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16536778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Teva
	Hctz			S	Unknown			Ivax
	Losartan			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Metoprolol Tartrate			S	Unknown			Not Reported
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Pantoprazole Magnesium			S	Unknown			Teva
	Penicillin G			S	Unknown			Teva
	Cefalexin			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Teva
	Losartan			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported

Celebrex	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Fosamax	S	Unknown		Not Reported
Hydralazine Hydrochloride	S	Unknown		Not Reported
Keflex	S	Unknown		Not Reported
Levaquin	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Pariet	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Diazide (Gliclazide)	S	Unknown		Not Reported
Lopressor	S	Unknown		Not Reported
Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	100 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Isoniazid	S	Unknown		Not Reported
Cipro	S	Unknown		Not Reported
Penicillin Nos	S	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Gold	C			Not Reported
Hydroxychloroquine	C			Not Reported
Iron Sucrose	C	Unknown		Not Reported
Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported
Colchicine	C			Not Reported
Coversyl [Perindoprilerbumine]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C			Not Reported
Levothyroxine Sodium	C			Not Reported
Ranitidine	C			Not Reported
Venofer	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16767573	EXPEDITED (15-DAY)		OT	PHHY2018CA068442		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown			Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Biw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Biw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Apo Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Oral	Unk		Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Biw		Not Reported
	Enbrel			S	Unknown	50 Mg, Biw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported

	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Orencia	S	Unknown	75 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	40 Mg, Biw	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Risedronate	C	Oral	35 Mg, Qw	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16792405	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2019JPN160709		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Segmental Glomerulosclerosis	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Predonine			C		Unk		Not Reported
	Mycophenolate Mofetil Capsule			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16982578	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20191009548		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S	Unknown	60 Milligram		Celgene
	Otezla			S	Unknown			Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Ibuprofen			S	Oral	600 Milligram		Not Reported
	Apo-Ibuprofen			S	Oral	600 Milligram		Not Reported
	Infliximab			S	Oral			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Unknown	1.7143 Milligram		Not Reported
	Methotrexate			S	Unknown	1.7857 Milligram		Not Reported
	Methotrexate			S	Unknown	1.4286 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Milligram		Not Reported
	Methotrexate			S	Unknown	1.4286 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Unknown	7.1429 Milligram	Not Reported
Methotrexate	S	Unknown	5.7143 Milligram	Not Reported
Methotrexate	S	Unknown	6.8571 Milligram	Not Reported
Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported

	Dexilant			C	Unknown		Not Reported
	Febuxostat			C	Unknown		Not Reported
	Folic Acid			C	Unknown		Not Reported
	Gravol			C	Unknown		Not Reported
	Mogadon			C	Oral		Not Reported
	Nitrazepam			C	Oral	5 Milligram	Not Reported
	Oxycodone			C	Unknown		Not Reported
	Prednisone			C	Unknown	20 Milligram	Not Reported
	Uloric			C	Unknown		Not Reported
	Xeljanz			C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16988122	EXPEDITED (15-DAY)		OT	CA-SA-2019SA298961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Cefixime			S	Unknown	Unk		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Salt Not Specified			S				Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown			Sanofi
	Zopiclone			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg Q0, 2, 6, 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17281615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518250		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-		Not Reported

				Use, Preservative-Free Prefilled Syringes	
	Acetaminophen	C			Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Methylprednisolone	C			Not Reported
	Naprosyn E	C			Not Reported
	Oxycontin	C	Unknown	Tablet (Extended Release)	Not Reported
	Oxyneo	C	Unknown	Tablet (Extended Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17455140	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000974			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Azathioprine			S		50 Mg, Qd		Not Reported
	Azathioprine			S		Retreatment With Low-Dose 50 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		Moderate Doses Of Prednisone		Not Reported
	Prednisone			S		2.5 Mg, Qd		Not Reported
	Belimumab			S		Unk		Not Reported
	Belimumab			S		10 Mg/Kg, Monthly		Not Reported
	Belimumab			S		Unk, Resumed 2 Weeks After Delivery		Not Reported

Mycophenolate	C	Unk	Not Reported
Mycophenolate	C	Switching Back	Not Reported
Mycophenolate	C	Continued During The Initial 6 Months Of Belimumab Infusions And Then Tapered Off	Not Reported
Warfarin	C	Unk	Not Reported
Warfarin	C	Resumed Warfarin	Not Reported
Low-Molecular-Weight Heparin	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17533248	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309558		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Off Label Use; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Uveitis	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Myochrysine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024031		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Q12h		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

		Phthalylsulfathiazole			S	Unknown	Unk			Not Reported
		Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk			Not Reported
		Rituximab			S	Intravenous drip	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025557		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583283	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000888			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Warfarin Sodium			S	Unknown	Unk		Ipca
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			C	Unknown	Unk		Not Reported
	Isoniazid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Rituxan			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568766			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

		Humira			S	Subcutaneous				Not Reported
		Cortisone Acetate			C	Subcutaneous				Not Reported
		Desoximetasone			C	Subcutaneous				Not Reported
		Diclofenac			C	Subcutaneous				Not Reported
		Xeljanz			C	Oral				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569483		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023661		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583562	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1479		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583582	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1504			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583834	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001844			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Solganal			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Cortisone			C	Intra-articular	Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Gold			C		Unk		Not Reported
	Prevacid			C		Unk		Not Reported
	Penicillamine			C		Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523564		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Intentional Product Use Issue; Neuropathy	Rituxan			S	Intravenous (not otherwise specified)	1 Every Week For 4 Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

Peripheral; Off Label Use; Paraesthesia; Rash; Thrombocytopenia	Leflunomide		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Acetaminophen		C	Oral	Not Reported
	Diphenhydramine		C	Oral	Not Reported
	Lyrica		C		Not Reported
	Synthroid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583878	NON-EXPEDITED		DE	NVSC2020US084343		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Unknown	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Unknown	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 400 To 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567774		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Orencia			S	Subcutaneous	Not Reported
	Sulfasalazine			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583952	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584003	EXPEDITED (15-DAY)		HO	CA-ROCHE-2571253			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Decreased	Methotrexate	S	Unknown	Solution		Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584031	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241562		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Resistance; Gastrointestinal Disorder; Pseudomonal Skin Infection; Therapeutic Product Effect Incomplete; Treatment Failure	Triamcinolone			S		Unk		Ranbaxy
	Tacrolimus			S	Topical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Clobetasol			S	Topical	Unk		Taro
	Pentoxifylline			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584210	EXPEDITED (15-DAY)		OT	NVSC2020CA083918		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	3 Mg (Powder For Solution)		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported

			otherwise specified)		
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	75 Mg, Qmo	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	2000 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Q2w	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported
	Arava	C	Oral	1 Df, Qd	Not Reported
	Cimzia	C	Subcutaneous	1 Df, Q2w	Not Reported
	Risedronate	C	Oral	1 Df, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020125866			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

	Prednisone			S	Unknown					Not Reported
	Simponi			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584625	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127462		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00023236		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack;	Apixaban			S	Unknown	Unknown		Unknown
	Warfarin			S	Unknown	Unknown		Unknown
	Rivaroxaban			S	Unknown	Unknown		Unknown

Treatment Failure	Clopidogrel		S	Unknown	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown	Unknown		Unknown
	Atorvastatin		S	Unknown	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Morphine	S	Unknown		Not Reported
	Cbd Oil	C			Not Reported
	Dronabinol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585240	EXPEDITED (15-DAY)		OT	NVSC2020CA083916		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Rituximab			S	Endocervical	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Qd 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075362		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk, 1x		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiosulfate			C				Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585303	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075074		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib Citrate			S				Not Reported
	Actemra			S				Not Reported
	Diovan			C				Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid			C				Not Reported

	Sertraline			C						Not Reported
	Valtrex			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585304	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075084		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Arava			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585306	EXPEDITED (15-DAY)		OT	CA-SA-2020SA074997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil			S		Unk G		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			C		2 G		Not Reported
	Venlafaxine Hydrochloride			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585763	EXPEDITED (15-DAY)		OT	NVSC2020CA083797		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Treatment Failure	Neoral		S	Subcutaneous	Unk	Novartis
	Neoral		S	Subcutaneous	Unk	Novartis
	Cyclosporine		S	Unknown	Unk	Novartis
	Methotrexate		S	Oral	20 Mg	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Actemra		S	Intravenous drip	8 Mg/Kg, Unk	Not Reported
	Actemra		S	Intravenous drip	8 Mg/Kg, Unk	Not Reported
	Enbrel		S	Subcutaneous	500 Mg (Every 1 Weeks)	Not Reported
	Orencia		S	Subcutaneous	125 Mg	Not Reported
	Plaquenil		S	Oral	Unk	Not Reported
	Plaquenil		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous drip	3 Mg/Kg,Unk	Not Reported
	Xeljanz		C	Oral	5 Mg (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585786	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031634		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585836	EXPEDITED (15-DAY)		OT	NVSC2020CA083902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug	Methotrexate Sodium			S	Subcutaneous	20 Mg, (16 Years)		Not Reported
	Neoral			S	Oral	20 Mg (16 Years)		Novartis

Ineffective; Rheumatoid Arthritis	Enbrel		S	Subcutaneous	50 Mg (3 Months)		Not Reported
	Plaquenil		S	Oral	20 Mg (16 Years)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3.0 Mg/Kg (12 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025893		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586685	NON-EXPEDITED		DE	NVSC2020US084340		59 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Oral	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Oral	400- 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015347561		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lower Respiratory Tract Infection; Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587086	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024299		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis			otherwise specified)		
	Actemra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronate	S	Oral	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587200	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2018488256		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Obstruction; Musculoskeletal Stiffness; Off Label Use; Product Use In Unapproved Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587396	EXPEDITED (15-DAY)		OT	NVSC2020CA066714		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not	3 Mg/Kg		Not Reported

				otherwise specified)		
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Xeljanz Xr		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587547	EXPEDITED (15-DAY)		OT	NVSC2020CA084494		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Unknown	Unk		Novartis
	Cyclosporine			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Qd		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

	Humira			S	Subcutaneous	Unk			Not Reported
	Hydroxychloroquine			S	Oral	Unk			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk			Not Reported
	Cimzia			C	Subcutaneous	200.0 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587578	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031637		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Dapsone			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587783	NON-EXPEDITED			NVSC2020US083346			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xolair			S	Unknown	Unk, Q4w		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Dupilumab			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Lycor			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported

	Plaquenil			S	Unknown					Not Reported
	Prednisone			C	Unknown	1 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588061	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020126107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Enbrel			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588436	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025383		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz			S	Unknown					Not Reported
	Methotrexate			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588455	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588457	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026044		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Mg 3 Every 2 Days		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported

	Ebastine	C	Unknown	Unk		Not Reported
	Ferrous Gluconate	C	Unknown			Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Methylprednisolone Acetate	C	Intra-articular	Unk		Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Oral	650 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17591609	DIRECT	Y	LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemodialysis; Intensive Care	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	11480152	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150902732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; C-Reactive Protein Abnormal; Cataract; Cerebrovascular Accident; Crying; Deformity; Depression; Disability; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Fine Motor Skill Dysfunction; Foot Deformity; Gait	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Senokot			C	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported

Disturbance; Hand Deformity; Hepatic Enzyme Increased; Hepatitis C; Hypokinesia; Impaired Healing; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Muscle Spasms; Musculoskeletal Disorder; Musculoskeletal Pain; Myalgia; Papule; Peripheral Swelling; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Shoulder Deformity; Surgical Failure; Swelling; Weight Decreased; Wrist Deformity	Ativan	C	Sublingual	Night At Bedtime	Not Reported
	Lovastatin	C	Unknown		Not Reported
	Flexeril	C	Oral		Not Reported
	Flexeril	C	Oral		Not Reported
	Cyclobenzaprine Hydrochloride	C	Subcutaneous		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12883751	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported

Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Methotrexate Sodium	S	Unknown	15 Unk, Unk		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Unk		Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Plaquenil /00072602/	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12893895	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150810477		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Nasopharyngitis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported

	Prednisone	C	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Arava	C			Not Reported
	Codeine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13059056	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015753		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S		20 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	250 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13244457	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13251590	EXPEDITED (15-DAY)		CA, OT	CA-APOTEX-2017AP006777		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Decreased	Orencia	S				Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Oral			Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Simponi	S				Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid		Not Reported
	Prednisone	C	Oral	5 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13519394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038533		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Sulfasalasin			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	14628698	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037929		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Every One Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	14633459	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019566		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Off Label Use; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15049818	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015756		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral			Apotex
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15076377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15400431	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083976		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	500 Mg, Bid		Bristol Myers Squibb
	Desoximetasone			S	Unknown			Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Altace	C	Unknown	5 Mg, Qd	Not Reported
	Asa	C	Unknown	81 Mg, Qd	Not Reported
	Folic Acid	C	Unknown	1 Df, Unk	Not Reported
	Methotrexate	C	Oral	15 Mg, Qd	Not Reported
	Omega 3 [Fish Oil;Tocopherol]	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown	20 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15899841	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019048311		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Drug Ineffective; Immunodeficiency; Nasal Congestion; Pain	Flector			S	Transdermal	1 Patch To Skin, Twice A Day		Pfizer
	Flector			S				Pfizer
	Diclofenac Sodium			S	Oral	Unk		Not Reported
	Oxymorphone			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Pennsaid			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Cbd			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15978351	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013839		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Orencia	S	Unknown			Bristol Myers Squibb
	Celebrex	S	Oral	200 Milligram, Q12h		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Q12h		Not Reported
	Arava	C	Unknown	20 Milligram, Qd		Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h		Not Reported
	Rituximab	S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16108792	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA062642			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

	Apo-Leflunomide	S				Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S				Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16153117	EXPEDITED (15-DAY)		OT	CA-COLGATE PALMOLIVE COMPANY-20190300924			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling;	Chlorhexidine Unspecified			S		Unk		Colgate
	Periogard Alcohol Free Rinse			S	Buccal	Unk		Colgate
	Chlorhexidine Gluconate Unspecified			S		Unk		Not Reported
	Chlorhexidine Gluconate Unspecified			S		Unk		Not Reported
	Periogard Unspecified			S		Unk		Colgate
	Acetaminophen			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not	728.0 Mg; 4 Every 1 Week		Not Reported

Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased			otherwise specified)		
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
	Actemra	S		Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Periarticular	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Leflunomide	S			Not Reported
	Oxycodone Terephthalate	S		Unk	Not Reported
	Sulfamethoxazole;Trimethoprim	S		Unk	Not Reported
	Oxycodone Hydrochloride	S		Unk	Not Reported
	Sulfamethoxazole	S			Not Reported
	Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Oxycodone;Paracetamol	S		Unk	Not Reported
Oxycodone;Paracetamol	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate Sodium	S		Unk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Oxycodone	S		Unk	Not Reported
Oxycodone	S		Unk	Not Reported
Apo-Acetaminophen	S			Not Reported
Oxycodone Hydrochloride;Paracetamol	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Arava	C		Unk	Not Reported
Pantoloc [Pantoprazole]	C		Unk	Not Reported
Desogestrel + Etinilestradiol	C		Unk	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Ibuprofen	C		Unk	Not Reported
Prednisone	C	Oral	7.5 Mg 1x/Day	Not Reported
Prednisone	C	Oral	Unk, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C		10 Mg, 2x/Day	Not Reported
Reactine [Cetirizine Hydrochloride]	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C			Not Reported
Cetirizine Dihydrochloride	C		Unk	Not Reported
Paracetamol	C			Not Reported
Hydroxychloroquine Sulfate	C		400 Mg, 1x/Day	Not Reported
Paracetamol Codeine	C			Not Reported
Tylenol [Paracetamol]	C		Unk	Not Reported

	Cetirizine			C						Not Reported
	Tylenol With Codeine			C						Not Reported
	Pantoprazole			C			Unk			Not Reported
	Hydroxychloroquine Phosphate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16889106	EXPEDITED (15-DAY)		OT	CA-SA-2019SA271272			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17064857	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190827902		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Headache; Nausea; Pain; Platelet Count Increased; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral	Dose Doubled In Jan-2020		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17335679	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-HORIZON-PRE-0036-2020			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Prednisone			S	Transplacental	Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported

Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
Dexamethasone	S	Transplacental	Unk	Not Reported
Dexamethasone	S	Transplacental	Unk	Not Reported
Vitamin D [Colecalciferol]	S	Transplacental	Unk	Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Paracetamol	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Ornidazole	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Vitamin K Nos	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Vulmizolin	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S		Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Potassium Chloride	S	Transplacental	Unk	Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk	Not Reported
Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
Hydrocortisone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Nadroparine	S	Transplacental	Unk	Not Reported
Etamsylate	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported
Cefotaxime	S	Transplacental	Unk	Not Reported

	Metoprolol Tartrate			S	Transplacental	Unk				Not Reported
	Albumin			S	Transplacental	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17530878	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001243			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hypersensitivity; Nausea; Rheumatoid Arthritis; Urticaria; Vertigo; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17552501	EXPEDITED (15-DAY)		OT	GB-CELLTRION INC.-2020GB020489			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17570310	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine	S			Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578248	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1031689		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Effusion; Pericardiotomy; Pleural Effusion; Prohormone Brain Natriuretic Peptide Increased; Rales; Serositis	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	2.5 G, Qd		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Riociguat			C	Unknown	6 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia	S	Unknown		Bristol Myers Squibb
	Arava	S	Unknown	20 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588707	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	6 Milligram, Qd		Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588868	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0830		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588873	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588875	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588876	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588922	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1533			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17589340	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-20_00008751		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590071	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241501		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590112	EXPEDITED (15-DAY)		HO	CA-SA-2020SA075289			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Off Label Use	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (1 Everyday)		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd, Tablet (1 Every 1 Day)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw (1 Every 1 Weeks)		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	80 Mg/Kg		Not Reported

					Actemra	S	Unknown	Unk	Not Reported
					Enbrel	S	Unknown		Not Reported
					Humira	S	Subcutaneous	40 Mg, Qow., Solution Subcutaneous	Not Reported
					Humira	S	Unknown	Unk	Not Reported
					Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
					Orencia	S	Unknown		Not Reported
					Orencia	S			Not Reported
					Orencia	S			Not Reported
					Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590113	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075134			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Atorvastatin Calcium			S				Not Reported
	Leflunomide			S				Sanofi
	Pregabalin			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590114	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA075343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi

	Leflunomide	S		10 Mg	Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S		15 Mg	Not Reported
	Methotrexate	S		20 Mg, Qw	Not Reported
	Sulfasalazine	S	Oral	1 G	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Rituximab	S		Unk	Not Reported
	Prednisone	C		10 Mg	Not Reported
	Prednisone	C		5 Unk	Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590131	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009143		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Wrist Surgery	Meloxicam			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075141			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S				Not Reported
	Humira			S				Not Reported
	Infliximab			S				Not Reported
	Otezla			S				Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported
	Allopurinol			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Codeine			C				Not Reported
	Cyclobenzaprine Hydrochloride			C				Not Reported
	Dilaudid			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported
	Ibuprofen			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Nexium [Esomeprazole Sodium]			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported
	Sulfasalazine			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590399	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076538		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Sodium Aurothiomalate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590401	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

	Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590669	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-00900		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Cyclophosphamide			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Docetaxel			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Anastrozole			S	Unknown	21-Day Cycle, 4 Cycles)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	7.1 Mg/Kg Real Body Weight, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590700	EXPEDITED (15-DAY)		HO	US-GYP-000097		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Herpes Simplex; Trichomoniasis	Prednisone			S	Unknown	5 Mg Daily		Geneyork Pharma
	Hydroxychloroquine			S	Unknown	200 Mg Twice Daily		Not Reported
	Metronidazole			S	Oral			Not Reported
	Paracetamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591184	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026344		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram		Not Reported
	Leflunomide	S	Unknown	20 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591627	DIRECT		HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Folliculitis; Oral Disorder; Pharyngeal Disorder; Skin Swelling; Therapy Cessation; Urticaria; Urticaria	Hydroxychloroquine (Plaquenil)			S	Oral			Not Reported
	Pravastatin			C				Not Reported
	Fosomax			C				Not Reported
	Prempro			C				Not Reported
	Premarin			C				Not Reported
	Sipronlactone			C				Not Reported
	Minoxidil			C				Not Reported
	Doxycycline			C				Not Reported
	Omeprazole			C				Not Reported
	Singular			C				Not Reported
	Ventolin			C				Not Reported
	Azelastine			C				Not Reported
	B-Complex			C				Not Reported
	Triple Omega Fish Oil			C				Not Reported
	Calcium			C				Not Reported
	Vit. D-3			C				Not Reported
	Evening Primrose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591702	EXPEDITED (15-DAY)		OT	NVSC2020CA083830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate	S	Unknown	25 Mg, Unknown		Not Reported
	Tacrolimus	S	Oral	2 Mg, Q12h		Novartis
	Tacrolimus	S	Oral	3 Mg, Q12h		Novartis
	Leflunomide	S	Unknown	20 Mg, Unknown		Not Reported
	Neoral	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	20 Mg, Unknown		Not Reported
	Certolizumab Pegol	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Rapamune	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine	S	Unknown	1 G, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591728	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085589		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported

	Enbrel			S	Unknown	Unk			Not Reported
	Enbrel			S					Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Humira			S					Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Orencia			S					Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Remicade			S					Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk			Not Reported
	Sodium Aurothiomalate			S					Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported
	Sulfasalazine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591840	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591841	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026360		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			C	Unknown	500 Milligram, Qd		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Gravol			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591924	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591928	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591942	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085582			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Humira		S						Not Reported
	Hydroxychloroquine		S	Unknown	Unk				Not Reported
	Hydroxychloroquine		S						Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk				Not Reported
	Orencia		S						Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk				Not Reported
	Remicade		S						Not Reported
	Sulfasalazine		S	Unknown	Unk				Not Reported
	Sulfasalazine		S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591972	NON-EXPEDITED			US-SA-2018SA048629			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Liver Function Test Increased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S		Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17592969	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068673		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	40 Mg		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S		10 Mg		Not Reported
	Kevzara			S				Sanofi

	Sulfasalazine	S				Not Reported
	Adalimumab	S	Subcutaneous	Unk		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Orencia	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Tocilizumab	S				Not Reported
	Tofacitinib	S				Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Prednisone	C		10 Mg		Not Reported
	Rabeprazole Sodium	C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17593152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594000	EXPEDITED (15-DAY)		OT	NVSC2020CA083912		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure	Neoral			S	Unknown	125 Mg, Bid, (2 Every 1 Day)		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unknown		Not Reported
	Arava			S	Unknown	20 Mg, Qd, (Every 1 Day)		Not Reported
	Azathioprine Sodium			S	Unknown	150 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw, (1 Every 1 Week)		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	150 Mg, Tid, (3 Evey 1 Day)		Not Reported
	Methotrexate			S	Oral	1 Df, Qw, (1 Every 1 Week)		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1 Day)		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid, (2 Every 1 Day)		Not Reported
	Citalopram Hydrobromide			C	Unknown	40 Mg		Not Reported
	Citalopram Hydrobromide			C	Unknown	40 Mg, Qd (Every 1 Day)		Not Reported
	Citalopram Hydrobromide			C	Unknown	1 Df, Qw		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd (Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594370	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085524		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Novartis

Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Ilaris	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hidroxicloroquina	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594417	EXPEDITED (15-DAY)		DE, HO	NVSC2020CA085101		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported

	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594574	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colonic Abscess; Drug Ineffective; Pruritus	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	350 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Enbrel			C	Unknown	50 Milligram		Not Reported
	Gold			C	Intramuscular	50 Milligram		Not Reported

	Leflunomide			C	Unknown	20 Milligram				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17431505	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1186390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Hydroxychloroquine			S	Unknown			Teva
	Trametinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595044	EXPEDITED (15-DAY)		OT	IT-ACCORD-177503		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S				Accord
	Dabigatran			S	Oral			Not Reported
	Daparox			S				Not Reported
	Lamictal			S				Not Reported
	Plaquenil			S				Not Reported
	Valium			S				Not Reported
	Sotalol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595150	NON-EXPEDITED			NVSC2020US086178			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17597821	DIRECT		DS			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Eye	Hydroxychloroquine	Y		S	Oral	Quantity:1 Tablet(S);		Unknown

Disorder; Vascular Device User	Orencia	Y	S	Intramuscular	Quantity:1 Injection(S);Other Frequency:Once A Week;	Er Squibb
	Heart Meds		C			Not Reported
	Diabetes Meds		C			Not Reported
	Inhalers		C			Not Reported
	Med For Migraines		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17598592	DIRECT		DS			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Manufacturing Materials Issue; Product Complaint; Product Substitution Issue; Therapy Non-Responder	Hydroxychloroquine 200mg Tab			S				Dr Reddys
	Omeprazole			C				Not Reported
	Hydroxychloroquinine			C				Not Reported
	Clarinex			C				Not Reported
	Turmeric			C				Not Reported
	Iron			C				Not Reported
	Mvi			C				Not Reported
	Vitamind3			C				Not Reported
	Aleve			C				Not Reported
	Tylenol			C				Not Reported
	Pseudoephedrine			C				Not Reported
	Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12351402	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK063971		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Glaxosmithkline
	Cortisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Apo-Diclofenac	S		Unk		Not Reported
	Desoximetasone	S		Unk		Not Reported
	Diclofenac Potassium	S		Unk		Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12764755	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12767211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015691		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			C	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	10 Milligram, Qd		Not Reported
	Desoximetasone			C	Oral	5 Milligram 2 Every 1 Day		Not Reported

	Zostavax	C	Subcutaneous	Unk		Not Reported
	Cortisone	C	Oral	10 Milligram, Qd		Not Reported
	Diclofenac	C	Subcutaneous	100 Milligram, Qd		Not Reported
	Voltaren Acti	C	Unknown	100 Milligram, Qd		Not Reported
	Cortisone Acetate	C	Subcutaneous			Not Reported
	Desoximetasone	C	Subcutaneous			Not Reported
	Diclofenac	C	Oral	50 Milligram, Bid		Not Reported
	Diclofenac	C	Oral	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12771269	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076855		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Varicella Zoster Vaccine Live		S	Subcutaneous	Unk	Not Reported
	Varicella Zoster Vaccine Live		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Diclofenac [Diclofenac Sodium]		C	Subcutaneous	100 Milligram	Not Reported
	Diclofenac [Diclofenac Sodium]		C	Oral	5 Milligram, Bid	Not Reported
	Cortisone		C	Oral	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz		C	Oral	10 Milligram, Bid	Not Reported
	Cortisone Acetate		C	Subcutaneous	Unk	Not Reported
	Desoximetasone		C	Oral	5 Milligram, Bid	Not Reported
	Desoximetasone		C	Oral	10 Milligram, Qd	Not Reported
	Desoximetasone		C	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13251617	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006643			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported
	Diclofenac			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13502224	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14547629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-040466		28 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Sinusitis; Anaphylactic Shock; Anxiety; Bronchitis; Depression; Device Malfunction; Electric Shock; Faeces Soft; Fatigue; Gait Disturbance; Headache; Influenza Like Illness; Long Qt Syndrome; Mouth	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported
	Leucovorin [Folinic Acid]			C	Unknown	Unk		Not Reported

Ulceration; Nausea; Off Label Use; Pain; Productive Cough; Pyrexia; Seasonal Allergy; Secretion Discharge; Sinusitis; Tongue Ulceration; Upper Respiratory Tract Infection Bacterial	Folic Acid	C	Unknown	Unk		Not Reported
	Ativan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14918934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043916		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Mg, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Tid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	2000 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not	2000 Milligram		Not Reported

						otherwise specified)			
			Apo-Azathioprine		S	Unknown	Unk		Not Reported
			Apo-Leflunomide		S	Oral	Unk		Not Reported
			Arava		S	Unknown	Unk		Not Reported
			Sulfasalazine		S	Unknown	Unk		Not Reported
			Actemra		S	Unknown	Unk		Not Reported
			Hydroxychloroquine		S	Unknown	Unk		Not Reported
			Tofacitinib		C	Unknown	Unk		Not Reported
			Xeljanz		C	Oral	5 Mg, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	15551969	EXPEDITED (15-DAY)		OT	PHHY2018CA135990		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk (Solution)		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Penicillin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16387991	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029881		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Milligram,As Required		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Two Times A Day		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16388028	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029853		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Diclofenac Potassium			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

	Sulfasalazine		S	Oral	500 Milligram, Once A Day	Not Reported
	Sulfasalazine		S	Oral	1 Gram, Two Times A Day	Not Reported
	Synthroid		S	Unknown	Unk	Not Reported
	Tecta		S	Oral	Unk	Not Reported
	Xeljanz		S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Depo-Medrol		C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16778008	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-025000		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16792776	EXPEDITED (15-DAY)		OT	PHHY2019CA209333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Ineffective; Infection	Cosentyx			S	Unknown	150 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported

	Plaquenil	S	Oral	200 Mg, Qd		Not Reported
	Arava	C	Unknown	20 Mg, Qd		Not Reported
	Methotrexate	C	Oral	1 Df, Qw		Not Reported
	Prednisone	C	Oral	1 Df, Qd		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Q12h		Not Reported
	Xeljanz	C	Oral	5 Mg, Q12h		Not Reported
	Xeljanz	C	Oral	5 Mg, Q8h		Not Reported
	Xeljanz	C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16811263	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190905771			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Paracetamol			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			S	Unknown			Not Reported
	Paracetamol/Diphenhydramine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported

Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Hydroxychloroquine /00072603/	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Paracetamol/Codeine Phosphate	C	Unknown		Not Reported
	Oros Hydromorphone Hcl	C	Unknown		Not Reported
	Tylenol W/ Codeine No. 3	C	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Celecoxib	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16881443	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-28961		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia;	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported

Treatment Failure	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Unknown	Unknown, Single-Use Pre-Filled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown, Aerosol	Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown	Not Reported
	Cephalexin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17416777	EXPEDITED (15-DAY)		OT	US-SA-2020SA038806		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pleural Effusion	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17422945	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010439		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

		Rabeprazole Sodium			C	Oral	20 Milligram, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17467057	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008069		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo Ibuprofen			S	Oral	600 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S	Oral	30 Milligram, Bid		Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported
	Apremilast			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cyclosporin			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Golimumab			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ibuprofen	S	Oral	600 Milligram, Every 1 Days	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	Unk, Qwk	Not Reported
	Motrin Children	S	Oral	600 Milligram	Not Reported
	Motrin Children	S	Unknown	6 Dosage Form, Qd	Not Reported
	Motrin Children	S	Oral	600 Milligram, Qd	Not Reported
	Motrin Children	S	Oral	Unk Milligram, Qd	Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

Sulfasalazine	S	Unknown		Not Reported
Apo-Cyclosporine	S	Unknown	Unk	Not Reported
Apo-Cyclosporine	S	Oral	Unk	Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	0.6 Milligram	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	Unk, Qwk	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Vitamin D3	C	Oral	200 International Unit	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17493046	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238891		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Sun
	Warfarin			S	Unknown	Unk		Taro
	Clopidogrel			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17581926	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA083381		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17584606	EXPEDITED (15-DAY)		OT	NVSC2020US082743		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596866	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-015777		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Aurobindo
	Dabigatran Etexilate			S	Oral	300 Milligram, Once A Day		Not Reported
	Daparox			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Valium			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Folic Acid			C		1 Df, Qw		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596898	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Folic Acid			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cetrizine			S		Unk		Not Reported

	Cimzia	S		Unk		Not Reported
	Etanercept	S		Unk		Not Reported
	Fosamax	S		Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596904	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241793		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	8.22 Milligram/Kilogram		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596948	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068521		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous			Not Reported
	Rituxan			S	Unknown	Dosage Form: Solution Intravenous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596953	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068456			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Actemra			S		567 Mg, Qm		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596954	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S				Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596980	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596997	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		Unk, Qd		Sanofi
	Plaquenil			S		200 Mg, Bid		Sanofi
	Cosentyx			S		150 Mg, Q4w		Not Reported
	Humira			S		400 Mg In 7 Years		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Cymbalta			C		60 Mg, Qd		Not Reported
	Esomeprazole			C	Oral			Not Reported
	Magnesium;Naproxen Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596998	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068558		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide	S	Unknown	Unk	Sanofi
	Hydroxychloroquine	S		Unk	Sanofi
	Sulfasalazine	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Sanofi
	Mefenamic Acid	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Synthroid	C		Unk	Not Reported
	Rabeprazole Sodium	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596999	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia;	Arava			S		Unk		Sanofi

Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Hydroxychloroquine	S		200 Mg, Qd		Sanofi
	Leflunomide	S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil	S	Unknown	200 Mg, Qd		Sanofi
	Plaquenil	S	Unknown	Unk		Sanofi
	Enbrel	S		Unk		Not Reported
	Orencia	S		Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Qd		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Advil [Ibuprofen]	C	Unknown	Unk		Not Reported
	Folic Acid	C	Unknown	Unk		Not Reported
	Ketorolac	C		Unk		Not Reported
	Methotrexate	C	Unknown	20 Mg, Qw		Not Reported
	Naproxen	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597002	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068605			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597003	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068651			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported

				Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
				Methotrexate	S		20 Mg, Qow		Not Reported
				Orencia	S				Not Reported
				Plaquenil	S		200 Mg, Bid		Sanofi
				Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
				Rituxan	S	Intravenous (not otherwise specified)			Not Reported
				Bupropion	C				Not Reported
				Sulfasalazine	C				Not Reported
				Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068702			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C		Unk		Not Reported
	Methotrexate			C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068717		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea;	Leflunomide			S		Unk		Sanofi

Renal Mass; Vomiting	Allopurinol	S		Unk	Not Reported
	Folic Acid	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Prednisone	S		Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Naproxen	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Oxycodone Hydrochloride	S		Unk	Not Reported
	Azathioprine	S		Unk	Not Reported
	Ciclosporin	S			Not Reported
	Medroxyprogesterone Acetate	S		Unk	Not Reported
	Etanercept	S		25 Mg ,Qw	Not Reported
	Infliximab	S		400 Mg	Not Reported
	Rituximab	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597077	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1212448		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate Monosodique			S	Oral	35 Mg		Teva
	Plaquenil			S	Oral	1 Dosageform		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C		500 Mg/25 Mg,		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C				Not Reported
	Diffu K, Gelule			C				Not Reported
	Atorvastatine			C				Not Reported
	Clopidogrel (Chlorhydrate De)			C				Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597242	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025396		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597342	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068726		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis	Arava			S				Sanofi
	Gold Bond			S				Sanofi
	Humira			S	Subcutaneous			Not Reported

Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate	S	Oral	10 Mg	Not Reported
	Plaquenil	S			Sanofi
	Arnica Montana	C			Not Reported
	Asa	C			Not Reported
	Calcium	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597343	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068740			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S		1 Df (1 Every 1 Days)		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Xeljanz			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Lyrica			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597347	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Drug Ineffective; Empyema; Foot Deformity; Hand Deformity; Joint Effusion; Joint Stiffness; Limb	Leflunomide			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Urethral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Unknown	400 Mg		Not Reported

Operation; Musculoskeletal Stiffness; Nodule; Pneumonia; Rheumatoid Arthritis; Scar; Toe Operation	Methotrexate	S		25 Mg, Qw	Not Reported
	Methotrexate	S		25 Mg, Qw	Not Reported
	Methotrexate	S		25 Mg, Qw	Not Reported
	Sulfasalazine	S		2000 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Calcium	C		1200 Mg	Not Reported
	Ergocalciferol	C		2000 Iu, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597348	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068745		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		Unk		Sanofi
	Bacitracin			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Neomycin Sulfate			S		Unk		Not Reported
	Polymyxin B Sulfate			S		Unk		Not Reported

	Actemra			S	Subcutaneous	Unk			Not Reported
	Prednisone			C	Intramuscular				Not Reported
	Xeljanz			C	Oral	10 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597351	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068446		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Arava			S		Unk Unk, Qd		Sanofi
	Meloxicam			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Paracetamol			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597410	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg, Qd		Sanofi
	Toradol			S	Unknown			Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Qw		Not Reported
	Sulfasalazine			C		2.0 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597412	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068814		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Arava			S		Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S		1 Df, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597474	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		300 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous	Unk (Subcutaneous Solution)		Not Reported
	Alendronate Sodium			C	Oral	70 Mg		Not Reported
	Atenolol			C		3 Df		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide;Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium			C	Oral	40 Mg		Not Reported

	Trihydrate					
	Hydrochlorothiazide	C	Oral	25 Mg, Qd		Not Reported
	Lorazepam	C	Oral	1 Mg, Qd		Not Reported
	Methotrexate	C		Unk		Not Reported
	Sulfasalazine	C	Oral	Unk		Not Reported
	Trimebutine	C		1 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597475	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597476	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

	Enbrel	S	Unknown	50 Mg		Not Reported
	Enbrel	S	Unknown	50 Mg, Qw		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	C		5 Mg, Bid		Not Reported
	Xeljanz	C		11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597487	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597495	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069320		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

		Hydroxychloroquine Sulfate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597496	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S				Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Total Daily Dose 40 Mg		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597501	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597502	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069085		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S		Unk		Sanofi
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Prednisone Acetate			S				Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hydroxychloroquine Sulphate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069113		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Peripheral Swelling; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597507	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Oral	7.5 Mg 1 Every 1 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597724	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085875			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Orencia	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597887	EXPEDITED (15-DAY)		HO	CA-SA-2020SA069360		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598089	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020050982		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise;	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline

Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac Potassium	S	Oral	75 Mg, Prn	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Voltaren (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Glaxosmithkline
	Apo - Diclo (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Not Reported
	Apo Lisinopril	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd	Not Reported
	Lisinopril	S	Unknown	Unk	Not Reported
	Lisinopril Dihydrate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Synthroid	S	Oral	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598822	EXPEDITED (15-DAY)		LT	NVSC2020CA085528		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain;	Rituximab			S	Intravenous (not otherwise specified)			Novartis
	Leflunomide			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Anakinra		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Unknown	Not Reported
	Urelumab		C	Unknown		Not Reported
	Rituximab		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598887	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Off Label Use; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571299		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599148	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020126926			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Nausea; Off Label Use; Paraesthesia; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Nodule	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk (10mg To 15mg)		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	30 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Sulfasalazine	S	Unknown	2 G, 1x/Day		Pfizer
Sulfasalazine	S	Unknown	4 G, 1x/Day		Pfizer
Sulfasalazine	S	Unknown	3 G, 1x/Day		Pfizer
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Cosentyx	S	Intramuscular	300 Mg, Unk		Not Reported
Cosentyx	S	Oral	40 Mg, Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk		Not Reported
Leflunomide	C		20 Mg, Unk		Not Reported
Leflunomide	C		10 Mg, Unk		Not Reported
Leflunomide	C		20 Mg, Unk		Not Reported
Tocilizumab	C	Subcutaneous	162 Mg, Weekly		Not Reported
Abatacept	C	Subcutaneous	125 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599397	NON-EXPEDITED		OT	US-APPCO PHARMA LLC-2082107			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome; Suspected Product Contamination	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026570		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity;	Orencia			S	Unknown			Bristol Myers Squibb

Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Lyrica		S	Oral		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Mycophenolate Mofetil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Piroxicam		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600344	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076298		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Tablet		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

					Orencia		S			Not Reported
					Allopurinol		C	Unknown	200 Mg, Qd (1 Every 1 Day)	Not Reported
					Prednisone		C		5 Mg, Bid	Not Reported
					Prednisone		C		10 Mg	Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
30-Mar-2020	17600442	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076641			Unknown	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Naproxen			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg Bid		Not Reported
	Prednisone			S	Oral	5 Mg Bid		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S		Unk (Suspension Intra-Articular)		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Infliximab			S		5 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported

		Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm			Not Reported
		Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Qow			Not Reported
		Triamcinolone			S	Subcutaneous	25 Mg, Qow			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600446	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Hydroxychloroquine Sulfate			S		5 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Intravenous Immunoglobulin			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Infliximab			S	Unknown	5 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600447	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076649			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5.0 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S		5 Mg, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S		12.5 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Infliximab			S		5 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600654	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10154		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported

Cimzia	S	Subcutaneous	Unknown, Solution		Not Reported
Cimzia	S	Unknown	Unknown		Not Reported
Cosentyx	S	Unknown	Unknown		Not Reported
Enbrel	S	Unknown	Unknown		Not Reported
Humira	S	Subcutaneous	Unknown, Solution		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Unknown			Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Otezla	S	Oral	Unknown		Not Reported
Otezla	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Simponi	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Penicillin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17601616	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10007		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect	Etanercept			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Biaxin			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Cephalexin Monohydrate			S	Unknown	Unknown		Not Reported
	Ciprofloxacin			S	Unknown	Unknown		Not Reported
	Clindamycin Phosphate			S	Unknown	Unknown		Not Reported

Decreased	Codeine	S	Unknown	Unknown	Not Reported
	Enalapril	S	Unknown	Unknown	Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Hctz	S	Unknown	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unknown	Not Reported
	Levaquin	S	Unknown	Unknown	Not Reported
	Losartan	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Metoprolol Tartrate	S	Unknown	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unknown	Not Reported
	Pariet	S	Unknown	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unknown	Not Reported
	Esomeprazole	C	Unknown	Unknown	Not Reported
	Gold	C	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unknown	Not Reported
	Iron Sucrose	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17602693	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026610		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17605425	DIRECT	Y	DE, LT			87 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Cough; Electrocardiogram Qt Prolonged; Urine Odour Abnormal	Hydroxychloroquine			S				Not Reported
	Azithromycin 250 Mg Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	13350239	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008095		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission; Product Dose Omission	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	2 Df, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	2 Df, Q.O.D.		Not Reported
	Folic Acid			S	Unknown	Unk, Q.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Actemra			S	Subcutaneous	162 Mg, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not	281 Mg		Not Reported

				otherwise specified)		
	Arava		S	Oral	20 Mg, Unk	Not Reported
	Cimzia		S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	25 Mg, Q.Wk.	Not Reported
	Adalimumab		S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/		S	Oral	200 Mg, Bid	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Methotrexate		C	Unknown	25 Mg, Q.Wk.	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	15711597	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-113698		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Amlodipine	C	Unknown	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Tofacitinib Citrate	C	Unknown	Unk		Not Reported
	Viread	C	Unknown	Unk		Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079854	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Duration 705		Not Reported

Decreased; Therapeutic Response Decreased; Treatment Failure	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S			Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported

	Anakinra			S	Unknown	Unknown				Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079890	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06218		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Tocilizumab			S	Unknown	Unknown		Not Reported
	Tocilizumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16085223	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06099		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Apo-Naproxen	S	Unknown	Unknown		Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16094586	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA057581		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16443477	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03342		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Leflunomide			S				Not Reported
	Minocycline Hydrochloride			S	Unknown	Unknown		Not Reported
	Myochrysine			S	Intramuscular	Unknown Solution		Not Reported
	Myochrysine			S	Subcutaneous	Unknown		Not Reported
	Myochrysine			S	Parenteral	Unknown Solution Intramuscular		Not Reported
	Myochrysine			S	Unknown	Unknown		Not Reported
	Myochrysine			S	Intramuscular	Unknown		Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral	Unknown		Not Reported

Otezla	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous drip	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Sirukumab	S	Unknown	Unknown	Not Reported
Sirukumab	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown Solution	Not Reported
Stelara	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Tofacitinib Citrate	S	Oral		Not Reported
Ustekinumab	S	Unknown	Unknown	Not Reported
Ustekinumab	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous drip	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Minocycline	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown Solution	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Salazopyrin	S	Unknown	Unknown	Not Reported
Apremilast	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Minocin	S	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported

	Prednisone	C	Unknown	Unknown		Not Reported
	Orencia	C	Unknown	Unknown		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unknown Powder For Solution		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia	C	Unknown	Unknown		Not Reported
	Orencia	C	Unknown			Not Reported
	Plaquenil	C	Unknown	Unknown		Not Reported
	Salazopyrin	C	Unknown	Unknown		Not Reported
	Rheumatrex	C	Unknown	Unknown		Not Reported
	Abatacept	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16788654	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA249407		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Diclofenac			S	Ophthalmic	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Q12h		Not Reported
	Topicort			S	Cutaneous	Unk		Sanofi
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi

Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Unknown	5 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Sanofi
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, Qd	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfathalidine	S	Oral	500 Mg	Not Reported
	Sulfathalidine	S	Oral	1000 Mg, Q12h	Not Reported
	Tofacitinib	S	Unknown	5 Mg, Q12h	Not Reported

	Tofacitinib Citrate	S	Unknown	5 Mg, Q12h		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16877937	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-28737		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Oral			Not Reported
Leflunomide	S	Unknown	Unknown		Not Reported
Lyrica	S	Unknown	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown		Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Plaquenil	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Simponi	S	Unknown	Unknown, Solution Subcutaneous		Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
Tocilizumab	S	Unknown			Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown		Not Reported
Xeljanz	S	Oral			Not Reported
Piroxicam	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16906473	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909001003			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk,		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17194720	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201912002914			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Chest Discomfort; Chest X-Ray Abnormal; Fall; Glaucoma; Joint Swelling; Macular Degeneration; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd (1in 1d)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 2 Wk)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk, Weekly, (1 In 1 Wk),		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk,Solution For Infusion In Pre-Filled Syringe		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 1 Wk)		Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Folic			C	Unknown	Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Prilosec			C		Unk		Not Reported
	Zantac			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Flexeril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17287199	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-00706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
	Intravenous Immunoglobulin	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Gamastan	S	Intramuscular		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-arterial	Unknown Suspension Intra Articular	Not Reported
Triamcinolone Acetonide	S	Intra-arterial	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S			Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported

	Folic Acid			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17521215	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193557		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Paradoxical Drug Reaction; Sleep Disorder; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Actavis
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17557563	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17597116	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201903-000649			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Gnathoschisis; Herpes Zoster; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Valganciclovir Hydrochloride			S	Oral	1800 Mg, Qd		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prograf			S	Oral	1.5 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Bayaspirin			C		Unk		Not Reported
	Rabeprazole Sodium			C		Unk		Not Reported
	Rabeprazole Sodium			C				Not Reported
	Halizon			C		Unk		Not Reported
	Pitavastatin Calcium			C		Unk		Not Reported
	Pitavastatin Calcium			C				Not Reported

	Alendronate	C	Unk	Not Reported
	Alendronate	C		Not Reported
	Daiphen	C	Unk	Not Reported
	Daiphen	C		Not Reported
	Nitrazepam	C	Unk	Not Reported
	Evoxac	C	Unk	Not Reported
	Magnesium Oxide	C	Unk	Not Reported
	Equa	C	Unk	Not Reported
	Januvia	C	Unk	Not Reported
	Humulin R	C	Unk	Not Reported
	Aiphagan	C	Unk	Not Reported
	Lumigan	C	Unk	Not Reported
	Timoleate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17601685	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002044			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Bid (One In Morning And One In Evening, Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	3 Dosage Form (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Amoxlcillin Trihydrate/Potassium Clavulanate			S	Unknown	Unk		Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Lercan			C		10 Mg		Not Reported
	Quinine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17601958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602357	NON-EXPEDITED			US-APPCO PHARMA LLC-2082131		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Synthroid			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Olmesartan Medoxomil And Hydrochlorothiazide			C	Unknown			Not Reported
	Troujeo			C	Unknown			Not Reported
	Ezetimibe			C	Unknown			Not Reported
	Vitamin B Complex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602740	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003001986			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603176	EXPEDITED (15-DAY)		HO	NVSC2020CA086171		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk			Not Reported
	Rituximab			S	Intravenous drip	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Sulfasalazine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605057	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076608		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605175	EXPEDITED (15-DAY)		OT	CA-SA-2019SA247463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug	Plaquenil			S		Unk		Sanofi

Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Arava	S		Unk Unk, Unk	Sanofi
	Buprenorphine	C		10 Ug, Qd	Not Reported
	Xarelto	C		15 Mg, Qd	Not Reported
	Bisoprolol	C		12.5 Mg, Qd	Not Reported
	Lasix [Furosemide Sodium]	C		20 Mg (20mg Od/Q2days Depending On Need)	Not Reported
	Lasix [Furosemide Sodium]	C		Unk	Not Reported
	Vitamin D [Vitamin D Nos]	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk Unk, Unk	Not Reported
	Calcium	C		Unk Unk, Unk	Not Reported
	Magnesium	C		Unk Unk, Unk	Not Reported
	Ramipril	C		12.5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605363	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09913		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue;	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605416	DIRECT	Y	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Coronavirus Infection; Pneumonia; Renal Failure; Ventricular Tachycardia	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatricurium			C				Not Reported
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605439	DIRECT	Y	LT			85 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Tachycardia	Plaquenil			S	Oral	Other Frequency:Load - Then 200mg;		Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605541	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP009047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk. (Therapy Duration 365 Unit Unspecified)		Not Reported
	Infliximab			S	Unknown	5 Mg/Kg, One Every Eight Week		Not Reported

					Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
					Methotrexate	S	Subcutaneous	25 Mg, Unk	Not Reported
					Sulfasalazine	S	Unknown	Unk, Qd	Not Reported
					Rituximab	C	Intravenous (not otherwise specified)	1 G, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605719	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10553		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605780	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200331857		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract;	Remicade			S	Intravenous (not			Not Reported

Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased			otherwise specified)		
	Desoximetasone	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Metformin Hydrochloride	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Altace	C			Not Reported
	Asa	C			Not Reported
	Ergocalciferol	C			Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C	Oral		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605804	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2082143			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606206	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1212925		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Teva
	Dabigatran Etexilate			S	Oral	300 Mg		Not Reported
	Daparox			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606630	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025455		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606828	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA085981		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple	Cosentyx			S	Unknown	Unk		Novartis
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Insulin	C	Oral	Unk	Not Reported
	Metformin	C	Unknown	2 Df, Bid	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17608508	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-015824		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Aurobindo
	Plaquenil			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Izalgi			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported

	Diffu K	C	Unknown	Unk		Not Reported
	Atorvastatine	C	Unknown	Unk		Not Reported
	Clopidogrel Hydrochloride	C	Unknown	Unk		Not Reported
	Procoralan	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17611030	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Electrocardiogram Qt Prolonged; Pneumonia Viral	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15620857	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556897-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

						Methotrexate		S	Unknown	Not Reported
						Methotrexate		S	Unknown	Not Reported
						Hydroxychloroquine Sulfate		S	Unknown	Not Reported
						Leflunomide		S	Oral	Not Reported
						Leflunomide		S	Oral	Not Reported
						Hydroxychloroquine		S	Unknown	Not Reported
						Xeljanz		C	Oral	Not Reported
						Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15626375	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555933-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15668473	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570151-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Humira			S	Subcutaneous			Not Reported

Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Off Label Use; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C		Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712088	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588120-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous drip	Powder For Solution Intravenous		Not Reported

					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
					Hydroxychloroquine	S	Unknown		Not Reported
					Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712568	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587985-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Toradol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15713594	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2583819-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15738111	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Meloxicam			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15741654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594158-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16156007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728799-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Septra	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16798598	EXPEDITED (15-DAY)		OT	CA-SA-2019SA250726		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S	Oral			Not Reported
	Diclofenac Sodium			S				Not Reported
	Topicort			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Sarilumab			S				Sanofi
	Sulfasalazine			S	Subcutaneous	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Desoximetasone			S				Sanofi
	Actemra			S				Not Reported

	Cortisone Acetate	S		Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported
	Leflunomide	C			Not Reported
	Atasol [Paracetamol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16805660	EXPEDITED (15-DAY)		DE	CA-TEVA-2019-CA-1108101		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis
	Atorvastatin Calcium			S	Unknown			Teva
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva
	Metformin			S	Unknown	1000 Milligram Daily;		Not Reported
	Omeprazole Magnesium			S	Oral			Teva
	Furosemide			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Flovent			S	Unknown			Not Reported

	Lasix	S	Unknown			Not Reported
	Nitrazadon	S	Unknown			Not Reported
	Plaquenil	S	Unknown	300 Milligram Daily;		Not Reported
	Salmeterol Xinafoate	S	Unknown			Not Reported
	Tylenol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17430893	NON-EXPEDITED			NVSC2020US036804			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Lymphocyte Abnormalities; Foetal Exposure During Pregnancy	Rituximab			S	Transplacental	Maternal Dose: 500 Mg/M2		Not Reported
	Azathioprine			S	Transplacental	Maternal Dose: 100 Mg, Bid		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 1 Mg/Kg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 3micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1.5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 2 Microgram/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1microgram/Kg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 10mg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 40 Mg		Not Reported

	Belimumab	S	Transplacental	Maternal Dose: Unk, Qmo	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 1000 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 400 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 200 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17432480	NON-EXPEDITED			NVSC2020US036797		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Rituximab			S	Intravenous (not otherwise specified)	500 Mg/M2		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Prednisone			S	Oral	1 Mg/Kg Qd		Novartis
	Prednisone			S	Unknown	10 Mg Qd		Novartis
	Azathioprine			S	Unknown	100 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Romiplostim			S	Subcutaneous	3 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	1.5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	2 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	1 Microgram		Not Reported
	Belimumab			S	Unknown	Unk Unk, Qmo		Not Reported

	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Arthrotec	C	Oral	Unk		Not Reported
	Arthrotec	C	Unknown	Unk		Not Reported
	Azathioprine	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Gold	C	Unknown	Unk		Not Reported
	Imuran /00001501/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17571510	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17586904	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024281		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, Qwk		Not Reported

Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608636	EXPEDITED (15-DAY)		OT	FR-FERRINGPH-2020FE01903		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Menopur			S	Subcutaneous			Ferring
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608696	EXPEDITED (15-DAY)		OT	IT-BAXTER-2020BAX006523		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematochezia	Diretif 10 Mg/Ml Soluzione Iniettabile	S	Unknown		Claris
	Dabigatran Etexilate	S	Oral		Not Reported
	Daparox	S	Unknown		Not Reported
	Lamictal	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Valium	S	Unknown		Not Reported
	Sotalol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608746	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001933			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Disorder; Blindness; Epstein-Barr Virus Infection; Eye Pain; Eye Pain; Intraocular Pressure Increased; Necrotising Retinitis; Ocular Hyperaemia; Retinal Detachment; Scleral Disorder; Uveitis; Varicella Zoster Virus Infection; Vision Blurred; Vitreous Floaters; Vitritis	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Cellcept			S	Unknown	1000 Mg, Bid		Not Reported
	Valacyclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608765	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1216776			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S				Teva
	Methotrexate			S				Barr
	Plaquenil			S		400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported

Alprazolam	C			Not Reported
Folic Acid	C			Not Reported
Naprosyn	C		1000 Milligram Daily;	Not Reported
Pantoloc	C			Not Reported
Prednisone	C		5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608937	EXPEDITED (15-DAY)		DS, HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000912			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea; Left Ventricular Dysfunction	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Qd		Ipca
	Fexofenadine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Novo Nordisk Pharms Novofem			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Hyoscine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609185	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANZ PHARMA-GSH201702-001124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Bone Density Decreased; C-Reactive	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Adalimumab			S	Unknown	Unknown		Not Reported

Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2 Qow	Not Reported
	Methotrexate	S	Unknown	Unk, Weekly	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported

	Enbrel		S	Subcutaneous	25 Mg, Weekly	Not Reported
	Tocilizumab		S	Unknown	250 Mg, Qd	Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)	280 Mg Qcy (Every 2 Weel)	Not Reported
	Isoniazid;Rifampicin		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Folic Acid		C			Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609386	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA086791		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Meperidine Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Bisoprolol			S	Unknown	Unk		Novartis
	Levofloxacin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qw		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	5 Mg		Not Reported

		Norfloxacin			S	Unknown	Unk			Not Reported
		Plaquenil			S	Oral	400 Mg, Qd			Not Reported
		Prednisone			S	Unknown	Unk			Not Reported
		Sulfasalazine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609994	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-177659		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610209	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020050661		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Furosemide			S	Unknown	Unk		Glaxosmithkline
	Daparox			S	Unknown	Unk		Glaxosmithkline
	Valium			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Dabigatran Etexilate			S	Oral	300 Mg, Qd		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610630	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026351		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Cefazolin	S	Unknown	Unk		Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Milligram, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol	S	Subcutaneous	400 Milligram, 1 Every 2 Weeks		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 1 Every 2 Weeks		Not Reported
	Leflunomide	S	Oral	10 Milligram		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1every One Week		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amlodipine	C	Unknown	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported
	Tofacitinib Citrate	C	Unknown	Unk		Not Reported
	Viread	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611049	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Etanercept	S	Unknown	Unknown		Not Reported
	Actemra	S	Unknown	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown		Not Reported
	Arava	S	Unknown	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous			Not Reported
	Certolizumab Pegol	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methylprednisolone	S	Unknown			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown		Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611066	DIRECT	Y	DS, OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Immunosuppressant Drug Level Increased	Plaquenil			S				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611141	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611326	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported

Incomplete	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Lyrica		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Piroxicam		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611609	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10259			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

	Plaquenil	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611785	EXPEDITED (15-DAY)		OT	IT-VALIDUS PHARMACEUTICALS LLC-IT-2020VAL000236			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			S	Unknown	Unk		Not Reported
	Dabigatran			S	Oral	Unk		Not Reported
	Daparox /00830803/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17614765	DIRECT	Y	DE, LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Cytokine Storm; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	Other Dose:400-200 Mg;		Not Reported
	Haldol			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported

	Cistaracurijm	C	Not Reported
	Docusate Sodium	C	Not Reported
	Exoxaparin	C	Not Reported
	Fentanyl	C	Not Reported
	Heparin	C	Not Reported
	Versed	C	Not Reported
	Propofol Continuous Infusion	C	Not Reported
	Pantoprazole	C	Not Reported
	Sennosides	C	Not Reported
	Sertraline	C	Not Reported
	Darunavir/Cobistat	C	Not Reported
	Apixaban	C	Not Reported
	Aspirin	C	Not Reported
	Donepezil	C	Not Reported
	Ketoconazole 2% Shampoo	C	Not Reported
	Nitroglycerin Sl	C	Not Reported
	Sertrraline	C	Not Reported
	Sevelamer	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	11626328	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2015032127		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme	Cimzia			S	Subcutaneous	Dosage Form: Solution		Not Reported
	Cimzia			S				Not Reported
	Cetirizine Hydrochloride			S		10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Ucb
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Zyrtec-D			S		10 Mg, Unk		Not Reported
	Zyrtec-D			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Controlled Release Tablets		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported

Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		25 Milligram, Ointment	Ucb
	Cirrus	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		5 Mg, Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		500 Milligram	Not Reported
	Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
	Prednisone	S		Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S		25 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		1 Milligram	Not Reported

Pseudoephedrine Hydrochloride	S		25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral		Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Adalimumab	S		Unk	Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S			Not Reported
Cortisone	S	Oral		Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported

Cortisone Acetate	S			Not Reported
Cortisone Acetate	S	Oral		Not Reported
Desoximetasone	S		Cutaneous Route	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S			Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S			Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Humira	S	Sunconjunctival	Unk Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravesical		Not Reported
Sarilumab	S			Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S		Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Golimumab	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Leflunomide	S			Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily	Not Reported

						(Qd)			
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Salazopyrin			C		Unk			Not Reported
	Atasol			C		Unk			Not Reported
	Tofacitinib Citrate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13058846	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015717		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13516082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038066		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine	S	Unknown			Not Reported
	Ciclosporin	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13669856	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA106082		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

	Orencia	S	Unknown	Unk Unk,Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Xeljanz	C	Oral	5 Mg,Bid		Not Reported
	Prednisone	C	Unknown	5 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	14217330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025441		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15509701	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016273080		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dysphagia; Gastrooesophageal Reflux Disease; Glaucoma; Pharyngeal Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Atorvastatin			C		20 Mg, Unk		Not Reported
	Latanoprost			C		Unk [125mg/2.5ml]		Not Reported
	Stiolto Respimat			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15619727	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555831-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15620477	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555079-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Aleve			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15627967	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558814-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Therapeutic Product Effect Decreased	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15629653	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557267-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Etanercept		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Imuran		C	Unknown	Not Reported
	Azathioprine		C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15635108	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556219-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Apo-Warfarin			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Arava	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15728721	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1969198-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	For 8 Years	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	For 8 Years	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Vitamin D3	C			Not Reported
Imuran	C			Not Reported
Gold	C			Not Reported
Arthrotec	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15732982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1858378-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16337732	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-048239		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Ibuprofen			S	Oral	600 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Unknown	60 Milligram		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported

Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Leflunomide	S	Oral		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	15 Milligram,1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, 4 Every1week	Not Reported
	Methotrexate	S	Unknown	12 Milligram,4every1week	Not Reported
	Methotrexate	S	Unknown	10 Milligram,4every 1week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram,4every 1week	Not Reported
	Methotrexate	S	Unknown	70 Milligram,1every1week	Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram,2every1day	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram,2every1week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported

	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C	Unknown		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Nitrazepam	C	Unknown	5 Milligram	Not Reported
	Oxycodone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Uloric	C	Unknown	80 Milligram,2every1day	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16527868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555951-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution-Dosage Form (Form Of Administration)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

Actemra	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16568503	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL128630		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn	Erelzi			S	Intravenous (not otherwise specified)	50 Mg, Unk		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	10 Mg, Qd		Not Reported
	Encorton			S	Unknown	15 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	20 Mg, Qd		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In		Not Reported

							Jan-2019)			
	Folic			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16820135	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201804-001105			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fatigue; Hepatomegaly; Malaise; Nausea; Pain In Extremity; Puncture Site Pain; Rash; Splenomegaly; Systemic Lupus Erythematosus; Vein Disorder; Vessel Puncture Site Bruise; Vessel Puncture Site Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Cerezyme			S	Intravenous drip	Dose/Unit: 3200.00 Frequency: Q2		Not Reported
	Cerezyme			S	Intravenous (not otherwise specified)	3200 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17486761	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202002001091			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acantholysis; Blister; Dermatitis; Herpes Zoster; Inflammation; Macule; Pain; Pruritus; Skin Plaque; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd, Tapering Dose		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Recombinant Varicella Zoster Virus Glycoproteine E			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17566404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318840		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Simponi	S	Subcutaneous			Janssen
	Simponi	S				Janssen
	Remicade	S	Intravenous (not otherwise specified)			Janssen
	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S				Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Ergocalciferol	C				Not Reported
	Imuran /00001501/	C	Unknown			Not Reported
	Arthrotec	C	Unknown			Not Reported
	Vitamin D3	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17575062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira			S	Subcutaneous	Unk			Not Reported
	Methotrexate			S	Unknown	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609231	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002203			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609364	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002205			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609365	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002204			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported

	Trametinib			S		2 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611781	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611782	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002280			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611783	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002281			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17613937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2572186			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614080	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202003002074			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Organ Transplant; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk (For Over 30 Years)		Concordia
	Cellcept			S	Unknown	500 Mg, Tid (For 1.5 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614116	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Prednisone	S	Unknown	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614240	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0121425			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614339	EXPEDITED (15-DAY)		DS	CA-ROCHE-2572169		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Sleep Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Therapeutic Product Effect Decreased; Treatment Noncompliance			otherwise specified)		
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614467	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026601		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Ebastine			C	Unknown			Not Reported

	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616393	DIRECT					63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Vertigo	Hydroxychloroquine 200 Mg Tablets Zydus - Substituted For Plaquenil			S	Oral	Quantity:180 Tablet(S);		Zydus Pharm
	Norvas			C				Not Reported
	Hctz			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Predinsdone			C				Not Reported
	Pravastatin			C				Not Reported
	General Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616524	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-509		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Cat Scratch Disease; Complication Associated With Device	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Westward
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616629	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Visual Impairment	Hydroxychloroquine			S		Quantity:1 Tablet(S);		Sandoz
	Valsartan			C				Not Reported
	Metoprolol			C				Not Reported
	Atorvastatin			C				Not Reported
	Levothyroxine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Apsirin			C				Not Reported
	Women'S Silver Centrum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616815	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			American Health
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616895	EXPEDITED (15-DAY)		OT	NVSC2020GB089786		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Cutaneous Lupus Erythematosus; Cutaneous Lupus Erythematosus; Disease Progression; Madarosis; Mucosal Pain; Product Use In Unapproved Indication; Skin Plaque	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Novartis
	Hydroxychloroquine			S	Transdermal	200 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3348747-00		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17629156	DIRECT	Y				22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine			S	Subcutaneous			Abbvie
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	12994284	EXPEDITED (15-DAY)		OT	CA-SA-2016SA199672		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	13660454	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1724612US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Qd		Not Reported
	Risedronic Acid			S	Unknown	Unk		Not Reported
	Risedronic Acid			S	Unknown	35 Mg, Q Week		Not Reported
	Risedronic Acid			S	Unknown	35 Mg, Q Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15108418	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0726		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Incomplete; Urinary Tract Infection	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Methotrexate			S	Oral	Not Reported
	Methotrexate			S	Subcutaneous	Not Reported
	Meloxicam			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15619709	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555775-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15620439	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556971-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Minocycline Hydrochloride	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15621423	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557292-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Radioactive Gold			S	Unknown			Not Reported

	Plaquenil			S	Unknown	Not Reported
	Actemra			S	Unknown	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Prednisone			S	Oral	Not Reported
	Leflunomide			S	Unknown	Not Reported
	Indometacin			S	Unknown	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Not Reported
	Cymbalta			C	Oral	Not Reported
	Folic Acid			C	Oral	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15621502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557034-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Rituxan	S	Intravenous (not otherwise specified)		Not Reported
					Etanercept	S	Unknown		Not Reported
					Hydroxychloroquine Sulfate	S	Unknown		Not Reported
					Apo-Azathioprine	S	Unknown		Not Reported
					Apo-Leflunomide	S	Unknown		Not Reported
					Arava	S	Unknown		Not Reported
					Sulfasalazine	S	Unknown		Not Reported
					Rituximab	S	Intravenous (not otherwise specified)		Not Reported
					Tofacitinib	C			Not Reported
					Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15622316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557239-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Impaired Work Ability; Nasopharyngitis; Nasopharyngitis; Rheumatoid Arthritis; Rheumatoid Arthritis; Stress; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

	Xeljanz			S	Oral		Not Reported
	Xeljanz			S	Unknown		Not Reported
	Xeljanz			S	Oral		Not Reported
	Apo-Leflunomide			S	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)		Not Reported
	Rituximab			S	Intravenous drip		Not Reported
	Orencia			S	Unknown		Not Reported
	Actemra			S	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine			C	Unknown		Not Reported
	Wellbutrin			C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15629333	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ABBVIE-18K-028-2557519-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Foa-Solution		Not Reported
	Rituxan			S	Subcutaneous			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S		Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15662825	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2569806-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Arava			S	Nasal			Not Reported
	Arava			S				Not Reported

Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Ilaris	S	Subcutaneous	Ilaris Single-Use Vial	Not Reported
	Ilaris	S	Subcutaneous	Ilaris Single-Use Vial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Gold	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported

	Leflunomide		S			Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine		S			Not Reported
	Oxyquinoline Sulfate		S	Unknown		Not Reported
	Oxyquinoline Sulfate		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15663251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570496-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15717406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587385-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; General	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S		Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Plaquenil		S		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Mobicox		C		Not Reported
	Remicade		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15811306	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617216-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Infusion	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15930868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655637-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Abnormal; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15994348	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2674858-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16079906	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-05955		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Actemra	S			Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Unknown	Unknown	Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported

	Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
	Apo-Naproxen	S	Unknown	Unknown		Not Reported
	Apo-Naproxen	S				Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Gamastan	S	Intramuscular	Liquid Intramuscular		Not Reported
	Tocilizumab	S	Unknown	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Unknown, Injectable Suspension		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16444293	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822475-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Arthritis; Rheumatoid Factor Positive; Synovitis			otherwise specified)			
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Actemra	S	Subcutaneous			Not Reported
	Actonel	S	Unknown			Not Reported
	Apo-Leflunomide	S	Oral	Cyclical		Not Reported
	Apo-Leflunomide	S	Oral			Not Reported
	Cimziasingle	S	Subcutaneous			Not Reported
	Arava	S	Oral			Not Reported
	Risedronate	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Risedronate Sodium	S	Oral			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16567681	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy;	Diclofenac Sodium			S	Unknown	150 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown			Not Reported

Synovial Disorder	Sulfasalazine	S	Unknown	2 Gram Daily;		Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram Daily;		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Piroxicam	C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16686320	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21297		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Walking Aid User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S			Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Atorvastatin	C	Unknown		Not Reported
Atorvastatin	C	Unknown	Unknown	Not Reported
Atorvastatin Calcium	C	Unknown	Unknown	Not Reported
Pantoloc	C	Unknown	Enteric-Coated	Not Reported
Pantoloc	C	Unknown		Not Reported
Pantoloc	C	Unknown	Unknown	Not Reported
Pantoprazole	C	Unknown	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unknown	Not Reported
Plaquenil	C	Oral		Not Reported
Plaquenil	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16687965	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210544		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial	Arava			S		366 Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Pregabalin			S		150 Mg		Not Reported

Lung Disease; Rheumatoid Arthritis	Methotrexate	S		Unk	Not Reported
	Sulfasalazine	S		1000 Mg, Bid	Not Reported
	Orencia	S		Unk	Not Reported
	Orencia	S			Not Reported
	Xeljanz	S		Unk	Not Reported
	Rituxan	S		1000 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Trazodone	C		200 Mg, Qd	Not Reported
	Lumigan Rc	C	Ophthalmic	1 Df, Qd	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C		10 Mg, Qd	Not Reported
	Tylenol [Paracetamol]	C		Unk	Not Reported
	Tylenol [Paracetamol]	C		3000 Mg, Qd	Not Reported
	Valsartan	C		1 Df, Qd	Not Reported
	Valsartan	C		Unk	Not Reported
	Wellbutrin	C		300 Mg, Qd	Not Reported
	Esomeprazole	C		40 Mg, Qd	Not Reported
	Nexium [Esomeprazole Sodium]	C		40 Mg, Qd	Not Reported
	Tylenol Extra Strength	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16720242	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Qd		Sanofi
	Diclofenac			S	Unknown	50 Mg, Bid		Not Reported

	Hydroxychloroquine	S	Oral	400 Mg, Qd (Prior To 2011)	Sanofi
	Indometacin	S		50 Mg, (20 To 50 Mg) Tid	Not Reported
	Leflunomide	S	Oral	10 Mg, Qd (Prior To 2016)	Sanofi
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	15 Mg, (10 To 15 Mg) Qw (Prior To 2011)	Not Reported
	Naproxen	S	Unknown	500 Mg, Q6h	Not Reported
	Plaquenil	S	Unknown	Unk	Sanofi
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16923698	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Diphenhydramine Hydrochloride			S		Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001502/			S	Unknown	Unk		Not Reported

	Simponi			S	Unknown	Unk			Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid			Not Reported
	Xeljanz			S	Oral	5 Unk			Not Reported
	Xeljanz			S	Oral	5 Unk			Not Reported
	Ezetrol			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17199927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3206389-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17559399	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03346		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported

Anakinra	S	Subcutaneous		Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown. Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown	Unknown Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution	Not Reported
Gold	S	Intramuscular	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown		Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Unknown	Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Sulfasalazine	C	Unknown	Unknown	Not Reported
Wellbutrin	C	Unknown	Unknown	Not Reported

	Xeljanz			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17559777	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17571111	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008956		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Q.O.Wk.		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
	Orencia			S	Unknown	500 Mg, Unk, 1 Every 4		Not Reported

							Weeks			
	Xeljanz			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17575454	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008927		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17591358	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009095		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611780	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611784	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002283			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611792	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17618992	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001932			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Injury; Fatigue; Headache; Therapeutic Response Delayed; Therapeutic Response Shortened; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk (Or, Dose, Frequency, Route Lot Number And Expiry Date Unknown)		Not Reported
	Actemra			S	Unknown	Unk (Suspended On 25-		Not Reported

						Feb-2020)			
	Sulfasalazine			C		Unk			Not Reported
	Humira			C		Unk			Not Reported
	Enbrel			C		Unk			Not Reported
	Methotrexate			C		Unk			Not Reported
	Pantoloc			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17619006	EXPEDITED (15-DAY)		DS	CA-ADVANZ PHARMA-202003001934			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Liver Disorder; Loss Of Personal Independence In Daily Activities; Oral Herpes	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620210	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009225		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Arthritis; Treatment Failure; Urticaria	Plaquenil /00072602/		S	Oral	200 Mg, Bid		Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate		S	Parenteral	Unk		Not Reported
	Sulfasalazine		S	Unknown	750 Mg, Qd		Not Reported
	Hydrochlorothiazide W/Lisinopril		C	Unknown	Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril Dihydrate		C	Unknown	Unk		Not Reported
	Prednisone		C	Unknown	5 Mg, Qd		Not Reported
	Rituxan		C	Unknown	Unk		Not Reported
	Tylenol Extra Strength		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620330	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002212			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Infection; Skin Lesion	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Aminosalicylic Acid			S		81 Mg, Qd		Not Reported
	Aminosalicylic Acid			S				Not Reported
	Mycophenolate Mofetil			S		1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Quinacrine			C		100 Mg, Qd		Not Reported
	Quinacrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620886	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug	Kineret			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Ciclosporin		S	Unknown		Not Reported
	Enbrel		S	Unknown	2.5 Mg 1 Every 2 Weeks	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Infliximab		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S			Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622122	EXPEDITED (15-DAY)		OT	CA-ROCHE-2573031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg Was Reduced To 7.5 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217045		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva

Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Celecoxib	S	Unknown		Teva
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Intravenous (not otherwise specified)		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Parenteral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Naproxen	S	Unknown		Teva
	Pregabalin	S	Unknown		Teva
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Allopurinol	S	Unknown		Not Reported
	Amitriptyline	S	Unknown		Not Reported
	Amitriptyline Hydrochloride/Perphenazine	S	Unknown		Not Reported
	Apo-Amitriptyline	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Diclofenac	S	Topical		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported

	Lyrica		S	Unknown		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S			Not Reported
	Misoprostol		S	Unknown		Not Reported
	Naprosyn [Naproxen		S	Unknown		Not Reported
	Nifedipine		S	Unknown		Not Reported
	Orencia		S	Subcutaneous	107.1429 Milligram Daily;	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Winpred		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Tofacitinib		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA079660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Codeine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622915	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pancytopenia	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623040	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt	Hydroxychloroquine			S	Oral			Not Reported

Prolonged	Azithromycin	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623288	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05347		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Advil			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported
	Ketorolac			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623349	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1578		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

			Hydroxychloroquine Sulfate		S	Unknown				Not Reported
			Leflunomide		S	Unknown				Not Reported
			Methotrexate		S	Unknown				Not Reported
			Remicade		S	Intravenous (not otherwise specified)				Not Reported
			Rituximab		S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342132		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624098	EXPEDITED (15-DAY)		HO, OT	NVSC2020US090011		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cardiomyopathy; Cardiotoxicity; Dyspnoea Exertional; Orthopnoea; Peripheral Swelling	Hydroxychloroquine			S	Unknown	200 Unk, Bid		Novartis
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624253	EXPEDITED (15-DAY)		OT	CA-EMD SERONO-E2B_90076287		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Metformin Hydrochloride			S	Unknown	Unknown		Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unknown Dosage		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran /00001501/			C	Unknown	Unknown		Not Reported
	Xarelto			C	Unknown	Unknown		Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624589	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-009614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625486	EXPEDITED (15-DAY)		HO, LT, OT	MX-ACCORD-178039		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Off Label Use; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolic Acid			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625490	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-242736		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, In Total		Sun
	Plaquenil			S	Oral	1 Dosage Form, Daily		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral	()		Not Reported
	Pantoprazole			C	Unknown	()		Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C	Unknown	()		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C	Unknown	()		Not Reported
	Diffu K, Gelule			C	Unknown	()		Not Reported
	Atorvastatine			C	Unknown	()		Not Reported
	Clopidogrel (Chlorhydrate De)			C	Unknown	()		Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	16162286	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2733052-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Contraindicated Product Administered; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625695	EXPEDITED (15-DAY)		DE	IE-ABBVIE-20K-229-3352301-00		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Seroquel			C				Not Reported
	Arava			C				Not Reported
	Depo-Medrone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Methotrexate			C				Not Reported
	Protium			C				Not Reported

	Valdoxan			C						Not Reported
	Alendronate			C						Not Reported
	Levothyroxine Sodium			C						Not Reported
	Prednisolone			C						Not Reported
	Sulfasalazine			C						Not Reported
	Sulfasalazine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625752	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217530		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	10991568	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150323608		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

	Xeljanz			S	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	14535544	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0125		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Dose: 12.5 Mg Once Daily		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Dose. 12.5 Mg 1x1 Daily		Not Reported
	Methotrexate Sodium			S	Oral	Dose: 12.5 Mg		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15066519	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0720		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Kineret	S			Not Reported
	Actemra	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S			Not Reported
	Gold	S	Subcutaneous		Not Reported
	Ilaris	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15407353	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911920		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Contraindicated Product Administered; Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Pain; Pain In Extremity; Pain In Jaw; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported

	Gold			S	Unknown				Not Reported
	Lyrica			S	Oral				Not Reported
	Orencia			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Apo-Hydroxyquine			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Mycophenolate Mofetil			S	Unknown				Not Reported
	Cimzia			S	Subcutaneous				Not Reported
	Leflunomide			S	Oral				Not Reported
	Plaquenil /00072602/			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15620412	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556731-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Apo Hydroxyquine	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15625609	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2557423-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Apo-Cyclosporine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Motrin	S	Oral	Not Reported
	Motrin	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Cyclosporine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Ibuprofen	S	Oral	Not Reported
	Colchicine	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Nitrazepam	C	Oral	Not Reported
	Oxycodone	C		Not Reported

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Colitis; Contraindicated Product Administered; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Nausea; Oxygen Saturation Decreased; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Diamicron			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Asacol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	225.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Norvasc			S	Oral			Not Reported
	Norvasc			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Aerius			C				Not Reported
	Crestor			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported

					Atacand Plus		C			Not Reported
					Bisoprolol Fumarate		C			Not Reported
					Depo-Medrol		C	Intra-articular		Not Reported
					Ferrous Gluconate		C			Not Reported
					Folic Acid		C			Not Reported
					Tylenol		C			Not Reported
					Vitamin D3		C			Not Reported
					Rosuvastatin Calcium		C			Not Reported
					Ebastine		C			Not Reported
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
06-Apr-2020	15702726	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580931-00			Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Humira			S	Subcutaneous			Not Reported		
	Arava			S	Unknown			Not Reported		
	Methotrexate			S	Unknown			Not Reported		
	Orencia			S	Unknown			Not Reported		
	Plaquenil			S	Unknown			Not Reported		
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported		
	Simponi			S	Subcutaneous			Not Reported		
	Sulfasalazine			S	Unknown			Not Reported		
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported		
	Celebrex			C				Not Reported		
	Lyrica			C				Not Reported		
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
06-Apr-2020	15707673	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584580-00		84 YR	Female	CAN	
Preferred Term	**Product**	**Comp.**	**OTC**	**Role**	**Route**	**Dosage Text**	**Duration**	**Mfr**		

Back Injury; Drug Ineffective; Fall; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15733752	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594187-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Minocyclin			S	Unknown			Not Reported
	Apo-Minocyclin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Azathioprine		S	Unknown	Not Reported
	Minocycline Hydrochloride		S	Unknown	Not Reported
	Minocycline		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide		C	Unknown	Not Reported
	Hydroxychloroquine Sulfate		C		Not Reported
	Xeljanz		C	Unknown	Not Reported
	Hydroxychloroquine		C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734078	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594192-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734387	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594151-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product	Humira			S	Subcutaneous			Not Reported

Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Xeljanz		C	Oral	Not Reported
	Prednisone		C	Oral	Not Reported
	Lyrica		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15739251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594156-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Varilrix		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Unknown	Not Reported
	Varicella Zoster Vaccine Live		S	Subcutaneous	Not Reported
	Cortisone Acetate		C	Subcutaneous	Not Reported
	Desoximetasone		C	Oral	Not Reported
	Desoximetasone		C	Subcutaneous	Not Reported
	Diclofenac		C	Subcutaneous	Not Reported
	Xeljanz		C	Oral	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15930738	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655654-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Altace			C	Unknown			Not Reported
	Asa			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported

	Folic Acid			C	Unknown	1.0		Not Reported
	Methotrexate			C	Oral			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Vitamin D			C	Unknown			Not Reported
	Docosahexaenoic Acid			C				Not Reported
	Eicosapentaenoic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15958056	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170820946		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Contraindication To Vaccination; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported

Humira	S	Subcutaneous	Not Reported
Gold	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Certolizumab	S	Subcutaneous	Not Reported
Azathioprine	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cellcept /01275102/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Pregabaline	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16040473	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr

	Meloxicam	S	Unknown		Teva
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mobicox	S	Unknown		Not Reported
	Orencia	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16301153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16381114	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2804954-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Amlodipine	C		Not Reported
	Arava	C		Not Reported
	Benadryl	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16441274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822469-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

		Rituximab			S	Unknown				Not Reported
		Prednisone			C	Oral				Not Reported
		Lyrica			C	Unknown				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16443280	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819775-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16497972	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S				Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Arava			S		10 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			C		Unk, Weekly (Qw)		Not Reported
	Meloxicam			C				Not Reported
	Synthroid			C				Not Reported
	Acetaminophen And Codeine Phosphate			C				Not Reported
	Apo-Prednisone			S	Oral	20 Nanogram		Not Reported

	Plaquenil [Hydroxychloroquine Phosphate]			S		200 Milligram, 2x/Day (Bid)				Not Reported
	Codeine			C						Not Reported
	Tylenol [Paracetamol]			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16714535	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16717736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebral Disorder; Condition Aggravated; Cystitis; Disturbance In Attention; Drug Intolerance; Gait Disturbance; Grip Strength Decreased; Hypersensitivity;	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Oral	400 Mg 3-4/Day		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Hydroxychloroquine			S				Sanofi
	Gold			S	Intramuscular	10 Mg, 1x		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

Intentional Product Use Issue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Pneumonitis; Therapeutic Product Effect Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17156996	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Janssen
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17173636	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product	Cimzia			S	Subcutaneous			Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Apo-Prednisone	S			Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram Solution	Ucb
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Sulfasalazine			S	Subcutaneous	500 Milligram				Not Reported
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17200098	EXPEDITED (15-DAY)		OT	SE-ADVANZ PHARMA-201912003018			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus; Drug Ineffective	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid ,1 Tablet Twice A Day For 2 Weeks		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form		Concordia
	Trombyl			C		75 Mg		Not Reported
	Candesartan			C		16 Mg		Not Reported
	Levaxin			C		25 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Dermovate			C		Unk		Not Reported
	Omeprazol			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17350398	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw)		Not Reported

Leflunomide	S				Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S		1 Gram, 2x/Day (Bid)		Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)		Not Reported
Xeljanz	C		5 Milligram, 2x/Day (Bid)		Not Reported
Xeljanz	C		11 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17391221	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170826218		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Distension; Adverse Reaction; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nail Disorder; Nausea; Off	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported

Label Use; Onychomycosis; Pain; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sleep Disorder; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tocilizumab	S		Not Reported
	Orencia	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Rheumatrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17420592	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Failure	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17425017	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0812		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17563093	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Alopecia; Amnesia; Contraindicated Product Administered; Delirium; Diabetes Mellitus; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Gait Disturbance; Glossodynia; Grip Strength Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Maternal Exposure During Pregnancy; Mobility Decreased; Muscular Weakness; No Adverse Event; Pain; Pain In Extremity; Pemphigus; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Walking Aid User; Weight Decreased; Wound Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

		Pseudoephedrine Hydrochloride W/Tri/00005601/			S	Unknown				Not Reported
		Reactine /00884302/			S	Unknown				Not Reported
		Naprosyn /00256201/			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17579775	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327856		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628411	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002097			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	400 Mg 2x15 Cprrev, Plaquinol, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628438	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202003002241			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fibromyalgia; Malaise; Pleural Effusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form,Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628439	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002041			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	Unk, (Coated Tablets)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628622	EXPEDITED (15-DAY)		DS, OT	FR-ADVANZ PHARMA-202003002294			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Chronic Obstructive Pulmonary Disease; Diabetes Mellitus; Infection; Pneumonia; Respiratory Distress; Wheelchair User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia
	Cortancyl			C		Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628632	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3352546-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Hypersensitivity; Rheumatoid Arthritis	Humira		S	Subcutaneous	Not Reported
	Codeine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Gold		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628737	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628958	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014088		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oral Pain; Oropharyngeal Pain; Stomatitis	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Subcutaneous	200 Milligram		Not Reported
	Benzylhydrochlorothiazide			C				Not Reported
	Coumadin			C				Not Reported
	Cyanocobalamin			C				Not Reported

	Eltroxin			C						Not Reported
	Metoprolol			C						Not Reported
	Pravachol			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629123	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020014089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Tocilizumab			S		160 Milligram		Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629213	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002163			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629303	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217500		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629306	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629352	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629366	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Sulfasalazine		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629396	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217963		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr

Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine	S	Unknown			Not Reported
	Leflunomide	S	Oral			Barr
	Actemra	S	Subcutaneous	23.1429 Milligram Daily;		Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Kevzara	S	Subcutaneous			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Esomeprazole	C	Unknown			Not Reported
	Magnesium	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629401	NON-EXPEDITED			US-AMGEN-USASP2020048450		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, ((0, 2, 6 Wks, Then Every 8 Wks.)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram, (Every 8 Weeks)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram, (Every 7 Weeks)		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Otrexup			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629497	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001847			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Decreased; Drug Tolerance Increased; Hypoacusis; Joint Injury; Joint Swelling; Migraine; Musculoskeletal Disorder; Therapeutic Product Effect Decreased; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid, One In The Morning One In Night		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629815	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002043			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Shortened Cervix	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17630225	EXPEDITED (15-DAY)		OT	NVSC2020CA090993			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	10 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631124	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3352969-00		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral	200 Mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631943	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217985		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Oral				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318931			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Mefenamic Acid			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported
	Tylenol /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632057	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue;	Alendronate Sodium			S	Oral			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Mg		Barr

Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Unknown	Barr
	Prednisone	S	Oral	Actavis
	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632099	NON-EXPEDITED		OT	NVSC2020US092034		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Diastolic Dysfunction	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632120	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217560			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S		20 Millimol Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632164	EXPEDITED (15-DAY)		OT	NVSC2020FR079225		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Ocular Toxicity	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632212	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014049		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Arava			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Cephalexin Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632213	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014044		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity;	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S				Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
	Glumetza			S		500 Milligram, 2x/Day (Bid)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S				Not Reported

Peripheral Swelling; Therapeutic Product Effect Decreased	Methotrexate		S	Oral		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S			Not Reported
	Xeljanz		S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Acetaminophen		C			Not Reported
	Altace		C			Not Reported
	Arava		C			Not Reported
	Asa		C			Not Reported
	Codeine		C			Not Reported
	D-Alpha Tocopherol		C			Not Reported
	Ergocalciferol		C			Not Reported
	Folic Acid		C			Not Reported
	Prednisone		C	Oral		Not Reported
	Rosuvastatin Calcium		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Plaquenil	S	Unknown	300 Mg, Qd		Not Reported
	Azathioprine	C	Oral	50 Mg, Qd		Not Reported
	Azathioprine	C	Oral	150 Mg, Qd		Not Reported
	Azathioprine	C	Oral	100 Mg, Bid		Not Reported
	Humira	C	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Ketoprofen	C	Unknown	Unk		Not Reported
	Methotrexate	C	Oral	Unk		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Q Week		Not Reported
	Prolia	C	Subcutaneous	Actual: 60 Mg, Every 6 Months		Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632612	EXPEDITED (15-DAY)		OT	CA-SA-2020SA073892			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased; Treatment Failure	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Oral	2.8571 Milligram Daily;	Not Reported
	Sulfasalazine		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633310	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217525		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown	22.8571 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin		S	Unknown	Ivax
	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Tofacitinib		S	Unknown	Not Reported
	Gabapentin		C	Unknown	Not Reported
	Tylenol Arthritis Pain 8h		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol			C				Not Reported
	Diclofenac			C				Not Reported
	Humira			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633498	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160217144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture;	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Simponi	S	Subcutaneous	Janssen
	Simponi	S		Janssen
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	14299100	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Gold			S		Unk			Not Reported
	Plaquenil			S	Oral				Not Reported
	Methotrexate			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	14535636	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo Hydroxyquine			S				Not Reported
	Apo-Mycophenolate			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Celebrex			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Cellcept			S				Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			C				Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C				Not Reported

	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15624086	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557445-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15679987	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2573622-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Statex (Morphine Sulfate)	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Statex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15711682	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587778-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Imuran	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16182582	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2738227-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Rheumatoid Arthritis; Sciatica	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Subcutaneous			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

Ramipril	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Ramipril	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Cosopt	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Levothyroxine Sodium	S	Unknown	Not Reported
Altace	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Intravenous (not otherwise specified)	Not Reported
Tylenol No.2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C		Not Reported
Acetaminophen/Caffeine/Codeine Phosphate	C		Not Reported
Caffeine W/Dihydrocodeine Bitartrate/Paracetamol	C		Not Reported
Caffeine	C		Not Reported
Dorzolamide Hydrochloride/Timololmaleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16805717	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2921109-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16822887	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2019GSK067189		25 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dermatitis; Headache; Herpes Zoster; Inappropriate Schedule Of Product Administration; Leukocytosis; Product Availability Issue; Product Dose Omission; Pyrexia;	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		630 Mg, Unk		Glaxosmithkline
	Mycophenolate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Rash; Skin Injury; Skin Lesion; Systemic Lupus Erythematosus; Urinary Tract Infection; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17257461	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020AU004219			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Mycophenolate Mofetil			S	Oral	500 Mg, Tid		Novartis
	Mycophenolate Mofetil			S				Novartis
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Unk, Biw (Mcg)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Rosuvastatin			S	Unknown	10 Mg		Not Reported
	Ezetimibe			S	Unknown	10 Mg		Not Reported
	Ramipril			S	Unknown	Unk Mg, Unknown (5-10)		Not Reported
	Topiramate			S	Unknown	200 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	5-Methyltetrahydrofolate			S	Unknown	Unk		Not Reported
	Oxycontin			S	Oral	10 Mg, Bid		Not Reported
	Endone			S	Oral	5 Mg, Qd		Not Reported
	Aspirin			S	Unknown	100 Mg, Unknown		Not Reported
	Prasugrel			S	Unknown	10 Mg, Qd		Not Reported
	Ivabradine			S	Unknown	7.5 Mg, Bid		Not Reported
	Sildenafil			S	Oral	12.5 Mg, Prn		Not Reported
	Gtn			S	Oral	Unk		Not Reported
	Cannabis Sativa Oil			S	Unknown	Unk		Not Reported

	Reboxetine	S	Unknown	4 Mg, Bid	Not Reported
	Cholecalciferol	S	Unknown	50 Unk, Qd (Mcg)	Not Reported
	Novorapid	S	Subcutaneous	Unk (Pump With Continuous Bgl Monitor)	Not Reported
	Glucagen Hypokit	S	Unknown	Unk	Not Reported
	Mirena	S	Unknown	52 Mg, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Biw	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17374357	NON-EXPEDITED			US-PFIZER INC-2020048790		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17394735	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202002000642			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Tablet) (Increased The Dose)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557550	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318948		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557559	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Pms		Not Reported
	Benadryl /00000402/			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Plaquenil /00072602/			S	Unknown				Not Reported
		Procytox			S	Intravenous (not otherwise specified)				Not Reported
		Tofacitinib Citrate			S	Oral				Not Reported
		Ezetrol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557586	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318928		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17558039	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Plaquenil /00072602/			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Oxycodone Terephthalate	C	Unknown		Not Reported
	Percocet /00446701/	C	Unknown		Not Reported
	Thiamine Hydrochloride	C	Unknown		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Acetaminophen W/Oxycodone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17566305	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Enbrel	S	Unknown	Duration- 730 And 731 (Unspecified Units)	Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Imuran /00001501/	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Arthrotec	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17566309	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320884		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not			Janssen

Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity			otherwise specified)	
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil /00072602/	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17575971	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP008932		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

Enbrel	S	Subcutaneous	25 Mg, Q.O.Wk.	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	25 Unk, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk (1 Every 6 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Unk, Cyclical	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Arava	C	Oral	10 Mg, Unk	Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	40 Mg, Unk	Not Reported
Prednisone	C	Unknown	250 Mg, Unk	Not Reported

	Simponi	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Wellbutrin	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17577750	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596897	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068369		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi

	Hydroxychloroquine Sulfate	S		Unk		Sanofi
	Methotrexate	S		Unk		Not Reported
	Actemra	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Orencia	S		Unk		Not Reported
	Plaquenil	S		Unk		Sanofi
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S		Unk		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole	S		Unk		Not Reported
	Actemra	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597473	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068824		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597488	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068873		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency	Leflunomide			S	Oral	5 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported

Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S	Unknown	50 Mg	Not Reported
	Humira			S	Subcutaneous	40 Mg	Not Reported
	Orencia			S	Unknown	750 Mg	Not Reported
	Remicade			S	Unknown		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid	Not Reported
	Prednisone			C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatitis; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Off Label Use; Skin Reaction; Synovitis; Thyroid Cancer	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Endocervical	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Etanercept			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Avapro			C	Unknown	Unk		Not Reported
	Biaxin			C	Unknown	Unk		Not Reported
	Humalog			C	Unknown	Unk		Not Reported
	Insulin			C	Oral	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported
	Nystatin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608759	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202002001099			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Platelet Count Decreased; Red Blood Cell Count Decreased; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Imiquimod			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635250	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014082		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636247	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000018			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Foetal Exposure During	Tacrolimus			S	Transplacental			Panacea Biotec
	Hydroxychloroquine			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported

Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Metamizole Sodium	S	Transplacental	Not Reported
	Nicotine	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Unknown	Not Reported
	Xarelto	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dalteparin Sodium	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Novaminsulfon	S	Transplacental	Not Reported
	Novaminsulfon	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Rituximab	S	Transplacental	Not Reported
	Enoxaparin Sodium	S	Transplacental	Not Reported
	Misoprostol	C	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Enoxaparin Sodium	C	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Mifegyne	C	Transplacental	Not Reported
	Cyclophosphamide	C	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636295	EXPEDITED (15-DAY)		LT	NVSC2020US090949			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Near Death Experience	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Benadryl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636540	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219972		54 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	20 Mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400mg/12h Dia 1 Seguido De 200mg/12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636766	EXPEDITED (15-DAY)		OT	CA-SA-2020SA085603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Topicort			S	Topical			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Prednisone			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported
	Simponi			S	Subcutaneous					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029039		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637833	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219073		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638187	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219970		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400mg / 12h Day 1 Followed By 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638596	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK047124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural	Gabapentin			S	Unknown	100 Milligram, Bid		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram; 1 Every 1 Month		Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3		Not Reported

Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure				Week	
	Myochrysine	S	Intramuscular	50 Milligram; 1 Every 3 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw (1 Every 1 Week)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qw (1 Every 1 Week)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid (2 Every 1 Day)	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Od	Not Reported
	Ergocalciferol	C	Unknown	Unk, Od (1 Every 1 Day)	Not Reported
	Ergocalciferol	C	Unknown	400 Iu International Unit(S), Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid (2 Every 1 Day)	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram, Unk	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Od	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram, Unk	Not Reported
	Prednisone	C	Unknown	5.0 Gigabecquerel, Od	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported

	Risedronate Sodium	C	Unknown	36 Milligram, Qw (1 Every 1 Week)	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Od	Not Reported
	Tylenol /00020001/	C	Unknown	1000 Milligram, Qd	Not Reported
	Vitamin A /00056001/	C	Unknown	Unk	Not Reported
	Vitamin C /00008001/	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638618	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219180		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638655	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218933		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling;	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown	Not Reported
	Rituximab			S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218942		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Overlap Syndrome; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639284	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported

Fibrosis; Therapeutic Response Decreased	Methotrexate	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639471	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001059			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiomyopathy; Cutaneous Lupus Erythematosus; Neutropenia; Renal Failure; Retinal Injury; Thrombocytopenia; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641570	EXPEDITED (15-DAY)		OT	NVSC2020US094182		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641778	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Lyrica			S	Oral				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Mycophenolate Mofetil			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Piroxicam			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	12736125	NON-EXPEDITED			US-PFIZER INC-2016421350		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Scratch; Impaired Healing; Therapeutic Product Effect Incomplete	Xeljanz			S		5 Mg, Unk		Pfizer
	Xeljanz			S		10 Mg, Unk		Pfizer
	Xeljanz			S		5 Mg, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Duloxetine			S		30 Mg, Unk		Not Reported
	Vitamin D2			S		50000 Iu, Weekly		Not Reported
	Alendronate			S		70 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	13519393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038017		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	13676502	EXPEDITED (15-DAY)		OT	CA-TEVA-780631ACC		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension;	Actonel			S	Unknown			Teva
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Risedronic Sodium			S	Unknown			Teva

Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronic Sodium	S	Oral		Teva
	Risedronic Sodium	S	Unknown		Teva
	Actemra	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Apo-Risedronate	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

	Hydroxychloroquine			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15621982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557440-00		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15623808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555897-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Event	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Bcg	C	Intravesical	Not Reported
	Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Risedronate	C	Oral	Not Reported
	Amoxicillin And Clavulanate	C	Unknown	Not Reported

	Potassium Adalimumab				C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15630623	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556317-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15651514	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-CA2015187246			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia;	Cetirizine Hydrochloride			S		10 Mg, Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S		Unk		Glaxosmithkline

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Oral	10 Milligram, Once Daily (Qd)	Glaxosmithkline
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride	S		Unk	Glaxosmithkline
	Zyrtec-D	S		10 Mg, Unk	Glaxosmithkline
	Zyrtec-D	S			Glaxosmithkline
	Cirrus	S		Unk	Glaxosmithkline
	Cetirizine Hydrochloride	S	Oral	10 Milligram, Once Daily (Qd)	Glaxosmithkline
	Cetirizine Hydrochloride	S			Glaxosmithkline
	Folic Acid	S		5 Mg, Unk	Glaxosmithkline
	Folic Acid	S		5 Milligram	Glaxosmithkline
	Folic Acid	S		1 Milligram	Glaxosmithkline
	Folic Acid	S		1 Mg	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		1 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		25 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		10 Milligram	Glaxosmithkline
	Diclofenac Sodium	S		Unk	Glaxosmithkline
	Paracetamol	S		Unk	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Diclofenac	S		Unk	Glaxosmithkline
	Topicort	S	Cutaneous	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S		Controlled Release Tablets	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S		25 Milligram, Ointment	Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Cimzia	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported

Fosamax	S	Oral	Unk	Not Reported
Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported

Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Stelara	S		Unk	Not Reported
Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Sarilumab	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Glaxosmithkline
Simponi	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol (Acetaminophen)	C		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported

	Hydroxychloroquine Sulfate		S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Adalimumab		S		Unk	Not Reported
	Golimumab		S		Unk	Not Reported
	Leflunomide		S	Oral	Unk	Not Reported
	Desoximetasone		S	Oral	Cutaneous Route	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15664903	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2571352-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

		Hydroxychloroquine			S	Unknown				Not Reported
		Rituximab			S	Intravenous (not otherwise specified)				Not Reported
		Hydroxychloroquine Sulfate			S	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15712495	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587774-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15738004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Meloxicam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15916855	EXPEDITED (15-DAY)		OT	CA-COLGATE PALMOLIVE COMPANY-20190100275			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect	Periogard Unspecified			S	Unknown	Unk		Colgate
	Chlorhexidine Gluconate Unspecified			S	Unknown	Unk		Colgate
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Decreased; Therapeutic Product Effect Decreased; Weight Increased	Enbrel	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Simponi	S	Periarticular	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Apo Acetaminophen	S	Unknown	Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
	Oxycodone Actavis	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Oxycodone Hydrochloride;Paracetamol	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
	Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
	Desogestrel And Ethinyl	C		Unk	Not Reported

Estradiol				
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C	Oral	7.5 Mg, Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Tylenol [Paracetamol]	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		400 Mg, 1x/Day	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Cetirizine Dihydrochloride	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		400 Mg, 1x/Day	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown		Not Reported
Paracetamol Codeine	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Tylenol No.1	C			Not Reported
Hydroxychloroquine Phosphate	C	Unknown		Not Reported

	Zopiclone			C		Unk			Not Reported
	Marvelon 28			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16575509	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852070-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychoroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Vitamin D3			C				Not Reported
	Ergocalciferol			C				Not Reported
	Colecalciferol			C				Not Reported
	Imuran			C				Not Reported
	Gold			C				Not Reported
	Arthrotec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16864058	EXPEDITED (15-DAY)		OT	DE-GILEAD-2019-0424518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan	S	Unknown	Unk	Gilead
	Roactemra	S	Unknown	162 Mg, Z(Weekly)	Not Reported
	Quensyl	S	Unknown	20 Mg, Bid	Not Reported
	Ramipril	S	Unknown	2.5 Mg, Bid	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Eliquis	S	Unknown	2.5 Mg, Bid	Not Reported
	Eliquis	S	Unknown	1 Dosage Form	Not Reported
	Omeprazole	S	Unknown	20 Mg, Bid	Not Reported
	Lyrica	C	Unknown	100 Mg, Tid	Not Reported
	Pregabalin	S	Unknown	100 Mg, Tid	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16991114	EXPEDITED (15-DAY)		OT	CA-SA-2019SA303996			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S				Sanofi

	Pseudoephedrine Hydrochloride	S			Sanofi
	Sulfasalazine	S		500 Mg	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S			Not Reported
	Apo Prednison	S			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17405411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008376		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral			Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous drip	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17433130	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0820		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure; Vasculitic Rash	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg (Previously)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg (Previously)		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks And 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 4 Weeks, 1 Every 4 Months, 1 Every 1 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

	Leflunomide	S	Oral			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Oral	12.5 Mg 1x1 Daily		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous	Dose. 12.5 Mg		Not Reported
	Neoral	S	Oral			Not Reported
	Neoral	S	Subcutaneous			Not Reported
	Remicade	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579771	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327850		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579774	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327867		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Prednisone	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17583352	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024371		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported

					Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk	Not Reported
					Simponi	S	Subcutaneous	Unk	Not Reported
					Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
					Sulfasalazine	S	Unknown	Unk	Not Reported
					Lyrica	S	Unknown	Unk	Not Reported
					Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
					Piroxicam	C	Unknown	Unk	Not Reported
					Prednisone	C	Unknown	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587303	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329619			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587307	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327870		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Simponi		S	Subcutaneous		Janssen
	Simponi		S			Janssen
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605637	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333273		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Simponi			S	Subcutaneous			Janssen
	Otezla			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605638	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333296		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported
	Codeine Phosphate	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17641623	EXPEDITED (15-DAY)		HO, OT	EG-ADVANZ PHARMA-202003002270			Unknown	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blindness; Blood Glucose Abnormal; Brain Oedema; Loss Of Consciousness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Insulin			C		30 Iu, Qd		Not Reported
	Menthol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642134	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002077			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Surgery; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029406		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644154	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1220064		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12 Day 1 Followed By 200 Mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644416	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002706			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Respiratory Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Morphine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644417	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645665	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1655		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Docusate Sodium	C	Oral			Not Reported
	Elavil	C	Unknown			Not Reported
	Tobramycin	C	Unknown	0.3% 4x1 Daily		Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)			Not Reported
	Doxycycline	C	Oral			Not Reported
	Prednisone	C	Oral			Not Reported
	Sulfasalazine	C	Oral	1.5 G 2x1 Daily		Not Reported
	Sulfasalazine	C	Unknown			Not Reported
	Wellbutrin	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645724	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Prednisone			S	Oral	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Novartis
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645727	NON-EXPEDITED			NVSC2020US094449		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For	Mycophenolate Mofetil			S	Unknown	Unk		Novartis

Unapproved Indication	Rituximab			S	Unknown	Unk			Not Reported
	Minocycline			S	Unknown	Unk			Not Reported
	Colchicine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646286	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646292	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646454	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002357			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Off Label Use; Prostatic Adenoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028979		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia	S	Unknown		Bristol Myers Squibb
	Azathioprine	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17647436	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356481-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648477	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-VALIDUS PHARMACEUTICALS LLC-SK-2020VAL000270			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios; Premature Baby	Metoprolol Tartrate	S	Transplacental	Unk	Validus
	Cefotaxime Sodium	S	Transplacental	Unk	Validus
	Cefotaxime Sodium	S	Transplacental	Unk	Validus
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Cefixime	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Paracetamol	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Omeprazole	S	Unknown	Unk	Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Benzylpenicillin Sodium	S	Transplacental	Unk	Not Reported
	Colecalciferol	S	Transplacental	Unk	Not Reported
	Cefazolin Sodium	S	Transplacental	Unk	Not Reported
	Albumin (Human)	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S	Unknown	Unk	Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
	Flebogamma Dif /00025201/	S		Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Bisulepin	S	Transplacental	Unk	Not Reported

	Folic Acid			S	Transplacental	Unk			Not Reported
	Etamsylate			S	Transplacental	Unk			Not Reported
	Nadroparine			S	Transplacental	Unk			Not Reported
	Ornidazole			S	Transplacental	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356478-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported

Methotrexate	S	Unknown	15 Milligram, Qwk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Wellbutrin	C	Oral			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649456	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Oseltamivir Phosphate			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Sodium Chloride 0.9% 1000 Ml			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported
	Zosyn 3.375 G			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Atropine			C				Not Reported
	Epinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649584	NON-EXPEDITED			US-TEVA-2020-US-1213903			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649858	NON-EXPEDITED			NVSC2020US093707			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029403		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651063	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Lyrica		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Mycophenolate Mofetil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Piroxicam		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651130	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029423		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Apo-Ramipril			S	Unknown	Unk, Qd		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd		Not Reported
	Acetaminophen, Caffeine, Dihydrocodeine Bitartrate	C	Unknown			Not Reported
	Acetaminophen;Codeine	C	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651159	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651582	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	11257960	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-046061		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

		Anakinra	S	Unknown	Unk		Not Reported
		Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
		Celebrex	S	Unknown	Unk		Not Reported
		Methotrexate Sodium	S	Unknown	1 Ml, Qwk		Not Reported
		Humira	S	Subcutaneous	Unk		Not Reported
		Prednisone	S	Intravenous (not otherwise specified)	7 Mg, Qd		Not Reported
		Apo-Leflunomide	S	Unknown			Not Reported
		Apo-Hydroxyquine	S	Unknown			Not Reported
		Apo-Mycophenolic Acid	S	Unknown			Not Reported
		Methotrexate	S	Unknown	1 Milliliter		Not Reported
		Methotrexate	S	Unknown	20 Milligram		Not Reported
		Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
		Cellcept [Mycophenolate Mofetil]	S	Unknown			Not Reported
		Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
		Rituximab	S	Unknown			Not Reported
		Xeljanz	C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	13064952	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161217720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Urticaria	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Acetylsalicylic Acid	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Pertussis Vaccine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14501669	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Folic Acid			S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Milligram, Qd		Not Reported
	Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported

Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
Naprosyne	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
Palafer Cf	S	Unknown	1 Dosage Form, 1 Every 24 Hrs	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Ascorbic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Actemra	S	Unknown		Not Reported
Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	1000 Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported

Methotrexate	S	Oral	20 Milligram, Cyclical	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	1000 Milligram, Qd	Not Reported
Celecoxib	S	Unknown		Not Reported
Folic Acid	S	Unknown	5 Milligram, Q2wk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	400 Milligram	Not Reported
Folic Acid	S	Unknown	5 Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	40 Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Unknown		Not Reported
Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	100 Milligram, Qd	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Teva Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported

	Celecoxib			C	Oral	200 Milligram, Qd				Not Reported
	Prednisone			C	Intracardiac	5 Milligram, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14750177	EXPEDITED (15-DAY)		DE, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-031026		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15219753	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-NODEN PHARMA DAC-NOD-2018-000052			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Noden Pharma
	Rasilez			S				Noden Pharma
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk, If Required; Trimester: First+Second;From Gestational Week 0-14		Not Reported

Salbutamol Sulfate	S	Transplacental	Unk	Not Reported
Delix /00885601/	S	Transplacental	Maternal Dose 20 Mg, Qd (Exposure Duration 0-13+6 Weeks)	Not Reported
Delix /00885601/	S			Not Reported
Quensyl	S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week;From Gestational Week 0-14	Not Reported
Quensyl	S	Transplacental	Unk	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S			Not Reported
Pantozol /01263204/	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week;From Gestational Week 0-14 (Busco Pantoprazole)	Not Reported
Pantozol /01263204/	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Torasemide	S	Transplacental	Unk	Not Reported
Advagraf	S	Transplacental	6 [Mg/D]; 0-13.6 Gestational Week, From Gestational Week 0-14	Not Reported
Advagraf	S	Transplacental	Unk	Not Reported
Advagraf	S			Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Ezetimibe Msd	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Exposure Duration: 0-14 Weeks. Trimester: First; Probably Only In Hospital	Not Reported

			In Week 5.	
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Novaminsulfon	S	Transplacental	300 Milligram, Qd	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Clexane	S			Not Reported
Heparin Lmw	S	Transplacental	Unknown	Not Reported
Heparin Lmw	S			Not Reported
Enoxaparin	S	Transplacental	From Gestational Week 0-14	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Rituximab	S	Transplacental	Unk	Not Reported
Heparin	S	Transplacental	Unk (Low Molecular Weight Heparin)	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Cyclophosphamide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15551940	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-967934			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus	S	Transplacental		Actavis
	Torem	S	Transplacental	100 [Mg/D]	Not Reported
	Quensyl	S	Transplacental	200 Milligram Daily; Daily Dose: 400 Mg Millgram(S) Every Days	Not Reported
	Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Inegy	S	Transplacental	40 [Mg/D] / 10 [Mg/D]	Not Reported
	Delix (Ramipril)	S	Transplacental	20 [Mg/D]	Not Reported
	Advagraf	S	Transplacental	6 [Mg/D]	Not Reported
	Pantozol	C	Transplacental	40 [Mg/D]	Not Reported
	Albuterol	C	Transplacental	Unk, Prn	Not Reported
	Cytotec	C	Transplacental	Unk	Not Reported
	Cyclophosphamid	C	Transplacental	3000 [Mg Cumulative]/ April -August 2011	Not Reported
	Xarelto 10 Mg Filmtabletten	C	Transplacental	Not Known, If Treatment Started Before Or After Missed Abortion.	Not Reported
	Clexane	C	Transplacental	200 [Mg/D (2x100)]	Not Reported
	Novaminsulfon	C	Unknown	For 5 Weeks	Not Reported
	Aliskiren	C	Transplacental	300 [Mg/D]	Not Reported
	Mifegyne	C	Transplacental	Unk	Not Reported
	Rasilez	C	Transplacental	300 [Mg/D]	Not Reported
	Salbutamol	C	Transplacental	If Required	Not Reported
	Prednisolon	C	Transplacental	Daily Dose: 10 Mg Milligram(S) Every 2 Day	Not Reported
	Ass	C	Transplacental	100 [Mg/D]	Not Reported
	Novaminsulfon	C	Transplacental	Probably Only In Hospital In Week 5	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15623961	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557378-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mycophenolate Mofetil Hydrochloride			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo Mycophenolate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Oral			Not Reported

	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Cyclosporine	S	Oral	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Pregabalin	S	Oral	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15635156	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105525		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Gram, Q2wk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	2000 Milligram		Not Reported

Abnormal; Synovitis	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Parenteral	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	Unk Unk, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15957810	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17533403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243621		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Creatinine Increased; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Product Use In Unapproved Indication	Stelara		S	Subcutaneous		Janssen
	Remicade		S	Intravenous (not otherwise specified)		Janssen
	Simponi		S	Subcutaneous		Janssen
	Gabapentin		S	Unknown		Not Reported
	Perindopril		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cosentyx		S	Unknown		Not Reported
	Etanercept		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Otezla		S	Unknown		Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17558247	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316516		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Methotrexate Sodium	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17577764	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Hydroxychloroquine			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17577767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329960			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sarilumab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605627	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Leflunomide		S	Unknown		Not Reported
					Methotrexate		S	Oral		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Orencia		S	Unknown		Not Reported
					Rituxan		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Tocilizumab		S	Unknown		Not Reported
					Xeljanz		S	Unknown		Not Reported
					Cimzia		C	Subcutaneous		Not Reported
					Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605641	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333272		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Tocilizumab	C	Endocervical	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605642	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332799		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

		Orencia			S	Intravenous (not otherwise specified)				Not Reported
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Lyrica			C	Oral				Not Reported
		Prednisone			C	Oral				Not Reported
		Xeljanz			C	Oral				Not Reported
		Xeljanz			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605650	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332795		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Folinic Acid			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605716	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen

Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra	S	Subcutaneous	Not Reported
	Anakinra	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17611318	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160614521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Ndc: 412545		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17623404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342106		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17623464	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340472		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product	Simponi			S	Subcutaneous			Janssen

Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Celebrex	S	Unknown		Not Reported
	Celebrex	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naprosyn /00256201/	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17647143	EXPEDITED (15-DAY)		HO, LT, OT	MX-ALKEM LABORATORIES LIMITED-MX-ALKEM-2020-01066		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram, Qd		Alkem
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Prednisone			S	Oral	30 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648078	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029659		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Increased; Urticaria	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648606	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029670		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported

Leflunomide	S	Oral	20 Milligram, Qd		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qh		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Methotrexate	S	Subcutaneous	175 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Milligram		Not Reported
Simponi	S	Subcutaneous			Not Reported
Risedronate	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648737	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2020061233		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone Sodium			S	Unknown	Unk		Glaxosmithkline
	Streptomycin			S	Unknown	Unk		Glaxosmithkline
	Cotrimoxazole			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	960 Mg, Qd		Glaxosmithkline
	Ceftriaxone			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Acyclovir			S	Unknown	Every 4 Hours.		Glaxosmithkline
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Dose Increased		Not Reported
	Prednisone			S	Unknown	Dose Reduced		Not Reported

		Doxycycline			S	Unknown	Unk			Not Reported
		Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648841	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202003002755			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17649603	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1219671		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram Daily;		Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid			C				Not Reported
	Nasonex			C				Not Reported

	Prednisone			C						Not Reported
	Trazodone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17651306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Folic Acid				C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652025	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202003002774			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002411			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Eosinophilic Myocarditis; Exposure During Pregnancy; Rash	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652041	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000624			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Xarelto			C		Unk		Not Reported
	Vitamin B12 Nos			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported

Magnesium	C	Unk	Not Reported
Ramipril	C	Unk	Not Reported
Buprenorphine	C	Unk	Not Reported
Vitamin D	C	Unk	Not Reported
Xeljanz	C	Unk	Not Reported
Prednisone	C	Unk	Not Reported
Vitamin B6	C	Unk	Not Reported
Arava	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652062	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1220063		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Unknown	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram Daily;		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Ascorbic Acid			C	Unknown			Not Reported

Biotin	C			Not Reported
D-Alpha Tocopherol	C	Unknown	2400 Milligram Daily;	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram Daily;	Not Reported
Diphenoxylate Hydrochloride	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	400 Iu (International Unit) Daily;	Not Reported
Esomeprazole	C	Unknown	80 Milligram Daily;	Not Reported
Ferrous Fumarate	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Hydroxocobalamin	C			Not Reported
Loperamide Hydrochloride	C	Unknown		Not Reported
Nasonex	C	Unknown	4 Dosage Forms Daily;	Not Reported
Nicotinamide	C			Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram Daily;	Not Reported
Nortriptyline Hydrochloride	C	Oral		Not Reported
Prednisone	C	Unknown	5 Gbq Daily;	Not Reported
Pyridoxine Hydrochloride	C			Not Reported
Riboflavin	C			Not Reported
Risedronate Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C			Not Reported
Thiamine Hydrochloride	C			Not Reported
Thiamine Mononitrate	C			Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram Daily;	Not Reported
Tylenol	C	Unknown	1000 Milligram Daily;	Not Reported
Vitamin A	C			Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Vitamin D3	C			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652287	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1036031		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Haematochezia	Furosemide	S		Unk	Not Reported
	Dabigatran Etexilate	S	Oral	300 Milligram, Qd	Mylan
	Daparox /00830803/	S		Unk	Mylan
	Lamictal	S		Unk	Mylan
	Plaquenil /00072602/	S		Unk	Mylan
	Valium	S		Unk	Mylan
	Sotalol	S		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17654933	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Endotracheal Intubation Complication	Hydroxychloroquine			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Azithromycin			C				Not Reported
	Albuterol			C				Not Reported
	Lasix			C				Not Reported
	Zosyn			C				Not Reported
	Humulin R			C				Not Reported
	Vancomycin			C				Not Reported
	Lovenox			C				Not Reported
	Tamiflu			C				Not Reported
	Rocephin			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran			C				Not Reported
	Ns			C				Not Reported
	D50w			C				Not Reported
	Pravachol			C				Not Reported
	Ativan			C				Not Reported
	Doxycycline			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	14535557	EXPEDITED (15-DAY)		CA, OT	CA-BIOVITRUM-2018CA0126			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	2 Every 1 Weeks 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Orencia			S	Endocervical			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	15635730	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478917-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3 Years	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	16946977	EXPEDITED (15-DAY)		LT, OT	CA-GLAXOSMITHKLINE-CA2019AMR190534		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Fatigue; Off Label Use; Suicidal Ideation	Benlysta			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	Unk		Glaxosmithkline
	Imuran			S	Oral	200 Mg, Qd		Glaxosmithkline
	Plaquenil			S		400 Mg, Qd		Not Reported
	Prednisone			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17395563	NON-EXPEDITED			US-AMGEN-USASP2020020542		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17433728	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019025070			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Sildenafil			S	Unknown	60 Milligram, Qd		Macleods
	Omeprazole 20 Mg			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole 20 Mg			S	Oral	20 Milligram, Bid		Not Reported
	Ramipril			S	Oral	1 Dosage Form, Bid (1-0-1) (1 In 12 Hr)		Not Reported
	Ramipril			S	Oral	2.5 Milligram		Not Reported
	Ramipril			S	Unknown	5 Milligram, Qd		Not Reported
	Pregabalin			S	Unknown	1 Dosage Form, Tid (1 - 1-1)		Macleods
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Q.W.		Not Reported

			(Solution For Injection In Pre-Filled Syringe)	
Quensyl	S	Unknown	1 Dosage Form, Bid (1-0-0)	Not Reported
Quensyl	S	Unknown	20 Milligram, Bid	Not Reported
Quensyl	S	Unknown	80 Milligram, Bid (1 - 0 - 1), 1 Df, Bid	Not Reported
Eliquis	S	Unknown	1 Dosage Form, Bid (1-0-1)	Not Reported
Eliquis	S	Unknown	2 Dosage Form, Qd	Not Reported
Eliquis	S	Unknown	2.5 Milligram, Bid	Not Reported
Spasmolyt	S	Unknown	1 Dosage Form, Bid ((1-0-1))	Not Reported
Spasmolyt	S	Unknown	30 Milligram, Qd (0 -0 -1)	Not Reported
Spasmolyt	S	Unknown	1 Dosage Form, Qd	Not Reported
Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Ambrisentan	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
Tocilizumab	S	Subcutaneous	162 Milligram, Q.W., Solution For Injection In Pre-Filled Syringe	Not Reported
Tocilizumab	S	Subcutaneous	162 Milligram, Q.W., Solution For Injection In Pre-Filled Syringe	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653559	NON-EXPEDITED		OT	US-SA-2020SA089843			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Arava			S				Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653880	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR-1221561		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Ebilfumin 75 Mg, Gélule			S	Oral	75 Mg		Teva
	Ceftriaxone Mylan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil			S	Oral	At D1 Then 400mg / Day, Unit Dose: 800 Mg		Not Reported
	Coversyl 5 Mg, Comprimé Pelliculé Sécable			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654444	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017303		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Plaquenil			S	Unknown	3 Dosage Form		Not Reported
	Plaquenil			S	Unknown	2 Dosage Form, Two Times A Day (One In Morning And One In Evening)		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654641	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030070		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia		S	Intravenous (not otherwise specified)	Bristol Myers Squibb
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029994			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

Diclofenac	C	Oral	100 Milligram			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654650	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030021		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654666	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1221569			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycine Dihydratee			S	Oral	500 Mg		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3357368-00		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis; Hepatocellular Injury	Kaletra 200/50	S	Oral	2 Comp/12h		Not Reported
	Kaletra 200/50	S				Not Reported
	Ceftriaxona	S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona	S				Not Reported
	Hidroxicloroquina	S	Oral	200mg/12h		Not Reported
	Hidroxicloroquina	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654834	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate Sodium			S	Unknown			Pfizer
	Celebrex			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655309	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002613			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fatigue; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Triatec			C				Not Reported
	Doliprane			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655685	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1219067		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	120 Milligram Daily;		Not Reported
	Apremilast			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Benadryl	C			Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C			Not Reported
	Febuxostat	C			Not Reported
	Folic Acid	C			Not Reported
	Gravol	C			Not Reported
	Mogadon	C	Oral		Not Reported
	Nitrazepam	C	Unknown		Not Reported
	Oxycodone	C			Not Reported
	Prednisone	C			Not Reported
	Uloric	C	Unknown	160 Milligram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655811	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220302		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva

Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate	S	Oral			Teva
	Gliclazide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Asacol	S	Unknown	2400 Milligram Daily;		Not Reported
	Diamicron	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Acetaminophen	C	Oral			Not Reported
	Atacand Plus	C				Not Reported
	Bisoprolol Fumarate	C				Not Reported
	Diphenhydramine	C	Oral			Not Reported
	Ferrous Gluconate	C				Not Reported
	Folic Acid	C				Not Reported
	Methylprednisolone Acetate	C	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone Acetate	C	Intra-articular			Not Reported
	Rosuvastatin Calcium	C				Not Reported
	Tylenol	C				Not Reported
	Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655893	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002355			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	(Strength: 400mg 2x15 Cprrev		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656013	EXPEDITED (15-DAY)		OT	GR-PBT-000004		68 YR	Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Disease Progression; Drug Ineffective; Product Use In Unapproved Indication; Vasculitic Rash	Tacrolimus			S	Unknown			Panacea Biotec
	Tacrolimus			S	Unknown			Panacea Biotec
	Thiamazole			C	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Two Monthly Intravenous Pulses		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656614	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656633	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea	Hydroxychloroquine	Y		S	Oral	Quantity:10 Tablet(S);		Not Reported
	Breo			C				Not Reported
	Dupixent			C				Not Reported
	Green Tea			C				Not Reported
	Magnesium			C				Not Reported
	Black Seed Oil			C				Not Reported
	Blessed Thistle			C				Not Reported
	Sunflower Lecithin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657153	EXPEDITED (15-DAY)		OT	PL-AMNEAL PHARMACEUTICALS-2020-AMRX-01107		54 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657180	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220398		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Asacol Also Known As Mesalamine	S	Unknown	2400 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Diamicron	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Ramipril			S	Oral			Actavis
	Ramipril			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Dorzolamide/Timolol			S	Unknown	2 Dosage Forms Daily;		Actavis

	Dorzolamide/Timolol	S	Unknown			Actavis
	Prednisone	S	Unknown			Actavis
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine	S	Unknown			Not Reported
	Levothyroxine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	15401123	EXPEDITED (15-DAY)		OT	DE-ABBVIE-18K-062-2483634-00		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

Neoral	S	Oral		Not Reported
Neoral	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Rituxan	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexat	S	Subcutaneous	20mg	Not Reported
Methotrexat	S	Oral	20mg, Solution For Injection/Infusion	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20mg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Leflunomide	S	Unknown	Film Coated Tablet	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported

	Xeljanz			C	Oral	2 Ot, Qd				Not Reported
	Xeljanz			C	Unknown	2 Ot, Qd				Not Reported
	Xeljanz			C	Oral	10 Mg, Qd (5 Mg, Bid)				Not Reported
	Xeljanz			C	Oral	2 Ot, Qd				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	15621780	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2557337-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Discomfort; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Viread			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	16079912	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Abatacept	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Subcutaneous	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Actemra	C	Unknown	Unknown	Not Reported
Azathioprine	C	Unknown	Unknown	Not Reported
Ciclosporin	C	Unknown	Unknown	Not Reported
Minocycline	C	Unknown	Unknown	Not Reported
Penicillamine	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported
Tocilizumab	C	Unknown	Unknown	Not Reported
D-Penicillamine	C	Unknown	Unknown	Not Reported
Prednisolone	C	Unknown		Not Reported
Cyclosporin	C	Unknown	Unknown	Not Reported
Phenylbutazone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658279	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01638		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658282	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01639		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658365	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2762682-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Allopurinol			C				Not Reported
	Pantoloc			C	Unknown			Not Reported
	Zyloprim			C				Not Reported
	Clomipramine			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658388	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine Sulfate	S		200 Milligram	Not Reported
	Methotrexate	S		20 Milligram	Not Reported
	Orencia	S		Unk	Not Reported
	Sulfasalazine	S		1 Gram	Not Reported
	Xeljanz	C	Oral	5 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown	100 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milliliter, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	12776517	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076645		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	14778692	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009922			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Methotrexate			C	Unknown	20 Mg, Q.Wk.				Not Reported
	Sulfasalazine			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15624165	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556702-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Wellbutrin			C	Unknown	Extended Release		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Bupropion			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15686123	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573639-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Injection Bp		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	C			Not Reported
Anakinra	C	Unknown		Not Reported
Ativan	C			Not Reported
Codeine	C	Unknown		Not Reported
Darifenacin	C			Not Reported
Desoximetasone	C	Oral		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Dilaudid	C	Unknown		Not Reported
Diphenhydramine	C			Not Reported
Furosemide	C			Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C		Sustained-Release	Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C			Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray,Metered Dose	Not Reported
Oxyneo	C	Unknown	Extended Release	Not Reported
Pantoprazole Sodium	C			Not Reported
Restasis	C	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported

	Trimethoprim	C	Unknown		Not Reported
	Urispas	C			Not Reported
	Vagifem	C	Vaginal		Not Reported
	Dexamethason	C	Intramuscular		Not Reported
	Dyclonine Hydrochloride	C			Not Reported
	Enablex	C		(Extended Release)	Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Lasix	C			Not Reported
	Morphine Sulphate	C	Unknown		Not Reported
	Dyclone	C			Not Reported
	Benadryl	C	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Darifenacin Hydrobromide	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoloc	C			Not Reported
	Triamcinolone Acetonide	C	Intra-articular		Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Orphenadrine Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15708189	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2586143-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

		Varicella Zoster Vaccine		S	Unknown	Liquid Intramuscular			Not Reported
		Etanercept		S	Subcutaneous				Not Reported
		Rituximab		S	Intravenous drip				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15713147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588025-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15848951	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633323-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15923770	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2653534-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase	Humira			S	Subcutaneous			Not Reported

Increased; Arthralgia;	Actemra	S	Unknown	Not Reported
Aspartate Aminotransferase	Actemra	S	Unknown	Not Reported
Increased; Basal Cell	Actemra	S	Unknown	Not Reported
Carcinoma; Blood	Actemra	S	Unknown	Not Reported
Parathyroid Hormone	Alendronate Sodium	S	Unknown	Not Reported
Decreased; C-Reactive	Apo-Leflunomide	S	Oral	Not Reported
Protein Increased;	Codeine	S	Unknown	Not Reported
Contraindicated Product	Enbrel	S	Unknown	Not Reported
Administered; Drug	Enbrel	S	Unknown	Not Reported
Eruption; Drug	Hydroxychloroquine	S	Oral	Not Reported
Hypersensitivity; Drug	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Ineffective; Drug	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Tolerance Decreased;	Leflunomide	S	Oral	Not Reported
Drug Tolerance	Methotrexate	S	Subcutaneous	Not Reported
Decreased; Erythema;	Methotrexate	S	Subcutaneous	Not Reported
Granuloma Skin;	Methotrexate	S	Subcutaneous	Not Reported
Hypercalcaemia;	Methotrexate	S	Subcutaneous	Not Reported
Hypersensitivity;	Methotrexate	S	Subcutaneous	Not Reported
Inflammation; Infusion	Methotrexate	S	Subcutaneous	Not Reported
Related Reaction; Loss Of	Methotrexate	S	Subcutaneous	Not Reported
Personal Independence In	Methotrexate	S	Subcutaneous	Not Reported
Daily Activities;	Methotrexate	S	Subcutaneous	Not Reported
Musculoskeletal Stiffness;	Methotrexate	S	Subcutaneous	Not Reported
Pain; Panniculitis;	Methotrexate	S	Subcutaneous	Not Reported
Peripheral Swelling; Rash;	Methotrexate	S	Subcutaneous	Not Reported
Rash Pruritic; Red Blood	Methotrexate	S	Subcutaneous	Not Reported
Cell Sedimentation Rate	Methotrexate	S	Subcutaneous	Not Reported
Increased; Rheumatoid	Methotrexate	S	Subcutaneous	Not Reported
Arthritis; Rheumatoid	Methotrexate	S	Subcutaneous	Not Reported
Nodule; Skin Necrosis;	Methotrexate	S	Subcutaneous	Not Reported
Skin Ulcer; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Product Effect Decreased;	Methotrexate	S	Subcutaneous	Not Reported
Therapeutic Product Effect	Methotrexate	S	Subcutaneous	Not Reported
Incomplete; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Response Decreased;	Methotrexate	S	Subcutaneous	Not Reported
Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Sulfasalazine	S	Intramuscular	Not Reported
Sulfasalazine	S	Intramuscular	Not Reported
Sulfasalazine	S	Parenteral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Myochrysine	S	Unknown	Not Reported
Ciclosporin	C		Not Reported
Prednisone	C	Unknown	Not Reported

	Xeljanz			C	Unknown					Not Reported
	Ciclosporin			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15932948	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2655966-00		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Responder; Underdose; Vomiting; Wheelchair User			otherwise specified)	
	Orencia	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Not Reported
	Triamcinolone	S	Intra-articular	Not Reported
	Triamcinolone	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Kineret	S		Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported

	Vaccinia Immune Globulin (Immunoglobulin G Human)	S	Unknown			Not Reported
	Folic Acid	C				Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16140356	EXPEDITED (15-DAY)		OT	PHHY2019CA070200		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16403034	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2809805-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Plaquenil	S	Oral		Not Reported
	Enbrel	S	Unknown	823	Not Reported
	Enbrel	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Apo Leflunomide	S	Unknown		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tylenol	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Tylenol W/Codeine No. 3	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Leflunomide	C			Not Reported
	Codeine	C			Not Reported
	Celecoxib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16408931	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA127221		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Voltaren			S	Unknown	Unk		Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Diclofenac Potassium			S	Unknown			Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac			S				Novartis
	Diclofenac			S				Novartis
	Diclofenac			S				Novartis
	Acetylsalicylic Acid Sandoz			S	Unknown	325 Mg		Not Reported
	Acetylsalicylic Acid Sandoz			S				Not Reported
	Acetylsalicylic Acid Sandoz			S				Not Reported
	Acetylsalicylic Acid Sandoz			S				Not Reported
	Vitamin C			S	Unknown			Not Reported
	Clopidogrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported

Gold	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Aspirin	S	Oral	Unk	Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Naprosyn	S	Unknown		Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown		Not Reported
Apo Sulfatrim	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Oral		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sulphamethoxazole	S	Unknown		Not Reported
Apo-Diclofenac	S	Unknown		Not Reported
Sulfatrim	S	Unknown		Not Reported
Tramadol Hcl	C	Unknown		Not Reported
Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16762680	EXPEDITED (15-DAY)		OT	DE-DEXPHARM-20190689			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown			Not Reported
	Eliquis			S		2.5 Mg Bid		Not Reported
	Roactemra			S				Not Reported
	Spasmolyt			S				Not Reported
	Spasmolyt			S				Not Reported
	Omeprazole			S	Oral	20 Mg Every 12 Hours: In The Morning And In The Evening		Not Reported
	Ramipril			S	Oral	In The Morning And In The Evening		Not Reported
	Volibris			S				Not Reported
	Sildenafil Citrate			S				Not Reported
	Lyrica			S		100 Mg, Tid		Not Reported
	Pregabalin			S		1 Df, 3x/Day (1 - 1- 1)		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17271238	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000259			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Eye; Dry Mouth; Lower Respiratory Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Salagen			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported

Folic Acid	C	Unk	Not Reported
Vitamin D3	C	25 Ug	Not Reported
Methotrexate	C	Unk	Not Reported
Celebrex	C	Unk	Not Reported
Arthrotec	C	Unk	Not Reported
Meloxicam	C	Unk	Not Reported
Omega 3	C	Unk	Not Reported
Orthotics	C		Not Reported
Orthotics	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17488060	NON-EXPEDITED			US-PFIZER INC-2020092938		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Disorder; Breast Cyst; Bronchitis; Chest Pain; Condition Aggravated; Dyspnoea; Fibromyalgia; Frustration Tolerance Decreased; Insomnia; Joint Swelling; Malaise; Memory Impairment; Musculoskeletal Stiffness; Nodule; Osteoarthritis; Pain; Product Dose Omission; Respiratory Disorder; Weight Increased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17532940	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain;	Cosentyx			S	Unknown	Unk		Novartis

Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Leflunomide	S	Unknown	20 Mg, Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	520 Mg		Not Reported
	Methotrexate	S	Unknown	20 Mg, Unknown		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17658870	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659181	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002316			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Irbesartan			C		Unk		Not Reported
	Lercanidipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659505	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030160		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Prescribed Underdose	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb

	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Endocervical		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030087		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronate Sodium	S	Unknown	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660024	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145583		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Incorrect Route Of Product Administration; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Celebrex			S	Unknown			Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500 Mg, Unk		Pfizer
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1 Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported
	Risedronate Sodium			S	Unknown	5 Mg, Unk		Not Reported

	Actemra	S	Unknown			Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk		Not Reported
	Desoximetasone	C	Unknown	5 Mg, 1x/Day		Not Reported
	Desoximetasone	C	Unknown	5 Mg, Unk		Not Reported
	Leflunomide	C	Unknown			Not Reported
	Prednisone Acetate	C	Unknown	5 Mg,1 Every 1 Day		Not Reported
	Tylenol [Paracetamol]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Lipitor			S	Oral			Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Arthrotec			S				Pfizer
	Cimzia			S		Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Dovobet			C	Topical			Not Reported
	Flovent			C				Not Reported
	Folic Acid			C	Oral			Not Reported
	Multi Vitamin & Mineral			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ventolin [Salbutamol]			C				Not Reported

	Vitamin D2			C	Oral	1000 Df, Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660080	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Myochrysine			S	Unknown			Not Reported
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660093	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146051			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk		Pfizer
	Celebrex	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Rituximab	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Belimumab	S	Unknown	Unk		Not Reported
	Breo Ellipta	S	Respiratory (inhalation)	Unk		Not Reported
	Colchicine	S	Unknown			Not Reported
	Dexilant	S	Oral	60 Mg, 1x/Day		Not Reported
	Estrogel	S	Topical	Unk Unk, 1x/Day		Not Reported
	Meloxicam	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2x/Day		Not Reported
	Prednisone	S	Unknown	50 Mg, Unk		Not Reported
	Ventolin Hfa	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660317	NON-EXPEDITED			US-PFIZER INC-2020147388		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Aralen Hydrochloride			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Myochrysine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661320	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661328	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Atorvastatin 80mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661548	EXPEDITED (15-DAY)		OT	NVSC2020CA096823		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral	S	Oral	Unk	Novartis
	Neoral	S	Subcutaneous	Unk	Novartis
	Rituximab	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate Disodium	S	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate Disodium	S	Oral	20 Mg, Qw	Not Reported
	Ciclosporin Sandoz	S	Subcutaneous	Unk	Novartis
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q2w	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2w	Not Reported
	Hydroxychloroquine	S	Oral	20 Mg	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Orencia	S	Unknown	75 Mg, Qmo	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Avara	C	Oral	20 Mg, Qd	Not Reported

	Rituxan			C	Unknown	500 Mg, Qd	Not Reported
	Cimzia			C	Subcutaneous	200 Mg, Q2w	Not Reported
	Risedronate			C	Oral	25 Mg, Qw	Not Reported
	Risedronate			C	Oral	30 Mg, Qw	Not Reported
	Plaquenil			C	Oral	200 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661837	EXPEDITED (15-DAY)		OT	NVSC2020CA097860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin Sandoz			S	Unknown			Novartis
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia		S	Subcutaneous	125 Mg			Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661903	DIRECT	Y	LT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Plaquenil			S				Not Reported
	Azithromycin Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662028	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002623			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Off Label Use	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd, Coated Tablet		Concordia
	Puran T4			C		Unk		Not Reported
	Pregabalin			C		50 Mg		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Alektos			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662053	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1223033		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral	Unknown Dosage		Not Reported
	Plaquenil			S	Oral	800 Mg		Not Reported
	Augmentin			C	Oral	Unknown Dosage		Not Reported
	Hypnovel			C				Not Reported

Sufentanil	C		Not Reported
Etomidate	C		Not Reported
Tracrium	C		Not Reported
Esmeron	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662107	EXPEDITED (15-DAY)		OT	NVSC2020CA097244		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral	5 Mg, Qd (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662141	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002380			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hydroxychloroquine			S	Oral	400 Mg, Qd (Fiim-Coated Tablet)		Concordia
	Enoxaparin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662224	EXPEDITED (15-DAY)		DE, HO, OT	SK-GLAXOSMITHKLINE-SK2020061907		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Cyclosporine A			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662227	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002617			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus; Stress	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662281	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002582			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662417	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003003386			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Zinc Salt Nos			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662684	EXPEDITED (15-DAY)		OT	NVSC2020US098481			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	(1.2-8.3) Mg/Kg		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662798	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1222453		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663000	EXPEDITED (15-DAY)		OT	NVSC2020CA098112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Cosentyx			S	Unknown	300 Mg, Qmo		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663200	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003002813			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663224	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002823			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Nivaquine			S	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663282	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002844			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Fall; Femur Fracture; Hypoacusis; Intentional Product Use Issue; Product Dose Omission;	Hydroxychloroquine			S	Unknown	2cp/Day, Qd		Concordia
	Hydroxychloroquine			S		1cp/Day For 15		Concordia
	Cardensiel			C		Unk		Not Reported

Unevaluable Event

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002921			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663508	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3361937-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663522	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362044-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663539	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362011-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665337	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine Oral Tablet			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665521	DIRECT	Y	DE, HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine 200mg Po			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	11925949	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-15K-028-1444053-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Joint Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported

Knee Arthroplasty; Myocardial Infarction; Myocardial Infarction; Near Death Experience; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Subcutaneous	Not Reported
	Gold	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Medical Marijuana	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

	Orencia	S			Not Reported
	Oxycodone	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S			Not Reported
	Kineret	C			Not Reported
	Rituximab	C			Not Reported
	Kineret	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Ilaris	C	Subcutaneous	Single-Use Vial	Not Reported
	Rituximab W/Urelumab	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14144042	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020346		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported

	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Once Every Four Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk 1 Every 4 Months	Not Reported
	Orencia	S	Unknown	500 Unk, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14243063	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex

Systemic Lupus Erythematosus	Winpred	S	Oral	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14243135	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021933		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	10 Mg, Q.O.D.		Apotex
	Leflunomide			S	Unknown	5 Mg, Q.O.D.		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	0.8 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14404773	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005233			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14558788	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262991-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Rheumatoid Arthritis; Soft Tissue Swelling	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Myochrysine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Gold		S	Other	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Apo-Hydroxyquine		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14746352	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

	Tylenol Arthritis Pain			C	Unknown	Unk				Not Reported
	Xeljanz			C	Unknown	Unk				Not Reported
	Acetaminophen			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15132896	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014806			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 Milligram, Qd, 40 [Mg/D]; 0-13.6 Gestational Week		Macleods
	Pantoprazole			S	Transplacental	Unk		Macleods
	Aspirin			S	Transplacental	100 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Bid, Tablet, From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk, Tablet, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	6 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	Unk, 1 Trimester		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk Unk, Qd, From Gestational Week 0-14		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk		Not Reported
	Metamizole Sodium			S	Transplacental	Unk		Not Reported

Metamizole Sodium	S	Transplacental	Unk,From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Nicotine	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
Ramipril	S	Transplacental	20 Milligram, From Gestational Week 0-13+6 Weeks) Maternal Dose 20 Mg	Not Reported
Hydroxychloroquine	S	Transplacental	400 Milligram, Qd, From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental	300 Milligram, Qd, 300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Ezetimibe	S	Transplacental	Unk, Tablet, From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	100 Mg Qd From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	Unk, Film Coated Tablet,From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd, 2 X 100	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional, Trimester: Preconceptional	Not Reported
Rasilez	S	Unknown		Not Reported
Enoxaparin Sodium	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported

	Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd	Not Reported
	Novaminsulfon	S	Transplacental	Unk, Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	Unk, 3000 [Mg Cumulative]; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15337014	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019548		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic;	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk, Therapy Duration: 59		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	160 Mg, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, Qd		Not Reported

Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15622524	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557260-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C				Not Reported
	Desoximetasone			C	Oral			Not Reported
	Xeljanz			C	Subcutaneous			Not Reported
	Zostavax			C	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Voltaren			C				Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15629606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555539-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Cough; Diarrhoea; Diarrhoea; Drug Ineffective; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15670302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571378-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

				otherwise specified)		
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Prednisone		C	Oral		Not Reported
	Prednisone		C	Oral		Not Reported
	Tylenol		C	Unknown		Not Reported
	Advil		C			Not Reported
	Dequalinium Chloride		C	Unknown		Not Reported
	Acetaminophen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15806693	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2618205-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Parenteral	Foa-Solution Inramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Foa-Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Codeine Sulfate	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Ciclosporin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16079861	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06082		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue;	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Apremilast			S	Oral			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Subcutaneous	Unknown		Not Reported

General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer	Cimzia	S	Subcutaneous	Unknown (Solution), Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unknown (Solution)	Not Reported
	Golimumab	S	Subcutaneous	Unknown	Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Unknown		Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Otezla	S	Oral		Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Subcutaneous	Unknown (Solution)	Not Reported
	Stelara	S	Subcutaneous	Unknown (Solution)	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Sulfamethoxazole	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Oral	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Mogadon	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown	(Extended Release)	Not Reported
Uloric	C	Oral		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Unknown (Delayed Release)	Not Reported
Dexilant	C	Unknown	Unknown, Prolonged Release	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Acide Folique	C	Unknown	Unknown	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16589246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2851920-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Gold			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16954774	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972637-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plantago Afra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Morphine		S	Unknown	Not Reported
	Codeine		S	Unknown	Not Reported
	Aclasta		S	Intravenous (not otherwise specified)	Not Reported
	Morphine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Asa		C	Unknown	Not Reported
	Hydrochlorothiazide		C		Not Reported
	Ergocalciferol		C		Not Reported
	Folic Acid		C		Not Reported
	Cannabis Sativa		C		Not Reported
	Tums		C		Not Reported
	Lipitor		C		Not Reported
	Methotrexate		C	Subcutaneous	Not Reported
	Calcium Carbonate		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17223484	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3215049-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Simponi	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17543919	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA072124		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Bid		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Endocervical	400 Mg	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Insulin	C	Oral	Unk (Drops)	Not Reported
Metformin	C	Unknown	2 Df, Bid	Not Reported
Metformin	C	Unknown	1 Unk	Not Reported
Plaquenil	C	Unknown		Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17552068	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2020JPN044468		40 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cytomegalovirus Infection	Belimumab			S	Intravenous drip	Unk		Glaxosmithkline

Diverticulitis; Therapeutic Product Effect Incomplete	Simponi	S	Subcutaneous		Janssen
	Simponi	S			Janssen
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S			Not Reported
	Arava	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17594562	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332781		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17605651	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332787		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi	S	Subcutaneous		Janssen
	Simponi	S			Janssen
	Remicade	S	Intravenous (not otherwise specified)		Janssen
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17605666	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332776		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Stelara			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Minocycline Hydrochloride	S	Unknown	Not Reported
	Minocycline Hydrochloride	S		Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17636246	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000165			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Rivaroxaban			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported

	Torasemide	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17656876	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2020148479		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Azithromycin			S	Oral	500 Mg, Daily (500 Mg On Day 1)		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily (Followed By 250 Mg Daily For 4 Days)		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day (400 Mg Twice Daily On Day 1)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (Followed By 400 Mg Daily For 4 Days)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663632	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018207		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day (1gr Cada 8 Horas)		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day (Dia)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported
	Dolquine			S				Not Reported
	Simvastatina Alter			S	Oral	0-0-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663750	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201706-003792			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Apoleflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Oral	Unk		Not Reported
	Xeljanz	C		Unk		Not Reported
	Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147529		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663950	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021948		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apremilast			S	Unknown	30 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	30 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	30 Mg, Bid		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664171	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1698			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664175	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664213	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3361763-00		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Kaletra 200/50			S	Oral			Not Reported
	Quetiapina			S	Oral			Not Reported
	Levofloxacino			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Risperidona			S	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina Hidrocloruro			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Product Use In	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Aralen		S	Unknown	Not Reported
	Humira		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664285	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664555	EXPEDITED (15-DAY)		OT	HK-ACCORD-178663		67 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis	Methotrexate			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665011	NON-EXPEDITED			US-PFIZER INC-2020152441		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145791		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Xeljanz			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Calcium/Vitamin D3			C		Unk		Not Reported
	Hydrocortisone			C		Unk Unk, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		20 Mg, 1x/Day		Not Reported
	Tylenol Arthritis Pain			C		2 Df, 2x/Day		Not Reported
	Xarelto			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021759		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

	Rituxan			S	Unknown	Unk				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665668	NON-EXPEDITED		HO, OT	NVSC2020US099010		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Hepatitis Viral; Nausea; Pyrexia	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665946	EXPEDITED (15-DAY)		DE, HO, OT	SK-HORIZON-PRE-0109-2020		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclosporine A			S				Not Reported
	Methotrexate			S				Not Reported
	Belimumab			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17666426	EXPEDITED (15-DAY)		OT	NVSC2020PT099374		48 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667117	EXPEDITED (15-DAY)		OT	NVSC2020CA098733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Hepatic Cirrhosis; Joint Dislocation; Joint Stiffness; Off Label Use; Osteoarthritis; Osteoporosis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Hydroxychloroquine Sulfate			S	Unknown	Unk			Not Reported
	Wellbutrin			C	Unknown				Not Reported
	Dilaudid			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667548	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2375555-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported
	Leucovorin Calcium			C				Not Reported
	Codeine			C				Not Reported
	Ibuprofen			C				Not Reported
	Dilaudid			C				Not Reported
	Plaquenil			C				Not Reported
	Acetaminophen			C				Not Reported
	Ventolin Hfa			C				Not Reported
	Nexium Dr			C				Not Reported
	Advair Diskus			C				Not Reported
	Allopurinol			C				Not Reported
	Cyclobenzaprine Hcl			C				Not Reported
	Atrovent Hfa			C				Not Reported
	Hydromorphone Hcl			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667774	EXPEDITED (15-DAY)		OT	NVSC2020CA098830			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Cosentyx			S	Unknown	150 Mg, Unknown		Novartis
	Methotrexate			S	Oral	15 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Otezla			S	Oral	30 Mg, Bid		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667856	EXPEDITED (15-DAY)		OT	NVSC2020CA098863		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017705			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3362555-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668434	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030217		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks, Duration 1 Days And 15 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks, Duration 2.0 Years		Not Reported

Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
Leflunomide	S	Oral	10 Milligram, Duration 2 Months	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Week, Duration 2 Months	Not Reported
Plaquenil S	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
Viread	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668438	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-017975		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Product Use In Unapproved	Clindamycin			S	Unknown	300 Milligram, Two Times		Aurobindo

Indication				A Day	
	Rifampin	S	Unknown	600 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day (Monday Through Friday)	Not Reported
	Clobetasol	S	Unknown	Unk Unk, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17669671	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Anxiety; Burning Sensation; Fatigue; Muscle Spasms; Nervous System Disorder; Nonspecific Reaction; Pain Of Skin; Pruritus	Hydroxychloroquine Sulfate Plaquenil			S	Oral	Quantity:1 Tablet(S);	4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	8792714	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-009507513-1209DEU004039			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin			S	Transplacental	Unk		Merck
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Merck
	Viemm 10 Mg Tabletten			S	Transplacental	From Gestational Week 0-14		Merck
	Aspirin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported

Enoxaparin Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Albuterol	S	Transplacental	From Gestational Week 0-14	Not Reported
Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Dipyrone	S	Transplacental	From Gestational Week 0-14	Not Reported
Ramipril	S	Transplacental	20 Mg Unk From Gestational Week 0-113+6	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Heparin	S	Transplacental	Unk	Not Reported
Clexane (Enoxaparin Sodium)	S	Transplacental	200 Mg/D (2x100)	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13059562	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015791		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis; Vasculitic Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.,		Not Reported
	Humira			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.,		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported

	Methotrexate			S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.O.Wk.	Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Q.O.Wk.	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk, Once Every 4 Weeks	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia			S	Unknown	500 Mg, Cyclical	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Cyclical	Not Reported
	Kineret			S	Subcutaneous	100 Mg, Qd	Not Reported
	Methotrexate Sodium			S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate			C	Unknown	Unk	Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Unk	Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid	Not Reported
	Xeljanz			C	Unknown	5 Mg, Unk	Not Reported
	Xeljanz			C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13059788	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015748		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis;	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Rituximab			C				Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	14235439	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15076484	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 14 Days		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk 1 Every 14 Days		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15391128	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955090		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral			Actavis
	Perindopril			S	Oral			Not Reported
	Perindopril			S	Unknown			Not Reported
	Plaquenil			S	Oral	200 Mg/ Day		Not Reported
	Cortancyl			S	Oral	20 Milligram Daily; 10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15625329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558387-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Duration:365.0		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Xeljanz			S	Oral				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Prednisone			C	Endocervical				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15760613	NON-EXPEDITED			US-PFIZER INC-2018522861		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Heparin Sodium			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Duloxetine			S	Oral	100 Mg, Daily		Not Reported
	Insulin			C		Unk		Not Reported
	Januvia			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Losartan/Hctz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15819449	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-DRREDDYS-GER/GER/19/0106738			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Not Reported

Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
	Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
	Salbutamol	S	Transplacental	From Gestational Week 0-14	Not Reported
	Hydroxychloroquine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Xarelto	S	Transplacental	From Gestational Week 0-5 082(Film Coated Tablet)	Not Reported
	Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
	Dalteparin Sodium	S	Transplacental		Not Reported
	Heparin (Salt Not Specified)	S	Transplacental	Unk Unk,Unk	Not Reported
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Enoxaparin Sodium	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Heparin Lmw	S	Transplacental	Unk	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational	Not Reported

							Week			
		Cyclophosphamide			C	Transplacental	3000 [Mg Cumulative]; Preconceptional			Not Reported
		Mifegyne			C	Transplacental	Unk; 13.6 Gestational Week			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15933671	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656078-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	16774890	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL			Female	DEU

INDUSTRIES LTD-
2019RR-219753

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Ranbaxy
	Ramipril			S	Unknown	5 Milligram		Ranbaxy
	Pregabalin			S	Unknown	100 Milligram, Tid		Sun
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Astrazeneca
	Omeprazole			S	Unknown	20 Mg, Bid		Astrazeneca
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Quensyl			S	Unknown	20 Mg Bid		Not Reported
	Eliquis			S	Unknown	2.5 Milligram, Bid		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Milligram		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	300 Milligram, Daily		Not Reported
	Eliquis			S	Unknown	2 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	16972574	EXPEDITED (15-DAY)		DE, OT	CA-ABBVIE-19K-028-		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Simponi			C	Unknown			Not Reported
	Rituximab W/Urelumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17182091	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019231676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Cimzia (Certolizumab Pegol)			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Methotrexate			S	Oral	Solution	Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram Solution	Not Reported
	Methotrexate Sodium			S	Unknown	Unk	Not Reported
	Orencia			S	Subcutaneous	Unk	Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine)			S	Unknown	Unk	Not Reported
	Prednisone			S	Oral	Unk	Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine			S	Subcutaneous	500 Milligram	Not Reported
	Xeljanz			C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17422218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04558		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown			Not Reported

Celecoxib	S	Unknown	Unknown	Not Reported
Celecoxib	S	Unknown	Unknown	Not Reported
Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Unknown	Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported

	Atorvastatin Calcium	C	Unknown		Not Reported
	Cipralex (Escitalopram)	C	Unknown		Not Reported
	Citalopram Hydrobromide	C	Unknown		Not Reported
	Conjugated Estrogens	C	Unknown		Not Reported
	Conjugated Estrogens	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Escitalopram	C	Unknown		Not Reported
	Estrace	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Gabapentin	C	Oral		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Oral		Not Reported
	Hydromorphone Hydrochloride	C	Oral		Not Reported
	Mupirocin	C	Topical	Unknown	Not Reported
	Pantoloc (Pantoprazole)	C	Unknown		Not Reported
	Shark Liver Oil	C	Unknown	Unknown	Not Reported
	Tapentadol Hydrochloride	C	Unknown		Not Reported
	Taro-Mupirocin	C	Topical	Unknown	Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported
	Tramadol Hydrochloride	C			Not Reported
	Tramacet	C	Oral		Not Reported
	Tramacet	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17631825	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200337612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated;	Simponi			S	Subcutaneous			Janssen

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis	Arava			S	Unknown		Not Reported
	Enbrel			S	Unknown		Not Reported
	Methotrexate			S	Unknown		Not Reported
	Orencia			S	Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17643631	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-015943			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Drug Reaction With Eosinophilia And Systemic Symptoms; Pemphigus; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Aciclovir			S	Unknown	Unk		Aurobindo
	Cefixime			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Fluconazole			S	Unknown	Unk		Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Paracetamol			S	Unknown	Unk		Aurobindo
	Risperidone			S		Unk		Aurobindo
	Terbinafine			S	Unknown	Unk		Aurobindo
	Ampicillin;Sulbactam			S	Unknown	Unk		Not Reported
	Ketoprofen			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Enoxaparin			S	Unknown	Unk		Not Reported

	Ceftazidime	S	Unknown	Unk		Not Reported
	Oxacillin	S	Unknown	Unk		Not Reported
	Clindamycin	S	Unknown	Unk		Not Reported
	Carbamazepine	S	Unknown	Unk		Not Reported
	Phenytoin	S	Unknown	Unk		Not Reported
	Phenobarbital	S	Unknown	Unk		Not Reported
	Teicoplanin	S	Unknown	Unk		Not Reported
	Rufinamide	S	Unknown	Unk		Not Reported
	Cotrimoxazole	S	Unknown	Unk		Not Reported
	Cisplatin	S	Unknown	Unk		Not Reported
	Fluorouracil	S	Unknown	Unk		Not Reported
	Asa	S	Unknown	Unk		Not Reported
	Lithium	S	Unknown	Unk		Not Reported
	Methylphenidate	S	Unknown	Unk		Not Reported
	Acetylcysteine	S	Unknown	Unk		Not Reported
	Ibuprofen	S	Unknown	Unk		Not Reported
	Acetaminophen	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17647577	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403510		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Prefilled Syringe		Not Reported

	Folic Acid			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17648818	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020061361		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Tacrolimus			S	Unknown	Unk Unk, Qd		Glaxosmithkline
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk, Qd		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk (Pulses)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17662183	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002382			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia
	Temesta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030971		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	100 Milligram, Qd		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Voltaren [Diclofenac Sodium]			C	Unknown	100 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668861	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1720		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Prednisone	S	Endocervical	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Cyclobenzaprine	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone Acetate	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate (Trade Name			S	Unknown			Not Reported

Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Unknown)				
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Lipitor	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Arthrotec	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Dovobet	C	Unknown		Not Reported
	Flovent	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Multi Vitamins & Minerals	C	Unknown		Not Reported
	Omeprazole	C	Unknown		Not Reported
	Ventolin	C	Unknown		Not Reported
	Vitamin D2	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1721		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

					Actemra	S	Intravenous (not otherwise specified)		Not Reported
					Apo-Azathioprine	S	Unknown		Not Reported
					Humira	S	Subcutaneous		Not Reported
					Humira	S	Unknown		Not Reported
					Humira	S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate	S	Endocervical		Not Reported
					Orencia	S	Intravenous (not otherwise specified)		Not Reported
					Remicade	S	Intravenous (not otherwise specified)		Not Reported
					Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1730			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Musculoskeletal Stiffness; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Aralen Hydrochloride			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669411	EXPEDITED (15-DAY)		HO	GR-TEVA-2020-GR-1222919		56 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Urinary Tract Infection; Urinary Tract Pain	Ciclosporin			S	Oral	50 Mg, 2x/Day		Ivax
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, 1x/Day		Not Reported
	Medrol			S	Oral	4 Mg, 1x/Day		Not Reported
	Thyrohormone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669462	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669590	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C		20 Mg, Qd		Not Reported
	Tylenol Arthritis Pain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Arava			S	Oral			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1.0 Df, Qw		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669592	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Injury	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Humira			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C				Not Reported

	Sulfasalazine			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669596	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA096531		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Arava			S	Oral	20 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669689	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1037212		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Acetaminophen			C	Unknown	6 Gram		Mylan
	Metronidazole			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009850			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk	Leflunomide			S	Transmammary	Unk		Apotex
	Hydroxychloroquine			S	Transmammary	Unk		Apotex
	Methotrexate			S	Transmammary	Unk		Not Reported
	Enbrel			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Prednisone			C	Transmammary	Unk		Not Reported

	Sulfasalazine			C	Transmammary	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669916	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S			1 DAY	Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S			2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670319	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003746		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670426	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2020-NL-1222817		31 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva

Delivery	Hydroxychloroquine Sulfate	S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram Daily;		Teva
	Certolizumab Pegol	S	Subcutaneous	200 Mg, Q2w		Not Reported
	Omeprazole	C	Oral	20 Milligram Daily;		Not Reported
	Novorapid	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Levofloxacino (2791a)			S	Unknown			Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Lopinavir+Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Ceftriaxona (501a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670925	EXPEDITED (15-DAY)		DE, OT	ES-CIPLA LTD.-2020ES02594			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Cipla
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Per Day		Not Reported
	Azitromicina			S	Oral	500 Milligram, Per Day		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown	Unk		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Per Day		Not Reported
	Prednisona			C	Oral	20 Milligram, Per Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671067	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Plaquenil			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671115	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Prednisone			S		1 Df, Qw		Not Reported

		Prevacid			C						Not Reported
		Risedronate Sodium			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671152	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223013		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Hidroxicloroquina (2143a)			S	Oral	2-5 Day: 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral	1 Day: 400mg / 12h, 2-5 Day: 200mg / 12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671318	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective;	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported

General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Actemra	S	Unknown	Unknown		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672057	NON-EXPEDITED			US-CELGENEUS-USA-20200403202		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672078	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1221322			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Flutter	Hydroxychloroquine Sulfate Watson			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672447	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-12513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Azathioprine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672893	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3363203-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Sulfasalazine			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Cimzia			S	Unknown				Not Reported
	Arthrotec			S	Unknown				Not Reported
	Lipitor			S	Oral				Not Reported
	Dovobet			C	Topical				Not Reported
	Folic Acid			C	Oral				Not Reported
	Omeprazole			C	Oral				Not Reported
	Flovent			C	Respiratory (inhalation)				Not Reported
	Ventolin			C	Respiratory (inhalation)				Not Reported
	Vitamin D2			C	Oral				Not Reported
	Multi Vitamin			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pneumococcal Vaccine Polysacch 23v			C	Unknown			Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Varicella Zoster Vaccine Live			C	Unknown			Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030963		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673612	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673774	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002881			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Malaise; Systemic Lupus Erythematosus Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673830	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002619			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Inflammation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674032	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018904		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674037	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018903		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674055	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018905		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day				Aurobindo
	Dolquine			S	Other	400 Milligram, Once A Day				Not Reported
	Dolquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Orencia			S	Endocervical			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674075	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018907		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Paracetamol			S	Intravenous (not	1 Gram, 3 Times A Day		Aurobindo

				otherwise specified)		
	Dolquine		S	Oral	400 Milligram, Once A Day	Not Reported
	Dolquine		S			Not Reported
	Ceftriaxone		S	Intravenous (not otherwise specified)	2 Gram, Once A Day	Not Reported
	Ceftriaxone		S			Not Reported
	Azithromycin		S	Oral	500 Milligram, Once A Day	Not Reported
	Azithromycin		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17675095	DIRECT	Y	DE			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Pulmonary Embolism; Unresponsive To Stimuli	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	12776522	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-024854		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	40 Milligram/Kilogram		Not Reported
	Actemra			S	Unknown	4 Milligram		Not Reported
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported

Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	250 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Prevacid	C	Unknown	30 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	50 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	14409544	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP005298		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction;	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported

Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Arava	S	Oral	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Voltaren /00372301/	S	Unknown	Unk		Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk		Not Reported
	Gold	S	Unknown	Unk		Not Reported
	Tramadol Hcl	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	14933830	EXPEDITED (15-DAY)		DS, OT	GB-SA-2018SA139931		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S				Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Erythromycin			S				Sanofi
	Arava			S				Sanofi
	Demerol			S				Sanofi
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Metronidazole			S				Sanofi
	Norfloxacin			S				Not Reported
	Cefaclor			S				Not Reported
	Erythromycin			S				Sanofi
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Pregabalin			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S	Unknown			Not Reported

Erythromycin Estolate	S		Unk	Not Reported
Levofloxacin	S			Not Reported
Arthrotec	S			Not Reported
Meperidine Hydrochloride	S			Not Reported
Plaquenil	S			Sanofi
Norfloxacin	S		400 Mg	Not Reported
Celecoxib	S	Oral	200 Mg	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Prednisone	S			Not Reported
Bisoprolol Fumarate	S			Not Reported
Bisoprolol Salt Not Specified	S			Not Reported
Humira	S	Subcutaneous	400 Mg	Not Reported
Diclofenac Sodium/Misoprostol	S			Not Reported
Methotrexate Sodium	S			Not Reported
Pethidine Hydrochloride	S			Sanofi
Sulfasalazine	S		500 Mg	Not Reported
Levofloxacin Hemihydrate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	15621514	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557370-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Apo Hydroxyquine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16205860	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039198		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Metformin Hydrochloride			S	Unknown	1000 Milligram Daily;		Actavis
	Desoximetasone			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Altace			C	Unknown	5 Milligram Daily;		Not Reported
	Asa			C	Unknown	81 Milligram Daily;		Not Reported
	D-Alpha Tocopherol/Fish Oil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Oral	15 Milligram Daily;		Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Milligram Daily;		Not Reported

	Vitamin D /00107901/			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16582688	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2852957-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Indocid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16844994	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019378939		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S		Unk		Pfizer
	Lansoprazole			S	Unknown	Unk		Pfizer
	Ramipril			S	Unknown	Unk		Pfizer
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Azathioprine	S	Unknown	Unk		Not Reported
	Belimumab	S	Unknown	Unk		Not Reported
	Dicumarol	S	Unknown	Unk		Not Reported
	Thyroxine	S	Unknown	Unk		Not Reported
	Thyroxine	S	Oral	Unk		Not Reported
	Metformin	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Metformin Hydrochloride	S		Unk		Not Reported
	Levothyroxine Sodium	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17180775	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054476		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity;	Cimzia			S	Subcutaneous			Ucb
	Cimzia			S				Ucb
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Milligram, Weekly (Qw)		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Simponi			S	Subcutaneous			Not Reported

Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Simponi	S		Solution And Suspension For Injection In Pre-Filled Syringe	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous	Solution	Ucb
	Orencia	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
	Apo Prednison	S			Not Reported
	Apo Prednison	S		Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		0.5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Phthalylsulfathiazole	S			Not Reported

Prednisone	S			Not Reported
Pseudoephedrine Hcl	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Subcutaneous	Solution	Not Reported
Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S			Not Reported
Orencia	S	Subcutaneous		Not Reported
Leflunomide	S	Oral		Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Etanercept	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Winpred	S	Oral		Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Diclofenac Sodium	S			Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Oral		Not Reported
Sarilumab	S			Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Apo-Hydroxyquine	S			Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral		Not Reported
Otezla	S	Oral		Not Reported

	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported
	Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Diclofenac	C		50 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17302274	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA014510		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Sanofi
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown	Unk		Not Reported

	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Erythromycin	S	Unknown	Unk	Sanofi
	Erythromycin	S	Unknown	Unk	Sanofi
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Sanofi
	Plaquenil	S	Oral	Unk	Sanofi
	Arthrotec	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17315972	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20.0 Mg, Qd (20.0 Milligram 1 Every 1 Days)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1 Days)		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Actemra			S	Unknown	Unk		Not Reported

	Enbrel	S	Unknown	25 Mg (Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow (Once Every 2 Weeks)	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17332071	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-01520		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported

Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown	Unknown	Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular	(Solution)	Not Reported

Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Celebrex	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported

	Prednisolone			C	Unknown	Not Reported
	Prednisolone			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported
	Prednisone			C	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported
	Xeljanz			C	Unknown	Not Reported
	Xeljanz			C	Unknown	Not Reported
	Xeljanz			C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17365657	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Prednisone			S				Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)	
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Desoximetasone		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17486747	EXPEDITED (15-DAY)		OT	IT-VELOXIS PHARMACEUTICALS-2020VELIT-000200		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Off Label Use	Envarsus			S	Unknown	Unk, Qd		Chiesi
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg Qd, Tapering Dose		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	10 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	7.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Immunoglobulin I.V			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported

	Methylprednisolone			C		Unk (Pulses)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17511082	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200240044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Stelara			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17517037	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate			S	Unknown					Not Reported
	Otezla			S	Unknown					Not Reported
	Plaquenil /00072602/			S	Unknown					Not Reported
	Sulfasalazine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17553274	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148132		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo Prednison			S	Unknown	7 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Milliliter, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Celecoxib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17558038	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318943		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Pain; Rheumatic Fever; Rheumatoid Arthritis; Spinal Stenosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Unevaluable Event; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Topicort /00028604/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Gold			C				Not Reported
	Morphine			C	Unknown			Not Reported
	Tofacitinib			C	Oral			Not Reported
	Acetaminophen W/Dextropropoxyphene			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17558095	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316684		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17567096	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318557		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported

Tremor	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605620	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Gold			S	Unknown				Not Reported
	Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605625	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333276		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605640	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333287		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17648281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403508		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Simponi			S	Subcutaneous			Janssen
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17651850	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Simponi			S	Subcutaneous			Janssen
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17658993	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030043		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown		Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomida	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Kineret	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17663375	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-018165		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lasilix			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline Tartrate Renaudin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Transipeg			C	Oral	Unk		Not Reported

	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk				Not Reported
	Nimbex			C	Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17670489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1222995		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Hydroxychloroquine			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva
	Kaletra			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673141	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673245	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018502		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Propofol			S	Intravenous (not otherwise specified)	6.6 Milligram/Kilogram, 1 In Hour, (Sedation)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673548	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017887		74 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	2 Dosage Form, Once A Day		Aurobindo
	Sandoz Co Amoxyclav [Amoxicillin Trihydrate;Clavulanate Potassium]			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	1 Dosage Form, Once A Day		Not Reported
	Primperan			S	Oral	1 Dosage Form		Not Reported
	Ritonavir Mylan			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Azithromycine Sandoz [Azithromycin]			S	Oral	4 Dosage Form, Once A Day		Not Reported
	Doliprane			S	Oral	1 Dosage Form		Not Reported
	Plaquenil			S	Oral	3 Dosage Form, Once A Day		Not Reported

	Darunavir Mylan			S	Oral	1 Dosage Form, Once A Day				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17673960	NON-EXPEDITED			US-AMGEN-USASP2020061784		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674049	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001167			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674369	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096501			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Hydroxychloroquine			S				Sanofi
	Colchicine			S				Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Methylprednisolone			S				Not Reported
	Sulfasalazine			S				Not Reported

	Azathioprine	S	150 Mg, Qd		Not Reported
	Bromocriptin Ct	S			Not Reported
	Ciclosporin	S			Not Reported
	Dilaudid	S			Not Reported
	Doxycycline Hyclate	S			Not Reported
	Enbrel	S			Not Reported
	Gold	S			Not Reported
	Humira	S	40 Mg		Not Reported
	Mercaptopurin	S			Not Reported
	Pamidronate Disodium	S			Not Reported
	Tenoxicam	S			Not Reported
	Ustekinumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674370	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097034			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674433	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020154341		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674454	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365014-00		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Azitromicina			S	Oral			Not Reported
	Azitromicina			S				Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674455	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3365006-00		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona			S				Not Reported
	Hidroxicloroquina			S	Oral			Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674480	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365040-00		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Interferon Beta-1b			S	Subcutaneous			Not Reported
	Interferon Beta-1b			S				Not Reported
	Dolquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674601	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222314			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Metformin			S	Unknown			Actavis
	Sumatriptan Succinate			S	Unknown			Teva
	Colchicine			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674602	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1222322		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Metformin			S	Unknown	1000 Milligram Daily;		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Furosemide			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Ipratropium Bromide/Salbutamol Sulfide			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole]			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol[Paracetamol]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674609	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-243893		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown	20 Milligram, Unk		Taro
	Prednisolone			S	Unknown	40 Milligram, Daily		Taro
	Sulfasalazine			S	Unknown	Unk		Sun
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674739	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222306		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Metformin Hydrochloride			S	Unknown			Actavis
	Metformin Hydrochloride			S				Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xarelto			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674823	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1741		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Calcium/Vitamin D3			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17674993	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1036998		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma Skin; Mycobacterium Marinum Infection	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Mylan
	Prednisolone			S	Unknown	Low-Dose		Mylan
	Prednisolone			S	Unknown	20 Milligram(Dose Was Increased To 40mg Daily)		Mylan

		Sulfasalazine			S	Unknown				Mylan
		Hydroxychloroquine			S	Unknown				Mylan
		Metoprolol			C	Unknown				Mylan
		Amlodipine			C	Unknown				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675138	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Codeine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C	Unknown	20 Mg, 1x/Day		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675164	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2607481-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pms Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675304	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-010799			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Graft Versus Host Disease In Skin	Prednisolone			S	Unknown			Bausch And Lomb
	Ciclosporin			S	Unknown			Not Reported
	Ibrutinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sirolimus			S	Unknown			Not Reported
	Bactrim Ds			C				Not Reported
	Quetiapine			C				Not Reported
	Valaciclovir			C				Not Reported

	Lamotrigine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223716		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h,		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Comp/12h, 2 Dosage Forms		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675600	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096344		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Plaquenil			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Sulfasalazine			S		1 G		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Certolizumab Pegol			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxyquinoline Sulfate			S				Not Reported
	Neoral			S				Not Reported
	Rapamune			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

					otherwise specified)				
	Tacrolimus			S	Oral	2 Mg, Q12h			Not Reported
	Tacrolimus			S	Oral	3 Mg, Q12h			Not Reported
	Imuran [Azathioprine]			C		25 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675601	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096537		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Arava			S	Oral			Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amoxil [Amoxicillin]			C				Not Reported
	Leflunomide			C				Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			C				Not Reported
	Bcg Vaccine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675643	EXPEDITED (15-DAY)		DE, OT	ES-HETERO-HET2020ES00415		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Hetero
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported

Azitromicina	S	Oral	500 Mg, Qd		Not Reported
Lopinavir/Ritonavir	S	Oral	2 Dosage Form, Bid		Not Reported
Ceftriaxone	C	Unknown	Unk		Not Reported
Enoxaparin Sodium	C	Unknown	Unk		Not Reported
Prednisona	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096830		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S		20 Mg, Qd (Every 1 Days)		Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Hyzaar			C				Not Reported
	Venlafaxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675748	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096669		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675757	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675841	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096882		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased;	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Paracetamol			S		Unk		Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported

Rheumatoid Arthritis; Somnolence; Visual Impairment	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Codeine	C		Unk		Not Reported
	Leflunomide	C		20 Mg, Qd		Not Reported
	Meloxicam	C		Unk		Not Reported
	Methotrexate	C		Unk Unk, Qw		Not Reported
	Synthroid	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675867	EXPEDITED (15-DAY)		OT	NVSC2020DE099946		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Metoprolol			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17675975	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097036		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Adalimumab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676188	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Not Reported
	Cortancyl			S	Oral	Unk		Mylan
	Plaquenil /00072602/			S	Oral	1 Dosage Form, Qd		Mylan
	Pantoprazole			C				Mylan
	Izalgi			C				Mylan
	Levothyrox			C				Mylan
	Diffu K			C				Mylan
	Atorvastatine /01326101/			C				Mylan
	Clopidogrel			C				Mylan
	Procoralan			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676221	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223885		43 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	2 Doses In Total		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676292	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096405		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676418	DIRECT	Y	OT			60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Hydroxychloroquine			S	Oral			Not Reported
	Atorvastatin			S	Oral			Not Reported
	Kaletra 200/50			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676757	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Januvia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17676812	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1224309		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycine Anhydre			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported
	Ceftriaxone Base			C	Unknown			Not Reported
	Inipomp			C	Unknown			Not Reported
	Rovamycine			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Xarelto 10 Mg, Comprimé Pelliculé			C	Oral			Not Reported
	Diffu K			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677150	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097010		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cellulitis; Musculoskeletal Discomfort	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677151	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083124		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug	Arava			S	Unknown	20 Mg		Sanofi
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported

Ineffective; Drug Intolerance; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Sulfasalazine	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Actemra	S	Unknown	567 Mg, Q4w		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Inflectra [Infliximab]	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677153	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043120		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	1 Df, Qm		Not Reported
	Rituximab			S				Not Reported

	Xeljanz	C	Oral	5 Mg, Bid			Not Reported
	Risedronate	C	Oral	35 Mg, Qw			Not Reported
	Arava	C	Oral	20 Mg, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677300	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016052		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	25 Milligram, Weekly (Qw)		Not Reported
	Naproxen			C				Not Reported
	Hydroxyzine			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677732	EXPEDITED (15-DAY)		HO	SE-BAUSCH-BL-2020-011319		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Pcs		Not Reported
	Sertraline			S	Oral			Not Reported
	Plaquenil			S	Oral	10-15 Pcs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677745	EXPEDITED (15-DAY)		DS, HO, OT	US-ADVANZ PHARMA-202004002453			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronary Artery Occlusion	Hydroxychloroquine			S				Concordia
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677821	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018906		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo
	Risperidone			S	Oral	1 Milligram, Once A Day		Aurobindo
	Quetiapine			S	Oral	25 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)	600 Milligram, Four Times/Day		Not Reported
	Losartan			C	Oral	50 Milligram, Once A Day		Not Reported
	Lorazepam			C	Oral	1 Milligram, Once A Day		Not Reported
	Furosemide			C	Oral	40 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17679795	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine 200mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	12440760	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-042673		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported

Arthralgia; Arthropathy; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Lupus-Like Syndrome; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Increased	Enbrel	S	Subcutaneous	Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	1.5 Milligram, Bid	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Pregabalin	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil S	S	Oral	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported

	Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Prednisone	S	Urethral	25 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Dosage Form	Not Reported
	Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	12889043	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013260		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Naproxen			S	Unknown	Unk		Apotex
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Apotex
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Gold			S	Unknown			Not Reported

Weight Decreased	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Vitamin C /00008001/	S	Unknown	Unk		Not Reported
	Tramadol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	12966916	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Risedronate Na			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13178489	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015826		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Venlafaxine Xr			S	Oral	150 Mg, Qd		Apotex
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported
	Reactine /00884302/			C	Unknown	10 Mg, Qd		Not Reported
	Ultram /00599202/			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	7.5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13473732	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S				Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S				Not Reported

Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S			Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S			Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Reactine /00884302/	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S			Not Reported
Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
Methotrexate	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Plaquenil /00072602/	S			Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	13710219	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP013547		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	75 Mg, Bid		Apotex
	Diclofenac			S	Oral	75 Mg, Unk		Apotex
	Diclofenac			S	Oral	1 Df, Unk		Apotex
	Diclofenac			S	Oral	2 Df, Qd		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Apotex
	Lisinopril			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	1 Df, Qd		Not Reported
	Prinivil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Voltaren Sr			S	Oral	75 Mg, Bid		Not Reported
	Tecta			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Voltaren Sr			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15020708	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0100319		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Toxicity To	Docetaxel			S	Unknown	21-Day Cycles		Not Reported

Various Agents	Anastrozole		S	Unknown		Not Reported
	Cyclophosphamide		S	Unknown	21-Day Cycles	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15622445	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557344-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Used Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Enteric Coated		Not Reported
	Abatacept			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C		Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Tocilizumab	C		Not Reported
	Actemra	C		Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15657201	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181128756		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

					Sulfasalazine		S	Unknown		Not Reported
					Xeljanz		S	Unknown		Not Reported
					Xeljanz		S	Unknown		Not Reported
					Hydroxychloroquine Sulfate		S	Oral		Not Reported
					Plaquenil /00072602/		S	Oral		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Arava		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15839308	EXPEDITED (15-DAY)		CA, HO, OT	DE-JNJFOC-20190118228			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Anomaly; Foetal Exposure During Pregnancy; Hospitalisation; Premature Baby; Small For Dates Baby	Infliximab, Recombinant			S	Transplacental			Janssen
	Etanercept			S	Transplacental			Not Reported
	Adalimumab			S	Transplacental			Not Reported
	Certolizumab			S	Transplacental			Not Reported
	Anakinra			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Leflunomide			S	Transplacental			Not Reported
	Abatacept			S	Transplacental			Not Reported
	Tocilizumab			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported
	Ciclosporin			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15839309	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20190118229			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Complication Of Pregnancy; Ectopic Pregnancy; Foetal Death; Gestational Diabetes; Gestational Hypertension; Haemorrhage; Hip Arthroplasty; Paternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Etanercept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16613478	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20190721988		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Stelara			S	Subcutaneous			Janssen
	Motrin			S	Oral			Johnson And Johnson
	Motrin			S	Oral			Johnson And Johnson
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported

Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Apremilast	S		Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Infliximab	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Codeine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Ciclosporin	S	Unknown	Not Reported
Colchicine	C	Oral	Not Reported

	Febuxostat	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Mogadon	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Uloric	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Oxycodone	C	Unknown	Not Reported
	Nitrazepam	C	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Dexilant	C	Oral	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16650736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qw		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Xeljanz	C				Not Reported
	Folic Acid	C	Oral	5 Mg		Not Reported
	Prednisone	C	Oral			Not Reported
	Tofacitinib Citrate	C				Not Reported
	Leflunomide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16651301	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qw		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg, Qw Solution		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S		125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Q6w		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

Wellbutrin	C	Unk		Not Reported
Xeljanz	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16740198	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0113518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1);		Not Reported
	Ramipril			S				Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Omeprazole			S		20 Mg, Bid		Not Reported
	Sildenafil			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Spasmolyt			S		1 Df, Qd (1-0-1)		Not Reported
	Spasmolyt			S	Unknown	30 Mg (0 -0 -1)		Not Reported
	Ambrisentan			S	Unknown			Not Reported
	Ambrisentan			S	Unknown	30 Milligram, Qd		Not Reported
	Lyrica			S	Unknown	100 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17114842	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015319			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Unknown
	Apixaban	S		2.5 Milligram, Bid	Unknown
	Eliquis	S	Unknown	1 Df, Bid (1-0-1)	Unknown
	Lyrica	S	Unknown	100 Milligram, Tid Capsule, Hard	Unknown
	Omeprazole	S	Oral	1 Df,2x/Day (1-0 -1)	Not Reported
	Pregabalin	S	Unknown	1 Df, Tid, 3x/Day (11-1)	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1-0-1)	Unknown
	Ramipril	S	Oral	1 Df, Bid, 2x/Day (1-0-1)	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw Pre-Filled Syringe	Unknown
	Sildenafil	S	Unknown	60 Milligram, Daily Dose	Not Reported
	Spasmolyt	S	Unknown	1 Df, 15 (Unit Unspecified), Qd (1-0-0)	Unknown
	Volibris	S	Oral	30 Milligram, Qd	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17216520	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107050		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Once A Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17386415	EXPEDITED (15-DAY)		OT	GR-EMD SERONO-E2B_90074536		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough;	Metformin			S	Unknown	Unk		Not Reported

Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Thyroxin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Dicumarol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17402570	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17403255	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016019500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		5 Milligram Solution		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Prednisone			C		50 Milligram, Once Daily (Qd)		Not Reported
	Isoniazid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17411075	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-03838		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Infliximab	S	Unknown	Unknown	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Oral		Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Azathioprine Sodium	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Cyclophosphamide	C	Intravenous (not	Unknown	Not Reported

			otherwise specified)			
	Docusate Sodium	C	Oral			Not Reported
	Elavil	C	Unknown	Unknown		Not Reported
	Prednisone	C	Oral			Not Reported
	Sulfasalazine	C	Oral			Not Reported
	Sulfasalazine	C	Unknown	Unknown		Not Reported
	Tobramycin	C	Unknown			Not Reported
	Doxycycline	C	Oral	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown		Not Reported
	Elavil	C	Unknown	Unknown		Not Reported
	Wellbutrin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17535019	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1196886		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17578035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009106			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Reactin /00884302/	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17583365	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025908		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported

	Methotrexate			S	Oral	Unk	Not Reported
	Methotrexate			S	Subcutaneous	Unk	Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram	Not Reported
	Sulfasalazine			S	Unknown	Unk	Not Reported
	Xeljanz			S	Unknown	Unk	Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17614338	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Levofloxacin			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Benadryl /00000402/			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Pms Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Procytox			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Ezetrol			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17623465	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17628959	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202003002234			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination; Headache; Nausea	Hydroxychloroquine			S	Unknown	1 Peice Daily, Film Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17655678	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1221608		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Lasilix 20 Mg/2 Ml, Solution Injectable En Ampoule			S	Intravenous (not otherwise specified)	2 Dosage Forms		Not Reported
	Plaquenil			S	Oral			Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)			Not Reported

	Perfalgan 10 Mg/Ml, Solution Pour Perfusion	C	Intravenous (not otherwise specified)		Not Reported
	Noradrenaline (Tartrate De)	C	Intravenous (not otherwise specified)		Not Reported
	Midazolam	C	Intravenous (not otherwise specified)		Not Reported
	Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion	C	Intravenous (not otherwise specified)	4 Dosage Forms	Not Reported
	Transipeg	C	Oral		Not Reported
	Potassium (Chlorure De)	C	Intravenous (not otherwise specified)		Not Reported
	Nimbex	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17656152	EXPEDITED (15-DAY)		CA, OT	FR-SA-2020SA091764			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Lovenox			S	Transplacental	1 Df, Qd		Sanofi
	Lovenox			S	Transplacental	Unk		Sanofi
	Plaquenil			S	Transplacental	400 Mg, Qd		Sanofi
	Plaquenil			S	Transplacental	Unk		Sanofi
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	1 Df, Qd		Not Reported
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	Unk		Not Reported
	Econazole Nitrate			S	Transplacental	300 Mg, Qd		Not Reported
	Cortancyl			S	Transplacental	1 Df, Qd		Not Reported
	Cortancyl			S	Transplacental	Unk		Not Reported
	Imurel [Azathioprine]			S	Transplacental	150 Mg, Qd		Not Reported
	Imurel [Azathioprine]			S	Transplacental	Unk		Not Reported
	Econazole			C	Transplacental	300 Mg, Qd		Not Reported
	Econazole			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030940		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk Unk, Qd		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Minocycline			C	Unknown	Unk		Not Reported
	Penicillamine			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	6 Milligram, Bid		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678136	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202004002834			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous	Solution		Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral	20 Milligram, Weekly (Qw)		Not Reported
	Orencia			S				Not Reported
	Prednisone			C	Oral			Not Reported
	Leflunomide			C				Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678265	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002747			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Fibrillation; Electrocardiogram Qrs	Hydroxychloroquine			S	Unknown	400 Mg, Bid (For One Day Followed By 200mg Twice Daily For Four Days)		Concordia

Complex Prolonged; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine		S	Unknown	200 Mg, Bid (For One Day Followed By 200mg Twice Daily For Four Days)	Concordia
	Azithromycin		S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
	Apixaban		C		5 Mg, Bid	Not Reported
	Metoprolol Succinate		C		25 Mg, Qd	Not Reported
	Flecainide		C		50 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678298	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244196		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster Disseminated	Hydroxychloroquine			S	Unknown	200 Milligram, Bid, Daily		Sun
	Prednisone			S	Unknown	5 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678709	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016085		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dry Skin; Fatigue; Pyrexia; Rash; Weight Decreased	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678744	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1224307		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycine Dihydratee			S	Oral	500 Mg D1 Then 250 Mg Per Day		Not Reported

	Plaquenil			S	Oral	600 Mg			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678760	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1777			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678767	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3367094-00		80 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anuria; Anuria	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Dolquine			S	Unknown			Not Reported
	Dolquine			S	Unknown			Not Reported
	Metformina			C	Oral			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Acovil			C	Oral			Not Reported
	Ganfort			C	Ophthalmic			Not Reported
	Pantoprazol			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Simvastatina			C	Oral			Not Reported
	Tramadol + Paracetamol			C	Oral			Not Reported
	Ceftriaxona			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678836	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017962		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	1000 Milligram, Once A Day		Aurobindo
	Levofloxacine Arrow Film-Coated Tablets 500mg			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678845	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-018482		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Aurobindo

Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
Cortancyl	S	Oral	20 Milligram, Once A Day (10-20?G)	Not Reported
Coversyl	S	Intracardiac	Unk	Not Reported
Coversyl	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678871	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002655			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Upper Respiratory Tract Infection	Hydroxychloroquine			S				Concordia
	Bactrim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678919	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004002835			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Impairment; Septic Shock	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679113	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003002035			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679121	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003002037			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective	Hydroxychloroquine	S	Unk	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679615	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020156142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Physical Health Deterioration; Mobility Decreased; Musculoskeletal Pain; Nervousness; Pain; Pain In Extremity	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Ciclosporin			S	Unknown			Not Reported
	Diclofenac Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679788	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097024		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Hydroxychloroquine Sulfate			S		2 Df, Qd (Dose: 200mg)		Sanofi
	Cefazolin			S		Unk		Not Reported
	Leflunomide			S	Oral	10.0 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25.0 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported
	Cimzia			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Rituximab			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution		Not Reported

				Subcutaneous)	
	Arava	C		Unk	Not Reported
	Viread	C		Unk	Not Reported
	Naproxen	C		2 Df, Qd (Dose: 500 Mg)	Not Reported
	Xeljanz	C	Oral	2 Df, Qd (Dose: 5.0 Mg)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679789	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096908		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679976	EXPEDITED (15-DAY)		HO, OT	DE-SANOFI-AVENTIS-2012SA019610		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Lip Disorder; Pigmentation Disorder; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Cyclophosphamide			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisolone			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680086	EXPEDITED (15-DAY)		DE, OT	FR-SGP-000004		59 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Mesenteric Vein Thrombosis; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication; Septic Shock	Methylprednisolone			S	Unknown			Sungen Pharma
	Methylprednisolone			S	Intravenous (not otherwise specified)			Sungen Pharma
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown	0.6 G/M²		Not Reported
	Cyclophosphamide			S	Unknown	0.6 G/M²		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680375	NON-EXPEDITED			US-APPCO PHARMA LLC-2082959			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness	Hydroxychloroquine Sulfate			S				Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680511	NON-EXPEDITED			US-APPCO PHARMA LLC-2082963			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680526	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020-13065		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Arava	S	Oral		Not Reported
	Ascorbic Acid	S	Unknown	Unknown	Not Reported
	Atenolol	S	Unknown		Not Reported
	Co Atenolol	S	Unknown		Not Reported
	Co Atenolol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Ferrous Fumarate	S	Unknown	Unknown	Not Reported
	Ferrous Fumarate;Folic Acid	S	Unknown	Unknown	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported

Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported

	Teva Pantoprazole	S	Unknown			Not Reported
	Vitamin C [Ascorbic Acid]	S	Unknown	Unknown		Not Reported
	Celebrex	C	Oral			Not Reported
	Celecoxib	C	Oral			Not Reported
	Prednisone	C	Unknown	Intracardiac		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680759	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003661			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Disorder	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680864	EXPEDITED (15-DAY)		OT	NVSC2020CA096830		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Cyclosporine			S	Unknown			Novartis
	Neoral			S	Oral			Novartis
	Hydroxychloroquine Sulfate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Remicade			S	Unknown	3 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680902	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224376		46 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 400 Mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680984	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099621			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi

	Methotrexate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680985	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100529		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate			S				Sanofi
	Paracetamol			S				Not Reported
	Arava			S		200 Mg, Qd		Sanofi
	Meloxicam			S				Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680986	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098964			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, 2 Every 1 Week		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine Sodium			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680987	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099339		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache;	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S		25 Mg, Qd		Not Reported

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S			Sanofi
	Sulfasalazine	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680988	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099287		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Arava			S				Sanofi
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Cymbalta			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680991	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099390			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

		Remicade			S	Intravenous (not otherwise specified)	Powder For Solution			Not Reported
		Simponi			S	Subcutaneous				Not Reported
		Actemra			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680992	EXPEDITED (15-DAY)		HO	CA-SA-2020SA099085			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Dehydration; Drug Ineffective	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680993	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17680994	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk Unk, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Metformin Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Sanofi
	Colchicine			S	Unknown			Not Reported
	Sitagliptin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681011	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099608		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681360	EXPEDITED (15-DAY)		OT	NVSC2020CA102910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi			S	Subcutaneous	Unk			Not Reported
	Stelera			S	Subcutaneous	Unk			Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Methotrexate			C	Unknown	Unk			Not Reported
	Arava			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681818	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019820		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ertapenem			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo
	Piperacillin+Tazobactam 4/0.5g Powderforsolutionforinfusion			S	Intravenous (not otherwise specified)	Unk Unk, Once A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681820	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-019814		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17681821	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019810		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17685294	DIRECT					52 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Dyspnoea; Heart Rate Irregular; Palpitations; Pneumonia	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	11595241	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1641772		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Cystitis; Cystitis; Diarrhoea; Dizziness; Nausea; Pain; Pneumonia; Sensitivity To Weather Change; Swelling; Urinary Tract Infection	Esbriet			S	Oral			Not Reported
	Esbriet			S	Oral			Not Reported
	Esbriet			S	Unknown			Not Reported
	Esbriet			S	Unknown	Dose Increased To 9 Capsules A Day, Every 1 Day		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Cephalexin [Cefalexin]	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Prednisone	C	Unknown	Therapy Duration: 2 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	15292197	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-AUROBINDO-AUR-APL-2018-041851			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe Tablets			S	Transplacental	From Gestational Week 0-14		Aurobindo
	Pantoprazole			S	Transplacental	40 Milligram, Once A Day		Aurobindo
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Once A Day		Not Reported
	Ramipril			S	Transplacental	20 Milligram, Once A Day, From Gestational Week 0-113+6		Aurobindo
	Simvastatin Film-Coated Tablet			S	Transplacental	From Gestational Week 0-14		Aurobindo
	Aspirin			S	Transplacental	100 Milligram, Once A Day (From Gestational Week 0-14)		Not Reported
	Aspirin			S				Not Reported
	Aliskiren			S	Transplacental	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Milligram, Once A Day		Not Reported
	Metamizole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Two Times A Day From Gestational Week 0-14		Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported

	Salbutamol	S	Transplacental	Unk, Once A Day,From Gestational Week 0-14	Not Reported
	Tacrolimus	S	Transplacental	6 Milligram, Once A Day	Not Reported
	Tacrolimus	S			Not Reported
	Torasemide	S	Transplacental	100 Milligram, Once A Day	Not Reported
	Heparin	S	Transplacental	Unk	Not Reported
	Clexane	S	Transplacental	From Gestational Week 0-14	Not Reported
	Clexane	S	Transplacental	200 Milligram, Once A Day	Not Reported
	Dalteparin	S	Transplacental	Unk	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682209	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-019426		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported

	Paracetamol			C	Unknown	Unk			Not Reported
	Xarelto			C	Oral	Unk			Not Reported
	Diffu K			C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682256	EXPEDITED (15-DAY)		HO, OT	SE-AUROBINDO-AUR-APL-2020-018861		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram		Aurobindo
	Prednisolone			S	Oral	10-15st.		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682362	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003499			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Promyelocytic Leukaemia; Neutropenia; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682415	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13043			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)		Not Reported
	Anakinra			S	Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral		Not Reported
	Methotrexate			S	Subcutaneous		Not Reported
	Naproxen			S	Unknown	Unknown	Not Reported
	Orencia			S	Intravenous (not otherwise specified)		Not Reported
	Prednisone			S	Oral		Not Reported
	Prednisone			S	Oral		Not Reported
	Sulfasalazine			S	Oral		Not Reported
	Triamcinolone			S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223766			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Actavis
	Azathioprine			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Unknown			Duramed
	Methotrexate			S	Unknown			Barr
	Pantoprazole			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

					Nifedipine		S	Unknown		Not Reported
					Rivotril		S	Unknown		Not Reported
					Zantac		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682516	EXPEDITED (15-DAY)		DE, OT	BR-ADVANZ PHARMA-202004002764			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682522	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Duramed
	Methotrexate			S	Unknown			Barr
	Pantoprazole			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Imuran			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rivotril			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682567	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202004003329			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Euthyrox			S	Unknown	125 Ug, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2020	17682578	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002839			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Infection; Joint Injury	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	13165412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005507		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	150 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	13852964	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070668		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			C	Oral	20 Milligram, Qd		Not Reported

	Risedronate			C	Oral	35 Milligram, Qwk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	15751693	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044237		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	25 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Indocid [Indometacin]			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Gold (198 Au) Colloidal			S	Unknown	Unk		Not Reported

	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Cymbalta	C	Unknown	30 Milligram, Qd	Not Reported
	Folic Acid Aventis	C	Oral	Unk Unk, Qwk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	16927061	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-096726		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Irritable Bowel Syndrome; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown	150 Milligram		Not Reported
	Sulfasalazin			S	Unknown	1000 Milligram, Bid		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Acetaminophen		C	Unknown	3000 Milligram, Qd	Not Reported
	Esomeprazole		C	Unknown	40 Milligram, Qd	Not Reported
	Esomeprazole Sodium		C	Unknown	Unk	Not Reported
	Lumigan Rc		C	Ophthalmic	Unk Unk, Qd	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]		C	Unknown	10 Milligram, Qd	Not Reported
	Trazodone		C	Unknown	200 Milligram, Qd	Not Reported
	Valsartan		C	Unknown	Unk, Qd	Not Reported
	Wellbutrin		C	Unknown	300 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17563464	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022239		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Anakinra			S	Unknown	50 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	50 Milligram		Not Reported

Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter		Not Reported
	Naproxen	S	Unknown			Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid		Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd		Not Reported
	Triamcinolone	S	Other	Unk		Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Triamcinolone Hexacetonide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682710	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1223867		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported

	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682746	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-018681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Once A Day		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine		S	Unknown	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682764	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-12491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported

Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous	Solution	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown. Solution	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Folic Acid	C	Unknown		Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported
Prednisone	C	Oral	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Unknown	Not Reported

	Xeljanz			C	Oral					Not Reported
	Leflunomide			C	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682792	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2020-019423		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg D1 Then 250 Mg Per Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Q4wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Benadryl [Acrivastine]			C	Unknown	Unk		Not Reported

				Codeine	C	Unknown	Unk		Not Reported
				Darifenacin	C	Unknown	Unk		Not Reported
				Desoximetasone	C	Unknown	Unk		Not Reported
				Dexamethasone	C	Unknown	Unk		Not Reported
				Dilaudid	C	Unknown	Unk		Not Reported
				Hydromorphone	C	Unknown	Unk		Not Reported
				Kadian	C	Unknown	Unk		Not Reported
				Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk		Not Reported
				Lasix [Furosemide]	C	Unknown	Unk		Not Reported
				Loperamide	C	Unknown	Unk		Not Reported
				Norflex [Orphenadrine Citrate]	C	Unknown	Unk		Not Reported
				Omnaris	C	Unknown	Unk		Not Reported
				Orphenadrine Citrate	C	Unknown	Unk		Not Reported
				Oxyneo	C	Unknown	Unk		Not Reported
				Pantoloc [Pantoprazole]	C	Unknown	Unk		Not Reported
				Pantoprazole	C	Unknown	Unk		Not Reported
				Restasis	C	Unknown	Unk		Not Reported
				Rituximab	C	Intravenous drip	Unk		Not Reported
				Synthroid	C	Unknown	Unk		Not Reported
				Trimethoprim	C	Unknown	Unk		Not Reported
				Urispas	C	Unknown	Unk		Not Reported
				Vagifem	C	Vaginal	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031379			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance;	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Apo-Leflunomide		S	Unknown	25 Milligram, Qwk		Not Reported
	Arava		S	Unknown	25 Milligram, Qwk		Not Reported
	Enbrel		S	Unknown	50 Milligram, Qwk		Not Reported
	Gold		S	Unknown			Not Reported
	Humira		S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate		S	Unknown			Not Reported
	Leflunomide		S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate		S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine		S	Intramuscular			Not Reported
	Sulfasalazine		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682830	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031430		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17682831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	12289723	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-LUPIN PHARMACEUTICALS INC.-2016-01536			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent;	Hydroxychloroquine			S	Transplacental	Unk (From Gestational Week 0-14)		Lupin
	Ramipril			S	Transplacental	20 Milligram, Qd (From Gestational Week 0-113+6)		Lupin
	Simvastatin Tablets			S	Transplacental	Unk (From Gestational		Lupin

Ventricular Septal Defect				Week 0-14)	
	Ezetimibe	S	Transplacental	Unk	Not Reported
	Ezetimibe	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Pantoprazole	S	Transplacental	40 Milligram, Qd (0-13.6 Gestational Week)	Not Reported
	Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd (From Gestational Week 0-14)	Not Reported
	Xarelto	S	Transplacental	Unk (From Gestational Week 0-5)	Not Reported
	Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
	Tacrolimus	S	Transplacental	6 Milligram, Qd (From Gestational Week 0-14)	Not Reported
	Torasemide	S	Transplacental	100 Milligram, Qd	Not Reported
	Salbutamol	S	Transplacental	Unk Unk, Qd ((From Gestational Week 0-14))	Not Reported
	Enoxaparin Sodium	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Nicotine	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Prednisolone	S	Transplacental	10 Milligram, Bid (From Gestational Week 0-14)	Not Reported
	Novaminsulfon	S	Transplacental	Unk (Trimester: First; Probably Only In Hospital In Week 5)	Not Reported
	Dalteparin Sodium	S	Transplacental	Unk	Not Reported
	Metamizole	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Rituximab	S	Transplacental	Unk (Trimester: Preconceptional)	Not Reported
	Heparin Lmw	S	Transplacental	Unk	Not Reported
	Aliskiren	S	Transplacental	300 Milligram, Qd (0-4.6 Gestational Week)	Not Reported

Heparin	C	Transplacental	Unk		Not Reported
Cyclophosphamide	C	Transplacental	Unk (3000 [Mg Cumulative]; Preconceptional)		Not Reported
Mifegyne	C	Transplacental	Unk (13.6 Gestational Week)		Not Reported
Cytotec	C	Transplacental	Unk (13.6 Gestational Week)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	12769848	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported

Terminal State; Thrombosis; Urticaria	Apo-Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Marijuana	S	Unknown	Unk	Not Reported

Loss Of Personal Independence In Daily Activities; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Mg, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	14217957	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronate	S	Unknown	70 Mg, Q.I.W	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk. (Duration:944)	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Q.I.W	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk (Duration: 366)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Mg, One Every 4 Weeks	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
	Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15402622	EXPEDITED (15-DAY)		HO, OT	CO-ACTELION-A-CH2018-179017		63 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Anxiety; Arrhythmia; Asthenopia; Blood Creatinine Increased; Bronchitis; Cardiac Failure; Chest Discomfort; Chest Pain; Choking; Coagulation Time Prolonged; Coagulopathy; Constipation; Diarrhoea; Discomfort; Dizziness; Dyspnoea; Ear Disorder; Eye Disorder; Fall; Fatigue; Feeling Abnormal; Fibromyalgia; Flatulence; Fluid Retention; Gait Disturbance; General Physical Health Deterioration; Head Discomfort; Headache; Hyponatraemia; Hypotension; Hysterectomy; Inflammation Of Wound; Intestinal Obstruction; Joint Swelling; Loss Of Control Of Legs; Malaise; Memory Impairment; Mitral Valve Calcification; Mitral Valve Disease; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Product Availability Issue; Pulmonary Artery Occlusion; Reflux Gastritis; Renal Disorder; Swelling Face; Swelling Of	Tracleer			S	Oral	62.5 Mg, Bid		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Riociguat			S	Unknown	Unk		Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Carvedilol			C				Not Reported

Eyelid; Syncope; Tremor; Vasodilatation; Walking Aid User

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15634974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Infliximab			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15635082	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105542		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Urelumab	C	Unknown	Unk	Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown	Unk Unk, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Xeljanz	S	Oral	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15840631	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001079			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16045300	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020351		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other	80 Milligram Daily;		Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16079806	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05468			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Clopidogrel Bisulfate			C	Oral	Unknown		Not Reported
	Ezetrol			C	Oral	Unknown		Not Reported
	Niaspan			C	Unknown	Unknown, Extended Release Tablet		Not Reported
	Nitroglycerin			C	Transdermal	Unknown		Not Reported
	Rosuvastatin Calcium			C	Oral	Unknown		Not Reported
	Tylenol			C	Oral	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16563279	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-17758		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown, Other Route		Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Triamcinolone Hexacetonide			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	16936907	EXPEDITED (15-DAY)		CA, OT	DE-BAUSCH-BL-2019-057945		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Maternal Dose: 5mg, Qd (One In One Day)		Not Reported
	Quensyl			S	Transplacental	Maternal Dose: 200 (Mg/D)/Varying Dosage Between 150 And 200 Mg Daily		Not Reported
	Mono-Embolex			C	Transplacental	Maternal Dose: 3000 (Ie/D)		Not Reported
	L-Thyroxin Jod Beta			C	Transplacental	Maternal Dose: 37.5 (Microg/D) / 75(Microg/D)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17528005	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA067701		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Novartis
	Diclofenac			S	Oral	2 Df, Qd		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral			Novartis
	Diclofenac			S	Oral	Unk, Qd		Novartis
	Diclofenac			S	Oral	Unk		Novartis
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported

Voltaren Sr	S	Oral	2 Df, Qd (75 Mg)		Not Reported
Voltaren Sr	S	Oral	Unk		Not Reported
Diclofenac Potassium	S	Oral			Novartis
Cambia	S	Oral	Unk, Qd		Not Reported
Cambia	S	Oral	Unk		Not Reported
Cambia	S	Unknown	75 Mg, Bid		Not Reported
Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)		Not Reported
Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)		Not Reported
Pantoprazole Magnesium	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	1 Df, Qd		Not Reported
Synthyroid	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	2 Df, Qd		Not Reported
Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17584672	EXPEDITED (15-DAY)		OT	NVSC2020US083168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Gastrointestinal Pain; Joint Swelling	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17595157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020012294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported

Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S			Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cortisone Acetate	S			Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral	And Oral	Not Reported
	Diclofenac	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S	Oral	25 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	4 Milligram	Ucb
	Leflunomide	S		Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)	Not Reported
	Pseudoephedrine Hcl	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S			Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous	Unk	Not Reported
	Topicort [Desoximetasone]	S	Topical	Unk	Not Reported
	Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S		5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Actemra	S	Intravenous (not	Unk	Not Reported

						otherwise specified)				
		Apo-Hydroxyquine			S		Unk			Not Reported
		Apo-Prednisone			S		Unk			Not Reported
		Arava			S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17597328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009074		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qd		Not Reported
	Methotrexate			S	Endocervical	25 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Meloxicam			C	Unknown	Unk			Not Reported
	Simponi			C	Unknown	Unk			Not Reported
	Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17652112	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1218243		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Diastolic Dysfunction; Fluid Overload; Left Ventricular Dysfunction; Right Ventricular Dysfunction; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Initial Dosage Not Stated; Tit		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Rated To 200mg Twice Daily In The First Year		Teva
	Prednisone			C	Unknown			Not Reported
	Rituximab			C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17675973	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA097041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetylsalicylic Acid	C				Not Reported
	Asa	C	Unknown			Not Reported
	Calcium	C	Unknown			Not Reported
	Lantus	C	Subcutaneous			Not Reported
	Lozide [Gliclazide]	C	Unknown			Not Reported
	Metformin	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17682990	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-12849		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown	Unknown		Not Reported

			Lumigan Rc		C	Ophthalmic	Unknown		Not Reported
			Lyrica		C	Unknown			Not Reported
			Sulfasalazin		C	Unknown			Not Reported
			Suphedrine [Pseudoephedrine Hydrochloride]		C	Unknown			Not Reported
			Trazodone		C	Unknown			Not Reported
			Valsartan		C	Unknown	Unknown		Not Reported
			Wellbutrin		C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683235	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003379			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Oxygen Consumption Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Nicardipine			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683260	EXPEDITED (15-DAY)		HO	SE-TEVA-2020-SE-1224953		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15st.		Actavis
	Sertraline			S	Oral	750 Mg		Not Reported
	Plaquenil			S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584741			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug	Rituxan			S	Intravenous (not			Not Reported

Intolerance; Lymphoma					otherwise specified)				
	Apo-Leflunomide			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Desoximetasone			C	Unknown				Not Reported
	Diclofenac			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683398	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585127		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Ergocalciferol	C			Not Reported
	Folinic Acid	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683443	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031020		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased;	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	2.68 Milligram, Q4wk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported

Ulcer	Methotrexate	S	Subcutaneous	15.0 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585203		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Methotrexate		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683494	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683880	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA101018		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	400 Mg, Solution		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	C	Subcutaneous			Not Reported
	Xeljanz	C	Oral	5 Mg		Not Reported
	Prednisone	C				Not Reported
	Aleve	C				Not Reported
	Arava	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683881	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	200 Mg, Qd		Sanofi
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100531		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Celecoxib			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported

		Sulfasalazine			S	Oral	1 G, Bid			Not Reported
		Naproxen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683915	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Hydroxychloroquine Sulfate			S		Unk, Bid		Sanofi
	Actemra			S				Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Xeljanz			S				Not Reported
	Acetaminophen			C				Not Reported
	Ativan			C				Not Reported
	Anakinra			C		Unk		Not Reported
	Codeine			C				Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Hydromorphone			C				Not Reported
	Kadian			C				Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Intra-articular	Suspension Intra-Articular		Not Reported
	Oxyneo			C				Not Reported
	Synthroid			C				Not Reported
	Urispas			C				Not Reported
	Trimethoprim			C				Not Reported
	Vagifem			C	Vaginal			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683917	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099622			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			C		20 Mg, Qd		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C		3 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100527		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported
	Xeljanz			C		5 Mg, Qd (2 Every 1 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683921	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine Sulfate	S	Oral			Sanofi
	Leflunomide	S	Oral			Sanofi
	Methotrexate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown			Not Reported
	Actemra	S				Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683933	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100719			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Colectomy; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Codeine			S				Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683934	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100245		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Plaquenil			S		Unk		Sanofi

Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Methotrexate	S		Unk		Not Reported
	Arava	S		Unk		Sanofi
	Sulfasalazine	S		Unk		Not Reported
	Actemra	S		Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683935	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100641		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Hydroxychloroquine Sulfate			S		400 Mg, Qd (1 Every 1 Day)		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Rituximab			S		Unk		Not Reported
	Orencia			S				Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Plaquenil	S				Sanofi
	Bisoprolol Salt Not Specified	S				Not Reported
	Cefixime	S				Not Reported
	Methotrexate	S				Not Reported
	Morphine Hydrochloride	S				Not Reported
	Nifedipine	S				Not Reported
	Pantoprazole	S				Not Reported
	Prednisone	S				Not Reported
	Clonazepam	S				Not Reported
	Zantac	S				Sanofi
	Zopiclone	S				Not Reported
	Imuran [Azathioprine]	S	Oral	100 Mg		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5.0 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683939	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100517			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		40 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17683954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585160			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Imatinib			S	Unknown			Not Reported
	Imatinib			S				Not Reported
	Imatinib			S				Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Imuran [Azathioprine]			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S				Not Reported
	Tacrolimus			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684002	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic	Leflunomide			S	Unknown			Barr

Enzyme Increased; Off Label Use; Pneumonia	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224903		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684130	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224385		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Leflunomide	S	Oral			Barr
	Methotrexate	S	Unknown			Barr
	Humira	S	Subcutaneous	80 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]	C				Not Reported
	Clopidogrel Bisulfate	C				Not Reported
	Metoprolol	C				Not Reported
	Pantoprazole	C				Not Reported
	Ramipril	C				Not Reported
	Rosuvastatin	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224905		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Subcutaneous			Barr
	Varenicline Tartrate	S	Oral	1 Milligram Daily;		Not Reported
	Actemra	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Unknown			Not Reported
	Tofacitinib Citrate	C	Unknown			Not Reported
	Valtrex	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684161	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia			S	Unknown				Not Reported
	Celebrex			C	Unknown				Not Reported
	Leflunomide			C	Unknown				Not Reported
	Sulfasalazine			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684208	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100329			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S		200 Mg, Qm		Not Reported
	Enbrel			S				Not Reported
	Folic Acid			S		1 Mg, Qd		Not Reported
	Humira			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684209	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA100717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Sulfasalazine			S				Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Acetaminophen			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)		
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Methotrexate		C		1 Df, Qw	Not Reported
	Meloxicam		C			Not Reported
	Synthroid		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684211	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Diclofenac			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Arthrotec			C				Not Reported
	Desoximetasone			C				Not Reported
	Ibuprofen			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Oral	Unk Unk, Qd		Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C		Unk Unk, Qd		Not Reported
	Tramadol			C	Oral	Unk Unk, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684214	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100514			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intestinal Perforation	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Leflunomide		S	Unknown	Sanofi
	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684329	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224395			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amenorrhoea; Anxiety; Burning Sensation; Drug Ineffective; Hypoaesthesia; Infection; Juvenile Idiopathic Arthritis; Nausea; Neuropathy Peripheral	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celexa [Celecoxib]			C	Oral			Not Reported
	Cholecalciferol			C	Oral			Not Reported
	Ethinyl Estradiol/Norgestimate			C	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684330	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684454	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223977		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Stress	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Dequalinium Chloride			C				Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684459	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Oral			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224831		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Leflunomide			S	Unknown			Barr

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Mobicox	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Depo-Medrol	C	Other	80 Milligram Daily; Suspension Intraarticular		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684526	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224892		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684531	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide	S	Oral			Barr
	Methotrexate	S	Oral			Not Reported
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Lyrica	S	Oral	300 Milligram Daily;		Not Reported
	Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684658	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA100513			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S				Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported

Ilaris	S				Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk		Not Reported
Ilaris	S				Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098969		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Allopurinol			S				Not Reported
	Amitriptyline Hydrochloride			S				Not Reported
	Diclofenac Sodium			S	Topical	Solution Topical		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Diclofenac Potassium			S				Not Reported

Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Arava	S			Sanofi
	Arava	S		Unk	Sanofi
	Arava	S		Unk, Apo-Leflunomide, Tablet	Sanofi
	Naproxen	S			Not Reported
	Naproxen	S		Unk	Not Reported
	Naproxen	S		Unk, Apo-Naproxen	Not Reported
	Prednisone	S		5 Mg, Apo-Prednisone	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		Unk, Winpred	Not Reported
	Celecoxib	S			Not Reported
	Celecoxib	S		Unk	Not Reported
	Celecoxib	S		Unk, Capsule	Not Reported
	Celecoxib	S		Unk, Capsule	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Misoprostol	S			Not Reported
	Pregabalin	S			Not Reported
	Sulfasalazine	S			Not Reported
	Amitriptyline	S			Not Reported
	Amitriptyline With Perphenazine	S			Not Reported
	Apo-Azathioprine	S			Not Reported
	Azathioprine	S			Not Reported
	Diclofenac Sodium And Misoprostol	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Etanercept	S			Not Reported
	Actemra	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Lyrica	S			Not Reported
	Nifedipine	S			Not Reported

					Orencia	S	Subcutaneous	750 Mg, Qw	Not Reported
					Rituximab	S	Intravenous (not otherwise specified)	2000 Mg	Not Reported
					Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
					Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17684872	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1223974		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported

	Urelumab			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685014	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100424		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Atenolol			C	Oral	50 Mg, Qd		Not Reported
	Hydrochlorothiazide			C		25 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685016	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100528		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling;	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	14 Mg, Qd		Not Reported
	Arava			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qm		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Furosemide			C	Unknown	Unk Unk, Qd		Not Reported
	Hydromorph Contin			C		18 Mg, Tid, Sustained		Not Reported

Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting					Release		
	Dilaudid		C	Unknown	4 Mg, Tid		Not Reported
	Lyrica		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224477			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685109	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224361			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685110	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685113	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224837		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685278	EXPEDITED (15-DAY)		LT	CA-SAMSUNG BIOEPIS-SB-2020-13385			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S			Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Intra-articular	Unknown	Not Reported
	Triamcinolone	S			Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224221		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Arthritis	Arava	S	Oral	20 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685527	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685606	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13343		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective For Unapproved Indication;	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Hydroxychloroquine	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Unknown		Not Reported
	Methotrexate	S	Oral	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Varicella-Zoster Immune Globulin	S	Subcutaneous	Liquid Intramuscular, Dose: Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685629	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223866		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685690	EXPEDITED (15-DAY)		OT	NVSC2020GB104678			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685725	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX008388		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Mycophenolate Mofetil			S	Unknown	Dosage Form: Not Specified		Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Plaquenil			S	Unknown	Dosage Form: Tablet		Not Reported
	Rituxan			S	Unknown	Dosage Form: Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cymbalta			C	Unknown	Dosage Form: Not Specified		Not Reported
	Domperidone			C	Unknown	Dosage Form: Tablet		Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685734	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Leflunomide	S	Oral	10 Milligram Daily;		Barr
	Methotrexate	S	Oral			Barr
	Methotrexate	S	Subcutaneous			Barr
	Leucovorin	S	Oral			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Arava	C				Not Reported
	Calcium Citrate; Magnesium Citrate	C				Not Reported
	Citalopram Hydrobromide	C				Not Reported
	Clobetasol Propionate	C	Topical			Not Reported
	Naproxen	C	Oral			Not Reported
	Pantoprazole Magnesium	C				Not Reported
	Escitalopram Oxalate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685735	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224422		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Urinary Tract Obstruction	Azathioprine Sodium			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685788	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Leflunomide		S	Unknown			Barr
	Methotrexate		S	Unknown			Barr
	Actemra		S	Unknown			Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	4800 Milligram Daily;		Not Reported
	Kevzara		S	Unknown			Not Reported
	Enbrel		S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685791	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224383			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685813	EXPEDITED (15-DAY)		DE	ES-ASTRAZENECA-2020SE51307		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Sudden Death	Quetiapine		S	Oral		Zeneca
	Hydroxychloroquine Sulphate		S	Oral		Not Reported
	Levofloxacin		S	Intravenous (not otherwise specified)		Not Reported
	Kaletra		S	Oral	200/50 Mg, 2 Df Daily, 120 Tablets	Not Reported
	Risperidone		S	Oral		Not Reported
	Losartan		C	Oral		Not Reported
	Clindamycin Hydrochloride		C	Intravenous (not otherwise specified)		Not Reported
	Lorazepam		C	Oral		Not Reported
	Furosemide		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685815	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12772		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown,		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not	Unknown,		Not Reported

				otherwise specified)		
	Sulfasalazine		S	Oral		Not Reported
	Sulfasalazine		S	Oral	Unknown	Not Reported
	Acetaminophen/Oxycodone Hydrochloride		C	Unknown	Unknown	Not Reported
	Celebrex		C	Oral	Unknown	Not Reported
	Furosemide		C	Unknown	Unknown	Not Reported
	Morphine		C	Unknown	Unknown	Not Reported
	Oxycodone Terephthalate		C	Unknown	Unknown	Not Reported
	Ramipril		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685895	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224217			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685905	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223975		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Methotrexate	S	Unknown		Barr
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685927	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224413			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Depo-Medrol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685928	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223947			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685929	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Symptom; Alopecia; Arthralgia; Bone Disorder; Cyst; Hand Fracture; Seronegative Arthritis; Urinary Tract Obstruction	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685979	EXPEDITED (15-DAY)		HO	US-ALEXION-A202005121		44 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Normocytic Anaemia; Off Label Use	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion
	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion
	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Norepinephrine			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	2 Mg, Q12h		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Rocephin			C	Unknown	Unk		Not Reported
	Propofol			C	Unknown	Unk		Not Reported
	Fentanyl			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685981	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224403			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Remicade			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17685990	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223963			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686061	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223940			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686242	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13015		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Infliximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab	S				Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Alendronate	S	Unknown			Not Reported
	Codeine	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Leflunomide	S	Unknown	Unknown		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Xeljanz	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Ciclosporin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686331	EXPEDITED (15-DAY)		OT	NVSC2020CA105008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plantago Afra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Qw		Not Reported
	Folic Acid			C	Unknown	5 Mg		Not Reported
	Ergocalciferol			C	Unknown	2000 Iu, Qd		Not Reported
	Cannabis Sativa			C	Unknown	Unk Unk, Qd		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686344	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3365681-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apnoea; Back Pain; Chest Pain; Cough; Diarrhoea; Drug Ineffective; Eye Irritation; Headache; Musculoskeletal Pain; Nasopharyngitis; Pleural Effusion; Pyrexia; Retinal Injury; Rhinorrhoea	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686390	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686431	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004003537			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Vision Loss; Macular Degeneration; Maculopathy; Retinal Toxicity; Retinopathy; Vision Blurred	Hydroxychloroquine			S		800 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686581	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-018504		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Ambisome			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported

	Tocilizumab			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17686584	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018508		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17690121	DIRECT		HO				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	400mg Bid For 1 Day Then 200bid For 1 Day Bid Po X 1 Day(S)		Not Reported
	Azithromycin			S		500mg Qd X 1 250mg Daily For 3 Days Qd Po X 3 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12769487	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Use Issue; Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Therapeutic Product Effect Incomplete; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Orencia	S	Unknown	200 Milligram	Bristol Myers Squibb
	Tylenol	S	Unknown	As Needed	Not Reported
	Enbrel	S	Unknown	50 Mg, Qwk(Loe)	Not Reported
	Enbrel	S	Unknown	40 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	2000 Mg(Intolerance)	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	800 Milligram	Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Acetaminophen	S	Unknown	325 Milligram	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Apo Hydro	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	200 Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not	5 Unit	Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Doxycycline	S	Unknown	100 Milligram, Bid	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown	20 Nanogram	Not Reported
Diphenhydramine Hydrochloride;Paracetamol	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Meloxicam	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Tylenol W/Codeine	C	Unknown		Not Reported
Celebrex	C	Oral	200 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Celecoxib	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported

	Leflunomide	C	Unknown	20 Milligram, 2 Every 1 Day		Not Reported
	Diphenhydramine	C	Oral	50 Milligram		Not Reported
	Glyburide (Micronized)	C	Unknown	Unk		Not Reported
	Hydrochlorothiazide	C	Unknown	Unk		Not Reported
	Lipitor	C	Unknown			Not Reported
	Metormin	C	Unknown			Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
	Ramipril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12913728	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091701			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoaesthesia; Infection; Nausea; Nephrolithiasis; Nerve Injury; Neutropenia; Off Label Use; Osteoarthritis; Pain In Extremity; Paraesthesia; Product Use Issue; Pulmonary Congestion; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	40 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, 152.0 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk, 122 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Every One Week		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk, 580.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral	400 Milligram, 580.0 Days		Not Reported

	Phosphate]					
	Apo-Hydroxyquine	S	Oral	400 Milligram		Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Naprosyn E	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12914292	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092847		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Arthropathy; Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Humira			S	Unknown	40 Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	12.5 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported

	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Cyclical	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk,Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Time In A Week	Not Reported
	Xeljanz	C	Unknown	Unk Unk, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13153195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Pain; Peripheral Swelling; Rash;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rocuronium	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Pencillin	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Rocuronium Bromide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13182370	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1856140-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Aleve	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Naproxen	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Prednisone Teva	S	Oral	Not Reported
	Plaquenil Sulfate	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13519381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038159		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia;	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb

Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Vomiting	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Celebrex	S	Unknown	200 Milligram	Not Reported
	Naprosyn [Naproxen Sodium]	S	Unknown	500 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13538108	EXPEDITED (15-DAY)		OT	CA-ROCHE-1933679			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Oral	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13850192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070656			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk,Cyclical		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actonel			C	Unknown	35 Milligram		Not Reported

Disorder; Tooth Infection; Weight Decreased	Naproxen		C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate		C	Unknown			Not Reported
	Risedronate Sodium		C	Unknown	35 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15163376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2154400		29 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ill-Defined Disorder; Systemic Inflammatory Response Syndrome; Ulcer; Vasculitis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15418599	EXPEDITED (15-DAY)		OT	DE-JNJFOC-20180917519		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Ciclosporin			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)		
	Apo-Leflunomide	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Oral	2 Ot	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15680209	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574019-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Humira		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Apo Celecoxib		S	Oral	Not Reported
	Arava		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Celecoxib		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15702743	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2581224-00		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Marijuana			C				Not Reported

	Risedronate	C	Oral		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Hydroxychloroquine	C	Oral		Not Reported
	Bupropion	C	Unknown		Not Reported
	Cannabis Sativa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15932044	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651975-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

		otherwise specified)	
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Diclofenac	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16135292	EXPEDITED (15-DAY)		OT	DE-SA-2018SA251992		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Plaquenil			S	Oral	2 Df, Qd		Sanofi

Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Plaquenil	S	Oral	10 Mg, Qd (5mg Bid)	Sanofi
	Plaquenil	S	Oral	10 Mg, Qd	Sanofi
	Plaquenil	S	Oral	Unk	Sanofi
	Leflunomide	S	Oral		Sanofi
	Methotrexate	S	Oral	20 Mg Tablet	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Sanofi
	Sulfasalazine	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk, Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Humira	S	Subcutaneous	Unk, Solution Subcutaneous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate Sodium	S		20 Mg	Not Reported
	Neoral	S	Oral		Not Reported
	Xeljanz	C	Unknown	2 Df, Qd, 2ot	Not Reported
	Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	10 Mg, Qd	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16396768	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2809469-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16640871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-070998			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Prednisone			C	Unknown					Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16724652	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA192974		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Voltaren			S	Unknown			Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Clopidogrel			S	Unknown	Unk		Not Reported
	Clopidogrel			S				Not Reported
	Clopidogrel			S				Not Reported
	Clopidogrel			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Vitamin C			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Asa			S	Unknown	325 Mg (Delayed Release)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported

	Humira	S				Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Motrin	S				Not Reported
	Motrin	S				Not Reported
	Motrin	S				Not Reported
	Naproxen	S	Unknown	Unk		Not Reported
	Naproxen	S				Not Reported
	Naproxen	S				Not Reported
	Naproxen	S				Not Reported
	Plaquenil	S	Oral	Unk		Not Reported
	Plaquenil	S				Not Reported
	Plaquenil	S				Not Reported
	Plaquenil	S				Not Reported
	Tramadol	S	Unknown	Unk		Not Reported
	Apo-Diclofenac	S	Topical			Not Reported
	Aspirin	S	Unknown			Not Reported
	Aspirin	S				Not Reported
	Aspirin	S				Not Reported
	Aspirin	S				Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Ibuprofen	S	Unknown			Not Reported
	Sulfamethoxazole	S	Unknown			Not Reported
	Trimethoprim	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16841034	EXPEDITED (15-DAY)		OT	GR-BAUSCH-BL-2019-026015		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperparathyroidism Secondary; Osteoporosis; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Bausch And Lomb
	Metformin Hydrochloride			S	Unknown			Santarus
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lansoprazole			S	Unknown			Not Reported

	Belimumab		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported
	Exemestane		S	Unknown	Not Reported
	Thyroxine		S	Oral	Not Reported
	Thyroxine		S	Unknown	Not Reported
	Dicumarol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16886720	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2946845-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sulfathalidine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Cortisone			S	Topical			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Failure; Wound			otherwise specified)		
	Remicade	S	Unknown	Powder For Infusion	Not Reported
	Cetirizine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexaat	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Arava	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
	Topicort (Hydrocortisone Acetate)	S	Cutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Ophthalmic		Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported

	Stelara	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Atasol	C	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	6965678	EXPEDITED (15-DAY)		OT	DE-RANBAXY-2009RR-23202		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome	Ceftriaxone			S	Unknown	Unk		Not Reported
	Co-Trimoxazole			S	Unknown	Unk		Mutual
	Doxycycline Hydrochloride			S	Unknown	Unk		Sun
	Hydroxycholoroquine Sulphate-Bp			S	Unknown	Unk		Sun
	Streptomycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17146486	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191211370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi Iv			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Calcium /00060701/	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17260297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Levothyroxine			S	Unknown	1 Df, Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Endocervical	400 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate			C	Ophthalmic	Unk, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown	One Once A Day		Not Reported
	Prednisone			C	Unknown	7 Mg, Qd		Not Reported
	Ramipril			C	Unknown	One Once A Day		Not Reported
	Tylenol No.2			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17332504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004133		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Unknown	50 Microgram, Qd		Not Reported
	Zingiber Officinale			C	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17517039	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200243785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Liver Function	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen

Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Uveitis	Cimzia	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naprosyn /00256201/	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Codeine	C	Subcutaneous	Not Reported
	Imuran /00001501/	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17577763	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329927		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Back Injury; Back Pain; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Proteinuria; Rheumatoid Arthritis; Swelling; Treatment Failure; Vasculitis	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Cyclophosphamide			C				Not Reported
	Docusate Sodium			C				Not Reported
	Doxycycline			C	Oral			Not Reported
	Elavil /00002202/			C	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Tobramycin			C	Intraocular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327866		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated	Simponi			S	Subcutaneous			Janssen

Product Administered; Drug Ineffective; Headache; Hepatotoxicity; Insomnia; Joint Swelling; Memory Impairment; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)		Janssen
	Actemra	S	Intravenous (not otherwise specified)	8.0 Mg/Kg	Not Reported
	Anakinra	S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Methotrexate	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Insulin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579770	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327863		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Pain; Constipation; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Hypersensitivity; Insomnia; Iodine Allergy; Nausea; Oedema; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Synovitis; Vomiting	Simponi	S	Subcutaneous	Janssen
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Venlafaxine	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	M-Eslon	C	Unknown	Not Reported
	Morphine	C		Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Statex	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Naprosyn /00256201/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579772	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327858		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Salazopyrin		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579773	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327868		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Actonel			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prolia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Minims Prednisolone Sodium Phosphate			S	Ophthalmic	0.5%		Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

	Cyclobenzaprine	C		Not Reported
	Desoximetasone	C		Not Reported
	Prednisone Acetate	C		Not Reported
	Tylenol /00020001/	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17605649	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332785		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthropathy; Drug Intolerance; Joint Swelling; Knee Arthroplasty; Therapeutic Product Effect Decreased; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17605713	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332775		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	For 3 Years		Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	11 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	4 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Codeine Phosphate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Pregabalin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17616081	EXPEDITED (15-DAY)		DE, HO	BR-ADVANZ PHARMA-202003002042			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623454	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340457		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not			Janssen

Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased			otherwise specified)	
	Actemra	S	Unknown	Not Reported
	Amlodipine Besilate	S	Oral	Not Reported
	Asacol	S	Unknown	Not Reported
	Diamicron	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gliclazide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Ebastine	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623463	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342096		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623466	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340460		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Crohn'S	Simponi			S	Subcutaneous			Janssen

Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623532	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340124		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug	Simponi			S	Subcutaneous			Janssen

Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Acetaminophen		C	Unknown	Not Reported
	Cyclobenzaprine		C	Oral	Not Reported
	Cyclobenzaprine		C	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Leflunomide		C	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone Acetate		C	Unknown	Not Reported
	Tylenol /00020001/		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623533	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340125		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Asa			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Acetaminophen	C			Not Reported
	Ultracet	C			Not Reported
	Calcite D	C	Unknown		Not Reported
	Citalopram	C			Not Reported
	Domperidone	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gabapentin	C			Not Reported
	Gliclazide	C	Unknown		Not Reported
	Lipitor	C			Not Reported
	Nifedipine	C			Not Reported
	Pantoloc /01263204/	C	Unknown		Not Reported
	Pantoprazole	C			Not Reported
	Risedronate	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Synthroid	C			Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340129		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S				Not Reported

					Penicilline G /00000901/		S	Unknown		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Sulfasalazine		S	Unknown		Not Reported
					Methotrexate		C	Unknown		Not Reported
					Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623540	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340132			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623542	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200340452		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Simponi		S	Subcutaneous	Janssen
	Arava		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Gold		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17666231	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029672		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

						otherwise specified)				
		Rocuronium Bromide			S	Unknown				Not Reported
		Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17672252	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413057		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17681010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Hydroxychloroquine Sulfate			S	Unknown			Sanofi

Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Sulfasalazine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Sanofi
	Enbrel		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Sanofi
	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Naproxen		C	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686409	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2020TUS018625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis;	Dexilant			S	Oral	60 Milligram, Qd		Takeda
	Colchicine			S	Unknown	Unk		Takeda
	Estrogel			S	Topical	Unk Unk, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Respiratory (inhalation)	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Meloxicam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Plaquenil /00072602/	S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone	S	Unknown	50 Milligram		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Ventolin Hfa	S	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686802	EXPEDITED (15-DAY)		OT	JP-LAURUS LABS LIMITED-202000088		41 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Placenta Accreta	Hydroxychloroquine			S	Unknown			Unknown
	Prednisolone			C	Unknown			Not Reported
	Tacrolimus			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17686999	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585020		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687059	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032291		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Musculoskeletal Discomfort; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687219	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244391			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687411	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1224814		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granuloma Skin; Mycobacterium Marinum Infection	Leflunomide			S	Unknown			Barr
	Prednisolone			S	Unknown	Low-Dose		Actavis
	Prednisolone			S	Unknown			Actavis
	Prednisolone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Teva
	Sulfasalazine			S	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687714	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100422		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

	Humira	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	20 Mg, Qd		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Arava			S				Sanofi
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687716	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100909		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate			S		100 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S				Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported
	Xeljanz			S		5 Mg, Bid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687718	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687719	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100913		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate			S	Oral	300 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		1 Df, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Risedronate Sodium			S				Not Reported
	Risedronate Sodium			S	Oral	35 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Mg		Not Reported
	Rituximab			S	Intravenous (not	1 G		Not Reported

					otherwise specified)				
	Hydroxychloroquine Sulfate			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100758		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Infection; Malaise; Nasopharyngitis; Product Dose Omission; Rheumatoid Arthritis; Tendon Rupture	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Simponi			S				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687722	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100911		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amoxicillin And Clavulanate Potassium			C				Not Reported
	Amoxil [Amoxicillin]			C				Not Reported
	Bcg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687786	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Arava			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	200 Mg, Bid		Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687792	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100987			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687797	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA101046		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg		Sanofi
	Methotrexate			S		15 Mg/M2, Qow		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S		1.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	30 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687801	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown			Sanofi
	Arava	S		20 Mg, Qd		Sanofi
	Meloxicam	S	Oral	7.5 Mg		Not Reported
	Methotrexate	S	Oral	20 Mg, Qw		Not Reported
	Actemra	S	Subcutaneous	Unk Unk, Qw		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Sulfasalazine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688091	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1040433		21 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Compartment Syndrome; Acute Respiratory Distress Syndrome; Drug Ineffective; Pancreatitis Necrotising; Sepsis; Shock Haemorrhagic	Prednisolone			S	Intravenous (not otherwise specified)	Pulse Therapy		Not Reported
	Prednisolone			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Mylan
	Plasma			S	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584496		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688210	EXPEDITED (15-DAY)		OT	NVSC2020IT104815		52 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Interaction; Hepatic Failure; Pneumonia Viral; Product Use In Unapproved Indication	Tacrolimus			S	Unknown	Unk		Novartis
	Tacrolimus			S				Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ritonavir			S	Unknown	Unk		Not Reported
	Ritonavir			S				Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Darunavir			C	Unknown	Unk		Not Reported
	Darunavir			C				Not Reported
	Cobicistat			C	Unknown	Unk		Not Reported
	Cobicistat			C				Not Reported
	Colchicine			C	Unknown	1 Mg On Day 8		Not Reported
	Colchicine			C	Unknown	0.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688319	NON-EXPEDITED			US-CELGENEUS-USA-20200404981			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression; Diarrhoea; Headache	Otezla			S	Oral	60 Milligram		Celgene
	Synthroid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

					Hydroxychloroquine		S		Not Reported
					Cosentyx		C	Unknown	Not Reported
					Gabapentin		C	Unknown	Not Reported
					Vitamin D		C	Unknown	Not Reported
					Folic Acid		C	Unknown	Not Reported
					Effexor		C	Unknown	Not Reported
					Baby Aspirin		C	Unknown	Not Reported
					Prilosec		C	Unknown	Not Reported
					Sulfasalazine		C	Unknown	Not Reported
					Femara		C	Unknown	Not Reported
					Prozosin		C	Unknown	Not Reported
					Meloxicam		C	Unknown	Not Reported
					Doxorubicin		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688373	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016273		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S		Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Erythematosus; Wound	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Every One Day	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Topicort /00028604/	S	Cutaneous	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688557	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202003002806			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Failure; Off Label Use; Organ Failure; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Rocephine			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Suxamethonium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688648	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1225642		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Hidroxicloroquina (2143a)			S	Oral	400mg/24h		Teva
	Linezolid (1279a)			S	Intravenous (not otherwise specified)			Teva
	Ambisome 50 Mg Polvo Para Dispersion Para Perfusion , 10 Viales			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688686	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13364		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

	Desoximetasone			C	Unknown	Unknown			Not Reported
	Methotrexate			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688704	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004002845			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Blindness; Cataract	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd (Coated Tablet)		Concordia
	Depakote			C		Unk		Not Reported
	Ozempic			C		Unk		Not Reported
	Selozok			C		Unk		Not Reported
	Pressetina			C		Unk		Not Reported
	Glifage			C		Unk		Not Reported
	Zetia			C		Unk		Not Reported
	Rosuvastatina			C		Unk		Not Reported
	Marevan			C		Unk		Not Reported
	Topiramato			C		Unk		Not Reported
	Venlafaxine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688786	EXPEDITED (15-DAY)		DE	FR-ADVANZ PHARMA-202004003713			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688866	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100693			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Arava			S				Sanofi
	Bisoprolol Salt Not Specified			S				Not Reported
	Cefaclor			S				Not Reported
	Celecoxib			S	Oral	200 Mg, Qd (1 Df, Every 1 Day)		Not Reported
	Demerol			S				Sanofi
	Erythromycin			S				Sanofi
	Erythromycin			S				Sanofi
	Levofloxacin			S				Not Reported
	Pregabalin			S				Not Reported
	Methotrexate			S				Not Reported
	Metronidazole			S				Sanofi
	Norfloxacin			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Arthrotec			S				Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Meperidine Hydrochloride			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Chloroquine Sulfate			S				Sanofi
	Myochrysine			S				Not Reported
	Humira			S				Not Reported

		Remicade			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688869	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100853			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688872	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100674		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Hydroxychloroquine	S				Sanofi
	Methotrexate	S				Not Reported
	Leflunomide	S				Sanofi
	Orencia	S				Not Reported
	Xeljanz	S				Not Reported
	Actemra	S	Subcutaneous	162 Mg, Qw		Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydrocortisone	C		Unk Unk, Bid		Not Reported
	Pantoloc [Pantoprazole]	C				Not Reported
	Prednisone	C		20 Mg, Qd		Not Reported
	Xarelto	C				Not Reported
	Tylenol 8 Hr Arthritis Pain	C		2 Df, Bid		Not Reported
	Calcium & Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688879	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200421346		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Uveitis	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sarilumab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S				Not Reported

	Tocilizumab			S						Not Reported
	Tofacitinib			S						Not Reported
	Xeljanz			S	Oral					Not Reported
	Prednisone			C						Not Reported
	Rabeprazole Sodium			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688898	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown; Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown; Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688907	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101008		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Oral	200 Mg	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	200 Unk	Sanofi
	Leflunomide	S	Unknown		Sanofi
	Methotrexate	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Vioxx	S	Oral		Not Reported
	Xeljanz	S	Oral	5 Mg	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100917			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Orencia			S	Intravenous (not			Not Reported

						otherwise specified)				
		Enbrel			S		50 Mg,Qw			Not Reported
		Myochrysine			S		25 Mg,Qw			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688918	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101017			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688919	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Azathioprine			S				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S				Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Q6w		Not Reported
	Pariet			C		20 Mg, Qd		Not Reported
	Folic Acid			C		5 Mg, Qd; 1 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689015	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689055	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226544		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness;	Leflunomide			S	Oral	20 Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr

Mobility Decreased; Nausea; Rheumatoid Arthritis	Risedronate Sodium	S	Oral			Teva
	Actemra	S	Subcutaneous			Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Apo-Leflunomide	S	Oral			Not Reported
	Arava	S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown			Not Reported
	Risedronate	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689154	EXPEDITED (15-DAY)		CA, DS, OT	FR-UCBSA-8027844			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal	Keppra			S		3000mg Daily		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Trileptal			S	Transplacental			Not Reported

Exposure During Pregnancy	Plaquenil		S	Transplacental	Not Reported
	Paracetamol		S	Transplacental	Not Reported
	Cortancyl		C	Transplacental	Not Reported
	Actonel		C	Transplacental	Not Reported
	Orocal D3		C	Transplacental	Not Reported
	Diffu-K		C	Transplacental	Not Reported
	Speciafoldine		C	Transplacental	Not Reported
	Kaleorid		C	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash; White Blood Cell Count Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689616	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Morphine Sulfate			S	Unknown			Actavis
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Remicade			S	Unknown				Not Reported
		Rituximab			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689640	EXPEDITED (15-DAY)		DE, HO, OT	SK-BAXTER-2020BAX007949		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Endoxan 1000 Mg Prasok Na Injekcny Roztok			S	Unknown	Unk		Baxter
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclosporine A			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689685	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226003		66 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Amoxixilina / Clavulanico (Amoxicillin\Clavulanic Acid)			S	Oral	875 Mg,1 Df		Teva
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not	600 Mg		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689693	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016133US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Azithromycine Sandoz [Azithromycin Monohydrate]			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101218			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S				Sanofi
	Bisoprolol Fumarate			S				Not Reported
	Cefixime			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Hydrochloride			S				Not Reported
	Nifedipine			S				Not Reported
	Pantoprazole			S				Not Reported
	Prednisone			S				Not Reported
	Clonazepam			S				Not Reported
	Zantac			S				Sanofi
	Zopiclone			S				Not Reported
	Azathioprine			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689717	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate		S	Unknown	200 Mg	Sanofi
	Leflunomide		S	Unknown	10 Mg, Qd	Sanofi
	Methotrexate		S	Unknown	15 Mg	Not Reported
	Etanercept		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Mg	Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Simponi		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid (2 Every 1 Day)		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S				Not Reported
	Penicillin G [Benzylpenicillin]			S				Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qm, Solution Subcutaneous		Not Reported
	Stelara			S		Unk, Q8w		Not Reported
	Stelara			S	Subcutaneous	Unk, Solution Subcutaneous		Not Reported
	Cetirizine			C		10 Mg, Bid		Not Reported
	Enbrel			C		50 Mg, Qw		Not Reported
	Lasix [Furosemide]			C		40 Mg, Qm		Not Reported
	Montelukast			C		10 Mg, Qd		Not Reported
	Synthroid			C		75 Mg, Qd		Not Reported
	Terbutaline Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689729	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi

Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam		S	Oral	7.5 Mg		Not Reported
	Methotrexate		S	Oral	20 Mg, Qw		Not Reported
	Actemra		S	Subcutaneous	1 Df, Qw		Not Reported
	Enbrel		S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira		S	Subcutaneous			Not Reported
	Sulfasalazine		C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689730	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689734	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101213		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported

Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Xeljanz	S	Unknown			Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Acetaminophen	C				Not Reported
	Anakinra	C	Unknown	100 Mg		Not Reported
	Ativan	C				Not Reported
	Codeine	C				Not Reported
	Darifenacine	C				Not Reported
	Desoximetasone	C				Not Reported
	Dilaudid	C				Not Reported
	Diphenhydramine	C				Not Reported
	Furosemide	C				Not Reported
	Hydromorphone	C				Not Reported
	Kadian	C				Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	40 Mg		Not Reported
	Loperamide	C				Not Reported
	Norflex [Orphenadrine Citrate]	C				Not Reported
	Omnaris	C				Not Reported
	Oxyneo	C				Not Reported
	Pantoprazole	C				Not Reported
	Restasis	C				Not Reported
	Rituximab	C	Intravenous (not otherwise specified)			Not Reported
	Synthroid	C				Not Reported
	Trimethoprim	C				Not Reported
	Urispas	C	Unknown	200 Mg		Not Reported
	Vagifem	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689790	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225158		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Leflunomide			S	Unknown			Barr

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Unknown	20 Mg, 1 Every 1 Week	Barr
	Actemra	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Mobicox	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C		80 Milligram Daily; Suspension Intraarticular	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17689979	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2609900-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Celebrex			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690106	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA102627		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690600	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-019705		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690705	EXPEDITED (15-DAY)		HO	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244413		35 YR	Male	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rash	Ciprofloxacin			S	Unknown	800 Milligram, Daily		Ranbaxy
	Doxycycline			S	Oral	Unk		Sun
	Hydroxychloroquine			S	Oral	600 Milligram, Daily		Sun
	Moxifloxacin			S	Oral	400 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17690772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226789		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate			S	Oral			Teva
	Risedronate			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	11607841	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20150923280		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Duodenal Ulcer Perforation; Exposure During Pregnancy;	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Zyrtec			S	Oral			Johnson And Johnson
	Zyrtec			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Dihydrochloride)			S	Oral			Johnson And Johnson
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fatigue; Gait Disturbance; General Physical Health Deterioration; Glossodynia; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infection; Infusion Related Reaction; Joint Range Of Motion Decreased; Joint Swelling; Knee Arthroplasty; Memory Impairment; Mobility Decreased; Muscular Weakness; Off Label Use; Pain; Pain In Extremity; Pemphigus; Pericarditis; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative Arthritis; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2 Diabetes Mellitus; Walking Aid User; Weight Decreased; Wound; Wound Infection	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therpay Duration 11 Monts	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravesical	Solution For Injection/Infusion	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported

Cortisone Acetate	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Desoximetasone	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Topicort (Hydrocortisone Acetate)	S	Cutaneous	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported

	Methotrexate Sodium	S	Oral	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Cosentyx	S		Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	12912114	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20160308952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Fatigue; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Amlodipine Besilate			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Unknown			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported

	Prednisone			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	12914315	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093127		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Gastric Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling;	Orencia			S	Intravenous (not otherwise specified)	760 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Tocilizumab			S	Unknown	360 Milligram, Q4wk		Not Reported
	Tocilizumab			S	Unknown	680 Milligram, Q4wk		Not Reported
	Tocilizumab			S	Unknown	360 Milligram, Qwk		Not Reported
	Tocilizumab			S	Unknown	360 Milligram		Not Reported
	Tocilizumab			S	Unknown	680 Milligram		Not Reported
	Tocilizumab			S	Unknown	380 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Rituximab			S	Unknown	1000 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	70 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported

Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	12.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q4wk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	380 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	360 Milligram, Qmo	Not Reported
	Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported

Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Unknown	10 Milligram	Not Reported
Myochrysine	S	Unknown	50 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Q4wk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Cyclosporin	C	Unknown	Unk	Not Reported
Cyclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Ibuprofen	S	Oral	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Etanercept	S	Unknown	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	13068783	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161203380			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Tremor	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Enbrel			S	Subcutaneous	Duration Is 9 Months		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical For -244.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Morphine /00036302/			S	Topical	1.0 Dosage Form		Not Reported
	Naprosyn /00256201/			S				Not Reported
	Zopiclone			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoprazole Magnesium			C	Oral			Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	13319448	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902949			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated	Rituxan			S	Intravenous (not			Not Reported

Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss			otherwise specified)			
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Powder For Suspension		Not Reported
	Desoximetasone	C	Oral			Not Reported
	Diclofenac	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Cortisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	13932857	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017314		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	25 Mg, Q.O.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Q.Wk.		Not Reported

Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk, 275 (Unspecified Unit)	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk, 365 (Unspecified Unit)	Not Reported
	Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Myochrysine	S	Unknown	50 Mg, Q.M.T.	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	14908110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP013244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased;	Meloxicam			S	Oral	7.5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Actemra			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported

Treatment Failure	Arava	S	Unknown	20 Mg, Q.Wk.		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/	S	Unknown			Not Reported
	Sulfasalazine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	14999486	EXPEDITED (15-DAY)		DE, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-175486		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Lorazepam			S	Unknown	Unk ()		Sun
	Montelukast			S	Unknown	Unk ()		Not Reported
	Celecoxib			S	Unknown	Unk ()		Not Reported
	Warfarin			S	Unknown	Regimen 1 ()		Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk ()		Not Reported
	Asa			S	Endocervical	Unk ()		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk ()		Not Reported
	Hydroxychloroquine			S	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15268901	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168136			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Clavulanate Potassium	C		Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15360741	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-TORRENT-00009759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Unknown
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Unknown
	Clexane			S	Transplacental	Exposure Duration: 0-14 Weeks		Unknown
	Dalteparin Sodium			S	Transplacental	Unknown		Unknown
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0-14		Unknown
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Unknown
	Heparin			S	Transplacental	Unknown		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Unknown
	Metamizole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Unknown
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6		Not Reported

			Gestational Week	
Prednisolone	S	Transplacental	From Gestational Week 0-14	Unknown
Ramipril	S	Transplacental	20 Mg Per Day, Exposure Duration: 0-113+6 Weeks / Maternal Dose 20 Mg, Unknown	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Unknown
Salbutamol	S	Transplacental	From Gestational Week 0-14	Unknown
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Unknown
Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Unknown
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15623907	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554647-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Amitriptyline	C		Not Reported
	Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15624422	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556711-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Warfarin			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15629635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557205-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; General Physical Health	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Deterioration; Knee Arthroplasty; Rheumatoid Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased	Enbrel	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15668157	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570296-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Erythromycin Estolate			S	Unknown			Not Reported
	Levofloxacin Hemihydrate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Metronidazole			S	Intravenous (not otherwise specified)	Dosage Form-Liquid Intravenous		Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Prednisone		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Erythromycin		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Levofloxacin		S	Unknown		Not Reported
	Bisoprolol Fumarate		S	Unknown		Not Reported
	Celecoxib		S	Oral		Not Reported
	Meperidine		S	Unknown		Not Reported
	Pregabalin		S	Unknown		Not Reported
	Cefaclor		S	Unknown		Not Reported
	Leflunomide Sandoz		S	Unknown		Not Reported
	Noritate		S	Unknown		Not Reported
	Plaquenil		S	Oral		Not Reported
	Act Diclo Miso		S	Unknown	Enteric Coated	Not Reported
	Diclofenac + Misoprostol Aurovitas		S	Unknown		Not Reported
	Methotrexate Sodium		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15676976	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573583-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Risedronate Sodium	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Plaquenil	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Actonel	S	Unknown			Not Reported
	Apo Risedronate	S	Unknown			Not Reported
	Apo Risedronate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Risedronate	S	Unknown			Not Reported
	Apo Risedronate	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine	C				Not Reported
	Hydroxychloroquine Sulfate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15713218	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2018GMK038625			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphopenia	Tacrolimus			S	Transplacental	Unk		Glenmark
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15801087	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617003-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leucovorin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown	2 Dosage Forms		Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16080823	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Celecoxib Capsules			S	Oral	Unk		Aurobindo

Celecoxib	S	Unknown	Unk	Aurobindo
Celecoxib	S			Aurobindo
Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	100 Milligram	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Celebrex	S	Oral	Unk	Not Reported
Celebrex	S			Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	1 Milliliter, Every Week	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16639635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2867070-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder;	Humira			S	Subcutaneous			Not Reported

Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Sulfasalazin		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Prednisone		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Etanercept		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16872434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2412613			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17157342	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Cimzia			S	Subcutaneous	Unk		Ucb

Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Cetirizine Hydrochloride	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Actemra	S			Not Reported
	Arava	S		Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Diclofenac Sodium	S			Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Fosamax	S		Unk	Not Reported
	Fosamax	S	Unknown		Not Reported
	Folic Acid	S			Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Humira	S	Subcutaneous	Solution	Ucb
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Methotrexate	S		Solution	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported

	Prednisone	S		Unk	Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Calcium /00060701/	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Quetiapine	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17531498	EXPEDITED (15-DAY)		DS, HO, OT	CA-GLAXOSMITHKLINE-CA2020044221		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Glaxosmithkline
	Diclofenac			S	Oral	2 Df, Qd		Glaxosmithkline
	Diclofenac			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Oral	Unk, Qd		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Oral	Unk		Glaxosmithkline

	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Voltaren Sr	S	Oral	2 Df, Qd (75 Mg)	Glaxosmithkline
	Voltaren Sr	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Cambia	S	Oral	Unk, Qd	Glaxosmithkline
	Cambia	S	Oral	Unk	Glaxosmithkline
	Cambia	S	Unknown	75 Mg, Bid	Glaxosmithkline
	Lisinopril	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)	Not Reported
	Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)	Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17685737	EXPEDITED (15-DAY)		DE	IE-JNJFOC-20200410813		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Mabthera			S				Not Reported
	Humira			S				Not Reported
	Protium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690794	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226002		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	200 Milligram Daily; 200 Mg/24h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; 600mg/24h		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690857	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032312		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Rituxan	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690973	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001159			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	9 Milligram, Qd		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Amoxicillin			S				Not Reported
	Co-Amoxiclav			S	Unknown	Unk		Not Reported
	Gentamycin			S	Unknown	Unk		Not Reported
	Tobramycin			S	Unknown	Unk		Not Reported
	Colomycin [Colistimethate Sodium]			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Tazobactam/Piperallin			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Cefradine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17690976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure;	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Vomiting	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691161	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101231			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		Unk		Sanofi

Product Effect Decreased	Leflunomide	S			Sanofi
	Leflunomide	S		20 Mg	Sanofi
	Methotrexate	S	Subcutaneous	7.5 Mg	Not Reported
	Methotrexate	S	Subcutaneous	7.5 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20.0 Mg	Not Reported
	Actemra	S			Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Diclofenac Sodium And Misoprostol	S		50 Mg, Bid	Not Reported
	Arthrotec	C		50 Mg, Bid	Not Reported
	Gold	C			Not Reported
	Imuran [Azathioprine]	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691162	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100870		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira			S	Subcutaneous	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Arava			C	Unknown	Unk			Not Reported
	Naproxen			C	Unknown	Unk			Not Reported
	Viread			C	Unknown	Unk			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691425	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225669		33 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Does 500 Mg		Not Reported
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Dose 250 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h, Unit Dose 2 Gm		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691428	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA104277		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Hepatitis Acute; Off Label Use; Thrombocytopenia	Hydroxychloroquine	S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine	S				Sanofi
	Hydroxychloroquine	S				Sanofi
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone	S				Not Reported
	Enoxaparin Sodium	S	Subcutaneous	40 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691526	EXPEDITED (15-DAY)		HO, LT	SI-ABBVIE-20K-261-3372991-00		48 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia; Thrombocytopenia	Kaletra			S	Oral	(80mg+20mg)/Ml Oral Solution, Dose 400mg/100 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Esmeron			C				Not Reported
	Metoclopramid			C				Not Reported
	Analgin			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691529	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003003107			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thyroid Cancer	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691630	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi

Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Celecoxib	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Sanofi
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Actemra	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Unknown			Not Reported
	Bifidobacterium Bifidum	C	Unknown			Not Reported
	Loperamide	C	Oral			Not Reported
	Pantoprazole	C	Unknown	Unk Unk, Tid		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691915	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692044	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101011		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Prednisone			S	Oral	20 Mg		Not Reported
	Myocrisin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not	8 Mg/Kg		Not Reported

Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure			otherwise specified)			
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous	50 Mg		Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Xeljanz	S	Unknown			Not Reported
	Xeljanz	S	Unknown	50 Mg, Bid		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Rituxan	S	Unknown	1 G, Bid		Not Reported
	Simponi	S	Unknown	50 Mg		Not Reported
	Apo Prednison	S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692427	EXPEDITED (15-DAY)		OT	CN-ADVANZ PHARMA-202004003310			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Coronavirus Infection; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692563	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004003424			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Off Label Use; Overdose; Pneumonia Bacterial; Septic Shock	Hydroxychloroquine			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd Film-Coated Tablet		Concordia

	Hydroxychloroquine	S	200 Mg, Qd Film-Coated Tablet	Concordia
	Hydroxychloroquine	S	400 Mg, Qd Film-Coated Tablet	Concordia
	Cefepim Amomed	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported
	Sufentanil	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported
	Atracurium Besilate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692890	NON-EXPEDITED			US-AMGEN-USASP2020063491		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Exposure To Product; Eye Disorder; Injection Site Pain; Pain; Sinusitis	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692900	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003924		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Quetiapine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Risperidone			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Losartan			C	Oral			Not Reported

Clindamycin Hydrochloride	C	Intravenous (not otherwise specified)		Not Reported
Lorazepam	C	Oral		Not Reported
Furosemide	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17692945	EXPEDITED (15-DAY)		OT	CN-ADVANZ PHARMA-202004003226			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Liver Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693787	EXPEDITED (15-DAY)		DE, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032939		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	500 Milligram	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Rituximab;Urelumab		C	Unknown		Not Reported
	Simponi		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693828	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre Filled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

	Sulfasalazine			S	Unknown	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17693966	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419466		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694029	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225643		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	1er Día 400 Mg/12 H, A Partir Del 2º Día 400mg/24 H		Teva
	Azitromicina (7019a)			S	Oral	500 Mg 1st Dose, Later 250mg / 24h		Not Reported
	Azitromicina (7019a)			S	Oral			Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; Single Dose		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17694856	EXPEDITED (15-DAY)		LT	FR-ELI_LILLY_AND_COMPANY-FR202004008033		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg, Daily		Eli Lilly And Co
	Plaquenil Sulfate			S	Oral	800 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695215	EXPEDITED (15-DAY)		DE	IT-AUROBINDO-AUR-APL-2020-019985		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695429	EXPEDITED (15-DAY)		HO	DE-BAXTER-2020BAX008027		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Epidermal Necrosis; Lip Disorder; Lip Disorder; Pigmentation Disorder; Skin Lesion; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis	Endoxan Lyophilisat			S	Unknown			Baxter
	Leflunomide			S	Unknown			Not Reported
	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisolone			S	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	12764963	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Aleve			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Prednisone Teva			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Oral	Unk		Not Reported

	Prednisone Acetate	S	Unknown	Unk		Not Reported
	Naproxen	C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram		Not Reported
	Folic Acid	C	Subcutaneous	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown	Unk		Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk		Not Reported
	Insulin	C	Unknown	Unk		Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid		Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13665971	EXPEDITED (15-DAY)		OT	TN-BAUSCH-BL-2017-019520		33 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13974821	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported

	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14235430	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2017AP021569		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Apo-Alendronate			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	500 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.I.W		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Ibuprofen			S	Oral	Unk		Apotex
	Ibuprofen			S	Oral	600 Mg, Unk		Apotex

Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Codeine	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	60 Mg, Bid	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Motrin	S	Oral	600 Mg, Qd	Not Reported
	Motrin	S	Oral	Unk Unk, Qd	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Two Every One Week	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Q.I.W	Not Reported

Methotrexate	S	Unknown	12 Mg, Q.I.W	Not Reported
Methotrexate	S	Unknown	10 Mg, Q.I.W	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.I.W	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Unknown	70 Mg, Q.Wk.	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	I1000 Mg, Q.12h	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	360 Mg, One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Mg, One Every Four Week	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Xeljanz	C	Unknown		Not Reported
Humira	C	Unknown	40 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported

	Methotrexate	C	Subcutaneous	10 Mg, Unk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate	C	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate	C	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	C	Unknown	12 Mg, Q.Wk.	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	C	Unknown	680 Mg, Unk	Not Reported
	Tocilizumab	C	Unknown	360 Mg, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Mogadon	C	Oral	5 Mg, Unk	Not Reported
	Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
	Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Uloric	C	Unknown	80 Mg, Unk	Not Reported
	Benadryl /00000402/	C	Unknown	Unk	Not Reported
	Colchicine	C	Oral	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Febuxostat	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14267213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032902		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Gold	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14497211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-027214			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14921412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044420		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	2.0 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	10.0 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	5.0 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Cyclosporine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	2 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Bid	Not Reported

Hydroxychloroquine Sulfate	S	Oral	10 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk		Not Reported
Apo-Hydroxyquine	S	Oral	Unk		Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk		Not Reported
Methotrexate Sodium	S	Oral	20 Milligram		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
Xeljanz	C	Oral	10 Milligram, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Qd		Not Reported
Xeljanz Xr	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16731204	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019152774		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Voltaren(Diclofenac)			S	Unknown	Unk		Glaxosmithkline
	Voltaren(Diclofenac)			S				Glaxosmithkline
	Voltaren(Diclofenac)			S				Glaxosmithkline
	Voltaren(Diclofenac)			S				Glaxosmithkline
	Vitamin C			S	Unknown	Unk		Glaxosmithkline
	Motrin			S	Unknown	Unk		Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Motrin			S				Glaxosmithkline
	Aspirin			S	Unknown	Unk		Glaxosmithkline
	Aspirin			S				Glaxosmithkline
	Aspirin			S				Glaxosmithkline
	Aspirin			S				Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Clopidogrel			S	Unknown	Unk		Glaxosmithkline
	Clopidogrel			S				Glaxosmithkline

Clopidogrel	S			Glaxosmithkline
Clopidogrel	S			Glaxosmithkline
Ibuprofen	S	Unknown	Unk	Glaxosmithkline
Sulfamethoxazole	S	Unknown	Unk	Glaxosmithkline
Arava	S	Oral	Unk	Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Asa	S	Unknown	325 Mg (Delayed Release)	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Apo-Diclofenac	S	Topical	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16743894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-056074			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Pregabalin 100 Mg Capsules, Hard			S	Unknown	1 Dosage Form, 3 Times A Day (1-1-1)		Not Reported
	Ramipril 2.5mg			S	Oral	1 Dosage Form, Two Times A Day		Aurobindo
	Sildenafil			S	Unknown	60 Milligram, Once A Day, Daily Dose		Aurobindo
	Eliquis			S	Unknown	1 Dosage Form, Two Times A Day (1-0-1)		Not Reported
	Eliquis			S	Unknown	2.5 Milligram, Two Times A Day		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Two Times A Day		Not Reported
	Quensyl			S	Unknown	40 Milligram, Once A Day, 1 Dosage Form, Two Times A Day (1-0-1)		Not Reported
	Quensyl			S	Unknown	2 Dosage Form, Once A Day (1 Df, Bid)		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form, Once A Day (15, Qd ((1-0-0))		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Volibris			S	Unknown	30 Milligram, Once A Day		Not Reported
	Volibris			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Volibris			S	Unknown	1 Dosage Form, Once A Day		Not Reported

	Lyrica		S	Unknown	100 Milligram, 3 Times A Day	Not Reported
	Eliquis		C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Omeprazole		C	Unknown	40 Milligram, Once A Day (20 Milligram, Bid)	Not Reported
	Quensyl		C	Unknown	40 Milligram, Once A Day (20 Mg Bid)	Not Reported
	Ramipril		C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Spasmolyt		C	Unknown	15 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16748699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2381845		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17004240	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103496		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aleve			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17035098	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136345		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition	Prednisone			S	Oral	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr

Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Leflunomide	S	Unknown			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone	S	Oral			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Rituxan	S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17040026	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3002083-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Solution Use Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Arava	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral		Not Reported
Topicort [Hydrocortisone Acetate]	S	Topical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Diclofenac	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Arava	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Atasol	C			Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17191010	EXPEDITED (15-DAY)		OT	NVSC2019CA076411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg Solution		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Prednisone			S	Oral	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Sulfasalazine			S	Subcutaneous	500 Mg			Not Reported
	Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17350586	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17554482	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022709		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb

Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Bristol Myers Squibb
	Orencia	S	Intravenous (not otherwise specified)	200 Milligram, Qmo	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Anakinra	S	Unknown	50 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported

Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Q2wk	Not Reported
Naproxen	S	Unknown		Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	50 Milligram, Bid	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

	Hydroxychloroquine Sulfate			S	Oral	5 Milligram, Qd				Not Reported
	Folic Acid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17566294	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200321035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17566419	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318563		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Contraindicated Product Administered; Drug	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported

Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Rheumatoid Arthritis	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Bimatoprost	C	Ophthalmic	Not Reported
	Nexium /01479302/	C	Unknown	Not Reported
	Suphedrine /00005601/	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported
	Tylenol /00020001/	C		Not Reported
	Valsartan	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Esomeprazole Sodium	C	Unknown	Not Reported
	Lumigan Rc	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17605662	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332777		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported

Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Glumetza	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Altace	C	Unknown	Not Reported
	Asa	C		Not Reported
	Codeine	C		Not Reported
	D-Alpha Tocopherol	C		Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17606950	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318841		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Subcutaneous			Janssen
	Remicade			S	Unknown			Janssen
	Infliximab, Recombinant			S	Unknown			Janssen
	Infliximab, Recombinant			S	Unknown			Janssen
	Adalimumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Azathioprine		C	Unknown	Not Reported
					Ciclosporin		C	Unknown	Not Reported
					Minocycline		C	Unknown	Not Reported
					Penicillamine		C	Unknown	Not Reported
					Prednisolone		C	Unknown	Not Reported
					Prednisone		C	Unknown	Not Reported
					Tocilizumab		C	Unknown	Not Reported
					Actemra		C	Unknown	Not Reported
					Phenylbutazone		C	Unknown	Not Reported
					Tofacitinib		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17655387	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3357377-00		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17666050	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3361715-00		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17667413	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000290			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Furosemide			S	Intravenous (not otherwise specified)	2 Df, Qd		Validus
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Perfalgan			C		Unk		Not Reported
	Noradrenalin /00127501/			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Tazocilline			C		Unk		Not Reported
	Transipeg /00754501/			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Nimbex /01302502/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17671057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, B.I.Wk.		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk (Cyclical)		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk Cyclical		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, T.I.W		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Q.O.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Actemra	S	Subcutaneous	162 Mg, B.I.Wk.		Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.O.Wk.		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Prednisone	C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17673259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009906		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Gabapentin	C	Oral	400 Mg, Tid			Not Reported
Tylenol Arthritis	C	Unknown	650 Mg, Qid			Not Reported
Xeljanz	C	Oral	5 Mg, Qd			Not Reported
Acetaminophen	C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17681180	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK101566			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Oligohydramnios; Premature Baby	Metoprolol Tartrate			S	Transplacental	Unk		Novartis
	Etamsylate			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Acetaminophen (Paracetamol)			S	Transplacental	Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Omeprazole			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Penicillin G Benzathine			S	Transplacental	Unk		Not Reported
	Cefotaxime			S	Transplacental	Unk		Not Reported
	Cefotaxime			S	Transplacental	Unk		Not Reported
	Hydrocortisone			S	Transplacental	Unk		Not Reported

					Vitamin K Nos	S	Transplacental	Unk	Not Reported
					Magnesium Lactate	S	Transplacental	Unk	Not Reported
					Bisulepin	S	Transplacental	Unk	Not Reported
					Nadroparine	S	Transplacental	Unk	Not Reported
					Privigen	S	Transplacental	Unk	Not Reported
					Privigen	S	Transplacental	Unk	Not Reported
					Flebogamma Dif	S	Transplacental	Unk	Not Reported
					Vitamin B Complex	S	Transplacental	Unk	Not Reported
					Albumin	S	Transplacental	Unk	Not Reported
					Ornidazole	S	Transplacental	Unk	Not Reported
					Cefixime	S	Transplacental	Unk	Not Reported
					Vulmizolin	S	Transplacental	Unk	Not Reported
					Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
					Vitamin D	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17695364	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020073		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17695454	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2752444-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Imuran	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Day 1 And Day 15 Every 6 Months	Not Reported
	Actemra	S	Unknown		Not Reported
	Lederle Leucovorin	S	Unknown		Not Reported
	Prevnar 13	S	Intramuscular		Not Reported
	Depo-Medrol With Lidocaine	S	Unknown	40-10 Mg/Ml	Not Reported
	Apo-Prednisone	S	Unknown	Taper Monthly	Not Reported
	Ketoprofen	S	Topical		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Leucovorin Calcium	S	Unknown		Not Reported
	Azathioprine Sodium	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586578		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Trihydrate;Clavulanate			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Potassium Azathioprine		S	Unknown		Not Reported
	Ciprofloxacin Hydrochloride		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696576	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1224670		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva
	Prednisone			S	Unknown	5 Milligram Daily; Daily		Actavis
	Acetaminophen			C	Unknown	Estimated 6g		Not Reported
	Metronidazole			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696653	EXPEDITED (15-DAY)		LT	CA-ROCHE-2585146		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Procytox			S	Intravenous (not otherwise specified)	Not Reported
	Procytox			S	Unknown	Not Reported
	Acetaminophen			C	Unknown	Not Reported
	Diphenhydramine			C	Oral	Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696778	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696796	EXPEDITED (15-DAY)		OT	AU-ROCHE-2586107			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Neuropathy Peripheral; Vision Blurred	Tocilizumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Lovan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696808	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3374580-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Dolquine			S	Oral			Not Reported
	Levofloxacino			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585673		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			S	Unknown			Not Reported

Erythematosus; Treatment Failure	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696968	EXPEDITED (15-DAY)		HO	CA-ROCHE-2585153		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17696992	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002838			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Hallucination, Visual; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697005	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003548			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697018	EXPEDITED (15-DAY)		OT	US-VELOXIS PHARMACEUTICALS-2018VELUS-000310			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphocytopenia Neonatal; Off Label Use; Premature Baby; Thymus Disorder	Envarsus Xr			S	Transplacental	Unk		Veloxis Pharmaceuticals
	Envarsus Xr			S				Veloxis Pharmaceuticals
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S				Not Reported
	Steroids			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697203	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Codeine			S	Unknown	Unk		Glaxosmithkline
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia (Certolizumab Pegol)			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697218	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.-2020ES02876			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Milligram, Qd (Per Day; 500 Mg/24h)		Cipla
	Dolquine			S	Oral	200 Milligram, Per Day (1 Comp/24h)		Not Reported
	Metronidazol [Metronidazole]			S	Oral	Unk		Not Reported

	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697219	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226965		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697469	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226211		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697552	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA101001		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	12 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		12.5mg, Qw		Not Reported
	Methotrexate			S		10 Mg, Qw		Not Reported

Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer; Unevaluable Event	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg Qw	Not Reported
	Methotrexate	S	Oral	10 Mg Qw	Not Reported
	Methotrexate	S		70.0 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		12.0 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qow	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Alendronate Sodium	S		70 Mg, Qw	Not Reported
	Leflunomide	S			Sanofi
	Leflunomide	S	Oral		Sanofi
	Sulfasalazine	S		500 Mg	Not Reported
	Codeine	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Qm	Not Reported
	Actemra	S		360 Mg	Not Reported
	Actemra	S		360 Mg	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported
	Actemra	S		2.68 Mg, Q4w	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Enbrel	S		25 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		780 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Q12h	Not Reported
	Ciclosporin	C			Not Reported
	Prednisone	C			Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697667	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226215		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697668	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226208		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab			S	Intravenous (not otherwise specified)					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033213		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697751	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226514		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug	Leflunomide			S	Oral	20 Milligram Daily;		Barr

Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide	S	Unknown			Barr
	Leflunomide	S	Oral			Barr
	Methotrexate	S	Unknown			Barr
	Methotrexate	S	Subcutaneous			Barr
	Methotrexate	S	Subcutaneous	12.5 Milligram Daily;		Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Anakinra	S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698407	EXPEDITED (15-DAY)		DE, OT	ES-FRESENIUS KABI-FK202003872		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unk		Fresenius Medical Care
	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral	400mg/24h		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698625	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Apo-Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Naproxen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17698783	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1226193		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Aleve		C	Unknown		Not Reported
					Arava		C	Unknown		Not Reported
					Prednisone		C	Unknown		Not Reported
					Simponi		C	Subcutaneous		Not Reported
					Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699111	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226577			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101058			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody	Arava			S		Unk		Sanofi
	Colchicine			S				Not Reported

Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Celecoxib	S				Not Reported
	Estradiol	S	Topical	Unk Unk, Qd		Not Reported
	Prednisone	S		50 Mg		Not Reported
	Meloxicam	S				Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil	S		2 Df, Qd		Sanofi
	Salbutamol Sulfate	S				Not Reported
	Sulfasalazine	S				Not Reported
	Belimumab	S				Not Reported
	Breo Ellipta	S	Respiratory (inhalation)			Not Reported
	Dexilant	S	Oral	60 Mg, Qd		Not Reported
	Rituximab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585119		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tridural		C	Unknown	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585610		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699673	NON-EXPEDITED			US-APPCO PHARMA LLC-2083078		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699692	EXPEDITED (15-DAY)		LT, OT	CH-PFIZER INC-2020161844		86 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Hypoglycaemia	Tazobac			S	Intravenous (not otherwise specified)	4.5 G, 3x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single (In Total)		Not Reported
	Cymbalta			C	Oral	60 Mg, 1x/Day		Not Reported
	Nexium Mups [Esomeprazole Magnesium]			C	Oral	20 Mg, 1x/Day		Not Reported
	Calciparine			C	Subcutaneous	5000 Iu, 2x/Day		Not Reported
	Lantus			C	Subcutaneous	20 Iu		Not Reported
	Lantus			C	Subcutaneous	10 Iu, 1x/Day		Not Reported
	Prednisone			C	Oral	10 Mg, 1x/Day		Not Reported
	Pregabalin			C	Oral	25 Mg, 2x/Day		Not Reported
	Torasemide			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586666		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Pregabalin	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699823	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226217		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Vioxx	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226721		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226582			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide		S	Unknown	10 Milligram Daily;	Barr
	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Arava		C	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]		C	Oral	400 Milligram Daily;	Not Reported
	Xeljanz		C	Oral		Not Reported
	Prednisone		C	Unknown		Not Reported
	Simponi		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226428		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Secretion Discharge; Spinal Stenosis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699865	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226602		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699945	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226474		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699946	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226195			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Abatacept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17699990	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428562		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17700384	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Narcan			S		Unk		Not Reported
	Cyclobenzaprine Hcl			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Wellbutrin Xl			S		Er 24h		Not Reported
	Wellbutrin Xl			S		Er 24h		Not Reported
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17700739	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020169		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Haemolytic Anaemia; Hepatitis; Hyperbilirubinaemia; Rectal Haemorrhage	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17702366	EXPEDITED (15-DAY)		LT	FR-JNJFOC-20200420365		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Risperidone			S	Oral			Janssen
	Plaquenil			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported
	Acebutolol			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Enoxaparine Sodique			C	Subcutaneous			Not Reported

			Macrogol 4000		C	Oral				Not Reported
			Amlodipine		C	Oral				Not Reported
			Clomipramine		C	Oral				Not Reported
			Zopiclone		C	Oral				Not Reported
			Nicardipine		C	Oral				Not Reported
			Hydrochlorothiazide		C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17702479	EXPEDITED (15-DAY)		OT	AU-ABBVIE-20K-008-3373197-00			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Humira			S	Subcutaneous			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sildenafil			S	Unknown			Not Reported
	Glyceryl Trinitrate			S	Unknown			Not Reported
	Prasugrel			S	Unknown			Not Reported
	Novorapid			S	Unknown			Not Reported
	Topiramate			S	Unknown			Not Reported
	Glucagen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reboxetine			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Ezetimibe			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Endone			S	Unknown			Not Reported

			Ivabradine		S	Unknown				Not Reported
			Mycophenolate Mofetil		S	Unknown				Not Reported
			Sulfasalazine		S	Unknown				Not Reported
			Prednisolone		S	Unknown				Not Reported
			Cholecalciferol		S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17702515	EXPEDITED (15-DAY)		LT	FR-BAUSCH-BL-2020-011521		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral			Not Reported
	Loxapine Base			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Theralene			S	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported
	Nicopatch			C	Transdermal	Transdermal Device Of 17.5 Mg / 10 Cm2		Not Reported
	Diazepam			C	Oral			Not Reported
	Atorvastatine			C	Oral			Not Reported
	Nicotine			C	Oral			Not Reported
	Macrogol 4000			C	Oral			Not Reported
	Nebivolol			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Ramipril			C	Oral			Not Reported
	Akineton			C	Oral			Not Reported
	Ezetimibe			C	Oral			Not Reported
	Kardegic			C	Oral	Sachet Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703331	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported

			Hydroxychloroquine Sulfate		S	Unknown	Unk			Not Reported
			Hydroxychloroquine Sulfate		S	Subcutaneous	Unk			Not Reported
			Methotrexate		S	Subcutaneous	Unk			Not Reported
			Methotrexate		S	Oral	Unk			Not Reported
			Remicade		S	Intravenous (not otherwise specified)	Unk			Not Reported
			Prednisone		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703341	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Pariet			C	Unknown	20 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17703445	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226725		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache;	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis; Tremor	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Zopiclone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17704032	DIRECT	Y	OT			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Hydroxychloroquine 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11433670	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Apo Hydroxyquine	S	Oral	400 Milligram	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Unk Prn	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Naproxen	S	Unknown	Unk Unk, Prn	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Cardio Aspirin	C	Unknown	81 Milligram	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Lantus	C	Subcutaneous	Unk	Not Reported
	Insulin [Insulin Human]	C	Unknown	Unk	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Calcium [Calcium Gluconate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk Prn	Not Reported
	Lozide [Gliclazide]	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid			Not Reported
	Vitamin D Nos	C	Unknown	Unk			Not Reported
	Calcium	C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11619820	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1477576-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Deformity; Hand Deformity; Hand Deformity; Hypertension; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Disorder; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical Frequency		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

					Plaquenil		S	Unknown		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Risedronate Sodium		S	Unknown		Not Reported
					Rituximab		S	Unknown		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Leflunomide		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11878759	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151223430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Muscular Weakness; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Simponi			S	Subcutaneous			Janssen
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclic(Every 2 Weeks) 40 Mg/0.8 Ml		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	12791907	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016449402		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		7.5 Mg, Every 10 Days		Pfizer
	Certolizumab Pegol			S		200 Mg, Every Other Week		Not Reported
	Certolizumab Pegol			S		Tapered To One Injection Every 21 Days		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13091523	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13109301	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-065623		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb

Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Enbrel	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Unknown	3 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 2 Every 1 Week	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported

Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Milligram	Not Reported
Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Unknown		Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	50 Milligram, Qwk	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Tocilizumab	S	Unknown		Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70.0 Gram	Not Reported
Gamastan	S	Intramuscular	70 Gram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Dosage Form	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported

	Naproxen Sodium	S	Unknown	Unk		Not Reported
	Etanercept	S	Subcutaneous	25 Milligram(2 Every 1 Week)		Not Reported
	Etanercept	S	Unknown	12.5 Milligram, Qwk		Not Reported
	Triamcinolone Hexacetonide	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13517171	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038205		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported

	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Adalimumab	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	25 Milligram		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13519755	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038176		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported

Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Mg, Unk	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	20 Milligram	Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Unknown	25 Milligram	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported

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FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Hydroxychloroquine Phosphate	S	Oral	400 Milligram, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	15 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Other	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown		Not Reported
Leflunomide	C	Oral	Unk	Not Reported
Lisinopril	C	Unknown		Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown		Not Reported
Diclofenac	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13667720	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951961		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13854282	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070658			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Q2wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Advil [Mefenamic Acid]	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Milligram, Qd	Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13856327	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070350		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Simponi		S	Subcutaneous		Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Unknown	Unk	Not Reported
	Methotrexate		S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate		S	Oral	25 Milligram	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
	Desoximetasone		S	Oral	Unk	Not Reported
	Cortisone Acetate		S	Unknown		Not Reported
	Diclofenac		S	Unknown	50 Milligram	Not Reported
	Folic Acid		S	Unknown	5 Milligram	Not Reported
	Fosamax		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone		S	Unknown		Not Reported
	Pseudoephedrine Hcl		S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Oral	Unk Unk, Bid	Not Reported
	Arava		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14757587	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009591			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex

Disorder; Rheumatoid Arthritis	Humira		S	Subcutaneous	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Desoximetasone		C	Unknown	Unk	Not Reported
	Plaquenil /00072602/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14778860	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14951428	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018213596		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity	Docetaxel			S		Unk, Cyclic 21-Day		Pfizer

			Cycles, 4 Cycles	
	Hydroxychloroquine	S	Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G	Not Reported
	Anastrozole	S	Unk Total Of 4 Months	Not Reported
	Cyclophosphamide	S	Unk, Cyclic 21-Day Cycles, 4 Cycles	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15032295	EXPEDITED (15-DAY)		OT	US-SA-2018SA149938		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S				Not Reported
	Hydroxychloroquine			S		Daily Dose: 7.01 Mg/Kg		Sanofi
	Cyclophosphamide			S		21-Day Cycles		Not Reported
	Docetaxel			S		21-Day Cycles		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15335557	EXPEDITED (15-DAY)		HO, LT, OT	MX-PFIZER INC-2018348261		67 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Bradycardia; Cardiac Failure Acute; Drug Interaction; Long Qt Syndrome; Presyncope; Sinus Bradycardia	Amiodarone Hcl			S	Oral	900 Mg, Daily (Every 24 Hours), Bolus Subsequent Dose		Pfizer
	Amiodarone Hcl			S	Unknown	200 Mg, 4x/Day		Pfizer
	Amiodarone Hcl			S	Intravenous (not otherwise specified)	300 Mg, Unk (Bolus)		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		200 Mg, Daily (Every 24 Hours)		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 4x/Day		Not Reported
	Furosemide			S	Unknown	20 Mg, 4x/Day		Not Reported
	Warfarin Sodium			S	Unknown	2.5 Mg, 4x/Day		Not Reported

	Digoxin	C	Unk		Not Reported
	Digoxin	C			Not Reported
	Digoxin	C			Not Reported
	Spironolactone	C	Unk		Not Reported
	Spironolactone	C			Not Reported
	Spironolactone	C			Not Reported
	Metoprolol	C	Unk		Not Reported
	Metoprolol	C			Not Reported
	Metoprolol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15411121	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185070		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Perindopril			S	Oral	Unk		Not Reported
	Perindopril			S	Unknown	Unk		Not Reported
	Repaglinide			S	Oral	()		Sun
	Plaquenil			S	Oral	200 Mg/Jour		Not Reported
	Cortancyl			S	Oral	10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15682732	EXPEDITED (15-DAY)		DS, LT, OT	PHHY2018CA168554		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort;	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported

Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Zyrtec-D	S	Unknown	10 Mg, Unk	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Dosage Form: Unspecified	Not Reported
	Topicort	S	Cutaneous	Unk	Not Reported
	Cirrus	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Fosamax	S	Oral		Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine	S			Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
	Apo-Prednisone	S	Oral		Not Reported

Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous	Dosage Form: Unspecified	Not Reported
Humira	S	Subcutaneous	40 Mg, 0.8ml	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Oral	1000 Mg, Bid	Not Reported
Sulfathalidine	S	Oral	500 Mg, Unk	Not Reported
Tofacitinib	S	Unknown	5 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, 2x/Day (Bid)	Not Reported
Paracetamol	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Mg	Not Reported
Reactine (Cetirizine Hydrochloride)	S			Not Reported
Stelara	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Mg	Not Reported
Sarilumab	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15843027	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20190118848		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not			Not Reported

Administered; Drug Ineffective; Foot Deformity; Foot Operation; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis			otherwise specified)	
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16001840	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1017013		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction;	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis

Adverse Reaction; Arthralgia; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Mobility Decreased; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac Potassium	S		Actavis
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Oral	Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Acetylsalicylic Acid	S		Not Reported
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S		Barr
	Methotrexate	S		Barr
	Naproxen	S	Unknown	Teva
	Naproxen	S		Teva
	Naproxen	S		Teva
	Naproxen	S		Teva
	Sulfamethoxazole And Trimethoprim	S	Unknown	Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Ibuprofen	S	Unknown	Actavis
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Aspirin	S	Oral	Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Gold Injections	S	Unknown	Not Reported
	Gold Injections	S		Not Reported
	Gold Injections	S		Not Reported

Gold Injections	S		Not Reported
Humira (Adalimumab)	S	Subcutaneous	Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Oral	Not Reported
Hydroxychloroquine Sulfate Tablets	S		Not Reported
Motrin	S	Unknown	Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Sodium Aurothiomalate Injection Bp	S	Parenteral	Not Reported
Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Vitamin C	S	Unknown	Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Voltaren	S	Unknown	Not Reported

		Acetylsalicylic Acid/Clopidogrel			S	Unknown				Not Reported
		Apo-Diclofenac			S	Unknown				Not Reported
		Apo-Sulfatrim			S	Unknown				Not Reported
		Tramadol Hydrochloride			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16047193	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020789		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Celebrex			S	Oral	200milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16397631	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL			Unknown	ITA

INDUSTRIES LTD-
2019R1-210010

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Infection Reactivation; Leishmaniasis; Sensation Of Foreign Body; Visceral Leishmaniasis; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk ()		Sun
	Hydroxychloroquine			S	Unknown	Unk ()		Sun
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16461090	EXPEDITED (15-DAY)		CA, DE, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-211015			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	20 Milligram, Daily		Sun
	Plaquenil 200 Mg, Comprime Enrobe			S	Transplacental	400 Milligram, Daily		Not Reported
	Diffu K, Gelule			S	Transplacental	1 Dosage Form, Daily		Not Reported
	Cortancyl 5 Mg, Comprime			S	Transplacental	1 Dosage Form, Daily		Not Reported
	Imurel			S	Transplacental	150 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16544910	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2019288608		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved	Methotrexate Sodium			S		Unk		Pfizer
	Methylprednisolone			S		Unk (High Dose)		Pfizer

Indication; West Nile Viral Infection	Rituximab	S	Unk		Pfizer
	Hydroxychloroquine	S	Unk		Not Reported
	Prednisone	S	6 Mg, Daily (Tapering Of The Dose)		Not Reported
	Mycophenolate Mofetil	S	Unk		Not Reported
	Trimethoprim Sulfamethoxazole	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16576751	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-034879		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acne; Appendicitis Perforated; Arthralgia; Asthenia; Bradycardia; Depressed Mood; Erythema; Fatigue; Gastrointestinal Disorder; Headache; Hypertension; Lethargy; Malaise; Nausea; Pain; Pain In Extremity; Peritonitis; Rash; Synovial Cyst	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Cipralex [Escitalopram]			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Colace			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17165875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis;	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	400 Milligram Daily;		Barr

Synovitis	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17188130	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000131			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinal Dystrophy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Cellcept			C		Unk		Not Reported
	Arotinolol Hydrochloride			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Takecab			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17200794	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019232735			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline

Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Folic Acid	S	Unknown	0.5 Milligram	Glaxosmithkline
	Paracetamol	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	400 Mg	Not Reported
	Cimzia	S			Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S			Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	400 Mg, We, 400 Milligram, Weekly (Qw)	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
	Simponi	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Subcutaneous	Solution	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Unknown	20 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Winpred	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Prednisone	S	Unknown	Unk	Not Reported

	Leflunomide	S	Oral	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
	Topicort Lp	S	Oral	Unk	Not Reported
	Diclofenac	C	Unknown	50 Milligram, Once Daily (Qd)	Glaxosmithkline
	Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Glaxosmithkline
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17215818	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952857US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased;	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Subcutaneous	Unk Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported

Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous	50 Mg	Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Mg, Q2weeks	Not Reported
	Hydroxychloroquine		S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine		S	Oral	20 Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	300 Mg	Not Reported
	Leflunomide		S	Oral	20 Mg, Qd	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Subcutaneous	17.5 Mg	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown	300 Mg, Qd	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17425099	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2020023487		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaemia; Dizziness; Haemolytic Uraemic Syndrome; Hypotension; Nausea; Product Dose Omission; Renal Injury; Urinary Tract Infection	Benlysta			S	Intravenous (not otherwise specified)	Unk Unk, We		Glaxosmithkline
	Cipro			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17543214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17605652	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332789		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use;	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration 2.0 Years		Janssen
	Actemra			S	Unknown			Not Reported

Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Vaginal		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Lyrica	S	Vaginal		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Simponi	S	Subcutaneous			Janssen
	Cimzia	S	Subcutaneous	Single Use		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown	5 Years		Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	7 Months		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623534	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340450		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Erythematosus; Underdose; Vomiting	Methotrexate			S	Oral				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Methotrexate			S	Subcutaneous				Not Reported
	Naproxen Sodium			S	Unknown				Not Reported
	Orencia			S	Subcutaneous				Not Reported
	Phthalylsulfathiazole			S	Unknown				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Oral				Not Reported
	Naprosyn /00256201/			C	Unknown				Not Reported
	Naprosyn /00256201/			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17641316	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17662286	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ADVANZ PHARMA-202003002885			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; General Physical Health Deterioration; Off Label Use; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17666360	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009894		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use;	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported

Product Use Issue; Rash; Rheumatoid Arthritis	Arava			S	Unknown	20 Mg, Qd	Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.	Not Reported
	Methotrexate			S	Oral	20 Mg, Unk	Not Reported
	Orencia			S	Unknown	Unk	Not Reported
	Simponi			S	Subcutaneous	Unk	Not Reported
	Simponi			S	Unknown	Unk	Not Reported
	Sulfasalazine			S	Unknown	300 Mg, Qd	Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid	Not Reported
	Magnesium			C	Unknown	Unk	Not Reported
	Methotrexate			C	Unknown	Unk	Not Reported
	Calcium			C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701011	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244837		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin			S	Unknown	Unk		Ranbaxy
	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Milligram, Daily		Not Reported
	Lopinavir+Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Milligram, Daily		Not Reported
	Prednisona (886a)			C	Oral	20 Milligram, Daily		Not Reported
	Ceftriaxona (501a)			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701054	EXPEDITED (15-DAY)		CA, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244979			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol		Y	S	Transplacental	Unk ()		Ohm Lab
	Keppra			S	Transplacental	Unk ()		Not Reported
	Trileptal			S	Transplacental	Unk ()		Not Reported
	Plaquenil			S	Transplacental	Unk ()		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk ()		Not Reported
	Cortancyl			C	Transplacental	Unk ()		Not Reported
	Diffu-K			C	Transplacental	Unk ()		Not Reported
	Actonel			C	Transplacental	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701285	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244571		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701299	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244572		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701322	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-019746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701422	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020069		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Once A Day		Aurobindo
	Effexor			S	Oral	150 Milligram, Daily		Not Reported
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported
	Acebutolol			C	Oral	400 Milligram, Once A Day		Not Reported
	Amlodipine			C	Oral	10 Milligram, Once A Day		Not Reported
	Clomipramine Hydrochloride			C	Oral	150 Milligram, 1 Month		Not Reported
	Enoxaparin			C	Subcutaneous	4000 International Unit, Daily		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligram, Once A Day		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form, Daily		Not Reported
	Nicardipine Hydrochloride			C	Oral	60 Milligram, Daily		Not Reported
	Oxazepam			C	Oral	100 Milligram, Once A Day		Not Reported
	Zopiclone			C	Oral	7.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17701432	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020070		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Once A Day		Aurobindo
	Loxapine			S	Oral	155 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Theralene			S	Oral	50 Milligram, Once A Day		Not Reported
	Akineton			C	Oral	4 Milligram		Not Reported
	Atorvastatine			C	Oral	40 Milligram, Once A Day		Not Reported
	Diazepam			C	Oral	10 Milligram, Once A Day		Not Reported
	Ezetimibe			C	Oral	10 Milligram, Once A Day		Not Reported
	Kardegic			C	Oral	75 Milligram, Once A Day		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	7.5 Milligram, Once A Day		Not Reported
	Nicopatch			C	Transdermal	7 Milligram, Once A Day		Not Reported
	Nicotine			C	Oral	12 Milligram, Once A Day		Not Reported
	Paracetamol			C	Oral	1 Gram, Once A Day		Not Reported
	Ramipril			C	Oral	1.25 Milligram, Once A Day		Not Reported
	Zopiclone			C	Oral	7.5 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702414	EXPEDITED (15-DAY)		HO, LT, OT	ES-SA-2020SA105860		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Thrombocytopenia	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi

		Metamizole Salt Not Specified			S	Intravenous (not otherwise specified)	2 G, Q8h			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702747	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine			S	Oral	1 Gram, Bid				Not Reported
	Tofacitinib Citrate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702855	EXPEDITED (15-DAY)			CA-SA-2020SA102454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pregnancy	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	, 20-12.5 Mg;Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17702988	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226290		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Milligram Daily; Route Of Administration: Sng		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703170	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2020-01206			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ear Infection; Respiratory Tract Infection; Secondary Immunodeficiency; Urinary Tract Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Mycophenolate Mofetil			S				Alkem
	Azathioprine			S	Unknown	Unk		Alkem

				Azathioprine		S				Alkem
				Hydroxychloroquine		S		Unk		Not Reported
				Rituximab		S	Unknown	Unk		Not Reported
				Rituximab		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703204	EXPEDITED (15-DAY)		OT	DE-HIKMA PHARMACEUTICALS USA INC.-DE-H14001-20-511		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone			S	Unknown			Hikma
	Ceftriaxone Sodium			S	Unknown			Not Reported
	Streptomycin			S	Unknown			Not Reported
	Prednisone			S	Unknown	()		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cotrimoxazole			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Acyclovir			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703265	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226288		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Drug Interaction;	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva

Tachyarrhythmia	Azitromicina (7019a)	S	Oral	500 Mg		Not Reported
	Tocilizumab (8289a)	C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona (501a)	C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703315	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003552			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sjogren'S Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703318	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202004002571			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Pneumonia; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703402	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020221		75 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Paracetamol			S	Oral	4 Gram, Once A Day		Aurobindo
	Nefopam Hydrochloride			S	Oral	80 Milligram, Once A Day		Not Reported
	Augmentin			S	Intravenous (not otherwise specified)	3 Gram, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported
	Amlor			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Colchimax (Colchicine/Papaver Somniferum Powder/Tiemonium			S	Oral	1 Dosage Form, Once A Day		Not Reported

	Methylsulphate) Arimidex	S	Oral	1 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703409	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020223		66 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Aurobindo
	Plaquenil			S	Oral			Not Reported
	Zithromac			S	Oral	500 Milligram, Once A Day		Not Reported
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703414	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020196		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Amoxicillin+Clavulanic Acid			S	Oral	1 Comp/8h		Aurobindo
	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Metronidazole			S	Oral	Unk		Aurobindo
	Dolquine			S	Oral	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703479	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3376441-00		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax Avium			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703559	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003551			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Hypertension; Multiple Organ Dysfunction Syndrome; Off Label Use; Paralysis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703593	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003545			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neoplasm Malignant; Papilloma Viral Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703666	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226209		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Quetiapina (1136a)			S	Oral	25 Mg		Teva
	Levofloxacino (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Risperidona (7201a)			S	Oral	1 Mg		Actavis
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Losartan (7157a)			C	Oral	50 Mg		Not Reported
	Clindamicina Hidrocloruro (616ch)			C	Intravenous (not otherwise specified)	600 Mg		Not Reported

	Lorazepam (1864a)			C	Oral	1 Mg				Not Reported
	Furosemida (1615a)			C	Oral	40 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703680	EXPEDITED (15-DAY)		OT	FI-ADVANZ PHARMA-E2B_00008842			Unknown	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lymphopenia; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703729	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003540			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chemotherapy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703911	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003504			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Disease Progression; Lymphopenia	Hydroxychloroquine			S	Oral	200 Mg, (Film Coated Tablet)		Concordia
	Repaglinide			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Glimepiride			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Perindopril			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Levocetirizine			C		Unk		Not Reported

	Finasteride			C		Unk			Not Reported
	Pregabaline			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704031	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection	Hydroxychloroquine 400 Mg			S	Oral			Not Reported
	Hydroxychloroquine 200 Mg			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704205	EXPEDITED (15-DAY)		HO, OT	LT-ADVANZ PHARMA-GSH201609-004911			Unknown	LTU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Body Temperature Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Enzyme Increased; Inflammatory Marker Increased; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704214	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003538			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Arava			S	Unknown	10 Mg		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported

Methotrexate	C	Unk	Not Reported
Sulfasalazine	C	Unk	Not Reported
Xeljanz Xr	C	Unk	Not Reported
Xeljanz	C	Unk	Not Reported
Pregabalin	C	Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C	Unk	Not Reported
Salazopyrin	C	Unk	Not Reported
Codeine	C	Unk	Not Reported
Prednlsone	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Cortisone	C	Unk	Not Reported
Dexilant	C	Unk	Not Reported
Vitamin D [Vitamin D Nos]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704217	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003541			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	1000 Mg, Bid		Concordia
	Orencia			S	Unknown	Unk		Not Reported
	Losec			C				Not Reported
	Clopidogrel			C		Unk		Not Reported
	Rosuvastatin			C				Not Reported
	Perindopril			C				Not Reported
	Nitrospray			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported
	Amlodipine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704377	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-01788		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Ototoxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	5 Milligram, Qd (Gradually Tappered)		Not Reported
	Prednisolone			C	Unknown	10 Milligram, Qd (Dose Increased)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705027	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004003546			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury; Off Label Use; Transaminases Increased	Hydroxychloroquine			S	Oral	Dose: 400 Unk		Concordia
	Paracetamol			C		Unk		Not Reported
	Rocephine			C		Unk		Not Reported
	Spiramycine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705063	NON-EXPEDITED			US-PFIZER INC-2020159965		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Sulfasalazine			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Meloxicam			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705271	EXPEDITED (15-DAY)		DE	ES-JNJFOC-20200419053		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Risperdal			S	Oral			Janssen
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Quetiapine			S	Oral			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Kaletra			S	Oral	200/50 Mg		Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida /00032601/			C	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705322	DIRECT		DE, HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Dysfunction; Cardio-Respiratory Arrest; Fall; Hallucination, Visual; Pulmonary Hypertension	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Triamcinolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705423	EXPEDITED (15-DAY)		HO, LT, OT	FR-ADVANZ PHARMA-202004003544			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd Film-Coated Tablet		Concordia

Metoclopramide Hydrochloride	C	Unk	Not Reported
Ciprofloxacine	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Piperacilline/Tazobactam	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705467	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100979		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution Subcutaneous		Not Reported
	Orencia			S	Subcutaneous	750 Mg		Not Reported
	Rituximab			S	Intravenous drip	2000 Mg		Not Reported
	Xeljanz			S				Not Reported
	Xeljanz			S	Oral	50 Mg, Bid (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705685	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2020162444		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Sudden Death	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705686	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162461		71 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported
	Primperan			S	Intravenous drip	30 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705727	EXPEDITED (15-DAY)		HO	CA-SAOL THERAPEUTICS-2020SAO00108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Rho D Immune Globulin			S				Saol Therapeutics
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, 1x/Month		Not Reported
	Arava			S		20 Mg		Not Reported
	Benzalkonium Chloride			S				Not Reported
	Benzalkonium Chloride/ Diphenhydramine Hydrochloride/ Phenylephrine Hy			S				Not Reported
	Boric Acid			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Disodium Edetate			S				Not Reported
	Enbrel			S	Subcutaneous	40 Mg, 1x/Week		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Methotrexate			S	Oral	15 Mg, 1x/Week		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

							otherwise specified)			
					Phenylephrine Hydrochloride	S				Not Reported
					Rituximab	S				Not Reported
					Simponi	S				Not Reported
					Sodium Borate	S				Not Reported
					Sulfasalazine	S	Oral			Not Reported
					Tofacitinib Citrate	S		10 Mg, 2x/Week		Not Reported
					Tofacitinib Citrate	S		5 Mg, 2x/Week		Not Reported
					Tofacitinib Citrate	S	Subcutaneous	5 Mg, 2x/Week		Not Reported
					Celebrex	C	Oral	400 Mg		Not Reported
					Ibuprofen	C	Oral	400 Mg		Not Reported
					Lipitor	C	Oral	10 Mg, 1x/Day		Not Reported
					Prednisone	C				Not Reported
					Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705848	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3376750-00		73 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Ageusia; Anosmia; Condition Aggravated; Nausea; Off Label Use; Oxygen Saturation; Productive Cough; Pyrexia	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Heparin			C		Prophylactic Dose		Not Reported
	Tocilizumab			C				Not Reported
	Methylprednisolone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705929	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1226300		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycine Anhydre			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

	Lovenox	C	Oral		Not Reported
	Paracetamol	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17705944	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226289		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1 Gram Every 8 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706122	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032305			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported

	Cimzia	S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate	S	Unknown	Unk		Not Reported
	Cortisone Acetate	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Folic Acid	S	Unknown	5 Milligram		Not Reported
	Fosamax	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706132	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706318	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162376			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Off Label Use; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706431	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226597		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tofacitinib Citrate		S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Aspirin [Acetylsalicylic Acid]		C	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		C	Subcutaneous		Not Reported
	Cymbalta		C	Unknown		Not Reported
	Hydromorphone		C	Unknown		Not Reported
	Remicade		C	Intravenous (not otherwise specified)		Not Reported
	Synthroid		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706435	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226417		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706545	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

	Folic Acid			C	Unknown					Not Reported
	Methotrexate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706575	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226588		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Oral			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown	100 Milligram Daily;		Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

						otherwise specified)			
		Rituximab			S	Intravenous (not otherwise specified)			Not Reported
		Simponi			S	Subcutaneous			Not Reported
		Vitamin D3			C				Not Reported
		Imuran [Azathioprine]			C				Not Reported
		Gold			C				Not Reported
		Arthrotec			C	Unknown	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226586		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706588	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226758		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706589	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1226786			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Off Label Use; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706590	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226708		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706609	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226204		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226631			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706659	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226499			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered	Leflunomide			S	Unknown			Barr

	Methotrexate			S	Unknown	Barr
	Prednisone			S	Unknown	Actavis
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Simponi			S	Subcutaneous	Not Reported
	Arava			S	Unknown	Not Reported
	Hydroxychloroquine			S	Unknown	Not Reported
	Actemra			S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226489			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole			C	Oral	40 Milligram Daily;		Not Reported

	Tenofovir Disoproxil		C	Unknown			Not Reported
	Tenofovir Disoproxil		C	Unknown			Not Reported
	Xeljanz		C	Unknown			Not Reported
	Zopiclone		C	Unknown	7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706692	EXPEDITED (15-DAY)		OT	NVSC2020DE069507		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Ramipril			S	Oral	Unk		Not Reported
	Amlodipine			S	Unknown	Unk		Novartis
	Esomeprazole			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Boswellia Serrata Extract			S	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706698	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226415		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

							otherwise specified)			
			Rituximab		S		Intravenous (not otherwise specified)			Not Reported
			Aspirin [Acetylsalicylic Acid]		C					Not Reported
			Folic Acid		C					Not Reported
			Methotrexate		C		Unknown			Not Reported
			Prednisone		C		Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706704	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226800		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706706	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226401			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug	Leflunomide			S	Unknown			Barr

Ineffective; Joint Swelling; Liver Injury	Methotrexate		S	Unknown			Barr
	Hydroxychloroquine Sulfate		S	Unknown			Not Reported
	Kevzara		S	Unknown			Not Reported
	Prednisone		C	Unknown			Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706708	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226422			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706711	EXPEDITED (15-DAY)		DE, LT	NVSC2020CA108434		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituximab	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Mg	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Leflunomida	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Kineret	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706712	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226575		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	20 Milligram Daily;		Not Reported
	Orencia			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706716	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226485		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706719	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C				Not Reported

	Tylenol W/Codeine No.3			C						Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706723	EXPEDITED (15-DAY)		LT	NVSC2020CA108426		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Oxycodone			S	Unknown	10.0 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Hidroxicloroquina			S				Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
Orencia	S				Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Rituximab	S				Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sodium Aurothiomalate	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Xeljanz	S	Oral	Unk (2 Every 1 Days)		Not Reported
Kineret	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706744	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226225			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706821	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226617		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	20 Mg, 4 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226496		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tylenol	S	Unknown			Not Reported
	Hydromorphone Hydrochloride	C				Not Reported
	Meloxicam	C	Unknown			Not Reported
	Methotrexate	C	Unknown			Not Reported
	Synthroid	C				Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706884	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226629		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

	Sulfasalazine			S	Oral	1 Gram Daily;				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706888	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226486		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Aspirin[Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706960	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

					Actemra	S	Unknown		Not Reported
					Humira	S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate	S	Unknown		Not Reported
					Rituximab	S	Unknown		Not Reported
					Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227023			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706969	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis	Enbrel			S	Subcutaneous		Not Reported
	Humira			S	Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown		Not Reported
	Orencia			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706970	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226578		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Nodule; Skin Necrosis; Skin Ulcer	Infliximab	S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine	S	Intramuscular			Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous drip	2000 Milligram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ciclosporin	C				Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707004	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226718		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronic Acid			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Myochrysine		S	Intramuscular		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous drip	2000 Milligram Daily;	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Ciclosporin		C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707742	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226778		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported
	Folic Acid			C	Unknown				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown				Not Reported
	Naproxen			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707753	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1225340			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Rheumatoid Arthritis	Cyclobenzaprine Hcl 5 Mg Tablet			S	Unknown			Actavis
	Xeljanz			S	Oral	10 Milligram Daily; 60/Btl		Not Reported
	Narcan 4 Mg Spray			S	Unknown	Spray		Not Reported
	Plaquenil 200 Mg Tablet			S	Unknown			Not Reported
	Hydrochlorothiazide 25 Mg Tablets			S	Unknown			Not Reported
	Wellbutrin Xl Tab Er			S	Unknown	150 Milligram Daily; Er		Not Reported
	Wellbutrin Xl Tab Er			S	Unknown	300 Milligram Daily; Er		Not Reported
	Prednisone 10 Mg Tablet			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707828	EXPEDITED (15-DAY)		HO	ES-009507513-2004ESP006461		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Ertapenem Sodium			S	Intravenous (not otherwise specified)	1 G Day		Merck
	Piperacillin Sodium (+) Tazobactam Sodium			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Azithromycin			S	Oral	500 Mg Per Day		Not Reported

	Dolquine			S	Oral	400 Mg Per Day				Not Reported
	Dolquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707836	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707886	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226781		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17710887	DIRECT		DE			50 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myocardial Infarction	Hydroxychloroquine	Y		S				Not Reported
	Biotin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	14994173	EXPEDITED (15-DAY)		OT	US-ACCORD-067914		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Retinal Toxicity; Visual Field Defect	Anastrozole			S				Accord
	Docetaxel			S		Four 21-Day Cycles		Not Reported
	Hydroxychloroquine			S		Hcq Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S		21-Day Cycles		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	15611218	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-091251		15 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Drug Intolerance; Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Nausea; Pneumonia; Proteinuria; Pyrexia; Respiratory Symptom	Mycophenolic Acid			S				Accord
	Tacrolimus			S				Accord
	Hydroxychloroquine			S				Not Reported
	Rituximab			C				Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			C		Pulse		Not Reported
	Methylprednisolone			C				Not Reported
	Amphotericin B/Amphotericin B/Liposome			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	16739695	EXPEDITED (15-DAY)		OT	DE-ACCORD-152822			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df Bid (1-0-1), 2x/Day		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1-1-1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown			Not Reported
	Ambrisentan			S				Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg Bid		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1-0-1), 5 Mg Per Day, 2.5 Mg Bid,		Not Reported
	Roactemra			S		162 Mg, Qw		Not Reported
	Spasmolyt			S		15 Mg, Qd (1-0-0),Also Received 30 Mg (0 -0 -1)		Not Reported
	Omeprazole			S	Oral	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg, Bid		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Spasmolyt			S		30 Mg (0 -0 -1)		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Ramipril			S	Unknown			Accord
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Volibris			S	Oral			Not Reported
	Trospium Chloride			S		30 Mg (0 -0 -1)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17678870	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002849			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Respiratory Distress Syndrome; Coma; Condition Aggravated; Off Label Use	Hydroxychloroquine	S	Oral	200 Mg, Qd, Film Coated Tablet	Concordia
	Hydroxychloroquine	S	Oral	Unk	Concordia
	Midazolam	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Morphine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17678874	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004002607			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia Bacterial; Renal Failure; Shock Haemorrhagic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Heparine			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17707942	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004003750			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17707946	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004003809			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

	Azithromycin			S	Unknown	Unk				Not Reported
	Azithromycin			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17707959	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004004072			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17707971	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003553			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Eye Disorder; Off Label Use; Product Dose Omission	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708013	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-GSH201610-005089			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Dilatation Atrial	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Methotrexate			S	Unknown	7.5 Mg Every 10 Days		Not Reported
	Methotrexate			S		Reduction In The Dose Of Methotrexate 7.5 Mg Every 10 Days		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg Every Other Week		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg Every Other Week		Not Reported
	Bromazepam			C				Not Reported
	Bromazepam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708019	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-MAPI_00011385			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Function Test Abnormal; Cardiotoxicity; Ejection Fraction Decreased; Product Use In Unapproved Indication; Sinus Tachycardia; Tachycardia; Ventricular Hypokinesia	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Doxycycline			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708183	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004004057			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708184	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202004003665			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Apr-2020	17708221	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002358			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Off Label Use; Pneumonia; Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	At 800mg Loading Dose (400 Mg, Bid (Fiim-Coated Tablet)		Concordia

	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	400 Mg, Qd		Concordia
	Enoxaparin	C		Unk		Not Reported
	Enoxaparin	C				Not Reported
	Paracetamol	C		Unk		Not Reported
	Etomidate	C		Unk		Not Reported
	Celocurine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17574299	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201806-002062			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	7.01 Mg/Kg, Qd (Total Cumulative Dose 402 G)		Concordia
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708342	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA108440			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported

Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Mg	Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708442	EXPEDITED (15-DAY)		OT	NVSC2020CA111350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Hypothyroidism; Obesity; Osteoarthritis; Osteopenia; Synovitis; Therapeutic Product Effect Incomplete	Cosentyx			S	Unknown	Unk Unk, Unknown		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Stelera			S	Unknown	Unk, 1 Every 8 Weeks		Not Reported
	Stelera			S	Subcutaneous	Unk		Not Reported
	Cetirizine			C	Unknown	10 Mg, Bid		Not Reported
	Enbrel			C	Unknown	50 Mg, Qw		Not Reported
	Lasix			C	Unknown	40 Mg, Qmo		Not Reported
	Montelukast			C	Unknown	10 Mg, Qd		Not Reported
	Synthroid			C	Unknown	75 Mg, Qd		Not Reported
	Terbutaline Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17708667	EXPEDITED (15-DAY)		OT	NVSC2020CH106927		33 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Leukopenia; Product Use In Unapproved Indication; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Methotrexate			S	Unknown	Unk Ukn		Not Reported
	Azathioprine			S	Unknown	Unk Ukn		Not Reported

	Hydroxychloroquine	S	Unknown	Unk Ukn		Not Reported
	Infliximab	S	Unknown	Unk Ukn		Not Reported
	Prednisone	S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17709300	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2020-020616			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17711723	DIRECT					28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia	Hydroxychloroquine	Y		S	Oral			Not Reported
	Propranolol			C				Not Reported
	Valium			C				Not Reported
	Prilosec			C				Not Reported
	Pristiq			C				Not Reported
	Norethidrone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	12974330	EXPEDITED (15-DAY)		OT	CA-ROCHE-1858733			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Increased; Synovitis	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate Sodium		S	Oral	Not Reported
	Methotrexate Sodium		S	Oral	Not Reported
	Myochrysine		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	13058853	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015743		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Calcium Carbonate	C	Unknown	Unk		Not Reported
	Elavil /00002202/	C	Unknown	Unk		Not Reported
	Hydrochlorothiazide	C	Unknown	Unk		Not Reported
	Imitrex /01044801/	C	Unknown	Unk		Not Reported
	Lyrica	C	Unknown	Unk		Not Reported
	Premarin	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Cymbalta	C	Unknown	Unk		Not Reported
	Tenormin	C	Unknown	Unk		Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Sumatriptan Succinate	C	Unknown	Unk		Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
	Amitriptyline	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	13059040	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015749		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm;	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Sulfasalazin			S	Unknown	2 G, Unk		Not Reported
	Sulfasalazin			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazin			S	Unknown	500 Mg, Unk		Not Reported

Toxicity To Various Agents	Arava			S	Unknown	Unk			Not Reported
	Arava			S					Not Reported
	Celebrex			S	Unknown	Unk			Not Reported
	Celebrex			S					Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.			Not Reported
	Enbrel			S	Unknown	50 Mg, Unk			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk			Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg, Unk			Not Reported
	Orencia			S	Subcutaneous	250 Mg, Unk			Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	13188059	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2017GMK026159			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye;	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Gabapentin			S	Unknown	100 Mg, Bid		Glenmark
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (Solution Subcutaneous)		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qw		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl Citrate			S	Epidural	Unk		Not Reported

Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Od	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Od, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Od, 1 Every 1 Day	Not Reported
	Arava	S	Oral	20 Mg, Od	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Mg, Od 1 Every 1 Day	Not Reported
	Apo Gabapentin	S	Oral	100 Mg, Bid (2 Every 1 Day)	Not Reported
	Apo Gabapentin	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Oral	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram, 1 Every 1 Hour	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Once Every 3 Weeks (Solution Intramuscular)	Not Reported
	Myochrysine	S	Intramuscular	Unk(Solution Intramuscular)	Not Reported

Myochrysine	S	Intramuscular	Unk(Solution Intramuscular); Once Every 3 Weeks	Not Reported
Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Weeks	Not Reported
Orencia	S	Subcutaneous	Unk, Qw, 1 Every 1 Week	Not Reported
Orencia	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Week	Not Reported
Orencia	S	Vaginal	750 Milligram, 1 Every 1 Month	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od, 1 Every 1 Day	Not Reported
Sulfasalazine	S	Oral	2.5 Gram, Od	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	468 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk, Od	Not Reported

D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hour	Not Reported
Esomeprazole /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole /01479302/	C	Unknown	400 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Od	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Df, Bid (Spray, Metered Dose)	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Cyclical	Not Reported
Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, 1 Every 1 Hour	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks (Intravenous Solution)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk (1 Every 2 Weeks)	Not Reported
Actonel	C	Unknown	36 Mg, Qw	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk, Od	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D /00107901/	C	Unknown	400 Df, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	Unk	Not Reported
Multivitamin /00097801/	C	Unknown	Unk	Not Reported
Omega 3 /01333901/	C	Unknown	1200 Mg, Bid	Not Reported

Omega 3 /01333901/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Biotin W/Calcium Pantothenate/Colec/06004901/	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	1 Df, Qd (1 Every 1 Day)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	1200 Mg, Bid	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk, Od	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclical	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk, Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Gigabecquerel, 1 Evrey 1 Hour	Not Reported
Pantoprazole	C	Unknown	400 Mg, Od	Not Reported
Pantoprazole	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported

Perfenazine	C	Unknown	40 Mg, Od, 1 Every 1 Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk, Od, 1 Every 1 Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Od	Not Reported
Fergon	C	Unknown	300 Mg, Od	Not Reported
Nortriptyline	C	Urethral	Unk	Not Reported
Vitamin E /00110501/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Omega-3 /01866101/	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	2.5 Milligram, Od	Not Reported
Actonel	C	Unknown	36 Mg, 1 Every 1 Week	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported

Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Diphenoxylate	C	Unknown	2.5 Mg, Od	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Ophthalmic	Unk	Not Reported
Oxycodone Hydrochloride W/Oxycodone Terephtha	C	Unknown	1 Df, Unk	Not Reported
Percocet /00867901/	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
Vitamin B12 Aaa	C	Unknown	Unk	Not Reported
Acetaminophen	C	Oral	1000 Mg, Od (1 Every 24 Hours)	Not Reported
Acetaminophen W/Oxycodone	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Unknown	480 Milligram, 1 Every 1 Month	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, 1 Every 1 Week (Qw)	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulf	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	13254993	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006561		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Bone Cyst; Crohn'S	Fentanyl			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)	488 Mg,Once Every Four Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.	Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.I.W	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Q.I.W	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Orencia	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Unk	Not Reported
	Gabapentin	C	Oral	100 Mg, Bid	Not Reported
	Genteal /00445101/	C	Unknown		Not Reported
	Lomotil /00034001/	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	Unk, Bid	Not Reported
	Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Q.H.	Not Reported
	Omega 3 /01334101/	C	Unknown	1200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Q.H.	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Unk	Not Reported

Vitamin D /00107901/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15208961	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1835963US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Raynaud'S Phenomenon; Renal Impairment; Scleroderma; Scleroderma Renal Crisis; Thrombocytopenia; Weight Decreased	Citalopram Hydrobromide Unk			S	Unknown	Unk		Allergan
	Alprazolam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q Week		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Folate			S	Unknown	5 Mg, Q Week		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15396329	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911207		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Tylenol			S	Unknown			Johnson And Johnson
	Paracetamol			S	Unknown			Johnson And Johnson

Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Paracetamol	S	Unknown	Johnson And Johnson
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

	Methotrexate	C	Unknown		Not Reported
	Acetaminophen W/Codeine Phosphate	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Tylenol W/Codeine No. 3	C	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Codeine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15493226	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022036		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Asacol			S	Oral	800 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, One Every 2 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported

Methotrexate	S	Oral	2.5 Mg, Q.Wk.	Not Reported
Methotrexate	S			Not Reported
Actemra	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Amlodipine Besilate	C	Unknown	Unk	Not Reported
Atacand Plus	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Depo-Medrol	C	Intra-articular	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15567436	NON-EXPEDITED			US-PFIZER INC-2018432992		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	15615412	EXPEDITED (15-DAY)		DS, LT, OT	CA-APOTEX-2016AP016280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment	Apo Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	15 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo Prednisone Tab 1mg Usp			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	400 Mg, Unk		Apotex
	Prednisone			S	Unknown	1 Mg, Unk		Apotex
	Prednisone			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Urethral	400 Mg, Qd		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	Unk		Apotex
	Cetirizine			S	Oral	10 Unk, Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Qd		Apotex
	Cetirizine			S	Unknown	25 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	1 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Apo-Prednisone			S	Oral	Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Unk, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported

Failure; Wheezing; Wound	Folic Acid	S	Oral	25 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Oral	5 Mg, Unk	Not Reported
	Folic Acid	S	Oral	1 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Alendronate	S	Oral	Unk	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 Df, Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported

Enbrel	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Mg, Unk	Not Reported
Humira	S	Sunconjunctival	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Unk, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Intracardiac	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Oral	500 Mg, Unk	Not Reported
Phthalylsulfathiazole	S	Oral	1000 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk Unk, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Unk, Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Mg, Unk	Not Reported

Cortisone	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone	S	Oral	25 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Unk, Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported

Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Topicort /00028604/	S	Other	Unk	Not Reported
Zyrtec /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	1 G, Bid	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	25 Unk, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
Folic Acid	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16646824	EXPEDITED (15-DAY)		HO, OT	PL-PFIZER INC-2019317440		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Sulfasalazine			S	Unknown	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	15 Mg, Qd (Every Day)		Not Reported
	Encorton			S	Unknown	10 Mg, Qd (Every Day)		Not Reported
	Plaquenil S			S		20 Mg, 1x/Day; Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Mg, Unk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16783255	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001712			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect	Hydroxychloroquine			S	Oral	400 Mg, Qd Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

Incomplete; Vomiting	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S		Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Arthrotec	S	Intracardiac	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk Subcutaneous Solution	Not Reported
	Humira	S	Subcutaneous	40 Mg; Subcutaneous Solution	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	1 Dosage Form, Weekly	Not Reported
	Metronidazole	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Metronidazole	S			Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Cefaclor	S	Unknown	Unk		Not Reported
Pregabalin	S	Unknown	Unk		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Celecoxib	S	Oral	200 Mg		Not Reported
Celecoxib	S	Oral	200 Mg, Qd		Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Apo-Bisoprolol	S	Unknown	Unk		Not Reported
Meperidine	S	Unknown	Unk		Not Reported
Levofloxacin	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Erythromycin Estolate	S	Unknown	Unk		Not Reported
Erythro Base	S	Unknown	Unk		Not Reported
Norfloxacin	S	Unknown	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	16944449	EXPEDITED (15-DAY)		HO	US-EMCURE PHARMACEUTICALS LTD-2018-EPL-0469		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hypokalaemia; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram		Emcure
	Hydroxychloroquine			S		4 Dosage Form		Not Reported
	Activated Charcoal			C	Oral	50 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17168352	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019228928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Liver Injury; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	1 Mg	Glaxosmithkline
	Folic Acid	S	Unknown	1 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Desoximetasone	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk, Solution	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Glaxosmithkline
	Quetiapine	C	Unknown	Unk	Glaxosmithkline
	Ramipril	C	Unknown	Unk	Glaxosmithkline
	Calcium Gluconate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17182234	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1154329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Blood Test Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Otezla			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported

		Cimzia Single-Use Prefilled Syringe			S	Subcutaneous				Not Reported
		Infliximab			S	Intravenous (not otherwise specified)				Not Reported
		Desoximetasone			C	Unknown				Not Reported
		Doxepin Hydrochloride			C	Unknown				Not Reported
		Enbrel			C	Unknown				Not Reported
		Tylenol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17298077	EXPEDITED (15-DAY)		OT	FR-ACCORD-168315		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17396502	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical			Not Reported

	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17560623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567748		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Penicillamine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Doxycycline	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Tobramycin	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17584892	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020125649		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17647567	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17659064	EXPEDITED (15-DAY)		DE, OT	TH-ROCHE-2577353		44 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cerebral Haemorrhage; Injection Site Extravasation; Intentional Product Use Issue; Off Label Use; Proteinuria; Renal Failure	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lopinavir			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Favipiravir			S	Unknown			Not Reported
	Darunavir			S	Unknown			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Piperacillin			S	Unknown			Not Reported
	Tazobactam			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Enoxaparin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17666251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009862		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Ineffective; Drug Intolerance; Treatment Failure	Cyclosporine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S			Apotex
	Apo-Leflunomide	S	Oral	Unk	Apotex
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz Xr	C	Unknown	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17666598	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201712-006550			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Orencia			S	Unknown	750 Mg, Weekly	Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly	Not Reported
	Celebrex			C		Unk	Not Reported
	Sulfasalazine			C		Unk	Not Reported
	Xeljanz			C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17667419	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200409451		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Chloraprep			S		Topical		Not Reported
	Chlorhexidine Gluconate			S	Unknown	Oral Rinse		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound			otherwise specified)		
	Oxycodone	S			Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Oxycodone And Acetaminophen	S	Unknown		Not Reported
	Periogard	S	Buccal	Alcohol Free	Not Reported
	Sulfamethoxazole	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported

	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Topicort /00028604/	S	Cutaneous	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Cetirizine Hydrochloride	C		Not Reported
	Desogestrel And Ethinylestradiol	C		Not Reported
	Ibuprofen	C		Not Reported
	Pantoloc /01263201/	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Paracetamol/Codeine	C		Not Reported
	Reactine /00884302/	C		Not Reported
	Tylenol /00020001/	C		Not Reported
	Tylenol With Codeine	C		Not Reported
	Atasol /00020001/	C	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672025	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413067		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Prednisone			C						Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672031	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072603/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672253	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411530		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Chloroquine Diphosphate			S	Unknown			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Orencia		S	Unknown		Not Reported
					Xeljanz		S	Oral		Not Reported
					Erythromycin		C	Unknown		Not Reported
					Morphine		C	Topical		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672254	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17679287	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex

Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Actemra		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	716.25 Mg, Unk	Not Reported
	Aspirin /00002701/		C	Unknown	Unk	Not Reported
	Clopidogrel Bisulfate		C	Oral	Unk	Not Reported
	Ezetrol		C	Oral	Unk	Not Reported
	Niaspan Er		C	Unknown	Unk	Not Reported
	Nitroglycerin		C	Transdermal	Unk	Not Reported
	Rosuvastatin Calcium		C	Oral	Unk	Not Reported
	Tylenol /00020001/		C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17687062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013397		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	0.5 Mg, Unk		Not Reported
	Folic Acid			S	Oral	25 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex

Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Apo-Hydroxyquine	S	Unknown	400 Mg, Qd	Apotex
	Cetirizine	S	Unknown	Unk	Apotex
	Cetirizine	S	Unknown	10 Mg, Unk	Apotex
	Diclofenac	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Acetaminophen	S	Unknown	Unk	Apotex
	Apo Folic Acid	S	Unknown	Unk	Not Reported
	Winpred	S	Oral	Unk	Apotex
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4omg/0.8ml	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported

Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Topicort Lp	S	Unknown	Unk	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Etanercept	S	Unknown	Unk	Not Reported

	Salazopyrin			C	Unknown	Unk				Not Reported
	Diclofenac			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17687090	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003003347			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17688732	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411522		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Surgery; Middle Insomnia; Migraine; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Synovitis; Therapeutic Product Effect Decreased; Weight Increased	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

		Sulfasalazine			S	Unknown				Not Reported
		Celebrex			S	Unknown				Not Reported
		Hydroxychloroquine Sulfate			S	Unknown				Not Reported
		Allopurinol			C	Unknown				Not Reported
		Clomipramine			C	Unknown				Not Reported
		Folic Acid			C	Unknown				Not Reported
		Pantoloc /01263201/			C	Unknown				Not Reported
		Zyloprim			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17702991	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226210		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Propofol Infusion Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709439	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226654		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			C				Not Reported
	Azitromicina (7019a)			C	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709444	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202004003560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Left Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Tofacitinib			C		Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Infliximab			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709445	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004003658			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonitis; Product Availability Issue	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709446	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004003877			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use;	Hydroxychloroquine			S	Oral	600 Mg, Qd		Concordia

Rhabdomyolysis	Hydroxychloroquine	S			Concordia
	Tocilizumab	C		200 Mg	Not Reported
	Cholecalciferol	C		3300iu/Mi	Not Reported
	Nitazoxanide	C		500 Mg	Not Reported
	Azithromycin	C		500 Mg	Not Reported
	Bisacodyl	C		5 Mg	Not Reported
	Ceftriaxone	C		1 G	Not Reported
	Enoxaparin Sodium	C		40mg/0.4ml	Not Reported
	Metamizole Sodium	C		1 G	Not Reported
	Midazolam	C		5 Mg	Not Reported
	Etomidate	C		20 Mg	Not Reported
	Esomeprazol	C		40 Mg	Not Reported
	Ondantor	C		8 Mg	Not Reported
	Furosemide	C		20 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709452	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245108		48 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia; Overdose	Pantoprazol			S	Intravenous (not otherwise specified)	Unk		Sun
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Pentasa			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245124		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Agranulocytosis	Azithromycin	S	Oral	500 Milligrams, Daily		Sun
	Plaquenil	S	Oral	600 Milligrams, Daily		Not Reported
	Ceftriaxone Base	C	Unknown	Unk		Not Reported
	Inipomp	C	Unknown	Unk		Not Reported
	Rovamycine	C	Unknown	Unk		Not Reported
	Paracetamol	C	Unknown	Unk		Not Reported
	Xarelto 10 Mg, Comprime Pellicule	C	Oral	Unk		Not Reported
	Diffu K	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709619	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1226843		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Mg		Teva
	Loxapine Base			S	Oral	155 Mg		Not Reported
	Plaquenil 200 Mg, Comprimé Pelliculé (Hydroxychloroquine Phosphate)			S	Oral	600 Mg		Not Reported
	Theralene			S	Oral	50 Mg		Not Reported
	Paracetamol			C	Oral	1 Gram		Not Reported
	Nicopatch 7 Mg/24 H, Dispositif Transdermique De 17,5 Mg/10 Cm²			C	Transdermal	7 Mg		Not Reported
	Diazepam			C	Oral	10 Mg		Not Reported
	Atorvastatine			C	Oral	40 Mg		Not Reported
	Nicotine			C	Oral	12 Mg		Not Reported
	Macrogol 4000			C	Oral			Not Reported
	Nebivolol			C	Oral	7.5 Mg		Not Reported
	Zopiclone			C	Oral	7.5 Mg		Not Reported
	Ramipril			C	Oral	1.25 Mg		Not Reported
	Akineton			C	Oral	4 Mg		Not Reported

	Ezetimibe			C	Oral	10 Mg				Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			C	Oral	75 Mg				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709667	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226969		80 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Thrombocytopenia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709805	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709830	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002639			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Treatment Noncompliance	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17709947	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226986		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; Every 8 Hours		Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710023	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP010277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility Decreased; Musculoskeletal Pain; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Surgery; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400.0 Mg, Qd		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	20.0 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	125.0 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710025	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226989		52 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710046	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226987		36 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 120 Tablets		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710093	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201812-004113			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	Unk		Concordia
	Prednisone			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710318	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588918		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

					Humira		S	Subcutaneous		Not Reported
					Hydroxychloroquine		S	Unknown		Not Reported
					Hydroxychloroquine		S	Subcutaneous		Not Reported
					Hydroxychloroquine Sulfate		S	Subcutaneous		Not Reported
					Methotrexate		S	Oral		Not Reported
					Methotrexate		S	Subcutaneous		Not Reported
					Methotrexate		S	Oral		Not Reported
					Methotrexate		S	Oral		Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Prednisone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710626	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226932		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Parenteral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Tofacitinib			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710627	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226939		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710635	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226954		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Arava	C				Not Reported
	Naproxen	C	Unknown	1000 Milligram Daily;		Not Reported
	Viread	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710680	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226998		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226993		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Arava			C				Not Reported
	Benadryl			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710749	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1040162			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios;	Omeprazole			S		Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Metoprolol			S	Transplacental	Unk		Not Reported

Premature Baby	Dexamethasone	S	Transplacental	Unk	Mylan
	Dexamethasone	S	Transplacental	Unk	Mylan
	Albumin	S	Transplacental	Unk	Mylan
	Penicillin-G	S	Transplacental	Unk	Mylan
	Prednisone	S	Transplacental	Unk	Mylan
	Prednisone	S	Transplacental	Unk	Mylan
	Vitamin D /00318501/	S	Transplacental	Unk	Mylan
	Hydroxychloroquine	S		Unk	Mylan
	Vitamin B Complex /00003501/	S	Unknown	Unk	Mylan
	Paracetamol	S	Transplacental	Unk	Mylan
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Mylan
	Flebogamma Dif /00025201/	S	Transplacental	Unk	Mylan
	Magnesium Lactate	S	Transplacental	Unk	Mylan
	Bisoprolol Fumarate	S	Transplacental	Unk	Mylan
	Privigen	S	Transplacental	Unk	Mylan
	Privigen	S	Transplacental	Unk	Mylan
	Fluconazole	S	Transplacental	Unk	Mylan
	Hydrocortisone	S	Transplacental	Unk	Mylan
	Vulmizolin	S	Transplacental	Unk	Mylan
	Cefotaxime	S	Transplacental	Unk	Mylan
	Cefotaxime	S	Transplacental	Unk	Mylan
	Potassium Chloride	S	Transplacental	Unk	Mylan
	Folic Acid	S	Transplacental	Unk	Mylan
	Bisulepin	S	Transplacental	Unk	Mylan
	Etamsylate	S	Transplacental	Unk	Mylan
	Nadroparine	S	Transplacental	Unk	Mylan
	Ornidazole	S	Transplacental	Unk	Mylan
	Methylprednisolone	S	Transplacental	Unk	Mylan
	Methylprednisolone	S	Transplacental	Unk	Mylan

	Cefixime			S	Transplacental	Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710751	NON-EXPEDITED			US-PFIZER INC-2020165061		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17710765	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020055142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline
	Pseudoephedrine Hcl			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	And Oral		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline
	Topicort			S	Subcutaneous	Unk		Glaxosmithkline
	Topicort			S	Topical	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Oral	25 Mg		Glaxosmithkline
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia (Certolizumab Pegol)			S	Subcutaneous	Unk		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	4 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711227	NON-EXPEDITED			US-PFIZER INC-2020167983		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug	Gabapentin			S		Unk		Pfizer

Hypersensitivity; Dyspnoea; Nausea; Swelling; Vomiting; Wheezing	Baclofen	S	Unk		Not Reported
	Hydroxychloroquine	S	Unk		Not Reported
	Voltaren [Diclofenac Sodium]	S	Unk		Not Reported
	Escitalopram Oxalate	S	Unk		Not Reported
	Linzess	S	Unk		Not Reported
	Tramadol	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711246	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227339		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226940		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Macule; Skin Cancer	Leflunomide			S	Unknown			Barr

	Methotrexate			S	Unknown				Barr
	Sulfasalazine			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711308	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226958		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Indometacin			S	Unknown			Not Reported
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711319	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226935		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate	Leflunomide			S	Oral			Barr

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Subcutaneous	12 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	15 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	12.5 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Unknown	10 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 1 Week	Barr
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Barr
	Alendronic Acid	S	Unknown	70 Mg, 1 Every 1 Week	Actavis
	Codeine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	200 Milligram Daily;	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711477	EXPEDITED (15-DAY)		OT	NVSC2020FR109492		31 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Febrile Neutrophilic Dermatosis; Drug Eruption; Pyrexia	Hydroxychloroquine	S	Unknown	400 Mg, Qd		Novartis
	Prednisone	C	Unknown	15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711543	EXPEDITED (15-DAY)		DE, OT	ES-ASTELLAS-2020US014740		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711604	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226653		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 2 Comp/12h		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711760	EXPEDITED (15-DAY)		OT	DE-SA-2020SA095744		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Granuloma; Infective Tenosynovitis; Joint Swelling; Leukocytosis; Mycobacterium Marinum Infection; Pain In Extremity; Papule; Scab; Skin Mass; Thrombocytosis	Hydroxychloroquine			S	Oral	200 Mg, Q12h		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2 Df, Bid (500 Mg)		Not Reported
	Prednisolone			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd (Two Weeks Before Presentation)		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisone			S		Increased To		Not Reported
	Prednisone			S		Unk		Not Reported
	Amlodipine			C				Not Reported
	Metoprolol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711810	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020167297		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226990		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712080	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226652		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg/24h		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Single Dose		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712085	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1226657		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating	Risperidone			S	Oral	2 Mg		Actavis

Drug Interaction	Plaquenil 200 Mg, Comprimé Pelliculé (Hydroxychloroquine Phosphate)		S	Oral	600 Mg		Not Reported
	Effexor L.P. 75 Mg, Gélule À Libération Prolongée		S	Oral	150 Mg		Not Reported
	Acebutolol (Chlorhydrate D')		C	Oral	400 Mg		Not Reported
	Oxazepam		C	Oral	100 Mg		Not Reported
	Enoxaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))		C	Subcutaneous	4000 Iu		Not Reported
	Macrogol 4000		C	Oral	2 Df		Not Reported
	Amlodipine		C	Oral	10 Mg		Not Reported
	Chlorhydrate De Clomipramine		C	Oral	150 Mg		Not Reported
	Zopiclone		C	Oral	7.5 Mg		Not Reported
	Chlorhydrate De Nicardipine		C	Oral	60 Mg		Not Reported
	Hydrochlorothiazide		C	Oral	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712129	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226773		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712237	EXPEDITED (15-DAY)		HO	GR-PFIZER INC-2011075813		56 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Urinary Tract Infection; Urinary Tract	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer

Pain	Neoral-Sandimmune (Ciclosporin)	S	Oral	50 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, 1x/Day		Not Reported
	Thyrohormone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712238	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712368	EXPEDITED (15-DAY)		OT	NVSC2020CA111106		78 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinal Toxicity	Hydroxychloroquine			S	Unknown	5.3 Mg/Kg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	2.7 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712393	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226967		65 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712394	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226772		30 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712397	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200432625		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Simponi			S	Subcutaneous			Janssen
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712720	EXPEDITED (15-DAY)		HO, OT	SE-PFIZER INC-2020167060		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Df		Pfizer
	Sertraline Hcl			S	Oral	750 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10-15 Df		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713099	DIRECT	Y	LT, OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713157	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020161842		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dementia; Drug Ineffective; Pneumonia; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713314	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428290		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

		Orencia			S	Unknown				Not Reported
		Rituximab			S	Intravenous (not otherwise specified)				Not Reported
		Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17713381	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17714374	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17714446	EXPEDITED (15-DAY)		OT	NVSC2020CA111134		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Hydroxychloroquine			S	Unknown	7.1 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715382	EXPEDITED (15-DAY)		HO	NVSC2020FR109498		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Product Use In Unapproved Indication; Pyrexia; Rash Pustular; Skin Plaque	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715446	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033914			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

	Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
	Remicade	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Zopiclone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715582	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020DEP000202		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus;	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Assertio Therapeutics
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Methotrexate	S	Unknown	20 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Salazopyrine	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715715	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020561		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Rocephine			S	Oral	2 Gram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715746	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-020590			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death; Off Label Use	Azithromycin			S	Unknown	Unk				Aurobindo
	Plaquenil			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715753	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020591			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715772	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020598			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Meloxicam			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Breo Ellipta			S		Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dexilant			S	Oral	60 Milligram, Once A Day		Not Reported
	Estrogel			S	Topical	Unk, Once A Day		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Two Times A Day		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown	Unk				Not Reported
	Ventolin Hfa			S		Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715790	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226775		54 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715830	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245242		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715834	EXPEDITED (15-DAY)		HO	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245240		16 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Fatigue; Intentional Overdose;	Sertraline			S	Oral	750 Milligram, Unk		Sun

Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone		S	Oral	10-15st.		Not Reported
	Plaquenil		S	Oral	10-15 St.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17715835	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245249		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Paracetamol			S	Oral	1gr Cada 8 Horas		Ohm Lab
	Simvastatina Alter 10 Mg Comprimidos Recubiertos Con Pelicula Efg ...			S	Oral	0-0-1 ()		Not Reported
	Dolquine 200 Mg Comprimidos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	12367074	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-034237		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	760 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Alendronate Sodium			S	Oral	70 Milligram, Qwk		Not Reported
	Codeine Sulphate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported

Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
	Simponi	S	Unknown	680 Milligram, Qmo	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Q4wk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported

Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Unknown	1000 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	360 Milligram, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	680 Milligram, Q4wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, Q4wk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported

			Etanercept	S	Unknown	25.0 Milligram, Qwk	Not Reported
			Etanercept	S	Unknown	50 Milligram, Qwk	Not Reported
			Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
			Naproxen	S	Unknown		Not Reported
			Azathioprine	S	Unknown		Not Reported
			Adalimumab	S	Subcutaneous	40 Milligram, Qcycle	Not Reported
			Celebrex	S	Unknown		Not Reported
			Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
			Prednisone	C	Unknown	20 Milligram	Not Reported
			Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
			Ciclosporin	C	Unknown	150 Milligram 1 Every 24 Days	Not Reported
			Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
			Prednisolone	C	Unknown	10 Milligram, Qd	Not Reported
			Humira	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	12881921	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013278		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Naproxen Sodium Tablets			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex

	Naproxen Sodium	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	12.5 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	12913793	EXPEDITED (15-DAY)		DS, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091772		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb

Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram, Qd	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Oral	25 Milligram	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	Unk	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported

Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	1 Gram, Bid	Not Reported
Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	1 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	25 Milligram	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported

Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	5 Unk	Not Reported
Prednisone	S	Unknown	1 Milligram	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Cetirizine	S	Oral	10 Milligram	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported

Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cortisone	S	Unknown	25 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Winpred	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported
Leflunomide	C	Oral		Not Reported
Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	13111752	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1876541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased;	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown	Therapy Duration: 9 Months	Not Reported
	Remicade	S	Unknown	Therapy Duration: 365 Nos Powder For Intravesical Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral	Film-Coated Tablet	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	7300 Days	Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown	For 2 Months	Not Reported

	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	13969809	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP018054		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Disease Recurrence; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Nausea; Off Label Use; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Pulmonary Mass; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Endocervical	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Ergocalciferol	C	Unknown		Not Reported
Imuran /00001501/	C	Unknown		Not Reported
Gold	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Arthrotec	C	Unknown	50 Mg, Bid	Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Unknown	Unk	Not Reported
Bisoprolol	C	Unknown	Unk	Not Reported
Digoxin	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Furosemid /00032602/	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C			Not Reported
Lyrica	C	Unknown	75 Mg, Qd	Not Reported
Naproxen	C	Unknown	500 Mg, Qd	Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Palafer	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported

	Prednisone	C	Unknown	10 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Toloxin /00017701/	C	Unknown	Unk	Not Reported
	Trazodone	C	Unknown	50 Mg, Qd	Not Reported
	Valsartan	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported
	Zinc Citrate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine	C	Unknown	200 Mg, Q.O.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	14502886	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007063		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qmo		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported

Therapeutic Product Effect Decreased; Therapy Non-Responder	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram,2every1day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Sulfasalazine	C	Oral	Unk	Not Reported
	Sulfasalazine	C	Oral	500 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	15935909	EXPEDITED (15-DAY)		DE, OT	IT-ACCORD-104696		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error;	Hydrochlorothiazide			S		Unk		Not Reported
	Lorazepam			S		Unk, Also Received As Concomitant.		Accord
	Montelukast			S		Unk, Also Received As Concomitant.		Not Reported
	Acetylsalicylic Acid			S		Unk, Also Received As		Not Reported

Pyrexia				Concomitant	
	Celecoxib		S	Unk, Also Received As Concomitant.	Not Reported
	Hydroxychloroquine		S	Unk, Also Received As Concomitant.	Not Reported
	Influenza Vaccine		S	Unk	Not Reported
	Warfarin		S	Regimen 1	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16081389	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013165		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, Every Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Plaquenil			S	Oral	300 Milligram, Once A Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Milligram, Every Week		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	1 Gram, Cyclical (1 Every		Not Reported

			otherwise specified)	1 Day)	
	Apo-Hydroxyquine	S	Unknown	Unk,Once A Day	Not Reported
	Actonel	S	Unknown	35 Milligram, Every Week	Not Reported
	Hydroxychloroquine	S	Unknown	Unk,Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100.0 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Two Times A Day	Not Reported
	Risedronate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16358401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-049379		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Malaise; Nausea; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown		Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Isoniazid	S	Unknown		Not Reported
	Lopressor	S	Unknown		Not Reported
	Losartan Potassium	S	Unknown		Not Reported
	Tecta	S	Unknown		Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Enalapril Maleate	S	Unknown		Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
	Clindamycin Phosphate	S	Unknown	Unk	Not Reported

	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
	Venofer	C	Unknown		Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Atenolol	C	Unknown		Not Reported
	Colchicine	C	Unknown		Not Reported
	Coversyl [Perindopril Erbumine]	C	Unknown		Not Reported
	Leucovorin [Folinic Acid]	C	Unknown		Not Reported
	Levothyroxine Sodium	C	Unknown		Not Reported
	Ranitidine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16710769	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2019SF17234			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S	Oral			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported

Volibris	S	Unknown	Not Reported
Volibris	S	Oral	Not Reported
Volibris	S	Oral	Not Reported
Eliquis	S	Unknown	Not Reported
Eliquis	S	Unknown	Not Reported
Quensyl	S	Unknown	Not Reported
Quensyl	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Sildenafil Citrate	S	Unknown	Not Reported
Roactemra	S	Subcutaneous	Not Reported
Roactemra	S	Subcutaneous	Not Reported
Spasmolyt	S	Unknown	Not Reported
Spasmolyt	S	Unknown	Not Reported
Spasmolyt	S	Unknown	Not Reported
Spasmolyt	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16782017	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000468			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Meperidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

Arava	S	Unknown	Unk	Not Reported
Bisoprolol Fumarate	S	Unknown	Tablet	Not Reported
Methotrexate	S	Oral	1 Df, Qw	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Cefaclor	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Erythromycin Estolate	S	Unknown	Unk	Not Reported
Levofloxacin	S	Unknown	Unk	Not Reported
Arthrotec	S	Unknown	Unk	Not Reported
Plaquenil /00072603/	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
Celecoxib	S	Oral	200 Mg, Unk	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	16879886	EXPEDITED (15-DAY)		OT	GR-ACCORD-156263		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Accord
	Levothyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Dicoumarol			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17299448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527600		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17336937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia	S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Desoximetasone	S	Unknown			Not Reported
	Etanercept	S	Unknown			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Prednisone	S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Cetirizine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17351623	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus

Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk, Qw	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil /00072603/	S	Oral	400 Mg, Qd	Not Reported
	Plaquenil /00072603/	S	Oral	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17426809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17475675	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190801306			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Simponi			S	Subcutaneous	365 Days		Janssen
	Simponi			S				Janssen
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Plaquenil /00072602/			C				Not Reported
	Amitriptyline			C				Not Reported

	Constella	C			Not Reported
	Reactine /00884302/	C	Oral		Not Reported
	Aerius /01009701/	C			Not Reported
	Zopiclone	C		7.5 Mg 1/2 -1 Tablet	Not Reported
	Zomig	C			Not Reported
	Vitamin C /00008001/	C			Not Reported
	Acyclovir /00587301/	C	Unknown		Not Reported
	Levofloxacin	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17557583	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318935		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17600443	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2020SA076630		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased;	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	5 Mg Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Naproxen			S	Oral	5 Mg, Qd		Not Reported
	Naproxen			S	Oral	3 Mg Qd		Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S				Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	50 Mg, Bid		Not Reported
	Prednisone			S	Unknown	50 Mg		Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qow		Not Reported

Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous	15 Mg/M2, Qow	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Sanofi
	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Triamcinolone Acetonide	S	Unknown		Sanofi
	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Bid	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Unknown	50 Mg	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Qow	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported

Humira	S	Subcutaneous	Form: Solution	Not Reported
Humira	S			Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Infliximab	S	Unknown	5 Mg	Not Reported
Infliximab	S	Unknown	3 Mg/Kg, Q6w	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S		250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q2m	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17605318	EXPEDITED (15-DAY)		OT	AU-SA-2020SA072232		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abortion Spontaneous; Adrenal Haemorrhage; Atrial Septal Defect; Cerebral Infarction; Deep Vein Thrombosis; Myocardial Hypoperfusion; Myocarditis; Pulmonary Embolism; Pulmonary Infarction; Thrombotic Microangiopathy; Transient Ischaemic Attack	Enoxaparin Sodium	S		200 Mg	Sanofi
	Acetylsalicylic Acid	S		100 Mg	Not Reported
	Hydroxychloroquine	S		200 Mg	Sanofi
	Cyclophosphamide Monohydrate	C	Intravenous (not otherwise specified)	1.5 G	Not Reported
	Heparin Sodium	C			Not Reported
	Rituximab	C		1 G	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17605656	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332784		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Endocervical	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17611349	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20151008546			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17664343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17678663	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224966		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	Unit Dose : 200 Mg 400mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17687239	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244297		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	()		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	()		Not Reported
	Perfalgan 10 Mg/Ml, Solution Pour Perfusion			C	Intravenous (not otherwise specified)	()		Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)	()		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	()		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Daily		Not Reported

	Transipeg			C	Oral	()				Not Reported
	Potassium (Chlorure De)			C	Intravenous (not otherwise specified)	()				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17691116	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1225788		62 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Hepatitis; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17693985	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17694005	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419292		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17694944	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2020-011287		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterium Marinum Infection	Prednisolone			S	Oral	Permanent 1-0-0		Not Reported
	Prednisolone			S	Oral	Intermittent Usage; Low-Dose; Two Weeks Before Presentation		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Intermittent Usage 1-0-0		Not Reported
	Sulfasalazine			S	Oral	2-0-2		Not Reported

	Hydroxychloroquine			S	Oral	1-0-1			Not Reported
	Metoprolol			C					Not Reported
	Amlodipine			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17715901	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1228878		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg		Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)			Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Mg		Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Mcg		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous			Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4gram		Not Reported
	Midazolam (2256a)			C	Intravenous drip	100 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17715963	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020588			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Discomfort; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17715964	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020558		85 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	1.25 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716028	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004070			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Ceftriaxone			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Oxazepam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716067	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010203			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	6 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	150 Mg, Qd		Not Reported
	Trazodone			S	Unknown	25 Mg, Qd		Apotex
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716273	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0122393			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy	Atorvastatin			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Peripheral; Rash; Skin Burning Sensation	Plaquenil		S	Oral		Not Reported
	Sulfasalazine		S			Not Reported
	Acetaminophen		C	Oral		Not Reported
	Asa Ec		C	Oral		Not Reported
	Folic Acid		C	Oral		Not Reported
	Vitamin D3		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716326	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227005		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716375	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-049454			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Simplex Hepatitis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Zydus Pharm

	Prednisone		S	Unknown	5 Milligram, Qd			Not Reported
	Prednisone		S	Oral	Unk			Not Reported
	Metronidazole		C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229781		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716579	EXPEDITED (15-DAY)		HO	MX-ADVANZ PHARMA-202004004174			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Product Effect Incomplete	Arava		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716681	EXPEDITED (15-DAY)		HO, OT	RO-ACCORD-136273		56 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Nodule	Methotrexate			S				Accord
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Insulin			C		40 Ui		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716778	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1225767		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Unresponsive To Stimuli; Ventricular Fibrillation	Azithromycin			S	Oral	On Day 1		Not Reported
	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	800 Milligram Daily; On Day 1		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716808	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.-2020ES03040			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Per Day		Cipla
	Dolquine			S	Oral	400 Milligram, Per Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Bid (Every 12 Hours; 2u/12 H)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716812	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589371			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17716905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milliliter, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717114	NON-EXPEDITED			US-PFIZER INC-2020168411			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer

	Plaquenil [Hydroxychloroquine Phosphate]	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Humira	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717266	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2588343		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Decreased; Crohn'S Disease; Death; Drug Ineffective; Drug Intolerance; Feeling Jittery; Joint Swelling; Limb Discomfort; Localised Infection; Malaise; Musculoskeletal Disorder; Nausea; Neck Pain; Night Sweats; Pain; Peripheral Swelling; Purulent Discharge; Pustular Psoriasis; Synovitis; Tachycardia; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 128.0 Days		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 176.0 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration:4 Months		Not Reported
	Xeljanz			S	Oral	Therapy Duration:6 Months		Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Calcium			C	Oral			Not Reported

	Celebrex	C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Ergocalciferol	C	Oral	Not Reported
	Leucovorin Calcium	C	Oral	Not Reported
	Lorazepam	C	Oral	Not Reported
	Magnesium	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717380	EXPEDITED (15-DAY)		DE	NVSC2020FI113463		7 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Product Use In Unapproved Indication; Respiratory Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Etanercept			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586707		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717567	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2020-IN-001291			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ototoxicity; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17717838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589516			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718033	EXPEDITED (15-DAY)		HO, LT	IT-ACCORD-179592		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Drug Interaction; Drug Level Above Therapeutic; Nausea; Vomiting	Tacrolimus			S		Bid, 3 Mg Bid		Accord
	Ceftriaxone			S				Not Reported
	Lopinavir/Ritonavir			S		400mg/100mg Bid		Not Reported
	Hydroxychloroquine			S		Bid		Not Reported
	Methylprednisolone			S		6.5 Mg Daily		Not Reported
	Allopurinol			C				Not Reported
	Atorvastatin			C				Not Reported
	Ramipril			C				Not Reported
	Omeprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588809		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718400	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Drug Ineffective; Epistaxis; Headache; Insomnia; Joint Swelling; Nausea; Rash; Transaminases Increased; Vasculitis	Leflunomide	S	Oral	20 Milligram Daily;	Barr
	Methotrexate	S	Subcutaneous		Barr
	Azathioprine	S	Oral	200 Milligram Daily;	Not Reported
	Azathioprine	S	Oral	50 Milligram Daily;	Not Reported
	Azathioprine	S	Oral	150 Milligram Daily;	Not Reported
	Mycophenolate Mofetil	S	Oral	2 Gram Daily;	Teva
	Mycophenolate Mofetil	S	Oral	1000 Milligram Daily;	Teva
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Imuran	S	Oral	50 Milligram Daily;	Not Reported
	Imuran	S	Oral	150 Milligram Daily;	Not Reported
	Imuran	S	Oral	200 Milligram Daily;	Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Ketoprofen	C			Not Reported
	Prednisone	C			Not Reported
	Prolia Pre-Filled Syringe. Preservative-Free	C	Subcutaneous		Not Reported
	Quetiapine	C	Oral	25 Milligram Daily;	Not Reported
	Rituximab	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718533	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588767		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718649	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-20K-144-3380621-00		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Kaletra 200/50			S	Oral			Not Reported
	Metilprednisolona			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported

					Ceftriaxona		S	Intravenous (not otherwise specified)		Not Reported
					Tocilizumab		S	Intravenous (not otherwise specified)		Not Reported
					Dolquine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718685	EXPEDITED (15-DAY)		DS, OT	CA-COLGATE PALMOLIVE COMPANY-20200400745			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain;	Chlorhexidine Unspecified			S	Unknown			Colgate
	Periogard Alcohol Free Rinse			S	Buccal	Alcohol Free		Colgate
	Chlorhexidine Gluconate Unspecified			S	Unknown	Oral Rinse		Colgate
	Oxycodone			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	3011.2 Milligram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2912 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Acetaminophen	S	Unknown		Not Reported
	Cortisone	S	Topical	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Sulfamethoxazole	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cetirizine	S	Unknown	10 Milligram	Not Reported
	Prednisone	S	Oral	7.5 Milligram	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram	Not Reported
	Sulfamethoxazole And	S			Not Reported

	Trimethoprim				
	Arava	S	Oral	20 Milligram	Not Reported
	Chloraprep	S		Topical	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Cutaneous		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Tofacitinib	S	Unknown	10 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Pantoprazole Sodium	C			Not Reported
	Pantoloc [Pantoprazole]	C			Not Reported
	Cetirizine Dihydrochloride	C			Not Reported
	Paracetamol/Codeine	C			Not Reported
	Atasol [Paracetamol]	C	Unknown		Not Reported
	Tylenol With Codeine	C			Not Reported
	Tylenol [Paracetamol]	C			Not Reported
	Desogestrel And Ethinylestradiol	C			Not Reported
	Ibuprofen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718785	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431648		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain;	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588479			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17718922	EXPEDITED (15-DAY)		DS	CA-ROCHE-2588501		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Rituxan			S	Intravenous drip	579.0		Not Reported
	Enbrel			S	Subcutaneous	9 Months		Not Reported

					Humira	S	Subcutaneous	7 Months	Not Reported
					Hydroxychloroquine Sulfate	S	Unknown		Not Reported
					Methotrexate Sodium	S	Oral		Not Reported
					Methotrexate Sodium	S	Subcutaneous		Not Reported
					Methotrexate Sodium	S	Oral		Not Reported
					Orencia	S	Unknown		Not Reported
					Remicade	S	Intravenous (not otherwise specified)	2 Years	Not Reported
					Xeljanz	S	Intravenous (not otherwise specified)	2 Years	Not Reported
					Xeljanz	S	Unknown	2 Years	Not Reported
					Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17719461	EXPEDITED (15-DAY)		OT	NVSC2020SE113735		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S	Unknown	"Nov 2016 Höjdes Mtx Till 8 Tab/V".		Novartis
	Methotrexate			S	Unknown	6 Tabletter		Novartis
	Methotrexate			S	Unknown	7 Tabletter		Novartis
	Methotrexate			S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon Under Många År".		Novartis
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C	Unknown	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17719494	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1227982		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Cardiomyopathy; Cardiotoxicity	Hydroxychloroquine		S	Unknown	Teva
	Rituximab		C	Unknown	Not Reported
	Cyclophosphamide		C	Unknown	Not Reported
	Doxorubicin Hydrochloride		C	Unknown	Not Reported
	Vincristine		C	Unknown	Not Reported
	Prednisolone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720141	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020167361		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, 2x/Day		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720803	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3378772-00		49 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Lopinavir/Ritonavir			S	Oral			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720916	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020972		55 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram (1 Total)		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720923	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020973		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Metamizol			S	Intravenous (not otherwise specified)	2 Gram, Four Times/Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram 1 Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17720925	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020974		47 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S				Not Reported

	Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported
	Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17721027	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245414		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun
	Hidroxicloroquina (2143a)			S	Oral	200 Mg/24h		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg/24h		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17722744	DIRECT	Y	DE			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive; Emergency Care	Hydroxychloroquine			S	Oral			Actavis
	Kaletra			S	Oral			Abbvie

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	10296970	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1105839		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthritis; Blood Creatinine Decreased; Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)	First Rpap Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown Dosing Details		Not Reported
	Actemra			S	Intravenous (not			Not Reported

Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased			otherwise specified)		
	Folic Acid	S	Unknown	Once Daily Except Friday	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Discontinued Due To Ophthalmic Problems	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Dilaudid	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Acetaminophen	S	Oral		Not Reported
	Acetaminophen	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Fosavance	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Hydrocortisone	C	Intravenous (not otherwise specified)		Not Reported
	Humira	C			Not Reported
	Orencia	C			Not Reported
	Remicade	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12489538	EXPEDITED (15-DAY)		OT	CA-009507513-1606CAN007831		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung	Remeron			S	Oral	15 Mg		Merck
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Lyrica	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Dosage Form Not Specified	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Dosage Form Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12913683	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092891		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone			S	Oral	Unk, Prn		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported

Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Dosage Form	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported

Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Apo Folic	S	Unknown	5 Milligram	Not Reported
Apo Prednison	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported

Sulfate]				
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	10 Milligram	Not Reported
Cortisone	S	Topical	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported

				Xeljanz		S	Unknown	Unk	Not Reported
				Xeljanz		S	Unknown	5 Milligram, Bid	Not Reported
				Salazopyrin		C	Unknown	Unk	Not Reported
				Atasol [Paracetamol]		C	Unknown	Unk	Not Reported
				Tofacitinib Citrate		C	Unknown	Unk	Not Reported
				Acetaminophen		C	Unknown	Unk	Not Reported
				Leflunomide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12919635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1851565		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	12923504	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1632295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Pre-Filled Syringe		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Abatacept	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13119773	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880386		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

		Naprosyn [Naproxen]			C	Unknown				Not Reported
		Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13165249	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886155		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nifedipine			C				Not Reported

	Palafer	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C			Not Reported
	Synthroid	C			Not Reported
	Toloxin [Digoxin]	C			Not Reported
	Valsartan	C			Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xarelto	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zinc Citrate	C			Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13233820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893888		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C				Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13250722	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894453		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown	Cyclical		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years Cyclical		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13315469	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808080		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Failure	Methotrexate Sodium	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Cortisone	C	Unknown			Not Reported
	Cyclobenzaprine	C	Unknown	1/2 Tablet As Needed		Not Reported
	Tylenol	C	Unknown	As Needed		Not Reported
	Prednisone Acetate	C	Unknown			Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Desoximetasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13579313	EXPEDITED (15-DAY)		OT	CA-009507513-1705CAN009323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Disorder; Muscle Spasms; Pyelonephritis	Remeron			S	Oral	Unk		Merck
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13842763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1973086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Methotrexate Sodium			S	Unknown	Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Not Reported
	Orencia			S	Unknown	Not Reported
	Arava			S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Not Reported
	Mobicox			C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	13947306	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875144		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Increased; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Cannabis Sativa			C				Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

	Oxycodone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	14471157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-004461		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	160 Mg, Unk		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	14535482	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Ankle Arthroplasty; Arthralgia; Arthropathy; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Foot Deformity; Foot Operation; Hepatotoxicity; Ill-Defined Disorder; Infection; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Neck Pain; Nodule; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S		400,0 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Gold	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S	Oral		Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Methotrexate	S		Dose: 17.5 Mg	Not Reported
	Methotrexate	S			Not Reported
	Actonel	S			Not Reported
	Apo-Leflunomide	S			Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

	Adalimumab	C	Unknown			Not Reported
	Xeljanz	C				Not Reported
	Methotrexate	C		Dosage Form: Not Specified		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15096452	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2018DE028935			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	Unk		Novartis
	Ramipril			S	Transplacental	20 Mg, Unk (Maternal Dose)		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Metamizole			S	Transplacental	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Rivaroxaban			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	400 Mg, Qd		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Aliskiren			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	100 Mg, Qd		Not Reported
	Torem			S	Transplacental	100 Mg, Qd		Not Reported
	Rasilez			S	Transplacental	300mg/D Unk		Not Reported
	Rasilez			S	Transplacental	100 Mg/D Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported
	Mifegyne			C	Unknown	Unk		Not Reported
	Cytotec			C	Unknown	Unk		Not Reported
	Cyclophosphamide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15100606	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0751		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15100628	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0716		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis;	Kineret			S	Subcutaneous			Not Reported

Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Azathioprine	S	Vaginal	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Imuran	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Cimzia	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15102944	EXPEDITED (15-DAY)		OT	PHHY2018DE028933		24 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Ezetimibe	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Novartis
	Aliskiren	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Ramipril	S	Unknown	20 Mg, Unk	Not Reported
	Torasemide	S	Unknown	0-14 Gw	Not Reported
	Simvastatin	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Metamizole	S	Unknown	Unk	Not Reported
	Salbutamol	S	Unknown	Unk, Unknown Freq. (0-14 Gw)	Not Reported
	Tacrolimus	S	Unknown		Not Reported
	Rivaroxaban	S	Unknown	0-14 Gw	Not Reported
	Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
	Hydroxychloroquine	S	Unknown	0-14 Gw	Not Reported
	Prednisolone	S	Unknown	0-14 Gw	Not Reported
	Acetylsalicylic Acid	S	Unknown	0-14 Gw	Not Reported
	Pantoprazole	S	Unknown	0-14 Gw	Not Reported
	Nicotine	S	Unknown		Not Reported
	Enoxaparin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15108415	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0742		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Event; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug	Kineret			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Warfarin		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15412513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186027		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Restasis			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15416072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187971		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15593099	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018445495		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Aphthous Ulcer; Blood Cholesterol Increased; Constipation; Diarrhoea; Headache; Oral Candidiasis; Sinusitis	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S		11 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Cymbalta			C		Unk		Not Reported

	Clonazepam			C		Unk			Not Reported
	Hydroxychloroquine			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15619576	EXPEDITED (15-DAY)		HO, OT	GR-ACCORD-091884		56 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Methotrexate			S	Unknown	15 Mg, Qw		Accord
	Citalopram			S	Unknown			Not Reported
	Captopril			S				Not Reported
	Alprazolam			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Mg, Qw		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine/Hydroxychloroquine Phosphate/Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Not Reported
	Adalimumab			S				Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15751882	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181226205		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Intravenous (not otherwise specified)			Janssen
	Stelara			S	Subcutaneous			Janssen
	Stelara			S				Janssen
	Reactine Unspecified (Cetirizine			S	Unknown			Johnson And Johnson

Glossodynia; Headache; Hypersensitivity; Hypertension; Hypoaesthesia; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Dihydrochloride)			
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo Prednison	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S		Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Otezla	S	Oral	Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Not Reported
	Topicort /00370301/	S	Unknown	Not Reported
	Salazopyrine	C	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Acetaminophen W/Dextropropoxyphene	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	15964988	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-ACCORD-107431			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Mg Per Day, Exposure Duration: 0-13+6 Weeks		Accord
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Accord
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Accord
	Ezetimibe			S	Transplacental	Also Received As Suspect, From Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 Mg/D, 0-13.6		Not Reported

			Gestational Week	
Salbutamol	S	Transplacental	From Gestational Week 0-14	Not Reported
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S	Transplacental	From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental	300 Mg/D, 0-4.6 Gestational Week	Not Reported
Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid Sandoz	S	Transplacental		Not Reported
Rivaroxaban	S	Transplacental		Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First, Probably Only In Hospital In Week 5	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Cytotec	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Cyclophosphamide/Cyclophosphamide Monohydrate	C	Transplacental	3000 Mg Cumulative, Preconceptional	Not Reported
Enoxaparin	C	Transplacental	Unk Unk, Unknown Freq.	Not Reported

(0-14 Gw), Also Received As Concomitant.

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16080946	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013597		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16232200	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110565		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability;	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi

Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16478155	EXPEDITED (15-DAY)		CA, DE, HO, OT	FR-ACCORD-135124			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole/Esomeprazole Magnesium/Esomeprazole Sodium			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental	Strength: 200 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported
	Diffu K			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Not Reported
	Cortancyl			S	Transplacental	Strength: 5 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported
	Imurel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16710864	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000394			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea;	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported

Therapeutic Product Effect Incomplete; Vomiting	Metronidazole	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Levofloxacin	S	Unknown	Unk		Not Reported
	Norfloxacin	S	Unknown	400 Mg, Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Arthrotec	S	Unknown	Unk		Not Reported
	Cefaclor	S	Unknown	Unk		Not Reported
	Celecoxib	S	Oral	200 Mg, Qd		Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
	Lyrica	S	Unknown	Unk		Not Reported
	Meperidine /00016301/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16719064	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217711		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported
	Celebrex			C	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	16880699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17182156	EXPEDITED (15-DAY)		OT	NVSC2019CA073777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cosentyx			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

		otherwise specified)		
Simponi	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Solution	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Injection)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported

	Sulfasalazine			S	Unknown	Unk			Not Reported
	Pantoprazole			C	Unknown	Unk			Not Reported
	Quetiapine			C	Unknown	Unk			Not Reported
	Ramipril			C	Unknown	Unk			Not Reported
	Calcium Gluconate			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17259008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516331		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17339418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530858		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Injectable Suspension	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17401839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542463		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Apo-Hydroxyquine		S	Subcutaneous	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Apo-Leflunomide		S		Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Neoral		S	Unknown	Not Reported
	Neoral		S	Subcutaneous	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Hydroxychloroquine		S	Subcutaneous	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17450107	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BIOVITRUM-2020CA0815		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Anti-Human	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Apo-Naproxen			S				Not Reported
	Apo-Naproxen			S				Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg 1x1 Daily		Not Reported

Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg 1x1 Daily	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulins [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral	1.3 Mg 2x1 Daily	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S			Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone	S	Intra-articular		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S			Not Reported
Gammagard	S	Intravenous (not otherwise specified)		Not Reported
Gammagard	S			Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo Prednisone	S	Oral		Not Reported
Apo Prednisone	S	Oral		Not Reported
Apo Prednisone	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Etanercept	S	Subcutaneous	12.5 Mg 1x1 Week	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Gamastan	S	Intramuscular		Not Reported
Immune Globulin (Human)	S	Unknown		Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Immune Globulin (Human)	S	Unknown		Not Reported

					Immune Globulin (Human)		S	Intravenous (not otherwise specified)	Not Reported
					Triamcinolone Hexacetonide		C	Unknown	Not Reported
					Triamcinolone Acetonide		C	Intra-articular	Not Reported
					Triamcinolone Acetonide		C	Unknown	Not Reported
					Triamcinolone Acetonide		C	Oral	Not Reported
					Triamcinolone Acetonide		C	Intra-articular	Not Reported
					Folic Acid		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17560345	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309909		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis;	Stelara			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Remicade			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral	And Oral		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Unknown For 5.0 Mg, Through Oral 25.0 Mg,		Not Reported

Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Folic Acid	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	Unknown For 5.0 Mg, Through Oral 25.0 Mg,	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicort /00370301/	S	Subcutaneous		Not Reported
	Topicort /00370301/	S	Topical		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported

		Prednisone			S	Unknown				Not Reported
		Prednisone			S	Unknown				Not Reported
		Hydroxychloroquine			S	Unknown				Not Reported
		Diclofenac			C	Unknown				Not Reported
		Salazopyrin			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17580229	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2020CA1335		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Operation; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Dose: 17.5 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Risedronate Sodium	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Risedronate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Hydroxychloroquine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17583318	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001754			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Erythema; Inflammation; Pneumonia; Purulence; Pyrexia; Tenderness	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17661978	EXPEDITED (15-DAY)		DS, OT	BR-ADVANZ PHARMA-202003002616			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bedridden; Blindness; Cardiac Disorder; Corneal	Hydroxychloroquine			S	Unknown	Unk, Qod		Concordia

Disorder; Drug Dependence; Gait Inability; General Physical Health Deterioration; Renal Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17669289	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010048		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Certolizumab Pegol			S	Subcutaneous	400 Mg, (Cyclical)		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17678101	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002848			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17682573	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202003002315			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Condition Aggravated; Death; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S	Oral	800 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Paracetamol			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Macrogol 3350			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Voriconazole			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17705879	EXPEDITED (15-DAY)		HO	CH-ABBVIE-20K-151-3376752-00		70 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral	800/200 Mg		Not Reported
	Kaletra			S	Oral	400/100 Mg		Not Reported
	Plaquenil			S	Oral	Initial Dose		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			C	Intravenous drip			Not Reported
	Co-Amoxi			C				Not Reported
	Triatec			C				Not Reported
	Metfin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17710430	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1226892		70 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Azithromycin			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17716184	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3380425-00		58 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Piperacillina Sodica/Tazobactam Sodico			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

					Hydroxychloroquine Sulfate		S	Unknown	Not Reported
					Infliximab		S	Intravenous (not otherwise specified)	Not Reported
					Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588833		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Oral			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721370	EXPEDITED (15-DAY)		OT	ES-ADVANZ PHARMA-GSH201807-002384			Unknown	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk			Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721385	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589389		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588807		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721388	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-GSH201907-001665			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Depressed Level Of Consciousness; Diarrhoea; Fatigue; Headache; Lethargy; Malaise; Mental Status Changes; Muscular Weakness; Myalgia; Nausea; Pyrexia; Tachycardia; Unresponsive To Stimuli; West Nile Viral Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown	6 Mg, Qd (Part Of A Regimen That Involved Tapering Of The Dose)		Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Unknown	High Dose		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Glucocorticoids			S	Unknown			Not Reported
	Sulfamethoxazole-Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported

Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589692			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721425	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201801-000313			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	4 Dosage Form, Tablet		Concordia
	Ondansetron Hydrochloride			S	Intravenous (not otherwise specified)	4 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721434	EXPEDITED (15-DAY)		HO, OT	IT-ADVANZ PHARMA-GSH201804-001135			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Back Pain; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Movement Disorder; Mycobacterial Infection; Mycobacterium Avium Complex Infection; Osteomyelitis; Osteomyelitis; Osteomyelitis Bacterial; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Concordia
	Prednisone			S	Oral	50 Mg, Qd, Administered Initially Which Was Later Tapered To 5 Mg/Day		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721454	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245365		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Paracetamol			S	Oral	1 Gr Cada 8 Horas		Ohm Lab
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721456	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245370		47 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721521	EXPEDITED (15-DAY)		OT	ES-HETERO-HET2020ES00451		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Mg, Qd		Hetero
	Dolquine			S	Oral	200 Mg, Qd		Not Reported
	Metronidazol /00012501/			S	Oral	Unk		Not Reported
	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589838		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721569	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Enbrel			S		25 Mg		Not Reported
	Orencia			S				Not Reported

	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Powder For Solution			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution Subcutaneous			Not Reported
	Actemra			S					Not Reported
	Bupropion			C					Not Reported
	Sulfasalazine			C					Not Reported
	Xeljanz			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589413		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721617	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588791		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

		Orencia			S	Unknown				Not Reported
		Celebrex			C	Unknown				Not Reported
		Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721663	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity;	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Peripheral Swelling;
Retinal Toxicity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588902		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721718	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004071			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Haematochezia; Musculoskeletal Pain; Osteoarthritis; Product Storage Error; Product Use Issue	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Dupilumab			S	Subcutaneous	600 Mg Once		Not Reported
	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721734	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227334		73 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg, 1			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Ertapenem (2881a)			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721767	EXPEDITED (15-DAY)		HO, LT, OT	NL-ADVANZ PHARMA-MAPI_00011545			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Oral	Unk, Coated Tablet		Concordia
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721783	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588811		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Leflunomide	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721825	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721865	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202004004073			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Hydroxychloroquine			S	Unknown	Unk Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721870	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590364			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17721927	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003827			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Off Label Use	Hydroxychloroquine			S	Oral	600 Mg, Qd		Concordia
	Enoxaparin			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Spiramycin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034287			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722162	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3377866-00		78 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bradycardia; Electrocardiogram Qt Prolonged	Kaletra		S	Oral		Not Reported
	Midazolam		S	Unknown		Not Reported
	Midazolam		S			Not Reported
	Dolquine		S	Oral	A Compressed Breakfast And Dinner	Not Reported
	Propofol		S	Unknown		Not Reported
	Propofol		S			Not Reported
	Omnic Ocas		C			Not Reported
	Manidon Hta		C			Not Reported
	Rilast Turbuhaler		C			Not Reported
	Simvastatina		C			Not Reported
	Kalpress		C			Not Reported
	Cortic		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722246	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722247	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulphathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590161			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722271	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]								
	Prednisone			S	Unknown				Not Reported
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Tylenol			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722293	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1227376		74 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Sinus Bradycardia	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			S	Oral	500 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Stilnox 10 Mg Compresse Rivestite Con Film			C	Oral	10 Mg		Not Reported
	Clexane T			C	Subcutaneous	8000 Ku		Not Reported
	Lansoprazolo Teva Italia 30 Mg Capsule Rigide Gastroresistenti			C	Oral	30 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722333	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1227342		81 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Condition Aggravated	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;		Teva
	Amoxicilina Acido Clavulanico Sala			S	Oral	1 Comp/8h		Teva
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	1 Comp/24h, 200 Mg		Not Reported
	Metronidazol (1966a)			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722337	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227335		50 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229997		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Risedronate Sodium			S	Unknown	35 Mg, 1 Every 1 Week		Teva
	Methotrexate			S	Subcutaneous	175 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

				otherwise specified)	
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722635	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA110668		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction;	Adalimumab			S	Subcutaneous	Unk		Novartis
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Ciclosporin Sandoz			S	Oral	Unk		Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Other (Solution For Injection)		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw (Solution For Injection)		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Other		Not Reported
	Apo Ibuprofen			S	Oral	600 Mg, Other		Not Reported
	Apo-Cyclosporine			S	Unknown	Unk (Oral Solution)		Not Reported
	Apo-Cyclosporine			S	Oral	Unk (Oral Solution)		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Insomnia; Joint Injury; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Apremilast	S	Unknown	Unk	Not Reported
	Apremilast	S	Unknown	60 Mg, Bid	Not Reported
	Apremilast	S	Oral	30 Mg, Bid	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Celebrex	S	Oral	200 Mg, Bid	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Other	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Biw	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Mg, 6qd	Not Reported
	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Other	Not Reported
	Motrin	S	Unknown	6 Df, Qd	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Qd	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported

Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	Unk (Tablet)	Not Reported
Tocilizumab	S	Unknown	360 Mg, Other	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Actonel	C	Oral	35 Mg, Qw	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk, Qw	Not Reported
Mogadon	C	Unknown	5 Mg, Other	Not Reported
Naproxen	C	Unknown	500 Mg, Other	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Other	Not Reported
Oxycodone	C	Unknown	10 Mg, Other	Not Reported

	Oxycodone	C	Unknown	40 Mg, Other	Not Reported
	Oxycodone Hydrochloride	C	Unknown	40 Mg, Other	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Mg, Other	Not Reported
	Oxyneo	C	Unknown	40 Mg, Other	Not Reported
	Oxyneo	C	Unknown	10 Mg, Other	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Uloric	C	Unknown	80 Mg, Bid	Not Reported
	Uloric	C	Oral	80 Mg, Bid	Not Reported
	Uloric	C	Unknown	Unk	Not Reported
	Uloric	C	Oral	80 Mg, Bid	Not Reported
	Uloric	C	Unknown	Unk	Not Reported
	Uloric	C	Oral	80 Mg, Bid	Not Reported
	Vitamin D3	C	Oral	2000 Iu, Other	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228692			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Not Reported
Remicade	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722673	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported
	Alendronate Sodium			C	Oral	70 Mg, Unk		Not Reported
	Atenolol			C	Unknown	3 Df, Unk		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide W/Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	40 Mg, Unk		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Lorazepam			C	Oral	1 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Trimebutine			C	Unknown	1 Df, Q.12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589505			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589415			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722899	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Diclofenac Sodium			S	Unknown			Actavis

Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone	S	Oral	Actavis
	Methotrexate	S	Intra-arterial	Barr
	Methotrexate	S	Unknown	Barr
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride,Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034249		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram, Qd		Bristol Myers Squibb
	Cimzia			S	Unknown	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous				Not Reported
	Actemra			S	Subcutaneous				Not Reported
	Apo-Leflunomide			S	Unknown				Not Reported
	Enbrel			S	Subcutaneous				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
	Leflunomide			S	Unknown				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17722977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589713			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590185		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723713	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020165921		48 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil Sulfate			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17723898	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020169257		51 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724074	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166830		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Cefotaxime Mylan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724350	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010222		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, 1 Every 4 Weeks		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Cranberry /01512301/			C	Unknown	Unk		Not Reported

			Olopatadine		C	Unknown	Unk		Not Reported
			Prednisone		C	Unknown	Unk		Not Reported
			Quinapril Hydrochloride		C	Unknown	Unk		Not Reported
			Sandoz Rabeprazole		C	Unknown	Unk		Not Reported
			Singulair		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17724725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Ill-Defined Disorder; Mental Disorder; Muscle Injury; Myalgia; Pruritus; Rash	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725036	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034298		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium + Vit D			C	Unknown			Not Reported

	Hydrocortisone	C	Unknown	2 Every One Days		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown			Not Reported
	Prednisone	C	Unknown	20 Milligram, Qd		Not Reported
	Tylenol Arthritis Pain	C	Unknown	2 Dosage Form, Bid		Not Reported
	Xarelto	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725448	EXPEDITED (15-DAY)		OT	NVSC2020CA062017		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Gastrointestinal Disorder; Joint Swelling; Malaise; Musculoskeletal Stiffness; Nausea; Pain; Spinal X-Ray Abnormal; Stress; Swelling; Tender Joint Count; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725450	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166847		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, Daily		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine [Spiramycin]			C	Unknown	Unk		Not Reported

		Paracetamol			C	Unknown	Unk			Not Reported
		Xarelto			C	Oral	Unk			Not Reported
		Diffu K			C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725452	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC-2020169681		57 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Advagraf			C	Oral	4 Mg, 1x/Day		Not Reported
	Calcimagon D3			C		Unk		Not Reported
	Cefuroxime			C	Intravenous (not otherwise specified)	1.5 G, 3x/Day		Not Reported
	Co-Amoxicillin			C	Intravenous (not otherwise specified)	1.2 G, 3x/Day		Not Reported
	Flagyl [Metronidazole]			C	Oral	500 Mg, 3x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lasix [Furosemide]			C	Intravenous (not otherwise specified)	40 Mg, 1x/Day		Not Reported
	Myfortic			C	Oral	720 Mg, 2x/Day		Not Reported
	Tazobac			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725640	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA202014192			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Human Normal Immunoglobulin			S	Unknown			Shire

Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Human Normal Immunoglobulin	S	Intravenous (not otherwise specified)	70 Gram	Shire
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, 1x/Week	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, 1x/Day:Qd	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	10 Milligram, 1x/Day:Qd	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725765	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC-20200432974		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Death; Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Durogesic Matrix	S	Transdermal	Patch 25 Mcg/H : 1 Tous Les 3 Jours		Janssen
	Plaquenil /00072602/	S	Oral	800 Mg/Jour Du 22 Au 23.03.2020, 400 Mg/Jour Du 24 Au 26.03.2020, 600 Mg/Jour Du 26 Au 30.03.2020		Not Reported
	Doxycycline	S	Oral			Not Reported
	Azithromycine	S	Oral			Not Reported
	Amoxicillin And Clavulanate Potassium	S	Intravenous drip			Not Reported
	Enoxaparin	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725781	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166844		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Incorrect Product Administration Duration; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Cefotaxime Mylan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725844	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034644		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

					otherwise specified)				
	Xeljanz			S	Oral	5.0 Milligram, Bid			Not Reported
	Methotrexate			C	Unknown	Unk			Not Reported
	Supeudol			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17725977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588805		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726014	EXPEDITED (15-DAY)		OT	NVSC2020CA115075			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	25 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unknown		Not Reported
	Folic Acid			S	Oral	25 Mg, Unknown		Not Reported
	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unknown		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unknown		Not Reported
	Topicort			S	Subcutaneous	Unk		Not Reported
	Topicort			S	Topical	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	4 Mg, Unknown	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589868		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma;	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Synovitis; Treatment Failure	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17726302	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020922		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram Per Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Every Hour		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Two Times A		Not Reported

							Day			
FDA Received Date	**Case #**	**Case Type**	**Health Prof**	**Outcomes**	**Mfr Control #**	**503B Facility**	**Age**	**Sex**	**Country**	
29-Apr-2020	17726305	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020924		64 YR	Female	CAN	

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Risedronate			S	Unknown	5 Milligram		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, Once A Day		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone Acetate			C	Unknown	5 Milligram, Once A Day		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17727439	DIRECT	Y	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Cardiac Arrest; Cardiogenic Shock; Renal Failure	Hydroxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral			Not Reported
	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:500 Mg/Vil;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12788076	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-077476		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram,2 Every One Week		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported

Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Ustekinumab	S	Subcutaneous		Not Reported
	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	0.6 Milligram	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	6 Dosage Form, Qd	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Codeine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	4 Dosage Form, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Arava	S	Oral	20 Milligram, 1 Every 1 Days	Not Reported
Celebrex	S	Oral	2000 Milligram, 2 Every 1 Days	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported

	Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
	Acide Folique	C	Unknown	Unk	Not Reported
	Motrin Children	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported
	Methotrexate	C	Oral	Unk, 1 Every 1 Week	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Cannabis Sativa	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	500 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12887733	EXPEDITED (15-DAY)		OT	CA-ROCHE-1696504		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C				Not Reported
	Arthrotec			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	12913692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091875		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intracardiac	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Tenormin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported

				Elavil [Amitriptyline Hydrochloride]	C	Unknown	Unk		Not Reported
				Imitrex [Sumatriptan]	C	Unknown	Unk		Not Reported
				Lyrica	C	Unknown	Unk		Not Reported
				Hydrochlorothiazide	C	Unknown	Unk		Not Reported
				Acetaminophen	C	Unknown	Unk		Not Reported
				Sumatriptan Succinate	C	Unknown	Unk		Not Reported
				Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
				Amitriptyline	C	Unknown			Not Reported
				Sumatriptan	C	Unknown			Not Reported
				Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13058759	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015760		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13059019	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOTEX-2016AP015792		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown	Unk		Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Plaquenil /00072602/	S			Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Xeljanz	S	Oral	Unk, Bid	Not Reported
Xeljanz	S	Unknown	5 Mg, Q.O.Wk.	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Plaquenil /00072602/	C	Oral	Unk	Not Reported
Prednisone	C	Unknown	Unk Unk, Qd	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13254176	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1893244		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13421846	EXPEDITED (15-DAY)		OT	CA-ROCHE-1899613			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 505.0		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 505.0		Not Reported
	Enbrel			S	Unknown			Not Reported

Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Orencia	S	Subcutaneous	Therapy Duration: -151.0	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 13.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Methotrexate Sodium	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13659278	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170611422		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported

Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pregabalin	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Actemra	S		Not Reported
	Actemra	S		Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran /00001501/	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Mycophenolate Mofetil	S		Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13976362	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018043		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	13995479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1995131		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Methotrexate	S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C			Not Reported
	Estradiol	C			Not Reported
	Furosemide	C			Not Reported
	Valsartan	C			Not Reported
	Xalatan	C	Ophthalmic		Not Reported
	Baclofen	C			Not Reported
	Levaquin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14128229	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020204		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14535486	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BIOVITRUM-2018CA0124		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Apo Sulfasalazine Tab 500mg	S		Not Reported
	Apo Sulfasalazine Tab 500mg	S		Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported

	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Cannabis Sativa	S		Not Reported
	Oxycodone	S		Not Reported
	Minocycline Hydrochloride	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Minocycline	S		Not Reported
	Oxyquinoline Sulfate	S		Not Reported
	Xeljanz	S		Not Reported
	Sulfasalazine	S		Not Reported
	Sulfasalazine	S		Not Reported
	Lyrica	C		Not Reported
	Urelumab	C	Unknown	Not Reported
	Kineret	C		Not Reported
	Lyrica	C	Oral	Not Reported
	Plaquenil	C		Not Reported
	Prednisone	C		Not Reported
	Rituximab	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14539305	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Plaquenil			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Imuran	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	C		Not Reported
	Desoximetasone	C		Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14633220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-003769		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram 4 Every 1 Week		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
	Winpred			S	Oral	5 Milligram, Qd		Not Reported

Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	200 Unk	Not Reported
Prednisone	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Etanercept	S	Subcutaneous	50 Milligram	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14667263	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007994		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Off Label Use; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	4000 Iu, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	4000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14784955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108888		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	14917260	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Bupropion	C	Oral	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	15108403	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S				Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Apo-Hydroxyquine (Hydroxychloroquine Sulfate)			S				Not Reported
	Rituxan (Rituximab)			S	Intravenous (not otherwise specified)			Not Reported
	Remicade (Infliximab)			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Vaginal			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C				Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	15291706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415739		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Enbrel			S	Subcutaneous	Unk Unk, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	10 Mg, 1x/Day		Not Reported

	Prednisone			C	Oral	6 Mg, 1x/Day		Not Reported
	Mefenamic Acid			C	Unknown	Unk		Not Reported
	Advil			C	Unknown	Unk		Not Reported
	Dequalinium Chloride			C		Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	15438740	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16008854	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis

Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Inflammation; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sinusitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Leflunomide	S	Unknown		Barr
	Leflunomide	S	Oral		Barr
	Paracetamol	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

Rituxan	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Cortisone Acetate	S	Topical		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Topicort Mild (Desoximetasone)	S	Oral		Not Reported
Topicort Mild (Desoximetasone)	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S			Not Reported
Apo Folic	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram Daily;	Not Reported
Sarilumab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Sulfathalidine	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Xeljanz	S			Not Reported
Desoximetasone	S	Oral		Not Reported
Leflunomide	C	Unknown		Not Reported
Atasol	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16177041	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190403869		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Paracetamol			S	Unknown			Johnson And Johnson
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16323123	EXPEDITED (15-DAY)		OT	AR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-208121		57 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
American Trypanosomiasis; Asthenia; Pyrexia	Prednisone			S	Unknown	40 Milligram, Daily		Mutual
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	16696905	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2019SA208335		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective;	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi

Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Leflunomide	S	Oral	Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
	Hydroxychloroquine	S	Oral	Unk Unk, Unk	Sanofi
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk Unk, Unk	Not Reported
	Plaquenil	S		Unk Unk, Unk	Sanofi
	Plaquenil	S		Unk Unk, Unk	Sanofi
	Sulfasalazine	S		Unk Unk, Unk	Not Reported
	Sulfasalazine	S		500 Mg, Unk	Not Reported
	Sodium Aurothiomalate	S		Unk Unk, Unk	Not Reported
	Sodium Aurothiomalate	S		Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S		Unk Unk, Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Orencia	S		Unk Unk, Unk	Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Remicade	S		Unk Unk, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Rituxan	S		Unk Unk, Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Rituximab;Urelumab	C		Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17024269	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-GSH201908-001839			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Hydroxychloroquine			S	Unknown	20 Mg, Bid (40 Mg/Day)		Concordia
	Hydroxychloroquine			S	Unknown	40 Mg, Bid (80mg/Day)		Concordia
	Ramipril			S	Oral	1 Dosage Form, Bid, (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	300 Mg, Tid		Not Reported
	Pregabalin			S	Unknown	1 Dosage Form, Tid		Not Reported
	Pregabalin			S	Unknown	100 Mg		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole			S	Oral	20 Mg, Bid		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Volibris			S	Unknown	Unk		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported

	Apixaban		S	Unknown	2.5 Mg, Bid	Not Reported
	Apixaban		S	Unknown	2 Dosage Form, Qd	Not Reported
	Roactemra		S	Subcutaneous	162 Mg, Qw, Solution For Injection In Pre-Filled Syringe	Not Reported
	Roactemra		S	Subcutaneous	162 Mg, Qw	Not Reported
	Sildenafil Citrate		S	Unknown	60 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17240218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509529		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported

Acetaminophen;Oxycodone Hydrochloride	C	Oral		Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral		Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral		Not Reported
Naproxen	C	Unknown		Not Reported
Naproxen	C	Oral		Not Reported
Naproxen	C	Oral		Not Reported
Oxycodone Hydrochloride	C			Not Reported
Rosuvastatin Calcium	C	Oral		Not Reported
Rosuvastatin Calcium	C	Oral		Not Reported
Valtrex	C	Oral		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17261745	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE-IL2019EME238237			Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Benlysta			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Clexane			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17262610	EXPEDITED (15-DAY)		OT	PHHY2019GR210755		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib	Ramipril			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lansoprazole			S	Unknown	Unk		Not Reported

Fracture; Upper Respiratory Tract Infection	Prednisolone			S	Unknown	Unk			Not Reported
	Metformin			S	Unknown	Unk			Not Reported
	Belimumab			S	Unknown	Unk			Not Reported
	Azathioprine			S	Unknown	Unk			Not Reported
	Exemestane			S	Unknown	Unk			Not Reported
	Thyroxin			S	Oral	Unk			Not Reported
	Dicumarol			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17265311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262233		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 11 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17358352	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532032		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Atenolol			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17365297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005932			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S				Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Solution		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17390099	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200153298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Stelara			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported

	Otezla		S	Unknown	Not Reported
	Plaquenil /00072602/		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Arava		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17423283	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-00169		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria Acute	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433123	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

				otherwise specified)		
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S			Not Reported
	Gold		S			Not Reported
	Plaquenil		S	Oral		Not Reported
	Methotrexate		C	Unknown	Not Sepcified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433128	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0819		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Kineret			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Hydroxyquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17433133	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0824		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17450609	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007837		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug	Hydroxychloroquine			S	Unknown	200 Mg, Q.12h		Apotex

Ineffective; Thrombosis	Leflunomide		S	Unknown	10 Mg, Qd		Apotex
	Methotrexate		S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine		C	Unknown	1000 Mg, Bid		Not Reported
	Sulfasalazine		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17557584	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318937		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Thiamine Hydrochloride			C				Not Reported
	Oxycodone Terephthalate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17580328	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0808		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Prescribed	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia	S	Subcutaneous		Not Reported
	Dextromethorphan Hydrobromide	S	Unknown		Not Reported
	Eletriptan Hydrobromide	S			Not Reported
	Eletriptan Hydrobromide	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Mg Once Monthly	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz Xr	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Month	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

Prednisone	S	Unknown		Not Reported
Remicade	S			Not Reported
Simponi	S			Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Calcium	C	Oral		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Cipralex	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown	Dose: 0.625 Mg	Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown	Dose: 0.5 Mg	Not Reported
Gabapentin	C	Oral		Not Reported
Gabapentin	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported

Cymbalta	C	Unknown			Not Reported
Hydrochlorothiazide	C	Unknown	Dose: 12.5 Mg		Not Reported
Hydromorphone Hcl	C	Oral			Not Reported
Hydromorphone Hcl	C	Oral			Not Reported
Mupirocin	C	Topical			Not Reported
Pantoloc	C	Unknown			Not Reported
Shark Liver Oil	C	Unknown			Not Reported
Tapentadol Hydrochloride	C	Unknown			Not Reported
Taro-Mupirocin	C	Topical			Not Reported
Tramacet	C	Oral			Not Reported
Tramadol Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17614242	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202003002062			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthropathy; Cholecystectomy; Emotional Disorder; Gait Disturbance; Herpes Zoster; Off Label Use	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	Coated Tablet1 Dosage Form, Qd		Concordia
	Aradois			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17633457	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1653		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cimzia Single-Use Prefilled Syringe	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Sulfasalazine	S		Not Reported
	Celebrex	S	Unknown	Not Reported

	Xeljanz	C	Oral	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Celebrex	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17640700	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA087400		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate			S	Other	1200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			S	Other	2 Df Bag		Not Reported
	Paracetamol			C	Other	4 G, Qd		Not Reported
	Paracetamol			C				Not Reported
	Lasilix [Furosemide]			C	Other	30 Mg, Qd		Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Doliprane			C				Not Reported
	Doliprane			C				Not Reported

		Diffu K			C	Other	3.6 G, Qd			Not Reported
		Diffu K			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17656097	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA080271		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate			S	Other	600 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	1000 Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Lovenox			S				Sanofi
	Paracetamol			S	Other	4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C	Other	2 Df, Qd		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Lasilix [Furosemide]			C	Parenteral	40 Mg, Qd		Not Reported
	Lantus			C	Subcutaneous	20 Iu, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Pantoprazole			C				Not Reported
	Pantoprazole			C				Not Reported
	Tienam			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17671014	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-		31 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Cough; Dyspnoea; Oropharyngeal Pain; Painful Respiration	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17682579	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANZ PHARMA-202003002825			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Lung Assist Device Therapy; Off Label Use; Pneumonia; Pulmonary Embolism; Respiratory Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Amikacin			S	Intravenous (not otherwise specified)	2200 Mg, Qd		Not Reported
	Furosemide			C		Unk		Not Reported
	Retinol			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Macrogol			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Heparine			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17692715	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004002846			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Off Label Use; Pneumonia Klebsiella; Staphylococcal Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd			Concordia
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd			Not Reported
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd			Not Reported
	Spiramycin			S		6 Mu, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17692947	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002601			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Ceftriaxone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17696997	EXPEDITED (15-DAY)		HO, OT	BE-ADVANZ PHARMA-202004003502			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	400 Mg, Bid, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Film-Coated Tablet		Concordia
	Haldol			C		Unk		Not Reported
	Paracetamol			C		1 Unk		Not Reported
	Fraxiparine			C		Unk		Not Reported
	Dafalgan Forte			C		1 G		Not Reported
	Morphine			C		10 Mg/Ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17702980	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Bausch And Lomb
	Erythromycin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meperidine Hydrochloride			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17712539	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010162		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation;	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex

Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort; Nasopharyngitis; Nausea; Night Sweats; Off Label Use; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Prednisone	S	Oral	5 Mg, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Calcium Folinate	S	Oral	5 Mg, Qd	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	12.5 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Acetaminophen	C	Oral	Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fentanyl	C	Unknown	1 Df, Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, Bid	Not Reported
	Metformin Hydrochloride W/Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, Qd	Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd	Not Reported
	Ranitidine	C	Oral	150 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid	Not Reported
	Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin B 12	C	Oral	1 Df, Qd	Not Reported

	Zopiclone		C	Oral	7.5 Mg, Qd		Not Reported
	Zostavax Ii		C	Unknown	Unk		Not Reported
	Celebrex		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17724510	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1948		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Kineret			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			S	Unknown	1000 Milligram		Not Reported
	Rituximab			S		1000 Milligram		Not Reported
	Acetaminophen			C	Oral			Not Reported

	Diphenhydramine Hydrochloride	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Naprosyn	C	Unknown		Not Reported
	Oxycontin	C	Unknown		Not Reported
	Oxyneo	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726348	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004004068			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Renal Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S				Concordia
	Cefepime			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Prednisone			S	Oral					Not Reported
	Sulfasalazine			S	Unknown					Not Reported
	Xeljanz			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726381	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-GSH201806-002096			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Altered State Of Consciousness; Decreased Appetite; Headache; Hypoglycaemia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Cellcept			C		500 Mg, Bid		Not Reported
	Alfacalcidol			C				Not Reported
	Amlodipine			C				Not Reported
	Pantoprazole			C				Not Reported
	Atenololol			C		50 Mg, Freq: Unk X 1 Days		Not Reported
	Prednisolone			C		10 Mg, Freq: Unk X 1 Days		Not Reported
	Furosemide			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Icodextrin			C				Not Reported
	Dianeal			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726434	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245618		67 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour ()		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726480	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-E2B_00007901			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Cardiac Arrest; Electrocardiogram Qt Prolonged; Electrocardiogram U Wave Present; Hypokalaemia; Hypomagnesaemia; Hypotension; Intentional Overdose; Overdose; Somnolence; Torsade De Pointes; Ventricular Fibrillation	Hydroxychloroquine			S	Unknown	60 Tablets, 1200 Mg Total Dose		Concordia
	Oxycodone, Paracetamol			S	Unknown	35 Tablets (5/325 Mg)35 Dosage Form Total		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590320			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726545	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus			otherwise specified)		
	Arava	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Cetirizine;Pseudoephedrine	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726564	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589944			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Naproxen	C			Not Reported
	Lyrica	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590207			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Lipitor			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726709	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004067			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Organ Dysfunction Syndrome; Off Label Use; Septic Shock	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726710	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589755			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan	S	Intravenous drip	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726929	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004141			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Amoxicillin Clavulanic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726960	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202004004250			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrocalcinosis; Off	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated		Concordia

Label Use						Tablet				
		Hydroxychloroquine			S	400 Mg, Qd, Film-Coated Tablet				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17726980	EXPEDITED (15-DAY)		OT	NL-ACCORD-071584		60 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Toxicity; Treatment Failure	Methotrexate			S				Accord
	Prednisone			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727001	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004251			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Respiratory Tract Infection Fungal	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Imipenem			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Chlorpromazine			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Urapidil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727035	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020168024		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax		S	Oral	250 Mg, 1x/Day	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	600 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020167372		65 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Pr Prolongation; Electrocardiogram T Wave Inversion; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727049	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017786		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589398		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Synthroid	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727113	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010387			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Qd		Not Reported
	Tramacet			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727115	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004004354			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use	Hydroxychloroquine			S	Intravenous (not otherwise specified)	400 Mg, Qd, Film-Coated Tablet		Concordia
	Piperacillin			C		Unk		Not Reported

	Amphotericine B			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727131	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589814			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown	Tablet (Extendedrelease		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727217	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3384129-00		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported
	Kaletra 200/50			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Azitromicina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

	Dolquine			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727246	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010388		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Tramacet			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727313	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201902-000459			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Muscular Weakness; Neuromyopathy; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd		Concordia
	Losartan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727336	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Phthalylsulphathiazole		S	Unknown	Unk	Not Reported
	Prednisone		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727348	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034905			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	1 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Oral	200 Milligram, Qd		Not Reported
	Depo-Medrol With Lidocaine			S	Intra-articular			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Ketoprofen			S	Topical	Unk, Qid		Not Reported
	Leucovorin Calcium			S	Unknown	1 Dosage Form, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Unk		Not Reported
	Prevnar 13			S	Intramuscular	0.5 Milligram, Total		Not Reported

	Rituximab			S	Intravenous (not otherwise specified)	1 Gram			Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727372	EXPEDITED (15-DAY)		HO	FR-SA-2020SA111792		67 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Off Label Use	Plaquenil			S	Oral	600 Mg, Qd		Sanofi
	Plaquenil			S				Sanofi
	Doliprane			S	Oral	4000 Mg, Qd		Not Reported
	Lovenox			S	Subcutaneous	1 Df, Qd		Sanofi
	Azithromycin			S	Oral	1 Df, Qd		Not Reported
	Kaleorid Lp			C	Oral	3 Df, Qd		Not Reported
	Metformin Almus			C	Oral	Unk		Not Reported
	Gliclazide Arrow			C	Oral			Not Reported
	Atorvastatin Arrow			C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727385	EXPEDITED (15-DAY)		DE, HO, OT	SK-ACCORD-180080		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Methotrexate			S		Unk		Accord
	Mycophenolic Acid			S				Accord
	Azathioprine/Azathioprine Sodium			S		Unk		Not Reported
	Belimumab			S		Unk		Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

	Mycophenolate Mofetil	S	Unk		Not Reported
	Prednisone	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727386	EXPEDITED (15-DAY)		OT	IT-ACCORD-180018		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Tacrolimus			S				Accord
	Mycophenolic Acid			S				Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Methylprednisolone			C		Unk (Pulses)		Not Reported
	Immunoglobulins			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S		Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		15 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727437	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010336		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthritis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd (Therapy Duration: 518 Unit Unspecified)		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728025	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033863			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Rabeprazole Sodium	C	Oral	20 Milligram, Every 14 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728203	EXPEDITED (15-DAY)		HO	MX-TEVA-2020-MX-1231149		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Nocardiosis; Perinephric Abscess; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram Daily; Scheduled For 2 Months		Teva
	Prednisone			S	Oral	30 Milligram Daily; Scheduled For 2 Months		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram Daily; Scheduled For 2 Months		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728379	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020AMR072153			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Burning Sensation; Muscle Spasms	Benlysta			S	Unknown	Unk		Glaxosmithkline
	Plaquenil (Hydroxychloroquine)			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728437	EXPEDITED (15-DAY)		CA	DE-TEVA-2020-DE-1228290			Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Talipes	Prednisolone			S	Transplacental			Actavis
	Hydroxychloroquine			S	Transplacental			Teva
	Certolizumab			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728554	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Powder For Solution For Pre-Filled Syringe		Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown			Actavis

Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazol	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain;	Alendronate Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia	S	Subcutaneous			Not Reported
	Cortisone Acetate	S	Unknown			Not Reported
	Desoximetasone	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Folic Acid	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Milligram Daily;		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728596	EXPEDITED (15-DAY)		OT	BE-ELI_LILLY_AND_COMPANY-BE202004006858		83 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Zyprexa Velotab 5mg			S	Oral	1/2 Tablet 2x/Day		Not Reported
	Zyprexa Velotab 5mg			S	Oral	1/2 Tablet 2x/Day		Not Reported
	Plaquenil S			S	Oral	1 Dosage Form, Bid		Not Reported
	Plaquenil S			S	Oral	1 Dosage Form, Daily		Not Reported
	Trazodone Eg			S	Oral	1/4 Tablet In Morning, At		Not Reported

					Noon, 1/2 Tablet In Evening,Patient Was Taking This Before Hospitalization	
	Algostase Mono	C				Not Reported
	Clexane	C				Not Reported
	Potassium 99	C	Oral			Not Reported
	L-Thyroxine Roche	C				Not Reported
	Perindopril	C				Not Reported
	Metformin	C				Not Reported
	Movicol Apelsin	C				Not Reported
	Prolopa	C				Not Reported
	Contramal	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728607	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1228759		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid	Acetaminophen			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	40 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Daily;	Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported

Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Remicade	S	Endocervical		Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Intravenous (not otherwise specified)		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported

	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17728614	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034852		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported

	Prednisone		S	Unknown		Not Reported
	Pseudoephedrine Hcl		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Salazopyrine		S	Unknown		Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Sulfathalidine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Methotrexate		S	Oral	25 Milligram	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729022	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020141193		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Hypoaesthesia; Joint Swelling; Muscular Weakness; Nerve Injury; Off Label Use; Pain; Product Use Issue; Sciatica; Spinal Stenosis	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	2 G, Q Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Plaquenil			S	Unknown	400 Mg, Q Unk		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Actonel Xr			C	Unknown	75 Mg Q Unk		Not Reported
	Baclofen			C	Unknown	10 Mg, Daily At Night (Qhs)		Not Reported
	Folic Acid			C	Unknown	5 Mg, 1x/Day		Not Reported
	Lyrica			C	Unknown	75 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	7.5 Mg, 1x/Day		Not Reported
	Vitamin D			C	Unknown	2000 Iu, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729036	NON-EXPEDITED			GR-LUPIN PHARMACEUTICALS INC.-2020-00627		40 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729108	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017788		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729119	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228814			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain;	Diclofenac Sodium			S	Unknown			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cortisone Aceta	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729176	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228816		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood	Diclofenac			S	Unknown			Actavis

Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Prednisone	S	Unknown		Actavis
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Apo Prednison	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown	400 Milligram Daily;	Not Reported

	Rituxan			S	Unknown				Not Reported
	Salazopyrine			S	Unknown				Not Reported
	Sulfathalidine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729197	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202004240		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Sudden Death	Propofol (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Salbutamol			S	Respiratory (inhalation)			Not Reported
	Azithromycin			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Metoclopramide Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)			Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Cefotaxime			C	Intravenous drip			Not Reported
	Midazolam			C	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729226	EXPEDITED (15-DAY)		HO	NVSC2020IN115852		29 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Bullous; Dysphagia; Mouth Ulceration; Ocular Hyperaemia; Product Use In Unapproved Indication; Skin Exfoliation; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	100 Mg, Bid		Novartis
	Mycophenolate Mofetil			C	Unknown	1.5 G, Bid		Not Reported
	Prednisolone			C	Unknown	30 Mg, Qd		Not Reported
	Prednisolone			C	Unknown	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729374	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000340			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown	Unk		Validus
	Meperidine Hydrochloride			S	Unknown	Unk		Validus
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd (1 Df, Every 1 Day)		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729385	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729388	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437131			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729389	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue;	Remicade			S	Intravenous (not			Janssen

Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress			otherwise specified)	
	Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi Iv	S	Intravenous (not otherwise specified)	Janssen
	Sulfasalazine	S	Unknown	Not Reported
	Mefenamic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729461	EXPEDITED (15-DAY)		OT	NVSC2020IN115930		51 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Product Use In Unapproved Indication; Tinnitus	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisolone			C	Unknown	40 Mg, Qd (Gradual Taper To 5 Mg/Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Administered; Exposure During Pregnancy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone		S	Unknown	Actavis
	Actemra		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Folic Acid		S	Unknown	Not Reported
	Fosamax		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729492	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Prednisone			S	Unknown			Actavis
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Breo Ellipta	S	Respiratory (inhalation)			Not Reported
	Colchicine	S	Unknown			Not Reported
	Dexilant	S	Oral	60 Milligram Daily;		Not Reported
	Estrogel	S	Topical			Not Reported
	Methotrexate	S	Oral			Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ventolin Hfa	S	Respiratory (inhalation)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729669	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020171686		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Off Label Use; Product Use In Unapproved Indication; Tachyarrhythmia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Ceftriaxon			C	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729787	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020171239		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use Issue; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Dolquine			S				Not Reported

	Propofol			S	Intravenous (not otherwise specified)	6.6 Mg/Kg Every Hour				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Mg, 1x/Day				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729799	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171243		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine Hcl			S	Oral	225 Mg, 1x/Day		Pfizer
	Loxapine			S	Oral	155 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Theralene			S	Oral	50 Mg, 1x/Day		Not Reported
	Paracetamol			C	Oral	1 G, 1x/Day		Not Reported
	Akineton [Biperiden Hydrochloride]			C	Oral	4 Mg		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	40 Mg, 1x/Day		Not Reported
	Ezetimibe			C	Oral	10 Mg, 1x/Day		Not Reported
	Kardegic			C	Oral	75 Mg, 1x/Day		Not Reported
	Nebivolol			C	Oral	7.5 Mg, 1x/Day		Not Reported
	Ramipril			C	Oral	1.25 Mg, 1x/Day		Not Reported
	Diazepam			C	Oral	10 Mg, 1x/Day		Not Reported
	Nicopatch			C	Transdermal	7 Mg, 1x/Day		Not Reported
	Nicotine			C	Oral	12 Mg, 1x/Day		Not Reported
	Zopiclone			C	Oral	7.5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729805	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020171215		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer
	Azithromycin			S				Pfizer
	Dolquine			S	Other	400 Mg, Daily (Via Nasogastric Tube)		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729811	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020171785		21 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Linezolid			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Ambisome [Amphotericin B]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729886	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171246		78 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Effexor Lp			S	Oral	150 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Risperidone			S	Oral	2 Mg, 1x/Day		Not Reported
	Acebutolol Hydrochloride			C	Oral	400 Mg, 1x/Day		Not Reported
	Oxazepam			C	Oral	100 Mg, 1x/Day		Not Reported
	Sodium Enoxaparin			C	Subcutaneous	4000 Iu, 1x/Day		Not Reported
	Macrogol 4000			C	Oral	2 Df, 1x/Day		Not Reported
	Amlodipine			C	Oral	10 Mg, 1x/Day		Not Reported

		Clomipramine Hydrochloride			C	Oral	150 Mg, Monthly			Not Reported
		Zopiclone			C	Oral	7.5 Mg, 1x/Day			Not Reported
		Nicardipine Hydrochloride			C	Oral	60 Mg, 1x/Day			Not Reported
		Hydrochlorothiazide			C	Oral	25 Mg, 1x/Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17729999	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017804		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram,Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S		125 Milligram, Weekly (Qw)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	5mg 2every 1day		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730004	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic	Acetaminophen			S	Unknown			Not Reported

Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium	S	Unknown		Actavis
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S			Barr
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported

Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
Salazopyrina	C			Not Reported
Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590432		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Sleep Disorder	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730396	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mobicox	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depomedrol	C	Intramuscular		Not Reported
	Diclofenac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730403	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012547			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil (Hydroxychloroquine Phosphate)	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	In Pre-Filled Syringe	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730404	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012542		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product	Diclofenac			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Apo Prednison	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Unknown	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednison	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Salazopyrine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported

		Xeljanz			S	Unknown				Not Reported
		Cortisone Acetate			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730463	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590245		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip	365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	731.0		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown	Emulsion		Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730576	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437119		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730976	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588779		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	11105334	EXPEDITED (15-DAY)		OT	CA-ROCHE-1574386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Duration : 1095 Days		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

Herpes Zoster; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Stomatitis; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Synthroid	C		Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Enablex [Darifenacin Hydrobromide]	C		Not Reported
	Ativan	C		Not Reported
	Loperamide	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Vagifem	C	Vaginal	Not Reported
	Cortisone	C	Intramuscular	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Abatacept	C		Not Reported
	Leflunomide	C		Not Reported
	Kineret	C		Not Reported
	Furosemide	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Darifenacin Hydrobromide	C		Not Reported

	Pantoprazole Sodium	C		Not Reported
	Oxyneo	C	Unknown	Not Reported
	Trimethoprim	C		Not Reported
	Restasis	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C		Not Reported
	Kadian	C	Unknown	Not Reported
	Codeine	C		Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C		Not Reported
	Desoximetasone	C		Not Reported
	Dexamethasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	11379748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1620025		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C				Not Reported

		Hydromorph Contin			C					Not Reported
		Dilaudid			C					Not Reported
		Amlodipine			C					Not Reported
		Eletriptan			C					Not Reported
		Cimzia			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	11720121	EXPEDITED (15-DAY)		DS	CA-ROCHE-1657676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	12454121	EXPEDITED (15-DAY)		OT	CA-ROCHE-1771508		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Plaquenil (Hydroxychloroquine Sulfate)	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Enbrel	S	Unknown	Therapy Duration: 190 Days	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic	Solution Opthalmic	Not Reported
	Cosopt	C	Unknown	Eye Drops	Not Reported
	Furosemide	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Gravol Ginger	C			Not Reported
	Zingiber Officinale	C			Not Reported
	Estrogel	C			Not Reported
	Calcium	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Morphine	C	Unknown	As Needed	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	12844829	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1042716		66 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate			S		7.5 Mg, Cycle (10 Days)		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Not Reported
	Certolizumab Pegol			S		200 Mg, Biweekly		Mylan
	Certolizumab Pegol			S		1 Df, Q21d		Mylan
	Bromazepam			C		Unk		Mylan
	Bromazepam			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13006742	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015239		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin;	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Alendronate			S				Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex

Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S	Oral	20 Mg, Unk	Apotex
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	760 Mg, Q.Wk.	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unspecified Unit)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	10 Mg, 1 Every 4 Weeks	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazin	S	Unknown	Unk	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Q.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported

Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	15 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Q.Wk.	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	360 Mg, Q.M.T.	Not Reported
Simponi	S	Subcutaneous	680 Mg, Q.M.T.	Not Reported
Etanercept	S	Unknown	50 Mg, Q.Wk.	Not Reported
Etanercept	S	Unknown	25 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported

					Sulfasalazine	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
					Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
					Prednisone	C	Unknown	10 Mg, Qd	Not Reported
					Prednisone	C	Unknown	10 Mg, Qd	Not Reported
					Xeljanz	C	Unknown	Unk	Not Reported
					Xeljanz	C	Oral	5 Mg, Bid	Not Reported
					Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
					Alendronate Sodium	C	Subcutaneous	70 Mg, Q.Wk.	Not Reported
					Sulfasalazine	C	Unknown	Unk	Not Reported
					Prednisolone	C	Unknown	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13116772	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878330		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Desoximetasone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13216626	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890689		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13251082	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895049		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Month(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13359948	EXPEDITED (15-DAY)		OT	CA-SA-2017SA042969		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Qw		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Qw		Not Reported
	Actemra			S		640 Unk		Not Reported
	Actemra			S		640 Unk		Not Reported
	Apo-Cyclosporine			S	Oral	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qw		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Other	50 Mg, 1 In 1 Week		Not Reported
	Enbrel			S		50 Unk		Not Reported
	Enbrel			S		50 Mg For 4 Yrs		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Humira			S		40 Unk		Not Reported
	Humira			S		40 Mg, Qw For 4 Years		Not Reported
	Apo-Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported

Certolizumab	S	Subcutaneous	200 Mg, Qw		Not Reported
Certolizumab	S		200 Unk		Not Reported
Certolizumab	S		200 Mg For 9.0 Month(S) Unk		Not Reported
Gold	S	Unknown	Unk Unk, Unk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw		Not Reported
Infliximab	S		300 Mg, Qw For 2 Years		Not Reported
Methotrexate Sodium	S	Unknown	Unk Unk, Unk		Not Reported
Rituximab	S	Unknown	Unk Unk, Unk		Not Reported
Orencia	S	Unknown	Unk Unk, Unk		Not Reported
Simponi	S	Unknown	Unk Unk, Unk		Not Reported
Azathioprine	S	Unknown			Not Reported
Ciclosporin	S	Oral	Unk		Not Reported
Prednisone	C				Not Reported
Piroxicam	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13657150	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA105823		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi

Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide	S	Oral	Unk Unk,Unk	Sanofi
	Minocycline Hydrochloride	S			Not Reported
	Minocycline Hydrochloride	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Arava	S			Sanofi
	Arava	S			Sanofi
	Leflunomide	S			Sanofi
	Leflunomide	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Plaquenil	S			Sanofi
	Plaquenil	S		400 Mg	Sanofi
	Oxycodone	S		10 Mg	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S		Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S		Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported

	Enbrel	S		Unk Unk,Unk		Not Reported
	Marijuana	S				Not Reported
	Xeljanz	S	Oral	Unk Unk, Bid		Not Reported
	Gold	S				Not Reported
	Ilaris	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Ilaris	S	Subcutaneous	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Unk Unk,Unk		Not Reported
	Rituximab	C		Unk		Not Reported
	Anakinra	C		Unk		Not Reported
	Lyrica	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	13868474	EXPEDITED (15-DAY)		OT	CA-ROCHE-1976526		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730.0 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15009839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2137691		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown	Therapy Duration: 2.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C				Not Reported
	Orencia			C	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15356144	EXPEDITED (15-DAY)		HO	CA-ROCHE-2179236		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Terminal State; Thrombosis	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ilaris	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15388757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Cortisone	S	Unknown	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Folic Acid	S	Oral	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Topicorte	S	Subcutaneous	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

Sarilumab	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Stelara	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Topicort Lp	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15461181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15843598	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190118854		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

	Leflunomide			S	Unknown				Not Reported
	Arava			S	Unknown				Not Reported
	Arthrotec			C	Oral				Not Reported
	Gold			C	Unknown				Not Reported
	Imuran			C	Unknown				Not Reported
	Vitamin D			C	Unknown				Not Reported
	Ergocalciferol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	15897378	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-002605		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus	Topicort			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Bausch And Lomb
	Cortisone Acetate			S	Oral			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Erythematosus; Wound	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Therapy Duration 365 (Unspecified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Therapy Duration: 365 (Unspecified)	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Paracetamol	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Apo Folic	S	Unknown		Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16066887	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1022788		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Misuse; Off Label Use;	Repaglinide			S	Oral	Unk		Not Reported
	Coversyl /00790702/			S	Oral	Unk		Mylan

Pruritus; Rash Maculo-Papular	Coversyl /00790702/	S	Unknown	Unk Unk,Unk		Mylan
	Plaquenil /00072603/	S	Oral	200 Mg/ Day		Mylan
	Cortancyl	S	Oral	10-20µg		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16217782	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190424225		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Remicade			S				Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Calcium Carbonate			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Cyclosporine			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Amlodipine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported
	Ferrous Fumarate			S	Unknown			Not Reported
	Insulin			S	Unknown			Not Reported

	Metformin	S	Unknown	Not Reported
	Nutropin	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Protropin	S	Intramuscular	Not Reported
	Ranitidine	S	Unknown	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Testosterone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16693247	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208351		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Plaquenil			S	Oral	400 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Codeine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Adalimumab			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported

	Simponi			S	Subcutaneous	50 Mg, Qm		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Unknown	30 Mg, Qw		Not Reported
	Prednisone			C		35 Mg, Qd		Not Reported
	Xeljanz			C	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C	Subcutaneous	50 Mg		Not Reported
	Adalimumab			C		Unk		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16693818	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208304		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S		640 Mg, Unk		Not Reported
	Actemra			S		640 Mg, Unk		Not Reported
	Actemra			S		640 Mg, Qw		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk Unk, Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg For 9.0 Month(S)		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg For 9.0 Month(S)		Not Reported
	Ciclosporin			S	Oral	Unk Unk, Unk		Not Reported
	Ciclosporin			S	Oral			Not Reported

Ciclosporin	S	Oral		Not Reported
Cimzia	S	Subcutaneous	200 Mg, Single-Use Prefilled Syringe	Not Reported
Cimzia	S	Subcutaneous	200 Mg Qw, Single-Use Prefilled Syringe	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Unk For 4 Years	Not Reported
Gold	S	Unknown	Unk Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qw For 4 Years	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Qw	Not Reported
Imuran [Azathioprine Sodium]	S	Unknown	Unk Unk, Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw For 2 Years	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Simponi	S	Unknown	Unk Unk, Unk	Not Reported
Rituxan	S	Unknown	Unk Unk, Unk	Not Reported
Piroxicam	C			Not Reported
Prednisone	C		Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16697274	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019344315			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema	Apixaban			S		2.5 Mg, Bid		Pfizer
	Apixaban			S	Unknown	2 Df, Qd		Pfizer

Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril	S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Pfizer
	Ramipril	S		5 Mg, Qd	Pfizer
	Lyrica	S	Unknown	100 Mg, Tid	Pfizer
	Lyrica	S		1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))	Pfizer
	Omeprazole	S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Pfizer
	Omeprazole	S	Oral	20 Mg, Bid (40mg/Day)	Pfizer
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Pfizer
	Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
	Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
	Ambrisentan	S	Oral	1 Df, Qd	Not Reported

			Ambrisentan		S	Unknown	30 Mg, Qd			Not Reported
			Ambrisentan		S		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16731220	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1095844		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Clear Cell Renal Cell Carcinoma; Complications Of Bone Marrow Transplant; Hair Follicle Tumour Benign; Hepatosplenic T-Cell Lymphoma; Hypotension; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Pyrexia; Splenomegaly; T-Cell Lymphoma; Tachycardia; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S				Ivax
	Etoposide			S	Unknown			Teva
	Etoposide			S				Teva
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	.7143 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Thalidomide			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S				Not Reported
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	33.3333 Milligram Daily;		Not Reported
	Remicade			S				Not Reported
	Acetazolamide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Amlodipine			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported

Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Leflunomide	S	Unknown	Barr
Leflunomide	S		Barr
Metformin	S	Unknown	Actavis
Nutropin	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Actavis
Protropin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported
Erelzi 25 Mg Solution For Injection In Prefilled Syringe	S	Subcutaneous	Not Reported
Etoposide	C		Not Reported
Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	C		Not Reported
Tacrolimus	C		Not Reported
Thalidomide Celgene -50 Mg Capsula Rigida - Celgene Europe Limited	C		Not Reported
Thalomid	C		Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	16805798	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201908000239			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Eye Haemorrhage; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Dupixent			S	Subcutaneous	Unk Loading Dose		Not Reported
	Dupixent			S	Subcutaneous	300 Mg, Qow		Not Reported
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17027053	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA305395		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Acetonide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qow		Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S		1.3 Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 G, Qw		Not Reported

	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17033136	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2019SA308981		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S		Unk		Sanofi
	Triamcinolone Acetonide			S	Intra-articular	Unk		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Naproxen			S		Unk		Not Reported
	Naproxen			S	Oral	3 Mg, Qd		Not Reported
	Naproxen			S	Oral	5 Mg, Qd		Not Reported
	Naproxen			S	Unknown	Unk Unk, Unk		Not Reported
	Naproxen			S				Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	50 Mg, Bid		Not Reported
	Prednisone			S		50 Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported

Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate	S		Unk Unk, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Q6w	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg	Not Reported
	Infliximab	S		Unk Unk, Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk, Q6w	Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Kineret	S	Subcutaneous	Unk Unk, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Qm	Not Reported
	Orencia	S	Intravenous drip	250 Mg, Q2m	Not Reported

Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S	Respiratory (inhalation)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Unk	Not Reported
Orencia	S		Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qod	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Biw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Abatacept	S	Intravenous drip	250 Mg, Qm	Not Reported
Adalimumab	S	Subcutaneous		Not Reported

	Adalimumab	S		Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S		50 Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S		Unk	Not Reported
	Orencia	S			Not Reported
	Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17069951	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001908			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bacterial Infection; Contusion; Cystitis; Fatigue; Feeling Abnormal; Hemiparesis; Hysterectomy; Insomnia; Pain; Pain In Extremity; Ph Body Fluid Abnormal; Pyrexia; Tremor; Vaginal Haemorrhage; Vulvovaginal Mycotic Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Teriflunomide			S	Oral	14 Mg, Qd (Coated Tablet)		Not Reported
	Teriflunomide			S	Oral	14 Mg, Qd		Not Reported
	Fludrocortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17259394	EXPEDITED (15-DAY)		HO	CA-ROCHE-2518182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17371160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538246		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Diclofenac			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17419878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543667		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17653955	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-017958		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Lopinavir;Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Once A Day		Not Reported

	Ceftriaxone			C	Unknown	Unk			Not Reported
	Prednisone			C	Oral	20 Milligram, Once A Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17668617	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002364			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Deep Vein Thrombosis; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Off Label Use; Overdose; Oxygen Saturation Decreased; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600mg In The Morning, 400mg In The Evening Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd, Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Not Reported
	Lovenox			S	Subcutaneous	0.7 Ml, Qd		Not Reported
	Paracetamol			S		4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Lasilix			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Tienam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17682088	EXPEDITED (15-DAY)		OT	DE-ACCORD-179153		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate	S	Subcutaneous			Accord
	Hydroxychloroquine	S	Oral			Not Reported
	Leflunomide	S	Oral	Intermittent Usage		Not Reported
	Sulfasalazine	S	Oral	Strength 500 Mg		Not Reported
	Prednisolone	S	Oral	Intermittent Usage Of Low-Dose Prednisolone. Also Received 30 Mg, 7.5 Mg, 5 Mg, 40 Mg, 20 Mg, 10 Mg		Not Reported
	Prednisone	S		Increased To		Not Reported
	Metoprolol	C				Not Reported
	Amlodipine	C				Not Reported
	Prednisone	S				Not Reported
	Prednisolone	S	Oral			Not Reported
	Prednisolone	S	Oral	Two Weeks Before Presentation		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17697006	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003543			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Off Label Use	Hydroxychloroquine			S	Oral	600 Mg, Qd (Film Coated Tablet)		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film Coated Tablet)		Concordia
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparine Sodique			C		Unk		Not Reported
	Insuline Glargine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17705408	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2020165611		45 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
	Sulfasalazine	S	Oral	2 Df, 2x/Day	Pfizer
	Prednisolone	S		Unk(Intermittent Usage Of Low-Dose Prednisolone)	Not Reported
	Prednisolone	S		20 Mg	Not Reported
	Leflunomide	S	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	40 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	30 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	20 Mg, 1x/Day(Two Weeks Before Presentation)	Not Reported
	Prednisone	S	Oral	20 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	15 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	7.5 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	5 Mg, 1x/Day	Not Reported
	Prednisone	S	Oral	4 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, 2x/Day	Not Reported
	Metoprolol	C		Unk	Not Reported
	Amlodipine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17711495	EXPEDITED (15-DAY)		LT, OT	FR-ASTRAZENECA-2020SE54654		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Other			Not Reported

	Hydroxychloroquine Sulfate	S	Other			Not Reported
	Hydroxychloroquine Sulfate	S	Other			Not Reported
	Hydroxychloroquine Sulfate	S	Other			Not Reported
	Loxen [Loxoprofen Sodium]	S	Intravenous (not otherwise specified)			Not Reported
	Movicol	S	Other	2 Df Bag		Not Reported
	Midazolam	S	Intravenous (not otherwise specified)	5mg/Ml Daily		Not Reported
	Paracetamol	C	Other			Not Reported
	Paracetamol	C	Other			Not Reported
	Doliprane	C				Not Reported
	Doliprane	C				Not Reported
	Lasilix [Furosemide]	C	Other			Not Reported
	Novorapid	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Diffu K	C	Other			Not Reported
	Diffu K	C	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17716072	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-020311		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Long Qt Syndrome; Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Salbutamol			S	Respiratory (inhalation)	0.1 Milligram, Four Times/Day		Not Reported
	Dolquine			S	Oral	400 Milligram, Two Times A Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	10 Milligram, 3 Times A Day		Not Reported
	Ipratropium Bromide			C	Respiratory	20 Microgram, Four		Not Reported

						(inhalation)	Times/Day		
		Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
		Cefotaxime			C	Intravenous drip	4 Gram, Two Times A Day		Not Reported
		Midazolam			C	Intravenous drip	100 Milligram, Once A Day		Not Reported
		Tocilizumab			C	Intravenous (not otherwise specified)	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17718313	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000337			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Bacterial; Pneumonia Bacterial; Staphylococcal Bacteraemia	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus
	Hydroxychloroquine Sulfate			S	Nasal	400 Mg, Qd		Not Reported
	Spiramycin			S	Nasal	6 Mu, Qd		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Vancomycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17721946	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227338		66 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Dolquine			S	Oral	400 Milligram Daily;		Not Reported

							Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			
	Dolquine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17724166	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166893		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17727561	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1042619		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Lasilix /00032601/			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Mylan
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Mylan
	Noradrenaline /00127501/			C	Intravenous (not otherwise specified)	Unk		Mylan
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Mylan
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Qd		Mylan
	Transipeglib			C	Oral	Unk		Mylan
	Potassium Chloride			C	Intravenous (not	Unk		Mylan

						otherwise specified)				
	Nimbex /01302502/			C		Intravenous (not otherwise specified)	Unk			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731644	EXPEDITED (15-DAY)		HO, LT, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245540		36 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Drug Level Increased	Tacrolimus			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Cobicistat/Darunavir			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731661	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004082			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Ear Pain; Eye Injury; Headache; Herpes Virus Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731724	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004144			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Hepatocellular Injury; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589712		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive	Actemra			S	Intravenous (not			Not Reported

Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete			otherwise specified)	
	Rituxan	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731830	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588961		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590384		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732413	EXPEDITED (15-DAY)		HO	CA-ROCHE-2587291		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported

Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Vancomycin	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Apo Amlo	C	Unknown	Not Reported
	Apo-K	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Epoetin Alfa	C	Unknown	Not Reported
	Escitalopram	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Insulin Lispro	C	Unknown	Not Reported
	Januvia	C	Unknown	Not Reported
	Kcl	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Metoprolol	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Slow-K	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Ventolin [Salbutamol]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732418	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245759		53 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedacion ()		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589459		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Duration 4 Month		Not Reported
	Methotrexate			S	Unknown	Duration 4 Month		Not Reported
	Orencia			S	Unknown	Duration 4 Month		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Duration 4 Month		Not Reported
	Prednisone			S	Unknown	Duration 4 Month		Not Reported
	Remicade			S	Unknown	Duration 4 Month		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Duration 4 Month		Not Reported
	Simponi			S	Subcutaneous	Duration 4 Month		Not Reported
	Xeljanz			S	Oral	Duration 4 Month		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590075		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	190.0 Days	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported

	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Zingiber Officinale	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732474	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004003662			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732521	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002893			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732668	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2020168162		38 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycin			S		500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Dexmedetomidine Hydrochloride			S		Unk		Pfizer
	Dexmedetomidine Hydrochloride			S				Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Hydroxychloroquine			S				Not Reported
	Favipiravir			C				Not Reported
	Methylprednisolone			C		1 Mg/Kg		Not Reported

Ceftriaxone	C	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17732774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587807		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733312	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229092		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-	Ciclosporin			S	Unknown			Ivax

Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Mycophenolate Mofetil	S	Unknown		Teva
	Methotrexate	S	Unknown		Barr
	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229034		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733337	EXPEDITED (15-DAY)		HO	ES-BAYER-2020-066313		49 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Betaferon			S	Subcutaneous	0.25 Mg		Bayer
	Betaferon			S				Bayer
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Kaletra			S	Oral	2 Df, Bid		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733717	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3387130-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588759			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17733953	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010365			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734070	NON-EXPEDITED		HO, OT	PL-AMGEN-POLSP2020070504		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Encorton [Prednisone Acetate]			S	Unknown	15 Milligram, Qd		Not Reported
	Encorton [Prednisone Acetate]			S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil S			S	Unknown	20 Milligram, Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Milligram		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In		Not Reported

						Jan-2019))				
		Folic Acid			C	Unk				Not Reported
		Insulin			C	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734176	EXPEDITED (15-DAY)		DE, OT	CH-SA-2020SA109443		72 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolytic Anaemia; Off Label Use; Thrombocytopenia; Thrombotic Microangiopathy	Plaquenil			S	Oral	800 Mg/Day From 22 To 23 Mar 2020, 400 Mg/Day From 24 To 26 Mar 2020, 600 Mg/Day From 26 To 30 Mar 2		Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S	Oral	200 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg		Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S	Intravenous drip	3.6 G, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Fentanyl			S	Transdermal	25 Ug/H		Not Reported
	Piperacillin + Tazobactam			C	Intravenous (not otherwise specified)	13.5 G		Not Reported
	Paracetamol			C		500 Mg, Qid		Not Reported
	Paracetamol			C		500 Mg		Not Reported
	Humulus Lupulus Extract;Valeriana Officinalis Extract			C				Not Reported
	Macrogol			C		Unk Unk, Qd		Not Reported
	Metoclopramide			C		10 Mg, Tid		Not Reported
	Relaxane			C		Unk Unk, Tid		Not Reported
	Supradyn [Minerals Nos;Vitamins Nos]			C		Unk Unk, Qd		Not Reported
	Redormin [Remifentanil Hydrochloride]			C		500 Mg, Qd		Not Reported

	Dexamethasone			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734253	EXPEDITED (15-DAY)		OT	CA-SA-2020SA112718		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S		Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Arava			S		Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg		Sanofi
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Oral	1000 Mg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Golimumab			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan			S	Unknown	Unk			Not Reported
	Simponi			S	Subcutaneous	Unk			Not Reported
	Sulfathalidine			S	Unknown	Unk			Not Reported
	Diclofenac			C		Unk			Not Reported
	Salazopyrin			C		Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734523	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2020171826		79 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734550	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020171235		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734833	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Oral	Not Reported
	Zyrtec-D	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported

						Sulfasalazine		S	Oral	Not Reported
						Sulfathalidine		S	Unknown	Not Reported
						Topicorten		S	Subcutaneous	Not Reported
						Xeljanz		S	Unknown	Not Reported
						Desoximetasone		S	Unknown	Not Reported
						Desoximetasone		S	Unknown	Not Reported
						Folic Acid		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734855	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012633			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17734929	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1042716			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17735914	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy;	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Tenosynovitis; Treatment Failure	Leucovorin Calcium	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Oral			Not Reported
	Otezla	S	Unknown			Not Reported
	Pantoprazole	S	Oral			Not Reported
	Pantoprazole Magnesium	S	Unknown			Not Reported
	Synthroid	S	Unknown			Not Reported
	Diltiazem Hydrochloride	C	Oral			Not Reported
	Fluticasone Propionate	C	Respiratory (inhalation)			Not Reported
	Mar-Pantoprazole	C	Unknown	Tablet (Delayed Release)		Not Reported
	Mometasone Furoate	C	Unknown			Not Reported
	Premarin	C	Unknown			Not Reported
	Salbutamol Sulfate	C	Respiratory (inhalation)			Not Reported
	Tramadol Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736149	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020176534			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rectal Cancer	Xeljanz Xr			S		11 Mg, 1x/Day (11mg Qd)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736227	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1043094		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden	Levofloxacin			S	Unknown	Unk		Not Reported

Death	Azithromycin		S	Oral	500 Milligram, Qd	Not Reported
	Lopinavir/Ritonavir		S	Oral	2 Dosage Form, Bid	Not Reported
	Hidroxicloroquina Sulfato		S	Oral	200 Milligram, Qd	Mylan
	Ceftriaxona /00672201/		C	Unknown	Unk	Mylan
	Enoxaparina Sodica		C	Subcutaneous	40 Milligram, Qd	Mylan
	Prednisona		C	Oral	20 Milligram, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736256	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Salbutamol Sulfate			C	Respiratory (inhalation)			Not Reported

	Mometasone Furoate	C	Unknown			Not Reported
	Mar-Pantoprazole	C	Unknown	Form Of Admin: Tablet (Delayed-Release)		Not Reported
	Fluticasone Propionate	C	Respiratory (inhalation)			Not Reported
	Diltiazem Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736716	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-021403		60 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day(Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day(Dia)		Not Reported

	Hydroxychloroquine	S				Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Tocilizumab	S				Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 Gram, Once A Day(Dia)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736737	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-093087		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Actonel			S	Unknown	35 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			C	Unknown	300 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17736746	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2020-021570		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxona			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Dolquine			S	Oral	200 Milligram, Two Times A Day		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Metilprednisolona			S	Intravenous (not otherwise specified)	250 Milligram, Once A Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	15369646	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181868		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	16139048	EXPEDITED (15-DAY)		OT	DE-ACCORD-117446		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate	S	Subcutaneous	20 Mg, Tablet Oral		Accord
	Plaquenil	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Powder For Solution Intravenous		Not Reported
	Leflunomide	S		Film-Coated Tablet		Not Reported
	Orencia	S	Subcutaneous	125 Mg		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
	Neoral	S	Subcutaneous			Not Reported
	Neoral	S	Oral			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral	Also Received Additionally, Film Coated Tablet		Not Reported
	Ciclosporin	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Also Received Oral Tablet		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Apo-Hydroxyquine	S	Oral	Unk, Also Received Subcutaneous Apo-Hydroxyquine Thrice		Not Reported
	Rituxan	S	Unknown	Solution Intravenous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736773	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2020-021363		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Diarrhoea; Hyponatraemia	Levofloxacin	S	Oral	500 Milligram, Once A Day		Aurobindo
	Dolquine	S	Oral	400 Milligram, Once A Day		Not Reported
	Kaletra	S	Oral	2 Dosage Form (2u/2 H)		Not Reported
	Kaletra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736776	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019740		77 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736804	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020847		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	800 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736808	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020857			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736838	EXPEDITED (15-DAY)		HO	ES-HETERO-HET2020ES00483		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg, Qd		Hetero
	Dolquine			S	Oral	400 Mg, Qd		Not Reported
	Kaletra			S	Oral	12 Hours Bid (200/50mg)		Not Reported
	Kaletra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587376		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736873	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-020465		82 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Haloperidol			S	Oral	5 Gtt Drops, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736886	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1228537		55 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycine Anhydre			S	Oral	250 Mg		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported
	Rocephine			S	Oral	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17736942	EXPEDITED (15-DAY)		DS	CA-ROCHE-2589878		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported

Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not	Not Reported

					otherwise specified)		
			Remicade	S	Intravenous (not otherwise specified)		Not Reported
			Simponi	S	Subcutaneous		Not Reported
			Simponi	S	Subcutaneous		Not Reported
			Sulfasalazine	S	Oral		Not Reported
			Sulfasalazine	S	Oral		Not Reported
			Sulfathalidine	S	Oral		Not Reported
			Sulfathalidine	S	Oral		Not Reported
			Tofacitinib	S	Unknown		Not Reported
			Tofacitinib Citrate	S	Unknown		Not Reported
			Topicort [Desoximetasone]	S	Cutaneous		Not Reported
			Salazopyrin	C	Unknown		Not Reported
			Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737066	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000161			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Heparin			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-		Not Reported

			14	
Torasemide	S	Transplacental		Not Reported
Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental		Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Simvastatin	S	Transplacental		Not Reported
Clexane	S	Transplacental	From Gestational Week 0-14, 200 Mg/D (2x100)	Not Reported
Salbutamol Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Salbutamol Sulfate	S	Transplacental		Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental		Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Xarelto	S	Transplacental		Not Reported
Pantoprazole	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental		Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-	Not Reported

			14	
Nicotine	S	Transplacental		Not Reported
Ramipril	S	Transplacental	20 Mg, Qd From Gestational Week 0-113+6	Not Reported
Ramipril	S	Transplacental	Maternal Dose 20 Mg, Unk	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental		Not Reported
Aliskiren	S	Transplacental		Not Reported
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Metamizole Sodium	S	Transplacental		Not Reported
Misoprostol	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Mifepristone	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Enoxaparin Sodium	S	Transplacental	(From Gestational Week 0-14)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737105	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease;	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr

Pruritus; Treatment Failure	Actemra	S	Subcutaneous			Not Reported
	Azathioprine	S	Subcutaneous			Not Reported
	Azathioprine	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Kevzara	S	Subcutaneous			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Ergocalciferol	C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Magnesium	C				Not Reported
	Metformin	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737108	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1229118		61 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deep Vein Thrombosis; Drug Interaction; Hypofibrinogenaemia; Melaena; Sepsis	Hidroxicloroquina (2143a)			S	Oral			Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)	20mg/24h Los Primeros 5 Dias, Posteriormente 10 Mg/24h Durante 5 Dias Más.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737152	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2020-DE-		82 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Milligram Daily; 1-0-1		Teva
	Hydroxychloroquine			S				Teva
	Azithromycin			C				Not Reported
	Azithromycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-May-2020	17737198	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1229150		56 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	800mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	13178708	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886825			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Bone Erosion; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Qwk		Not Reported
	Methotrexate Sodium			S	Unknown	Qwk		Not Reported

Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Rheumatoid Arthritis; Syncope; Urticaria	Orencia	S	Intravenous (not otherwise specified)	Qmo		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 396.0 Nos		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Prevacid	C	Unknown			Not Reported
	Xeljanz	C	Oral	Therapy Duration: 7.0 Day(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	14308678	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050900		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

				otherwise specified)		
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S		Unk	Not Reported
	Methotrexate		C	Subcutaneous	25 Mg, Weekly (Qw)	Not Reported
	Methotrexate		C	Oral	25 Mg, Weekly (Qw)	Not Reported
	Plaquenil		C		200 Mg, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737230	EXPEDITED (15-DAY)		HO	CA-ROCHE-2590268		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737254	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590321		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Actemra		S	Intravenous (not otherwise specified)		Not Reported
	Anakinra		S	Subcutaneous		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737289	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737294	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017839		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S	Oral	5milligram, 2 Every 1 Days		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-May-2020	17737316	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020161825		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported

Product Use In Unapproved Indication	Sulfate]

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	12182291	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1723643		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Urethral			Not Reported
	Methotrexate Sodium			S	Oral	(2.5 Mg- 8 Tablets Orally Once Weekly)		Not Reported
	Methotrexate Sodium			S	Unknown	Solution For Injection		Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 24.0 Year(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	Therapy Duration 24.0 Years		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution For Injection		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Cymbalta			C				Not Reported

	Methotrexate			C	Oral					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	12891950	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOPHARMA INC-2016AP013468			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S				Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown	Unk Unk, Unknown		Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Remicade			S	Unknown	Unk			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituxan			S	Unknown	Unk			Not Reported
	Rituximab			S	Unknown	Unk			Not Reported
	Rituximab			S					Not Reported
	Plaquenil /00072602/			S	Unknown	Unk			Not Reported
	Plaquenil /00072602/			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13053281	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870963			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Methotrexate			S	Oral	Not Reported
	Methotrexate			S	Oral	Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Not Reported
	Zopiclone			C	Unknown	Not Reported
	Folic Acid			C	Oral	Not Reported
	Pantoprazole			C		Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown	Not Reported
	Xeljanz			C		Not Reported
	Pantoprazole Magnesium			C	Oral	Not Reported
	Tenofovir Disoproxil			C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13054285	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra	C	Subcutaneous	Unk		Not Reported
	Enbrel	C	Subcutaneous	Unk		Not Reported
	Humira	C	Unknown	40 Mg, Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Orencia	C	Unknown	Unk		Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava	C	Unknown	Unk		Not Reported
	Prednisone	C	Unknown			Not Reported
	Simponi	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13058845	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015768		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	22.5 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S			Not Reported
Methotrexate	S	Oral	22.5 Mg, Q.Wk.	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Parenteral	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Parenteral	25 Mg, 1 Every 4 Weeks	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk Unk, Qd	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	6 Mg, Qd	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	6 Mg, Bid	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
D-Penicillamine	C	Unknown	Unk	Not Reported
Phenylbutazone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13228895	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832720		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown	Therapy Duraiton: 5 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13251533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006675		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	Unk (Therapy Duration: 129 Unit Unspecified)		Not Reported

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Enbrel	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	125 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Mefenamic Acid	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C	Unknown	Unk	Not Reported
	Advil /00044201/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13932807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017292		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex

Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Actemra	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Tramadol Hydrochloride	C	Oral	50 Mg, Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Rabeprazole Sodium	C	Unknown	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13939347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017491		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Tylenol /00020001/			C	Unknown	Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13946397	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017455		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

	Azathioprine		S	Unknown	Unk	Not Reported
	Apo-Azathioprine		S	Unknown	Unk	Not Reported
	Anakinra		S	Subcutaneous		Not Reported
	Imuran /00001501/		S	Unknown	Unk	Not Reported
	Methotrexate Sodium		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel		S	Subcutaneous	25 Mg, B.I.Wk.	Not Reported
	Etanercept		S	Subcutaneous	25 Mg, B.I.Wk.	Not Reported
	Gold		S	Intramuscular	Unk	Not Reported
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported
	Kineret		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	13976657	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018044		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, 1 Every 2 Week		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported

	Methotrexate	S	Oral	12.5 Mg, Qd		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, 1 Every 4 Weeks		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Q.M.T.		Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14223391	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP021500		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Unk, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 G, Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Cannabis Sativa			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

Thrombosis; Urticaria	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	7 Mg, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	Unk	Not Reported
	Rituximab W/Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14235971	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021661		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	6 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported
	Mefenamic Acid			C	Unknown	Unk		Not Reported
	Advil /00044201/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14747260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105393		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Caffeine;Codeine;Paracetamol			S	Unknown			Not Reported
	Tylenol No.2			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

	Codeine Phosphate			S	Unknown				Not Reported
	Codeine			S	Unknown				Not Reported
	Diphenhydramine			C					Not Reported
	Methylprednisolone			C					Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown				Not Reported
	Tylenol			C					Not Reported
	Acetaminophen			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	14815456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111505		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15268961	EXPEDITED (15-DAY)		HO	CA-ROCHE-2166736		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

					Naproxen		S	Unknown		Not Reported
					Orencia		S	Unknown		Not Reported
					Prednisone		S	Unknown		Not Reported
					Xeljanz		S	Oral		Not Reported
					Folic Acid		C	Unknown		Not Reported
					Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15327981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175377		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Imuran [Azathioprine]			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15330290	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported
	Cimzia			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15337341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019544		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Lipitor			S	Unknown	40 Mg, Qd		Not Reported

	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Oral	300 Mg, Qd		Not Reported
	Spiriva	S	Unknown	2.5 Mg, Bid		Not Reported
	Zenhale	S	Unknown	200 Mg, Bid		Not Reported
	Zenhale	S	Unknown	400 Mg, Bid		Not Reported
	Zenhale	S	Unknown	200 Mg, Qd		Not Reported
	Tiotropium Bromide Monohydrate	S	Unknown	2.50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15342993	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176790		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	15389857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082887		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram, Q4wk, 84 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	725 Milligram		Not Reported
	Chlorhexidine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Chlorhexidine Gluconate	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone Actavis	S	Unknown	Unk	Not Reported
Periogard	S	Buccal	Unk	Not Reported
Apo Acetaminophen	S	Unknown	Unk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Unknown	Unk	Not Reported
Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Milligram	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported

	Paracetamol	C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd		Not Reported
	Tylenol With Codeine	C	Unknown	Unk		Not Reported
	Paracetamol Codeine	C	Unknown	Unk		Not Reported
	Cetrizine	C	Unknown	Unk		Not Reported
	Plaquenil S	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16119797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027001		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Eye Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Orencia			S	Unknown	Therapy Duration 10.0 Month(S)		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Therapy Duration 30 Days		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration 6.0 Years		Not Reported
	Leflunomide			S	Unknown	62.0 Days		Not Reported
	Methotrexate			S	Unknown	123 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16462022	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Apo-Acetaminophen	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Apotex
	Hydroxychloroquine	S	Oral	200 Mg, Unk	Apotex
	Acetaminophen	S	Unknown	325 Mg, Unk	Apotex
	Apo-Prednisone	S	Unknown	20 Ng, Unk	Apotex
	Leflunomide	S	Unknown	200 Mg, Qd	Apotex
	Leflunomide	S	Oral	20 Mg, Qd	Apotex
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	10 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk (4 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	40 Mg, Unk (4 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	50 Mg, Qd	Not Reported
	Enbrel	S	Unknown	40 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Unknown	200 Mg, Unk	Not Reported
	Orencia	S	Unknown	750 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported

Remicade	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Synthroid	C			Not Reported
Acetaminophen/Codein Phosphate	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	25 Df, Q.Wk.	Not Reported
Methotrexate	C	Unknown	Unk Unk, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Tylenol With Codeine No.3	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Tylenol With Codein #3	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16641652	EXPEDITED (15-DAY)		OT	CA-ROCHE-2361846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	16695071	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079550			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema	Apixaban			S	Unknown	2.5 Milligram, Bid		Bristol Myers Squibb
	Apixaban			S	Unknown	2 Dosage Form, Qd		Bristol Myers Squibb

Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
	Quensyl	S	Unknown	40 Milligram, Bid	Not Reported
	Quensyl	S	Unknown	20 Milligram, Bid	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form	Not Reported
	Omeprazole	S	Oral	1 Dosage Form, Bid	Not Reported
	Omeprazole	S	Oral	20 Milligram	Not Reported
	Ramipril	S	Oral	1 Dosage Form, Bid	Not Reported
	Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
	Sildenafil Citrate	S	Unknown	60 Milligram, Daily Dose	Not Reported
	Pregabalin	S	Unknown	100 Milligram, Tid	Not Reported
	Pregabalin	S	Unknown	1 Dosage Form	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17159637	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1122784			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual	Spasmolyt			S	Unknown	30 Milligram, Qd(30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1)		Mylan
	Spasmolyt			S	Unknown	1 Dosage Form, Qd (1 Df, Qd; 1 Number Of Units In The Interval: 1)		Mylan
	Spasmolyt			S	Unknown	15 Milligram, Qd		Mylan

Impairment	Pregabalin	S	Unknown	1 Df, Tid (1 – 1 - 1)	Not Reported
	Pregabalin	S	Unknown	300 Milligram, Qd (100 Milligram, Tid)	Not Reported
	Omeprazole	S	Oral	2 Dosage Form, Qd(1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12)	Not Reported
	Omeprazole	S	Unknown	40 Milligram, Qd	Not Reported
	Ramipril	S	Oral	2 Dosage Form, Qd(1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12)	Not Reported
	Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	Unk	Not Reported
	Sildenafil	S	Unknown	60 Milligram, Qd (60 Milligram, Daily Dose)	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 – 0 - 1)	Mylan
	Quensyl	S	Unknown	2 Dosage Form, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The	Mylan
	Quensyl	S	Unknown	40 Milligram, Qd, (20 Mg Bid)	Mylan
	Quensyl	S	Unknown	80 Milligram, Qd, (1 Df, Bid (1 - 0 - 1))	Mylan
	Eliquis	S	Unknown	1 Df, Bid (1 – 0 - 1)	Mylan
	Eliquis	S	Unknown	5 Milligram, Qd (2.5 Milligram, Bid)	Mylan
	Tocilizumab	S	Subcutaneous	162 Milligram, Qw (162 Milligram, Qwk)	Mylan
	Tocilizumab	S	Subcutaneous	162 Milligram, Qw	Mylan
	Volibris	S	Oral	30 Milligram, Qd	Mylan

	Volibris	S	Oral	1 Dosage Form, Qd		Mylan
	Lyrica	S	Unknown	300 Milligram, Qd(100 Milligram, Tid)		Mylan
	Apixaban	S		5 Milligram, Qd(2.5 Milligram, Bid)		Mylan
	Apixaban	S		5 Milligram, Qd(2.5 Milligram, Bid)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17250187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513966		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syring, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Cefalexin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17260727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515953		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Penicillin-G			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Calcium			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17454345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007815		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported

					Humira		S	Subcutaneous	Unk	Not Reported
					Orencia		S	Unknown	Unk	Not Reported
					Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
					Sulfasalazine		S	Unknown	500 Mg, Unk	Not Reported
					Desoximetasone		C	Unknown	10 Mg, Qd	Not Reported
					Diclofenac		C	Unknown	100 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17674805	EXPEDITED (15-DAY)		DE, HO, OT	SK-ORION CORPORATION ORION PHARMA-20_00008910		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Jc Virus Infection; Mental Impairment; Pneumonia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cyclosporine A			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17683228	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004002752			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Shock	Hydroxychloroquine			S	Oral	600 Mg, Qd (Film-Coated		Concordia

				Tablet)	
	Hydroxychloroquine	S	Oral	400 Mg, Qd (Film-Coated Tablet)	Concordia
	Cordarone	S	Intravenous (not otherwise specified)	600 Mg, Qd	Not Reported
	Cordarone	S	Intravenous (not otherwise specified)	900 Mg, Qd	Not Reported
	Noradrenaline	C		Unk	Not Reported
	Anaklnra	C		Unk	Not Reported
	Aspirina	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17684289	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1038428		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		1 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Mylan
	Envarsus			S	Unknown	Unk, Qd		Mylan
	Belimumab			S	Unknown	Unk		Mylan

	Belimumab	S	Unknown	Unk		Mylan
	Belimumab	S	Unknown	Unk		Mylan
	Belimumab	S	Unknown	Unk		Mylan
	Mycophenolate Mofetil	S	Unknown	1 Dosage Form, Qd		Mylan
	Rituximab	C		Unk		Mylan
	Methylprednisolone	C		Unk (Pulses)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17696993	EXPEDITED (15-DAY)		HO, OT	BR-ADVANZ PHARMA-202004003349			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination; Off Label Use; Psychotic Disorder	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet		Concordia
	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet		Concordia
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Metamizole Sodium			C		Unk		Not Reported
	Sodium Heparin			C		Unk		Not Reported
	Methylprednisolone Sodium Succinate			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Methadone Hydrochloride			C		Unk		Not Reported
	Piperacilina+Tazobactam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17696996	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004003506			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Acute Kidney Injury; Off Label Use	Hydroxychloroquine	S	Oral	600 Mg, Qd	Concordia
	Hydroxychloroquine	S	Oral	400 Mg, Qd (Film-Coated Tablet)	Concordia
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Concordia
	Fludrocortisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17703365	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-019744		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Deep Vein Thrombosis; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Overdose; Oxygen Saturation Decreased; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Paracetamol			S	Unknown	4 Gram, Once A Day		Aurobindo
	Paracetamol			S				Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	800 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	1200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Other	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	600 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	0.6 Milliliter, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	0.7 Milliliter, Once A Day		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported
	Movicol			C	Unknown	2 Dosage Form, Once A Day		Not Reported
	Movicol			C				Not Reported
	Lasilix			C	Parenteral	40 Milligram, Once A Day		Not Reported
	Pantoprazole			C	Oral	40 Milligram, Once A Day		Not Reported
	Pantoprazole			C				Not Reported
	Lantus			C	Subcutaneous	20 International Unit, Once A Day		Not Reported

	Tienam			C	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17721926	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202004003973			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Pressure Fluctuation; Diarrhoea; Dizziness; Off Label Use; Pneumonia; Pyrexia	Hydroxychloroquine			S	Oral	400 Mg, Bid		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Azithromycin			C		Unk		Not Reported
	Kaletra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17737409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589933		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Nitroglycerin			C				Not Reported
	Gabapentin			C	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17737424	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-021232		96 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Extrasystoles	Azithromycin Film-Coated Tablets			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Lasix			C	Unknown	25 Milligram, Once A Day		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Normix			C	Unknown	Unk		Not Reported
	Dobetin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Deltacortene			C	Unknown	Unk		Not Reported
	Pantorc			C	Unknown	20 Milligram, Once A Day		Not Reported
	Cardirene			C	Unknown	75 Milligram, Once A Day		Not Reported
	Metoprololo			C	Unknown	50 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739425	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown			Not Reported
	Meloxicam	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form: Suspension Intra-Articular		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Pantoprazole Magnesium	C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739591	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-021847		74 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram,1 Total		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739633	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra		S	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)				
		Simponi			S	Unknown				Not Reported
		Sulfasalazine			S	Unknown				Not Reported
		Topicort [Desoximetasone]			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739663	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depomedrol			C	Intramuscular	Form Of Admin: Suspension For Infusion		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739711	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202004004131			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Renal Failure; Respiratory Distress	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739722	EXPEDITED (15-DAY)		HO, OT	BE-ADVANZ PHARMA-202004004406			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemolysis; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739747	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245893		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Sun
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739833	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1945		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder;	Methotrexate (Trade Name			S	Oral			Not Reported

Rheumatoid Arthritis; Treatment Failure	Unknown) Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Flexeril			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Visanne			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739836	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1679		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Gait Disturbance; Joint Swelling; Muscular Weakness; Nerve Injury; Pain; Paraesthesia; Rheumatoid Arthritis; Sciatica; Spinal Stenosis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Q Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Q Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actonel Xr			C	Unknown	Every Unspecified Unit (Q)		Not Reported
	Baclofen			C	Unknown	Every Night (Hs)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Vitamin D			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739897	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590110		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra	S	Subcutaneous	8.0 Months	Not Reported
	Azathioprine	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Esomeprazole Sodium	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Nicotinamide	S	Unknown		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Sarilumab	S	Subcutaneous		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Thiamine Hydrochloride	S	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17739900	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245906		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Mg Dia ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740011	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2020-00693		31 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	5 Milligram/Kilogram		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740014	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01594		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740015	NON-EXPEDITED		LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-01647		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	R Chop			C	Unknown	Unk		Not Reported
	Doxorubicin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740016	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2020-00911		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Nausea	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

	Sulfasalazine			C	Unknown	Unk Unk, Tid				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740017	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01472			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740069	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004004409			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Hand Fracture; Hip Fracture; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740109	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201812000036			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			C				Not Reported
	Acetaminophen And Codeine Phosphate			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported

	Actemra	C	Unk	Not Reported
	Simponi	C	Unk	Not Reported
	Lyrica	C	Unk	Not Reported
	Arthrotec	C	Unk	Not Reported
	Tylenol	C	Unk	Not Reported
	Rabeprazole	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740137	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2020-DE-1229760		71 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Flutter; Off Label Use	Hydroxychloroquine			S	Oral	1200 Milligram Daily;		Teva
	Hydroxychloroquine			S		200 Milligram Daily;		Teva
	Hydroxychloroquine			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740608	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy;	Diclofenac			S	Unknown			Not Reported

Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740634	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk. Therapy Duration 823 Unit Unspecified		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.I.W		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Tylenol /00020001/			S	Unknown			Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Acetaminophen With Codeine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk, Q.Wk.		Not Reported

	Acetaminophen And Codeine		C	Unknown	Unk			Not Reported
	Celecoxib		C	Unknown	Unk			Not Reported
	Hydromorphone Hcl		C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740669	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245901		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740724	EXPEDITED (15-DAY)		DE, OT	ES-GLAXOSMITHKLINE-ES2020073213		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Long Qt Syndrome; Sudden Death	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Tid		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, Qid		Glaxosmithkline
	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline
	Dolquine			S	Oral	400 Mg		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Cefotaxim			C	Intravenous drip	4 G, Bid		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported

	Midazolam			C	Intravenous drip	100 Mg, Qd		Not Reported
	Ipratropii Bromidum			C	Respiratory (inhalation)	20 ?G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740754	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201907-001630			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Epstein-Barr Virus Infection Reactivation; Face Oedema; Leukocytosis; Oedema Peripheral; Pyrexia; Rash; Rash; Rash; Rash Pruritic; Rebound Effect; Transaminases Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Methylprednisolone			S	Unknown	60 Mg, Qid		Not Reported
	Methylprednisolone			S	Unknown	80 Mg, Bid		Not Reported
	Methylprednisolone			S	Oral	Unkunknown (Tapered To Oral Methylprednisolone)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

						otherwise specified)			
	Acetaminophen			C					Not Reported
	Caffeine			C					Not Reported
	Codeine Phosphate			C					Not Reported
	Meprobamate			C					Not Reported
	Dorzolamide Hydrochloride			C					Not Reported
	Timolol Maleate			C					Not Reported
	Folic Acid			C					Not Reported
	Levothyroxine			C					Not Reported
	Methotrexate			C					Not Reported
	Prednisone			C					Not Reported
	Ramipril			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740826	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Leflunomide			S	Unknown	20.0 Mg, Unk		Apotex
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Sulfasalazine			C	Unknown	2.0 G, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Q.12h		Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588677		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	Duration 7 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Duration 579		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Cyclical Duration 2 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	1 In1 Week		Not Reported
	Methotrexate			S	Subcutaneous	1 In1 Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Duration:7.0 Months		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740840	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S		400 Ml, Qd		Sanofi
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib Citrate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740849	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590808		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17740856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591172		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported

					Orencia		S	Subcutaneous		Not Reported
					Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
					Remicade		S	Intravenous (not otherwise specified)		Not Reported
					Simponi		S	Subcutaneous		Not Reported
					Sulfasalazine		S	Oral		Not Reported
					Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591623			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution For		Not Reported

						otherwise specified)	Infusion			
		Rituxan			S	Intravenous (not otherwise specified)				Not Reported
		Simponi			S	Subcutaneous				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591821		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741494	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020171727		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Ceftriaxone			S				Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741579	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171234		63 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	Unk		Pfizer
	Hydroxyzine Arrow			S	Oral	25 Mg, Single		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741587	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171158		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Discomfort; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741728	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-035310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741744	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589836		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741749	EXPEDITED (15-DAY)		OT	CH-SA-2020SA114056		51 YR	Male	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Plaquenil			S	Oral	In Total		Sanofi
	Amoxicillin Sodium/Potassium Clavulanate			S	Intravenous drip	1.2 G, Qid		Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid		Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid		Not Reported
	Clexane			S	Subcutaneous	40 Mg, Qd		Sanofi
	Clexane			S	Subcutaneous	40 Mg, Bid		Sanofi
	Clexane			S	Subcutaneous	Unk		Sanofi
	Clexane			S	Subcutaneous	40 Mg, Bid		Sanofi
	Paracetamol			S	Intravenous (not otherwise specified)	Max 3x/D ; As Necessary		Not Reported
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G, Tid		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Ipramol			C		Unk		Not Reported
	Temesta [Lorazepam]			C				Not Reported
	Tavanic			C				Not Reported
	Atracurium			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Dormicum [Midazolam Hydrochloride]			C		Unk		Not Reported
	Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]			C		Unk		Not Reported
	Antibiotics For Otic And Nasal Use			C		Unk		Not Reported
	Torasemide			C				Not Reported
	Potassium			C				Not Reported
	Benerva			C				Not Reported
	Heparin			C		Unk		Not Reported

	Solu-Medrol	C	Unk	Not Reported
	Novorapid	C	Unk	Not Reported
	Relistor	C	Unk	Not Reported
	Novasource Gi Control	C	Unk	Not Reported
	Ventolin [Salbutamol]	C	Unk, Prn	Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17741774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591992			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Sulfasalazine			C				Not Reported